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

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Title:	**Communication Skills Training for Interprofessional Teams in the Pediatric Cardiac Intensive Care Unit**
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TABLE OF CONTENTS

ABBREVIATIONS AND DEFINITIONS OF TERMS

AHD	Advanced Heart Disease
CAT-T	Communication Assessment Tool-Team
CHOP	Children's Hospital of Philadelphia
CICU	Cardiac Intensive Care Unit
CPS-P	Control Preferences Scale for Pediatrics
CSACD	Collaboration and Satisfaction About Care Decisions
CST	Communication Skills Training
FCC	Family-centered Care
HAD	Hospital Anxiety and Depression Scale
ICU	Intensive Care Unit
IES-R	Impact of Event Scale-Revised
IOM	Institute of Medicine
IPE	Interprofessional Education

MIPS	Medical Interaction Process System
PC^4	Pediatric Cardiac Critical Care Consortium
PERCS	Program to Enhance Relational and Communication Skills
PFS-ICU 24	Pediatric Family Satisfaction with Care in the Intensive Care Unit
PPCS	Pediatric Palliative Care Specialists
PTSD	Post-traumatic Stress Disorder
SDM	Shared Decision-making

ABSTRACT

Context:

A large proportion of children with advanced heart disease (AHD) die in the pediatric cardiac intensive care unit (CICU), where parents describe obtaining a realistic understanding that their child had a life-limiting disease only 2 days prior to death. Delayed or inadequate communication within teams or with families may contribute to this lack of understanding (as shown in children with other serious illnesses), while interactions with pediatric palliative care specialists (PPCS) have been shown to improve communication and understanding of prognosis. The limited number of PPCS, however, means that all clinicians in the CICU must have the skills to support parental decision-making, including giving bad news and eliciting parental goals for their child.

Objectives:

1. To develop a communication skills training (CST) program for interprofessional teams in the pediatric CICU via a co-design process.
2. To evaluate CICU clinicians' perceived feasibility and acceptability of the CST.
3. To evaluate CST impact on communication skills and team function in actual family meetings.
4. To learn parents' perspectives about communication challenges in the CICU.
5. To determine the parents' perceived acceptability of the parent-facing aspects of the CST program.
6. Evaluate clinician fidelity to intervention plan.

Study Design:

Cohort study with pre and post assessments around an intervention.

Setting/Participants:

Clinicians at CHOP and parents of children previously hospitalized in the ICU will be invited to participate in the co-design portion of the study. A separate group of volunteer attending intensivists, cardiologists, cardiac surgeons, front line clinicians, nurses, and social workers from the pediatric CICU at the Children's Hospital of Philadelphia (CHOP) will undergo the CST program intervention and participate in observed family meetings. Other clinicians who are participating in an observed family meeting will also be enrolled. Parents or legal guardians and their children in the CICU who have been there for at least 7 days and are expected to stay at least another 7 days will also be consented and enrolled.

Study Interventions and Measures:

Intervention:

The intervention is a CST for a group of interprofessional clinicians that will include practice in communication skills of giving bad news and eliciting goals of care and building team collaboration. Parental-facing aspects of the intervention include parental preparation

for family meetings and provision of written summary of the family meeting after its completion.

Measures:

The Co-design process to develop the intervention will have focus groups to evaluate the interventions' content and feasibility and a survey to measure participant engagement in the focus groups.

The impact of the CST program on CICU clinicians' perceived usefulness and satisfaction with the training will be measured with a post-CST survey. This survey will also measure clinician burnout, demographics and experience with modalities of communication pre and during the COVID-19 pandemic. Furthermore, a random sample of 8 clinicians participating in the CST will complete an acceptability interview regarding their thoughts on the intervention.

For the actual family meetings, assessment of the impact of the CST on communication and team function in actual family meetings pre and post-CST will be done by coding audio recordings using the same tools as in simulated encounters and qualitative coding of content. Collaboration will be measured using the amount of time different members of different disciplines speak, and team member perception and satisfaction with collaboration will be measured using a validated tool.

Parents' experiences in family meetings and perspectives on communication with the clinical team will be measured with a pre-intervention survey or interview. Parents' acceptability of the parent preparation process for the family meeting and of the written summary received after the meeting will be measured during the post-intervention survey and interview.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Clinicians and Parents Participating in Co-design		
Study Phase	**Enrollment**	**Co-design**
Visit Number	**1**	**2-12**
Study Days	**1**	**2-400**
Enrollment	X	
Get Feedback through Focus Group		X
Measure Engagement through Survey		X

Clincians Participating in Intervention				
Study Phase	**Enrollment**	**Intervention**	**Follow-up**	
Visit Number	**1**	**2-11**	**5-30**	**6-21**
Study Days	**1**	**2-200**	**9-500**	**36-310**
Enrollment	X			
Communication Skills Training (up to 10 hours)		X		
Online course evaluation survey including Maslach burnout score and COVID-19 questions		X		
Post-CST actual clinical encounters			X	
Follow-up actual meeting survey			X	
Acceptability interview				X

Clinicians Not Participating in Intervention		
Study Phase	**Enrollment**	**Pre or Post-Intervention**
Visit Number	**1**	**2-17**
Study Days	**1**	**2-540**
Enrollment	X	
Observed Family Meeting		X
Online Survey		X

Parent-patient Dyads Participating in the Survey (Prior to Intervention)		
Study Phase	**Enrollment**	**Follow-Up**
Visit Number	**1**	
Study Days	**1**	**2-730**
Enrollment	X	
Online Survey	X	
Medical record review (patient or family not contacted)		X

Parent-patient Dyads Participating in the Interview (Prior to Intervention)	
Study Phase	**Enrollment**
Visit Number	**1**
Study Days	**1**
Enrollment	X
In-person Interview	X

Parent-patient Dyads Participating in the Survey and Interview (After Intervention)					
Study Phase	**Enrollment**	**Follow-Up**	**Follow-Up**	**Follow-Up**	**Follow-Up**
Visit Number	**1**	**2**	**3**	**4**	
Study Days	**1**	**1-10**	**1-60**	**2-60**	**2-730**
Enrollment	X				
Recording of Family Meeting		X			
Online Survey			X		
Interview				X	
Medical record review (patient or family not contacted)					X

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

Parents caring for children with serious illness describe many unmet communication needs. Unfortunately, parents often describe the process of making medical decisions for their seriously ill child as insufficiently empathetic, lacking in genuine partnership with their child's providers, and reliant upon inadequate and poorly timed information[1-5]. For many families with a seriously ill child, decision-making also occurs against a backdrop of heightened parental anxiety[6], depression[7-9], and stress[10]. The stress families experience is exacerbated by inadequate communication with their family member's health care providers[11]. Longer stays in the intensive care unit (ICU) are associated with an increased likelihood of conflict between families and clinicians[4]. Parental stress after a child's hospitalization in an ICU is frequently significant enough to meet criteria for post-traumatic stress disorder (PTSD)[12], and parental distress can persist for months or years after ICU discharge[12-14]. Parents of patients who have died in the ICU are more likely to experience complicated grief if they received inadequate information or emotional support from providers prior to their child's death[15,16].

This is especially significant for parents of children with advanced heart disease (AHD). Parents of seriously ill children, including children with AHD, must make difficult decisions about their child's care in situations that are emotionally charged and uncertain. The child's chance of recovery may be unclear, and some parents face the possibility that their child may die. Parents rely on their child's provider for guidance and most want to share in decision-making[17-20]. With evidence of missed opportunities of decision-support for families, clinicians caring for seriously ill children require evidence-based training in order to gain skills in basic palliative care[21].

Basic pediatric palliative care skills are essential for clinicians and clinical teams caring for children with AHD[22], of whom a large proportion die in the cardiac intensive care unit (CICU)[23]. Parents describe obtaining a realistic understanding that their child had a life-limiting disease only 2 days prior to death[1]. Delayed or inadequate communication may contribute to this lack of understanding (as shown in children with other serious illnesses)[24-26], while interactions with pediatric palliative care specialists (PPCS) have been shown to improve communication and understanding of prognosis[27,28]. The limited number of PPCS, however, means that all clinicians in the CICU must have the skills to support parental decision-making, including giving bad news and eliciting parental goals for their child.

To improve the lives of seriously ill patients and the caregivers making decisions for them, there must be evidence-based interventions that provide guidance to clinicians on how to effectively communicate with families. Shared decision-making (SDM) has been widely recommended to improve communication between clinicians and families. Formal family meetings, where several clinicians and multiple family members meet at a planned time to discuss treatment plans or goals of care, are often missed opportunities to promote SDM. Communication training has been shown to improve physician skills in discussing end of life care in simulated patient encounters[29-31]. Unfortunately, the data showing the impact of provider training on patient level outcomes is not clear[32-34]. There is also limited data on

how training interprofessional clinical teams in communication in the ICU impacts team collaboration[35].

1.2 Name and Description of Investigational Product or Intervention

The communication skills training (CST) program for clinicians will encourage the use of best practices in conducting family meetings where teams give bad news and elicit goals of care as well as build team collaboration. The CST will be developed by modifying the VitalTalk[36] CST to adapt it to interprofessional training, the pediatric CICU setting, and CHOP-developed Family Meeting Resources. The family-facing intervention includes standardized preparation for family meetings and provides a written summary of the family meeting to families. The combined aspects of the intervention are now known as CICU Teams and Loved ones Communicating (CICU TALC).

1.3 Relevant Literature and Data

AHD remains a leading cause of non-accidental death for children[22], with a large proportion of these patients dying in the CICU[23]. In one study, the majority of parents whose children died of AHD believed that their child would have a normal lifespan until only 2 days prior to death[1]. 38% of these parents had considered limitations of interventions before their child's provider raised the issue. 20% of parents never had a discussion about limitations of interventions[1]. When counseling parents of newborns with a hypoplastic left heart, cardiologists and surgeons also fail to offer palliative care as an option 40% of the time[37]. This omission is particularly surprising since many of these professionals would prefer a palliative approach if faced with making the decision for their own child[38]. Clinicians' reluctance to offer these choices may be explained by frequently cited barriers to having these conversations: lack of training for clinicians, insufficient time, and personal discomfort in discussing terminal prognosis[21]. Evidence-based solutions will be necessary to successfully bridge this communication gap that limits parents' awareness of options for their children with AHD.

Shared decision-making (SDM) has been widely recommended to improve communication between clinicians and families. Shared decision-making is a model of provider-patient and family communication that has been highlighted by several professional organizations as having the potential to bridge this communication gap. SDM requires providers to engage with patients and families about treatment options, hear the family's values and collaborate in making decisions[39]. The American Academy of Pediatrics (AAP) lists SDM as a core principle of family-centered care (FCC) along with respecting each child and their diversity, building on family strengths while supporting decision-making, and providing support to patients throughout their lifespan[40]. In 2007, based on the Institute of Medicine's (IOM) recommendations[41], the American College of Critical Care Medicine encouraged the use of SDM in all ICUs[42]. The recommendations included regular meetings between ICU staff and families with full disclosure of prognosis and treatment options, and training to increase staff communication and mediation skills[42].

Family meetings are often missed opportunities to consistently meet families' needs. Formal family meetings, where several clinicians and multiple family members meet at a planned time to discuss treatment plans or goals of care, have been widely promoted in the ICU to

operationalize SDM and FCC with some success[43-46]. Qualitative research has helped delineate theoretical frameworks for family meetings and the kind of communication they can offer[47,48]. These frameworks distinguish between information transfer and the emotional work or support offered by clinicians, and they underscore the importance of both in meetings. Several guides for how best to conduct family meetings have been proposed building on clinical expertise and available evidence[47,49-51].

In the few studies about family meetings in the pediatric ICU, clinicians perceived family meetings as opportunities to communicate with families and support them[52]. However, only a small percentage of families of patients admitted to the pediatric ICU participated in family meetings despite the life-changing decisions that were required of parents; and even if family meetings occurred, many were not documented in the medical record[53,54].

Additionally, more careful content analysis of some family meetings identified many missed opportunities to listen and respond to families, to acknowledge and address emotions and to deploy key principles of palliative care[55-57]. While family meetings offer the prospect of supporting family decision-making, even when they occur, they do not consistently achieve their proposed purpose.

Pediatricians lack training in the basic palliative care skills shown to improve patient and family outcomes for seriously ill patients. Palliative care professionals have been called upon to ensure SDM is offered to patients in the pediatric ICU[58,59] because of their aligned commitment to honest, clear communication with the team and families, family-centered decision-making, and provision of emotional and spiritual support. Trials have demonstrated that interventions with palliative care specialists improve patient and family outcomes for adult patients[60,61] and satisfaction among pediatric palliative patients[28]. These findings support earlier involvement of PPCS when caring for seriously ill patients.

While PPCS are an important resource for facilitating more clear and empathetic communication, the IOM's report Dying in America highlights the inadequate transfer of palliative care skills to other clinicians caring for pediatric patients with serious illness[21]. In fact, few pediatric trainees are exposed to training in palliative care[62-65]. This is particularly problematic given the insufficient number of PPCS in the United States[21,66]. As a result, the IOM recommends that all clinicians caring for seriously ill patients gain basic palliative care skills, including how to communicate about patient and family goals[21]. Despite recognition by pediatric professional organizations of the need for communication training for clinicians[40,42], sufficient training is still far from being achieved[67-71].

Clinicians can learn basic palliative care communication skills from CST, but it is unclear whether CST has an impact on patient and family outcomes. The evidence that clinicians can increase their skills and confidence in communication at multiple points in their career is robust[72-77]. Several steps in research of CST have been studied with the goal of eventually improving outcomes for patients and families. First, CST can change clinician perception of their skills and their confidence in having conversations. The Program to Enhance Relational and Communication Skills (PERCS), a pediatric communication training program, has demonstrated that participants endorse an improved sense of preparation for difficult discussions, increased communication skills, and confidence after completing the training[78].

Boss demonstrated similar findings with a communication training directed toward neonatologists[79].

Furthermore, studies of CST can demonstrate an increase in clinician skills in simulated encounters. The training program VitalTalk (initially called OncoTalk) has demonstrated that resident physicians gain skills in giving bad news and discussing transitions to palliative care during simulated encounters. These outcomes were assessed using a coding scheme developed for the study that scored audio recordings of simulated clinician-patient encounters[29].

Studies of CST can also demonstrate a change in clinician behavior in actual encounters with patients and families, not just simulated ones. Fallowfield's randomized controlled trial demonstrated differences in videotaped actual encounters that were coded using the Medical Interaction Process System (MIPS) scale[80]. Subjects reduced their number of leading questions and interruptions while increasing the number of open-ended questions and expressions of empathy provided[74,75]. Bonvinci demonstrated an improvement in expressions of empathy during outpatient clinical encounters that were audio recorded and coded using a Global Rating Scale to measure empathy[81].

Finally, research in CST needs to demonstrate that it impacts patient level outcomes with respect to satisfaction, distress, quality of communication, decision-making support or reduction in anxiety, PTSD and depression. However, systematic reviews of the literature have demonstrated inconclusive evidence that CST has an impact on patient satisfaction, distress or quality of life in oncology[82,83]. Studies outside oncology are also mixed. Wilkinson led a positive randomized controlled trial of CST for palliative care nurses demonstrating improvement of nurses' skills in several communication behaviors. In this trial, researchers coded audio recordings using the Communication Skills Coverage Rating Scale[84] and surveyed patients with the Patient Satisfaction with Communication Questionnaire[74]. Patients whose nurses received the intervention were significantly more satisfied than those whose nurses had not. Curtis' randomized trial that trained residents and nurse practitioners to assess patient or family outcomes did not demonstrate a difference on a Quality of Communication or Quality of End of Life Communication Questionnaire[33]. For this study, surveys were mailed to subjects up to 10 months after the intervention[33]. Some potential limitations to this study were that the surveys were completed months after the interaction, and did not reference a particular encounter with the provider, but asked survey responders to consider all encounters with the selected provider.

In order to identify an evidence-based CST that should be disseminated and reimbursed more widely, it is necessary to more conclusively demonstrate a connection between training and actual patient outcomes. To achieve this goal with adequate confidence in its reproducibility, Weiner recommends the development of manualized training programs and the consistent use of expert assessment of the communication process using validated coding schemes[82] and validated patient surveys rating the quality of communication[85].

Interprofessional training in health care can increase team collaboration and communication, but its impact on patients and team collaboration has not been sufficiently studied. Clinical teams caring for seriously ill patients are comprised of a large number of regularly rotating clinicians from a variety of disciplines posing challenges to ensuring reliably high quality

teamwork and communication within teams[86]. Optimizing team communication and collaboration is essential for patient safety as well as ensuring consistent messaging to families about the patient's care[87,88]. Leaders of healthcare organizations[89,90] recognize the benefits of interprofessional team training for promoting better team function, and the IOM specifically highlights the need in palliative care[21]. The IOM defines interprofessional as multiple professions working together toward a common goal[21]. They recommend a mixed-methods research approach to help close the evidence gap in clearly linking interprofessional training to improved health and system outcomes[91].

Both simulation and classroom-based training have been shown to improve teamwork processes like communication, cooperation and coordination over extended periods of time[89]. True collaboration of team members also minimizes the hierarchical structures in medicine by encouraging team members to listen and anticipate the concerns of other disciplines, to take collective responsibility for patient outcomes, and to acknowledge collective successes[86].

In the neonatal ICU, nurses perceive a lower level of collaboration than physicians, demonstrating a gap that needs to be addressed[92]. In the adult ICU, when nurses reported a higher level of nurse-physician collaboration, patients had better outcomes[93]. However, a prospective intervention in the ICU to improve collaboration, as measured by the Bagg's Collaboration and Satisfaction About Care Decisions (CSACD) scale, did not demonstrate significant effects[94]. Other interprofessional trainings or focus groups have demonstrated increases in perception of team collaboration by different members[95,96]. A small number of interprofessional trainings have already been developed to train clinicians in conducting family meetings[97] and to improve family outcomes in the ICU[35,98], but none have also measured team collaboration. To ensure that interprofessional CST training impacts team collaboration and function, these outcomes must be measured independently.

Another gap in the literature pertains to creating evidence-based CST in the pediatric setting. Because decision-making by parents for their children is different than the experience of surrogates making decisions for previously competent adults, communication about pediatric patients also requires a focus on family system functioning in addition to goals or desires of patients themselves[59]. Psychological outcomes of parents are tied to their perception of being supported by clinicians, family and friends. How parents shift their goals for their child is distinct from the shift experienced by surrogates making decisions for previously competent adult patients[99-101]. Parents often describe having a duty to be a good parent to their child, and their understanding of this role is central to their decision-making[102]. Therefore, successful interventions that have worked in the adult patient realm still need to be adapted and tested accordingly for pediatric ICU settings. Even within the pediatric ICU world, distinct subcultures exist in cardiac intensive care versus pediatric intensive care and neonatology fields, with both unique and overlapping needs.

To address these critical gaps in our understanding of the impact of interprofessional CST on family outcomes in the pediatric CICU, we will evaluate the impact of an adapted CST on both simulated and actual patient encounters to evaluate CST's effect on families of patients in the CICU and team function in multiple settings.

1.4 Compliance Statement

This study will be conducted in full accordance with all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46 and the Good Clinical Practice: Consolidated Guideline approved by the International Conference on Harmonisation (ICH). All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to assess the impact of a modified communication skills training (CST) program to change clinician behavior in family meetings for patients with AHD in the pediatric CICU.

2.1 Primary Objective (or Aim)

The primary objective of this study is to develop a communication skills training (CST) program for interprofessional teams in the pediatric CICU.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Evaluate CICU clinicians' perceived feasibility and acceptability with the CST
- Evaluate CST impact on communication skills and team function in the actual family meeting
- Evaluate clinicians' burnout rates and changes that CICU clinicians have implemented regarding family meetings due to the 2020 COVID-19 pandemic
- Evaluate the fidelity of clinician behavior to the intended intervention
- Learn about parents perspectives about communication challenge
- Learn about parental acceptability about parent-facing intervention elements including preparation for family meetings in the CICU and the written summary received after the family meeting

The following secondary endpoints will be used to assess CICU clinicians' perceived feasibility and acceptability with CST:

- Perceived acceptability of CST
- Metrics of enrollment rates and missing data
- Post-CST clinician survey
- Acceptability interview carried out with randomized subset of 8 intervention participants.

The following secondary endpoints will be used to assess CST impact on clinician behavior in simulated family meetings:

- Communication skill acquisition
- Team collaboration

The following secondary endpoints will be used to assess CICU clinicians' burnout rate and changes that CICU clinicians have implemented regarding family meetings due to the 2020 COVID-19 pandemic:

- Maslach burnout score[103]
- COVID change in practice survey

The following secondary endpoints will be used to assess CST impact on clinician behavior in actual family meetings:

- Communication skill acquisition
- Team collaboration
- Team member perception and satisfaction with collaboration
- Fidelity of clinician behavior to intervention

The following secondary endpoints will be used to assess parents' perspectives about communication challenges in the CICU:

- Satisfaction feelings when communicating with the clinical team with decision-making
- Understanding of patient's medical condition
- Trust in medical team
- Levels of anxiety, depression, and post-traumatic stress

The following secondary endpoints will be used to assess parents' acceptability of the parent-facing elements of the intervention; including preparing for the meeting and their perception of the written summary after the family meeting

- A survey on the experiences and acceptability of using the Family Meeting Worksheet, as well as survey questions about their acceptability of the Family Meeting Summary Worksheet

The following secondary endpoint will be used to assess co-design participant engagement in the co-design process

- Engagement in co-design

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a non-randomized cohort study with pre and post assessments around an intervention.

Clinicians and Parents Participating in Co-design of Intervention

Eligible clinicians will be approached in person and via email. If they express willingness to participate in the co-design portion of the study, they will be consented. Eligible parents of children previously hospitalized in an ICU will be approached via email or phone. If they express willingness to participate in the co-design process, they will be consented. After enrollment into the study, clinicians and parents will participate in a total of 11 sessions as focus groups to gather feedback on the CST program. Participants will be asked which aspects of the training they believe would facilitate their participation in a family meeting and sense of collaboration, which opportunities might have been missed and whether the training addressed the core competencies in collaboration. After the 11 sessions have been completed, participants will then be asked to complete a survey measuring their engagement

in the co-design process. Based on participant experience and feedback in the co-design sessions, the training will be modified to ensure its goals are met.

Clinicians Participating in Intervention

Clinicians in the CICU eligible for the intervention will be approached via email and in administrative meetings and individually consented at the beginning of the study.

After the consent process, clinicians will go through the interprofessional CST. The CST will occur over the course of 10 hours and will include short didactic sessions around giving bad news, eliciting parental goals, the core competencies of interprofessional collaborative practice[88], and adaptation for the CICU of the common components of a family meeting as represented in the CHOP Family Meeting Resources (http://intranet.chop.edu/sites/social_work/family-meeting-resources.html). Skills practice groups will include no more than 6 learners at a time. Didactic sessions may be in person or may be performed independently online as needed. Whether in-person or online, sessions may be audio or video recorded. There will be an online survey immediately after the CST to evaluate the clinicians' perception of effectiveness of the course. One month after the completion of the CST, a random sample of 8 participants will take part in a 15-30 minute acceptability interview regarding the CST.

Following the CST, a set of at least 23 actual family meeting encounters with trained clinicians will be audio recorded and coded.

A measure of team function will be assessed pre and post-CST by comparing the amount of time different members of the clinical team speak, and the kind of input offered by members of different disciplines within the team for simulated and actual family meetings. Team member perception and satisfaction with collaboration will be measured after their participation in clinical encounters both pre and post-CST by administering the modified Baggs CSACD-N tool to all clinician team members who participate in an actual encounter. This tool will capture each discipline's experience with collaboration with other team members and satisfaction with care decisions. Finally, fidelity of clinician behavior to the intended intervention in post-intervention family meetings will be determined by a fidelity checklist.

Actual meetings will each last 30-120 minutes. Clinicians participating in the intervention will be enrolled for the entirety of the study, lasting up to four years. They will have at least 21 points of contact with the research team, but some clinicians may participate more frequently due to the unknown composition of the observed actual family meetings.

Clinicians Not Participating in Intervention

Clinician team members participating in an observed family meeting who will not undergo the CST (because they were not eligible, did not wish to participate in the study, or were not approached because sufficient clinicians were already enrolled) will be consented before the scheduled meeting to being audio or video recorded only in the observed family meeting. They will also be administered a survey at the end of the meeting. Clinicians not participating in the intervention will be enrolled for only the duration of their observed family meeting and may be enrolled more than one time during the course of the study.

Parent-patient Dyads Participating in the Survey or Interview Prior to Intervention

Potential subjects will be screened using the protocol inclusion and exclusion criteria. Parent-patient dyads will be recruited into the study in person or over the phone. The goal for enrollment will be 100 parent-patient dyads for the survey and up to 30 parent-patient dyads for the interview. 100 parent-patient dyads who are enrolled will be given an online survey on a laptop computer or via email to obtain baseline data assessing parental satisfaction, understanding, trust in the clinical team and emotional well-being. Medical record review of this group of patients will utilize EPIC and the PC^4 database, but will not require patient or parent involvement. 30 enrolled parent-patient dyads will participate in an interview assessing their experiences in family meetings and their perspectives on communication with the clinical team.

Parent-patient Dyads Participating in the Survey or Interview After Intervention

Potential subjects will be screened using the protocol inclusion and exclusion criteria. Parent-patient dyads will be recruited into the study in person, over the phone, or via e-mail. The goal for enrollment will be up to 50 parent-patient dyads, with 30 evaluable parent-patient dyads. Parent-patient dyads who are enrolled in the post-intervention follow-up phase will be asked for access to information entered into the REDCap based Family Meeting Worksheet if they choose to use it, will be given an online survey in person or via e-mail to obtain post-intervention data assessing parental satisfaction, understanding, trust in the clinical team, emotional well-being and parents' acceptability of the parent-facing elements of the intervention, which includes preparation for the meeting and their perception of the written summary after the family meeting. Medical record review of this group of parents will utilize EPIC and the PC^4 database, but will not require patient or parent involvement. A subset of enrolled patient-parent dyads will also be invited to participate in an interview assessing parents' acceptability of the parent-facing elements of the intervention.

3.1.1 Enrollment Phase

Clinicians and Parents Participating in Co-design of the intervention

Potential clinician subjects and parents of previously hospitalized patients will be screened using the protocol inclusion and exclusion criteria. Clinicians will be recruited into the study through an open announcement of the study by the study team at faculty meetings and via a faculty listserv that will give them contact information to follow up with a study team member if they are interested in participating (See Appendix 11.1 for recruitment email). Approximately 15 clinicians will be enrolled for the co-design. Parents will be approached via a Family Advisory Council invitation and email listserve call. Approximately 5 parents of previous patients who have been admitted to the ICU will be enrolled.

Clinicians Participating in Intervention

Potential clinician subjects will be screened using the protocol inclusion and exclusion criteria. CICU clinicians will be recruited into the study through an open announcement of the study by the study team at faculty meetings and via a faculty listserv that will give them contact information to follow up with a study team member if they are interested in

participating (See Appendix 11.2 for recruitment email). The goal for enrollment will be at least 20 CICU clinicians.

Clinicians Not Participating in Intervention

Clinician team members participating in an observed family meeting who will not undergo the CST (because they were not eligible, did not wish to participate in the study, or were not approached because sufficient clinicians were already enrolled) will be consented to being audio or video recorded and completing a survey before the scheduled family meeting.

Parent-patient Dyads Participating Prior to Intervention

Potential subjects will be screened using the protocol inclusion and exclusion criteria. Parent-patient dyads will be recruited into the study in person or over the phone. The goal for enrollment will be up to 100 parent-patient dyads for the survey and up to 30 parent-patient dyads for the interview. Up to 100 parent-patient dyads who are enrolled will be given an online survey on a laptop computer or via email to obtain baseline data assessing parental satisfaction, understanding, trust in the clinical team and emotional well-being. Medical record review of this group of patients will utilize EPIC and the PC^4 database, but will not require patient or parent involvement. 30 enrolled parent-patient dyads will participate in an interview assessing their experiences in family meetings and their perspectives on communication with the clinical team.

3.1.2. Co-Design of Intervention Phase

Instead of a pilot, we will conduct a co-design of the intervention with relevant stakeholders of the intervention. Experienced based co-design encourages collaborative work between vulnerable patients, their parent caregivers, and staff in complex healthcare environments[104], allowing for the specific needs of participants to be addressed and included in the adaptation of the intervention.[105] The co-design process itself impacts clinical practice due to changes in clinician behavior after participation in the co-design.[106] The process usually takes 9-12 months to complete and has been described as a 6 stage process: 1) setting up the project, 2) gathering staff experiences through observation and in-depth interviews, 3) gathering patient and caregiver experiences through narrative based interviews, 4) bringing staff, patients and caregivers together to share experiences of the service and shared priorities for improvement, 5) small groups of caregivers and staff working on the identified priorities, and 6) celebrating and reviewing the event.[104]

The CST elements that will be evaluated by the co-design group will be largely modeled after the VitalTalk CST training for the ICU, named Critical Care Communication.[107] We will discuss the acceptability of modification of the VitalTalk CST in three ways: 1) The intervention might focus on interprofessional training rather than singularly on one profession (i.e., physicians). Exercises may be designed specifically to require teamwork in communication, highlighting the complementary skill sets of different team members. Collaboration will be emphasized and didactics will review core competencies as described by the Interprofessional Education Collaborative.[88] 2) The training may be adapted for a pediatric CICU setting while preserving several of the learning goals previously tested. We will work with Dr. Bob Arnold and pediatric CICU attending, Dr. Aaron Dewitt, MD, to develop cases that are clinically accurate and relevant to having clinicians acquire

previously described learning goals (giving bad news and eliciting parental goals for their child).[29] 3) The training will integrate the CHOP-developed Family Meeting Resources, including a pre-meeting worksheet to be filled out by clinicians prior to a family meeting, an outline for how to conduct a standard family meeting, and a Next Steps Worksheet to make clear what occurred in the meeting and what to expect moving forward. [See Appendix 11.3] The pre-meeting worksheet prompts clinicians to articulate the goals of the meeting, anticipate challenges, and identify who will be present and lead the meeting. The outline for a standard family meeting was developed by compiling the best evidence for how to conduct a family meeting.[47,50,51,108,109]

The CST will be conducted over a total of 10 hours and will include short didactic sessions around giving bad news, eliciting parental goals, the core competencies of interprofessional collaborative practice, and the common components of a family meeting. Participating clinicians will be provided cognitive road maps for communication tasks that were based on empirical studies of patient preferences. Didactics will also emphasize how members of different disciplines make important contributions to discussions with families. The majority of the time will be spent on skills practice using the VitalTalk model of building on learner's strengths and creating a safe environment for learning new skills, facilitated by myself or another VitalTalk trained facilitator. Skills practice groups will include no more than 6 learners at a time. Because the VitalTalk methodology relies upon well-trained actors to play the role of patients and family members for facilitated skills practice by clinician learners, we will train actors currently working as actors for CHOP's Vital Talk program. To successfully engage with actor parents and clinicians, teams will need to function collaboratively, drawing upon unique knowledge that each team member will be provided about the case and family. Actors will not participate in human subjects research and will merely perform a service for the study.

A more complete outline of the CST and how it will be discussed with the co-design group is described below in the Appendix 11.4.

Clinicians will participate in focus groups to gather feedback on the CST program throughout the co-design process. Participants will be asked which aspects of the training might facilitate their participation in a family meeting and sense of collaboration, which opportunities might have been missed, and whether the training addresses the core competencies in collaboration. Based on participant feedback, the training will be modified to ensure its goals are met.

After the completion of all focus group sessions, participants will be asked to complete a short survey. The survey is a modified version of a validated tool that allows for analysis by subscale.[110-112] The subscales used in the Co-design survey are a 14-item section measuring participants' perceptions of the Co-design leader's effectiveness and a 10-item section measuring participants' perceptions of their own involvement and commitment to the Co-design process. This information is supplemented with demographic information.

A more complete outline of the focus group is described below in the Appendix 11.5. The survey tool appears in Appendix 11.6.

3.1.3 Pre-CST Intervention Phase

Clinicians Not Participating in Intervention: Consented clinicians not participating in the intervention will be audio recorded in their previously scheduled family meetings. Clinicians not participating in the intervention will complete an online survey after the actual family meeting that they are observed participating in.

3.1.4 CST Intervention

After the pre-intervention phase, clinicians participating in the intervention will go through the interprofessional CST. The CST will occur over the course of 10 hours and will include short didactic sessions around giving bad news, eliciting parental goals, the core competencies of interprofessional collaborative practice, and the common components of a family meeting. Didactic sessions may be in person or may be performed independently online as needed. Whether in-person or online, sessions may be audio or video recorded. Clinicians must complete all parts of the CST training in order to continue to be enrolled in the study. Supplemental handouts that will be used in the training are available in Appendix 11.3. After completion of the intervention, clinicians who participate in the training will be given a course evaluation to determine clinicians' perception of the usefulness and satisfaction with CST. They will be asked to rate their level of agreement with aspects of the course on a 5 point Likert-type scale. Post-intervention survey will also include clinician burnout measures, demographics, and changes in family meeting communication since the onset of the COVID-19 pandemic. One month after completion of the CST training, a random sample of 8 participating clinicians will complete a 15-30 minute acceptability interview regarding the CST training.

3.1.5 Follow-Up Phase

Clinicians Participating in Intervention: After CST, a set of actual family meeting encounters with these trained clinicians will be audio recorded and coded, ensuring there are 23 meetings with each category of person trained. We estimate a total of 28 meetings will need to be recorded in order to obtain 23 meetings with each discipline. Clinicians participating in the intervention will complete an online survey after the actual family meeting that they are observed participating in.

This survey will measure team member perception and satisfaction with collaboration. We will administer the modified Baggs CSACD-N tool to all clinician team members who participate in an actual encounter, which will capture each discipline's experience with collaboration with other team members and satisfaction with care decisions.

Clinicians Not Participating in Intervention: Consented non-participating clinicians will have their normal, scheduled family meetings. Actual family meeting encounters with these clinicians will be audio or video recorded and coded. Clinicians not participating in the intervention will complete the same online survey as those clinicians participating in the intervention after the observed actual family meeting.

Parent-patient Dyads Participating in the Survey or Interview After Intervention: Potential subjects will be screened using the protocol inclusion and exclusion criteria. Parent-patient dyads will be recruited into the study in person, over the phone, or via e-mail. The goal for enrollment will be up to 50 parent-patient dyads, with 30 evaluable parent-

patient dyads. Parent-patient dyads who are enrolled in the post-intervention follow-up phase will be asked for access to information entered into the REDCap based Family Meeting Worksheet if they choose to use it, will be given an online survey in person or via e-mail to obtain post-intervention data assessing parental satisfaction, understanding, trust in the clinical team, emotional well-being and parents' acceptability of the parent-facing elements of the intervention, which includes preparation for the meeting and their perception of the written summary after the family meeting. Medical record review of this group of parents will utilize EPIC and the PC^4 database, but will not require patient or parent involvement. A subset of enrolled patient-parent dyads will also be invited to participate in an interview assessing parents' acceptability of the parent-facing elements of the intervention.

3.2 Blinding

The study will not be blinded given the differences in recording prior to and after the COVID pandemic.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

Study duration for clinicians and parents participating in the co-design is expected to last up to 12 months since their schedules are not conducive to completing the tasks more efficiently. The expectation is that they will meet approximately one hour a month for 11 months.

Study duration for clinicians participating in the intervention is expected to last up to 4 years. The CST intervention will occur over the course of 10 hours lasting over several months. Clinicians will have at least 21 points of contact with the research team, but some clinicians may participate more frequently due to the unknown composition of the observed actual family meetings.

For each post-family meeting survey administration, clinicians will be contacted no more than 3 times via email to request that they complete the survey. Templates for the emails requesting that they complete the surveys are demonstrated in Appendix 11.6 and Appendix 11.7. The surveys are expected to take approximately 5-10 minutes to complete. The full survey is located in Appendix 11.10.

Study duration for non-participating clinicians will last the duration of their family meeting (30-90 minutes), and post-meeting surveys are expected to take approximately 5-10 minutes to complete.

Study duration for parent–patient dyads participating prior to the intervention will last approximately 20 minutes for those participating in the survey for visit 1 and their medical record review will occur at discharge from the hospital which may range from 2-730 days after enrollment. Study duration will be 30-60 minutes for those participating in the interview.

Study duration for parent-patient dyads participating after the intervention will last approximately 30-60 minutes for the recording of the family meeting for visit 2, 20 minutes

for those participating in the survey for visit 3, and approximately 20 minutes for those participating in the interview for visit 4. Medical record review will occur at discharge from the hospital which may range from 2-730 days after enrollment.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study will be conducted within the Children's Hospital of Philadelphia. The co-design phase will be conducted with participants from units within the hospital and parents with children who had previously been hospitalized at CHOP, and the intervention and evaluation of the intervention will occur exclusively in the CICU at CHOP.

For clinicians participating in the co-design, approximately 15 clinician staff will be enrolled and 5 parents will be enrolled.

For clinician subjects participating in the intervention, recruitment will stop when at least 20 CICU clinicians are enrolled.

For non-participating clinicians, recruitment will stop when we obtain at least 56 family meetings per discipline of participating clinician team member.

We estimate that approximately 300 clinicians who are not participating in the intervention may be observed subjects in the actual meetings.

For parent-patient dyads participating prior to the intervention, recruitment will stop when 100 evaluable parent-patient dyads are enrolled for the survey and 30 evaluable parent-patient dyads are enrolled for the interview.

For parent-patient dyads participating after the intervention, recruitment will stop when up to 30 evaluable parent-patient dyads are enrolled for the survey and a subset of up to 15 parent-patient dyads will be asked to participate in the interview.

3.4 Study Population

3.4.1 Participants in Co-design

3.4.1.1 Inclusion Criteria

- Clinicians including attending physicians, front line clinicians (fellows, nurse practitioners, or physician assistants), bedside nurses, and social workers working at CHOP or parents of children previously hospitalized in an ICU at CHOP.

3.4.1.2 Exclusion Criteria

- None

3.4.2 Clinicians Participating in Intervention

3.4.2.1 Inclusion Criteria

- Pediatric CICU clinicians (attending intensivists, cardiologists, cardiac surgeons, front line clinicians, nurses, and social workers) at CHOP who volunteer to undergo communication skills training.

3.4.2.2 Exclusion Criteria

- Clinicians who will not participate in CHOP's CICU chronic care meeting in the following year.

3.4.3 Clinicians Not Participating in Intervention

3.4.3.1 Inclusion Criteria

- Clinicians who plan to participate in family meetings in the pediatric CICU that will be observed by the research team.

3.4.3.2 Exclusion Criteria

- None

3.4.4 Parent-patient Dyads Participating in the Survey or Interview Pre-Intervention Phase

3.4.4.1 Inclusion Criteria

- Parent must be the legal decision maker of a patient who has been admitted to the CHOP CICU for at least 7 days
- Patient has been admitted to the CICU at CHOP for ≥7 days following onset of study and the medical team believes the patient will remain in the CICU for at least 7 more days
- Parent/guardian ≥ 18 years old
- Child < 18 years old at time of enrollment
- Parent/guardian is English-speaking
- Parent/guardian has no cognitive impairments that prevent them from being a surrogate decision maker

3.4.4.2 Exclusion Criteria

- Parent is not the legal decision maker of a patient who has been admitted to the CHOP CICU for at least 7 days
- The medical team does not believe the patient will remain in the CICU for at least 7 more days
- Parent/guardian < 18 years old
- Child is ≥ 18 years old at time of enrollment
- Parent/guardian is not English-speaking
- Parent/guardian has cognitive impairments that prevent them from being a surrogate decision maker

3.4.5 Parent-patient Dyads Participating in the Survey or Interview Post-Intervention

3.4.5.1 Inclusion Criteria

- Parent must be the legal decision maker of a patient who has been admitted to the CHOP CICU for at least 7 days

- Patient has been admitted to the CICU at CHOP for ≥7 days following onset of study and the medical team believes the patient will remain in the CICU for at least 7 more days OR the patient has already been admitted to the CICU 14 days
- Parent/guardian ≥ 18 years old
- Child < 18 years old at time of enrollment
- Parent/guardian is English-speaking

3.4.5.2 Exclusion Criteria

- Parent is not the legal decision maker of a patient who has been admitted to the CHOP CICU for at least 7 days
- Parent/guardian < 18 years old
- Child is ≥ 18 years old at time of enrollment
- Parent/guardian is not English-speaking

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Enrollment Phase

4.1.1 Subjects Participating in Co-design: Visit 1

- Eligibility determined for clinician and parent subjects
- Written or eConsent obtained

4.1.2 Clinicians Participating in Intervention: Visit 1

- Eligibility determined for clinician subjects
- Written or eConsent obtained

4.1.3 Clinicians Not Participating in Intervention: Visit 1

- Eligibility determined for non-participating clinicians
- Written or email consent obtained

4.1.4 Parent-patient Dyads Participating in the Survey Prior to the Intervention: Visit 1

- Eligibility determined for parent-patient dyads
- Informed consent obtained in person or via phone
- Administration of online baseline survey about parental satisfaction, understanding, decision-making preferences, trust, and emotional well-being

4.1.5 Parent-patient Dyads Participating in the Interview Prior to the Intervention: Visit 1

- Eligibility determined for parent-patient dyads

- Informed consent obtained in person or via phone
- Administration of in-person interview regarding parental experiences in family meetings and perspectives about communication with the clinical team

4.2 Co-design of Intervention Phase

4.2.1 Subjects Participating in Co-design: Visit 2-12

- Clinicians and parents undergo focus groups about the proposed communication skills training program and an engagement survey (details of the CST are provided in Appendix 11.4)

4.3 Pre-Intervention Phase

Before clinicians that are participating in the intervention are trained, their communication and team function skills will be assessed in actual encounters. Actual encounters with parents and patients will involve participating clinicians and non-participating clinicians.

4.3.1 Clinicians Not Participating in Intervention: Visit 2

- Non-intervention participating clinicians recorded during family meeting
- Administration of online baseline survey about clinicians' perception of team function

4.3.2 Parent-patient Dyads Participating in the Survey: Visit 2

- Medical record review. No parents will be contacted

4.4 Intervention Phase

- Participating clinicians will undergo the communication skills training program.

4.4.1 Clinicians Participating in Intervention: Visit 2-11

- Administration of CST program over the course of 10 hours. Sessions may be audio or video recorded.
- Administration of online course evaluation survey, burnout scale, demographics, and communication in family meetings since COVID-19 pandemic

4.5 Follow-Up Phase

After clinicians who participate in the intervention are trained, their communication and team function skills will be assessed in actual encounters. Actual encounters with parents and patients will involve participating clinicians and non-participating clinicians.

4.5.1 Clinicians Participating in Intervention: Visit 5-30

- Clinician audio recorded during actual family meeting
- Administration of follow-up online survey about clinicians' perception of team function in person or via email

4.5.2 Clinicians Participating in Intervention: Visit 6-21

- Administration of 15-30 minute acceptability interview to each of 8 randomly sampled clinicians

4.5.3 Clinicians Not Participating in Intervention: Visit(s) 2-17

- Non-participating clinician recorded during family meeting
- Administration of follow-up online survey about clinicians' perception of team function

4.5.4 Parent-patient Dyads Participating after Intervention: Visit 1

- Eligibility determined for parent-patient dyads
- Informed consent obtained in person, via phone, or by eConsent
- Patient medical record review

4.5.5 Parent-patient Dyads Participating after Intervention: Visit 2

- Recording of family meeting

4.5.6 Parent-patient Dyads Participating after Intervention: Visit 3

- Administration of online survey about parental satisfaction, understanding, decision-making preferences, trust, emotional well-being, use and acceptability of Family Meeting Preparation Worksheet, and acceptability of Family Meeting Summary Worksheet.

4.5.7 Parent-patient Dyads Participating after Intervention: Visit 4

- Administration of an interview in-person, by phone or over CHOP secure video channel regarding the acceptability of parent preparation for the family meeting process and of the written summary received after the meeting.

4.6 Subject Completion/Withdrawal

Clinicians, parents, and parent-patient dyads may withdraw from the study at any time without prejudice to their employment status or the care of their child at The Children's Hospital of Philadelphia. It will be documented whether or not each clinician and parent-patient dyad completes the study. The Investigator may also withdraw subjects who violate the study plan or to protect the subject for reasons of safety or for administrative reasons.

4.6.1 Early Termination Study Visit

During any of the visits, if any subject decides to withdraw prior to completion of all study materials, the research team will review the individual circumstances and decide whether any data already collected will be included in further analyses. These decisions will be based on whether enough data has been collected to adequately complete our planned analysis. If at any time any subject requests to have information they have submitted withdrawn from consideration, we will abide by their request and remove that data from our research database.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Evaluations, Measures

Measures for Co-Design

- Follow-Up focus group (See Appendix 11.5 for focus group guide)
- Post-focus group survey (See Appendix 11.6 for survey)
    - *Demographics of co-design participants:* The following baseline data will be collected: role in the co-design, gender, race, and ethnicity.
    - *Perception of co-design process and level of engagement:* Modified version of "Coalition Effectiveness Inventory"[110-112] that consists of one 14-item section measuring participants' perceptions of the Co-design leader's effectiveness and one 10-item section measuring participants' perceptions of their own involvement and commitment to the Co-design process.

Measures for Post-Intervention

- *Course Evaluation - Satisfaction with CST and perception of skill usefulness:* This course evaluation is designed to determine clinicians' perception of usefulness and satisfaction with the CST program. They will be asked to rate their level of agreement with aspects of the course on a 5 point Likert-type scale. Furthermore, the current burnout rate of clinicians will be assessed using the Maslach burnout score.[103] Additionally, changes that CICU clinicians have implementedregarding family meetings due to the 2020 COVID-19 pandemic will be recorded. Finally, clinician demographics will be collected including role in CICU, gender, race, and ethnicity. See Appendix 11.11 for complete course evaluation, Maslach burnout score, and COVID Change in Practice survey
- *Intervention fidelity checklist:* The Fidelity Checklist is a list of 7 behaviors of clinicians used to determine if clinicians used the tools and documents taught in the intervention. See Appendix 11.12 for the Intervention Fidelity Checklist
- *Acceptability Interview - 1 month follow-up:* We will do a semi-structured interview with clinicians reviewing their experience of the intervention process including what worked well and what they would recommend changing. Emphasis will be placed on virtual aspects of the training given the novelty of the implementation due to the COVID-19 pandemic. The semi-structured interview guide is in Appendix 11.13

Surveys for Clinicians Participating in Actual Family Meetings

- *Demographics of clinician participants:* The following data will be collected regarding clinician subjects: discipline, age, gender, ethnicity, race, number of years in practice, estimated number of family meetings conducted in a week, estimated average time spent on conducting family meetings, previous experience with communication skills training.

- *Team member perception and satisfaction with collaboration:* The Baggs CSACD-N tool[94,109] will measure team member perception and satisfaction with collaboration both pre and post-CST. Clinicians will rate their level of agreement for 9 items on a 7-point Likert-type scale from "Strongly disagree" to "Strongly agree." This tool will capture each discipline's experience with collaboration with other team members and satisfaction with care decisions.

Survey Measures for Parent-patient Dyads

- *Demographics of parent-patient dyads*: The following baseline data will be collected regarding parent-patient dyads: age, gender, ethnicity, race, education level, and health literacy.
- *Parental preference for decision making control*: The Control Preferences Scale for Pediatrics (CPS-P)[113] is a 5-item sorting measure of parent preferences for participation in treatment decision making.
- *Parental anxiety and depression*: The Hospital Anxiety and Depression Scale (HAD)[114] is a 14-item measure of depression and anxiety.
- *Parental post-traumatic stress*: The Impact of Event Scale-Revised (IES-R)[115] is a 22-item measure of post-traumatic stress disorder.
- *Parental trust in medical team*: The Trust in Physician Scale[116] is a 10-item measure of trust in physicians.
- *Parental satisfaction with decision-making*: The Pediatric Family Satisfaction with Care in the Intensive Care Unit (PFS-ICU 24)[117] is a 24-item tool and will measure (1) satisfaction with care and (2) satisfaction with medical decision-making, modified for parents/caregivers of critically ill children. The Communication Assessment Tool-Team (CAT-T)[118] is a 15-item tool that will measure patient perception of communication with the medical team and is adapted to team environments. A more complete outline of the survey is described below in the Appendix 11.14.
- *Parental feelings about communication with the clinical team*: myICU[119] is an 11 item tool adapted by the authors of the tool to assess a surrogate's perceptions of how comfortable the surrogate feels discussing potential concerns they have with their child's medical team regarding their child's care in the ICU.
- *Parental involvement in other family meetings*
- *Fidelity of Parent Preparation and Acceptability:* Parents will be surveyed on whether they were given the Family Preparation Worksheet and whether clinicians followed up on how they used the worksheet. They will be asked what they thought of the worksheet. They will also be asked about their acceptability of the Family Meeting Summary Worksheet. The use and acceptability survey was adapted from a Shared Decision Making tool. [120] See Appendix 11.15 for specific items.
- *Medical record review*: Patient data will be retrieved from Epic and PC[4] national database registry. Data listed below are main patient record variables. See Appendix 11.18 for full list of PC[4] variables

    - Child's name
    - Child's MRN#

- Child's date of birth
- Child race/ethnicity
- Parent/legal guardian race
- Parent/legal guardian contact number
- Parent/legal guardian e-mail address
- Parent/legal guardian address
- Length of stay in the CICU
- Length of stay in the hospital
- EPIC Problem List
- Medication list and administration dates throughout hospitalization
- Limitations of interventions during study period
- Date of limitations of interventions during study period
- ICD-9 codes associated with hospitalization
- Date of discharge from CICU / Date of death/ discharge from hospital
- Discharge disposition from CICU and hospital (floor / home / rehab facility / palliative care / hospice)
- Palliative care consult
- Ethics consult
- Gestational age
- Fundamental Cardiac Diagnosis
- Chromosomal abnormalities
- Syndromes
- Cardiothoracic surgery and date
- Primary insurance type
- Discharge 30 day mortality status
- Number of prior cardiothoracic operations
- Reason for CICU encounter
- Non-cardiothoracic surgery
- Encounter cardiothoracic diagnosis
- Encounter medical diagnosis
- DNR/DNI on file
- Withdrawal of life sustaining therapy
- Bleeding requiring reoperation and date
- Unplanned reoperation/reintervention and date
- Sternum left open and date
- Cardiac arrest and date
- Stroke and date
- Risk group as measured by the STAT mortality category
- operative or post-operative complications

- Specialty notes related to CICU family meeting
- CICU Summary Worksheet

Interviews for Parent-patient Dyads in the Pre-Intervention

- The interviews will cover parents' experiences in family meetings and perspectives on communication with the clinical team. (See interview guide under Appendix 11.16)

Interviews for Parent-patient Dyads in the Post-Intervention

- The interviews will assess parents' acceptability of the parent-facing elements of the intervention, including preparing for the meeting and their perception of the written summary after the family meeting. (See interview guide under Appendix 11.17).

Quantitative Coding of Audio Recordings of Actual Family Meetings

- *Modified VitalTalk coding scheme named SCOPE*[29,121,122]*:* The small number of new codes added will measure engagement by the attending physician of team members from other disciplines, and adherence to elements of best practices in family meetings (e.g., facilitating introductions of participants, setting an agenda, and summarizing what was discussed in the meeting). Coders will be trained in the coding scheme using a manual with detailed definitions of all the codes.
- *Medical Interaction Process System (MIPS)*[80]*:* MIPS is a previously validated coding scheme with good psychometric properties that was developed for training clinicians in communication and related research[80]. It has been used extensively in communication analysis[83,123]. MIPS draws upon a patient-centered approach and codes individual utterances between providers and patients allowing for coding of both content and affective information.
- *Time each member speaks during meeting:* Team function will be analyzed by comparing the change in the number of minutes clinicians from each discipline speak in pre and post-CST meetings using linear regression and controlling for the length of the meetings.
- *Performance Assessment for Communication and Teamwork (PACT-Novice)*[124,125]: The PACT Tool Set was developed to assess performance on team work and communication and builds upon the framework of TeamSTEPPS, a widely used system designed to improve patient safety, communication, and teamwork skills among health care professionals. The PACT-Novice tool will allow us to quickly train study staff to evaluate teamwork and communication behaviors.
- *Bruce et al*. *Evaluation Tool*[126]*:* This novel evaluation tool was recently developed to assess family meetings, including clinician skills, team function, meeting leadership, and other elements of successful family meetings.

Clinician Schedule of Evaluations

Diagnostics/Measures	Co-design	Pre-CST Actual Meetings	Post-CST Evaluation	Post-CST Actual Meetings
Focus Group	X			
Focus Group Survey	X			
Course Evaluation including Maslach burnout score and COVID-19 questions, demographics.			X	
1 Month Follow-Up Acceptability Interview			X	
Demographics		X		X
CSADC-N		X		X
SCOPE		X		X
MIPS		X		X
PACT-Novice		X		X
Bruce et al. Evaluation Tool		X		X
Time each member speaks		X		X

Qualitative Coding of actual family meetings

- Using a grounded theory, audio recordings will also be coded by 2 coders for thematic content to better understand team functioning and collaboration
- Video recordings will be used for speaker attribution in the coding phase.

Qualitative Coding of parent-patient dyad interviews

- Using a grounded theory, audio recordings will also be coded by 2 coders for thematic content to better understand parental experiences communicating with the medical team in the CICU.

5.2 Efficacy Evaluations

5.2.1 Diagnostic Tests, Scales, Measures, etc.

To gather feedback on the proposed CST program, clinicians and parents who participated in the co-design will be asked in focus groups which aspects of the training would facilitate their participation in a family meeting and sense of collaboration, which opportunities might have been missed, and whether the training addresses the core competencies in collaboration. Based on participant experience and feedback in the co-design sessions, the training will be modified to ensure its goals are met. A more complete outline of the co-design group is described below in the Appendix 11.5.

Clinicians who participate in the intervention will be given a course evaluation to determine their perception of the usefulness and satisfaction with CST. They will be asked to rate their level of agreement with aspects of the course on a 5 point Likert-type scale, have their level of burnout assessed using the Maslach burnout score,[103] complete questions regarding changes that they have implemented regarding family meetings due to the 2020 COVID-19 pandemic, and provide basic demographics. A random sample of 8 clinicians will also complete a 15-30 acceptability interview 1 month after the completion of the CST training.

To evaluate team member perception and satisfaction with collaboration in actual family meetings, a validated tool will be used. The Baggs CSACD-N tool[94,109] will measure team member perception and satisfaction with collaboration both pre and post-CST.

To evaluate clinician behavior in actual meetings we will revise a content-based coding scheme for observable behaviors that reflect skills learned in the training. We will start with a coding scheme previously used in the VitalTalk studies given the significant overlap in learning goals[29,121,122]. The small number of new codes added will measure engagement by the attending physician of team members from other disciplines, and adherence to elements of best practices in family meetings (e.g., facilitating introductions of participants, setting an agenda, and summarizing what was discussed in the meeting). Coders will be trained in the coding scheme using a manual with detailed definitions of all the codes. All coders will code 2 or 3 co-design encounters together to obtain a consensus. Coders will also be trained in the Medical Interaction Process System (MIPS) coding scheme. MIPS draws upon a patient-centered approach and codes individual utterances between providers and patients, allowing for coding of both content and affective information[80]. Because multiple clinicians will participate in any meeting, acknowledgement of a skill will be attributed both collectively to the clinician team and to the individual from a specific discipline. For example, it may be the case that before CST only the social worker verbally expresses empathy, but post-CST attending physicians and bedside nurses also verbally express empathy in a meeting. This would be considered a change in clinician behavior if either more verbal expressions of empathy are made overall or if more clinicians from different disciplines make the same total number of verbal expressions of empathy. To evaluate if there are differences in clinician behavior pre and post-CST, coders will be blinded to whether an audio file was made prior to or after CST, and whether it was in a simulated or actual clinical encounter by playing files in a random order.

To evaluate team function, the time each member speaks during the simulated or actual family meeting will be measured. We will compare the change in the number of minutes that clinicians from each discipline speak in pre and post-CST meetings using linear regression and controlling for the length of the meetings. We will slightly modify a team function tool, the PACT-Novice to measure team function in the team meetings[125]. In addition, we will use an evaluation tool which was recently developed by Bruce et al. that can be used to assess family meetings and clinician skills used during meetings to assess individual and team function[126].

To evaluate the fidelity of the intervention implementation in the post-intervention phase, a Fidelity Checklist used for each recorded meeting will be used.

Taken together, the aforementioned measures will be used to assess the efficacy of the study intervention, including the development of the CST program, its perceived usefulness and satisfaction, its impact on communication skills and team function in simulated family meetings, and its impact on communication skills and team function in actual family meetings.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The focus group will yield qualitative data on how to improve the CST program.

6.2 Secondary Endpoints

The following secondary endpoints will be used to assess CICU providers' perception of usefulness and satisfaction:

- Standard descriptive statistics and differences in means and medians will be determined for perception of usefulness and satisfaction with CST.

The following secondary endpoints will be used to assess CST impact on clinician behavior in simulated and actual family meetings:

- Feasibility of the study will be evaluated by tracking trial enrollment and retention rates, consent rates, rates of missing data on parent and team reported outcomes, duration of family and team meetings.
- Acceptability of the study will be evaluated with an acceptability interview and an acceptability satisfaction survey.[120]
- SPIKES skills acquisition as assessed by the SCOPE tool. SPIKES is an acronym that stands for setting, perception, invitation, knowledge, emotion, and summary. It is a stepwise approach for giving bad news by preparing the setting; assessing the patient's perception; making an invitation to disclose the news; sharing the knowledge about the news; responding to the patient's emotion; and summarizing the plan[29].
- NURSE skills acquisition as assessed by SCOPE tool. NURSE is an acronym that stands for naming, understanding, respect, support, and exploring. It measures clinicians' use of verbal empathetic expressions by how they name emotions; express understanding; show respect or praise for a patient's behavior; articulate support for the patient; and explore the patient's emotional state[29].
- Change in Medical Interaction Process System (MIPS) profile. MIPS is a previously validated coding scheme with good psychometric properties that was developed for training clinicians in communication and related research[80]. It has been used extensively in communication analysis[83,123]. MIPS draws upon a patient-centered approach and codes individual utterances between providers and patients, allowing for coding of both content and affective information[80].
- Team Function. Team function will be analyzed by comparing the change in the number of minutes clinicians from each discipline speak in pre and post-CST meetings using linear regression and controlling for the length of the meetings.
- Team function will also be measured by changes in PACT-Novice scores and with the family meeting evaluation tool developed by Bruce et al.[126]
- Change in kind of input offered by members of clinical team.

The following secondary endpoints will be used to assess clinician burnout and changes in communication in family meetings during COVID-19 pandemic

- The Maslach burnout scale, which uses Likert-type scales to measure aspects of burnout syndrome, including emotional exhaustion, depersonalization, and decreases in feelings of accomplishment.[103,127]
- COVID-19 impact on communication in family meetings is a novel tool with 18 questions measuring the modality of communication with families and colleagues prior to during COVID-19 pandemic.

The following secondary endpoints will be used to assess CST impact on clinician behavior only in actual family meetings:

- *Modified Baggs CSACD-N tool*[94,128]: The Baggs CSACD-N tool will measure team member perception and satisfaction with collaboration both pre and post-CST and will be given to all participating clinician team members. This tool will capture each discipline's experience with collaboration with other team members and satisfaction with care decisions. The difference in team member perception of collaboration will be measured using the CSACD-N pre and post-CST training. Means and standard deviations will be calculated for the tool and t-tests will determine if there are significant differences for each discipline pre and post-CST.
- Qualitative thematic analysis of family meetings that will identify if there are differences in themes prior to and after CST

The fidelity of the intervention implementation will be assessed by a Fidelity Checklist.

- The fidelity checklist will be scored by a study team member while reviewing the family meeting recording and reviewing information in Epic and parental survey responses. A summary score will be calculated for each family meeting conducted and descriptive statistics will be calculated for the post-intervention family meetings.

The following secondary endpoints will be used to assess parents' perspectives about communication challenges in the CICU when talking with the clinical team:

- In-person interviews prior to the intervention: These interviews will assess parents' experiences in communicating in the CICU with the clinical team. A constructivist grounded theory approach will guide qualitative analysis of interview transcripts.
- *Control Preferences Scale for Pediatrics (CPS-P)*[113]*:* The CPS-P will measure parent preferences for participation in treatment decision making pre-intervention and will be included in the survey given to 37 participating parent-patient dyads. Descriptive statistics will be calculated for quantitative data from this survey.
- *Hospital Anxiety and Depression Scale (HAD)*[114]*:* The HAD Scale will measure parental levels of depression and anxiety pre-intervention and will be included in the survey given to 37 participating parent-patient dyads. Descriptive statistics will be calculated for quantitative data from this survey.
- *Impact of Event Scale-Revised (IES-R)*[115]*:* The IES-R will measure parental levels of post-traumatic stress disorder pre-intervention and will be included in the survey given to 37 participating parent-patient dyads. Descriptive statistics will be calculated for quantitative data from this survey.

- *Trust in Physician Scale*[116]*:* The Trust in Physician Scale will measure parental levels of trust in the clinical team pre-intervention and will be included in the survey given to 37 participating parent-patient dyad. Descriptive statistics will be calculated for quantitative data from this survey.
- *Pediatric Family Satisfaction with Care in the Intensive Care Unit (PFS-ICU 24)*[117]*:* The PFS-ICU will measure parental satisfaction with care and medical decision-making (modified for parents/caregivers of critically ill children) pre-intervention and will be included in the survey given to 37 participating parent-patient dyads. Descriptive statistics will be calculated for quantitative data from this survey.
- *Communication Assessment Tool-Team (CAT-T)*[118]*:* The CAT-T, adapted to team environments, will measure parental perception of communication with the medical team pre-intervention and will be included in the survey given to 37 participating parent-patient dyads. Descriptive statistics will be calculated for quantitative data from this survey. This study will generate data that: a) is of substantial descriptive interest; b) will enable the evaluation of this population of CICU clinicians; c) will enable us to test the study's hypotheses; and d) will enable us to estimate the size and precision of the associations between the variables specified in the hypotheses.
- *MyICU:* The MyICU survey[119], is an 11 item tool adapted by the authors of the tool to assess a surrogate's perceptions of how comfortable the surrogate feels discussing potential concerns they have with their child's medical team regarding their child's care in the ICU. Descriptive statistics will be calculated for quantitative data from this survey

The following secondary endpoints will be used to assess parents' acceptability with the family-facing intervention elements:

- *Fidelity of Parent Preparation and Acceptability*: Parents will be surveyed on their use of and acceptability of Family Meeting Preparation Worksheet,[120] and their acceptability of the Family Meeting Summary Worksheet. Items will be calculated with descriptive statistics and presented with means/medians.
- *Acceptability interviews with parents:* These interviews will assess parental acceptance of the parent-facing elements of the intervention and will be coded by 2 study team members using a grounded theory approach.

The following secondary endpoints will be used to assess co-design participant engagement in the co-design process:

- A survey comprising a 14-item section measuring participants' perceptions of the Co-design leader's effectiveness, a 10-item section measuring participants' perceptions of their own involvement and commitment to the Co-design process, and demographic information.

6.3 Statistical Methods

6.3.1 Baseline Data

Clinicians Participating in Actual Family Meetings and Intervention

Burnout scales, COVID-19 communication, and demographic characteristics will be summarized by standard descriptive summaries (e.g., means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

Parent-patient Dyad Survey Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g., means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender). Descriptive statistics will be calculated for quantitative data from the survey.

Parent-patient Dyad Interview Data

Transcriptions of audio recorded interviews will be coded using Nvivo 11 by 2 coders. A consensus method will be used for discrepancies. A constructivist grounded theory approach will guide qualitative analysis of interview transcripts.

Qualitative Data from Focus Groups

Two coders will develop themes using a grounded theory approach and will code the transcripts of the focus groups. NVIVO software will be used to apply codes to the transcripts by 2 independent coders. Discrepancies will be resolved by consensus.

Focus Group Survey Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g., means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender). Descriptive statistics will be calculated for quantitative data from the survey.

6.3.2 Efficacy Analysis

Qualitative analysis of focus groups conducted during the co-design session will identify themes for elements of the training that may need to be modified.

To evaluate the reliability and validity of the coding scheme, audio recordings from simulated family meetings will be coded and compared to coded audio recordings from pre-intervention simulated family meetings. Inter-rater reliability will be confirmed by having a random sample of 10% of the audio files coded twice by different coders. Only codes with K statistic greater than 0.6 will be included in the final analysis. Convergent validity of the revised coding scheme will be assessed by computing the correlations between the revised VitalTalk coding scheme and the comparable content categories of the MIPS. For this, audio files will be coded using both coding systems and spearman rank correlations will be calculated between the two systems. Coefficients greater than 0.50 will indicate a good level of concurrence between the behaviors measured by the two interaction systems. To evaluate if there are differences in clinician behavior pre and post-CST, coders will be blinded to whether an audio file was made prior to or after CST, and whether it was in a simulated or actual clinical encounter by playing files in a random order.

To evaluate differences in individual skills acquired (SPIKES, NURSE, interprofessional competencies) in simulated family meetings, we will use the McNemar test to compare the proportion of subjects possessing a skill pre-CST in simulated encounters with the proportion who possessed the skill after CST. Each skill will be analyzed separately. The comparison will be made for each behavior assessed and each clinician discipline that demonstrates the behavior. We will also estimate the probability that a participant who did not demonstrate a skill in the pre-CST would demonstrate that skill in the post-CST as a simple ratio. We will estimate 95% confidence intervals using standard techniques. We will also use paired t-tests to examine if there is a difference in skill acquisition (using the continuous version of each of the skill outcomes) between the pre- and post-CST intervention and Wilcoxin signed rank tests.

Team function will be analyzed for simulated family meetings by comparing the change in the number of minutes that clinicians from each discipline speak in pre and post-CST meetings using linear regression and controlling for the length of the meetings.

To assess the impact of the CST program in actual family meetings, audio recordings from actual family meetings will be coded and compared to coded audio recordings form pre-intervention actual family meetings. Since there are generally at least 2 clinicians in each team encounter, we will examine the individual skill acquisition within each part of the team encounter. Within each discipline, there are several clinicians involved in multiple team meetings. We will use fixed-effects regression with a clinician identifier variable as a covariate so that we can examine the effect of CST intervention on skill acquisition, adjusting for the effects of individual clinicians.

Team function will be analyzed in the same way as in simulated meetings by comparing the change in the number of minutes that clinicians from each discipline speak in pre and post-CST meetings using linear regression and controlling for the length of the meetings.

The difference in team member perception and satisfaction with collaboration will be measured after their participation in clinical encounters both pre and post-CST by administering the modified Baggs CSACD-N tool to all clinician team members who participate in an actual encounter. This tool will capture each discipline's experience with collaboration with other team members and satisfaction with care decisions. Means and standard deviations will be calculated for the tool and t-tests will determine if there are significant differences for each discipline pre and post-CST.

Hypotheses will be tested using logistic regression modeling with significance of the two-tailed hypothesis tests set at alpha equal to 0.05.

Clinician perception of the usefulness of CST and satisfaction with the training will be identified by descriptive statistics and differences in the mean and median scores will be calculated to determine retention in perceptions of usefulness one month after the training.

6.4 Sample Size and Power

We hypothesize that the CST will change clinician behavior by increasing the number of skills demonstrated in a simulated family meeting. Sample size calculations using existing data about acquisition of skills being evaluated in the CST[29] demonstrated that a total of 20

clinicians will be needed to identify significant changes in the following skill outcomes: discussing the big picture, responding to emotion, and performing several empathetic verbal skills using 80% power and an alpha=0.05.

Sample size calculations for determining change in clinician skill acquisition by discipline requires that there be an adequate number of actual encounters recorded such that they can be analyzed by provider type. Sample size calculations for simulated family meetings apply here as well in that we will need to have at least 20 team encounters pre and post-CST intervention to be able to look at the change in outcome before and after the intervention. Since there are generally at least 2 clinicians in each team encounter, we will examine the individual skill acquisition within each part of the team encounter. Within each discipline, there are several clinicians involved in multiple team meetings. We will use fixed-effects regression with a clinician identifier variable as a covariate so that we can examine the effect of CST intervention on skill acquisition, adjusting for the effects of individual clinicians.

Team function will be analyzed by comparing the change in the number of minutes that clinicians from each discipline speak in pre and post-CST meetings using linear regression and controlling for the length of the meetings. Sample size calculations based on previous data[87] and assuming 80% power and an alpha=0.05 will only require 3 paired respondents pre and post-CST to identify significant differences.

A sample size of 130 parent-patient dyads for the survey and 30 parent-patient dyads for the interview is based on using CONSORT recommendations for pilot study sample size calcuations. We calculated the parent-patient dyad sample size by estimating the required sample size for the future stepped wedge study using the Hospital Anxiety and Depression Scale (HADS) as the primary outcome for parents, as HADS is a frequently used outcome in palliative care research with well-established psychometric properties.[129,130] We will assume a one sided 80% CI for the effect size of 0.1 times the SD, to exclude the minimum clinically important difference if the null hypothesis is true.[131] The minimally important difference is a change of 2 on the HADS scale. The estimated sample size for the main study would be 286. For the pilot study, we estimated the number of participants required as around 30% of the number required for the main Phase 3 trial therefore, we aim to enroll a total of 46 parent-patient dyads pre and post the intervention. In previous studies enrolling parents and children with serious illness, our approach-to-enrollment rate was above 50%. Assuming 45% or more of parent-patient dyads approached will enroll and there are 150 eligible patients per year, we will need to approach approximately 350 parent-patient dyads to enroll 130 evaluable parent-patient dyads for the survey and 30 evaluable parent-patient dyads for the interview prior to the intervention. We have allotted 24 months to enroll 46 evaluable parent-patient dyads for the survey and 20 evaluable parent-patient dyads for the interview pre-intervention.

6.5 Interim Analysis

None planned.

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Blinding

No blinding will be used in the study given the differences in acquiring data prior to and after the COVID pandemic.

8.2 Data Collection and Management

All data will be stored on CHOP approved and maintained computers with compliant firewalls and security settings. All data will be saved onto CHOP password protected servers that are maintained by IS. All computers accessing data will be password-protected, and encrypted data files will be used when necessary to share data between users. Any paper files produced will be maintained in a locked file cabinet in locked offices. Data will be shared using CHOP secured shared drives or encrypted flash drives, or encrypted emails. If flash drives or other removable media are used, they will conform to meet CHOP IT standards for encryption and password protection according to CHOP policy A-3-6 (http://intranet.chop.edu/patcare/a-3-6.pdf). The information will not be released to those outside the study team.

Subjects Participating in Co-Design

Focus group data will be digitally recorded, transcribed, and de-identified. De-identified transcripts will be imported into NVIVO, a qualitative data analysis program.

Clinicians Participating in Intervention

Survey responses from clinicians will be entered into the web-based questionnaire in REDCap. At the time of administration, the instruments will be coded with a number that is linked to the participant, so that once the study is complete, none of the research information can be linked back to any particular participant. Only research team members will have access to the raw data, to the statistical database, and to the database that links study ID numbers with participants' personal information.

Audio or video recordings of intervention sessions will be stored on CHOP approved and maintained computers with compliant firewalls and security settings. Online intervention sessions will use a video conference service that meets the relevant CHOP IT standards and is HIPPAA compliant. All data will be saved onto CHOP password protected servers that are maintained by IS.

Data collected as part of this study will be entered and stored into REDCap. REDCap is a research-focused electronic data capture system, under an agreement with the software's development consortium, led by Vanderbilt University. REDCap supports two secure, web-based applications designed exclusively to support data capture for research studies. REDCap is a PHP web application served by Apache Tomcat over a 128 bit SSL connection using a signed certificate. The application relies on a study-specific data dictionary defined in an iterative self-documenting process that will be conducted by all members of the research team. The data dictionary is the foundation for custom case report form design and

validated coding of variables. Authentication of research staff will be performed via LDAP using CHOP's enterprise Active Directory service. The application generates a complete audit trail of user activity, provides reporting, and has an automated export mechanism to common statistical packages (SAS, SPSS, Stata, R/S-Plus).

The REDCap MySQL database is replicated in real time to a completely redundant instance of MySQL. The redundant instance is available for restoration of the primary database or for manual failover in the case of primary database failure. Time-stamped backup files are made from the replicated database daily by CHOP Research Information Systems using automated backup routines. Backup files are encrypted and transferred to a secure file server accessible only to designated personnel. A rolling seven day window of backup files is maintained in an immediately available online state, with a larger window maintained in a compressed file archive available at a reduced speed of access. Daily destructive database backup files are stored on the database server and are deleted only after successful backup of the entire database to file. In the event of data error, loss or corruption, research personnel will work with CHOP Research Information Systems to determine the most appropriate recovery strategy.

Data and backups are stored in the CHOP Research Information Systems Storage Area Network (SAN). Access to the SAN directories where data are stored will be limited to Research Information Systems personnel, with authentication performed using CHOP's enterprise Active Directory service.

Audio or video recordings of family meeting sessions will be stored on CHOP approved and maintained computers with compliant firewalls and security settings. Online family meetings sessions will use a video conference service that meets the relevant CHOP IT standards and is HIPPAA compliant. All data will be saved onto CHOP password protected servers that are maintained by IS. Audio transcripts of the family meeting will be made, and de-identified and then will be imported into NVIVO, a qualitative data analysis program. Video recordings will only be used for speaker attribution.

Parent-patient Dyads Participating in the Survey or Interview

Both survey responses and responses from the Family Meeting Preparation Worksheet from parent-patient dyads will be entered into the web-based questionnaire in REDCap. At the time of administration, the instruments will be coded with a number that is linked to the participant, so that once the study is complete, none of the research information can be linked back to any particular participant. Only research team members will have access to the raw data, to the statistical database, and to the database that links study ID numbers with participants' personal information.

Data collected as part of this study will be entered and stored into REDCap.

Interview data will be digitally recorded or recorded with an online video conference service that meets the relevant CHOP IT standards and is HIPPAA compliant and will be transcribed, de-identified and imported into NVIVO, a data analysis program.

Medical record review will be done by DBHI and PC4 groups and shared with the research team using secured shared drives and electronic files via secured email.

8.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with institutional policies and HIPAA on subject privacy. The Investigator and other research team members will not use such data and records for any purpose other than conducting the study. During the consent process and before administering the surveys, clinicians and parent-patient dyads will be told that their responses will be kept confidential. Clinicians and parents participating in the co-design focus groups and parent-patient dyads participating in the interviews will be told that all identifying information will be removed from transcripts. Once transcribed, the original co-design focus group audio files will be destroyed, reducing risk to breach of confidentiality. Original interview audio and video files will be destroyed once the study is completed and analyses are submitted and accepted into peer-reviewed journals. Clinicians completing surveys after actual family meetings will also be assured that their responses to the surveys will be kept confidential from other members of the medical team and from patients and families that they care for. In addition, parent-patient dyads will also be told that medical information audio and video recorded during the observed family meetings or acquired from the Family Meeting Worksheet in RedCap will be kept confidential. PHI for all patients will be deleted after completion of the study by deleting the audio and video files that contain that information.

After publication of data and analyses, identifiable information will be removed from the database and data collection materials.

Data used for future studies will not contain any identifiable information. The investigator will obtain a data use agreement between the PI and any recipient researchers before sharing a dataset that is not readily identifiable.

A Certificate of Confidentiality (CoC) issued by the NIH now covers this research. A CoC helps protect participant identifiable information.

A CoC protects private information from all legal proceedings. Unless participant consents, information from this research study that identifies them will not be shared outside this research.

- No one can be forced to share participant identifiable information for a lawsuit.
- information can't be used as evidence even if there is a court subpoena.

If participant consents, information could be shared for:

- Other future scientific research;

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Heart, Lung, And Blood Institute of the National Institutes of Health may need information to assess this project.

- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

8.4 Regulatory and Ethical Considerations

8.4.1 Data and Safety Monitoring Plan

The master list encoding study code identifiers to personal identifiers will be encrypted and access will be restricted to the PI and members of the research team. All study data, including the master list and PHI, will be retained for at least 6 years following study completion. All completed study documents will be stored in locked cabinets, and all computer-entered data will be stored and analyzed on password-protected computers at The Children's Hospital of Philadelphia. Access to documents and data will be limited to the PI and members of the research team. The PI will be responsible for ensuring that all those with access to the information understand the requirements for use of the data on password protected computers and servers. Any transfer of data between members of the research team will be done through encrypted emails, flash drives, or external hard drives that meet CHOP IT standards. The PI will monitor data progress and/or subject safety.

8.4.2 Risk Assessment

Subjects Participating in Co-design: The study risks include a breach of confidentiality of responses in focus groups and survey responses. This presents no more than minimal risk of everyday life. Participation in the study will not be required for employment and others outside the research team will not be notified of an individual provider's participation in this study, including the CST co-design program. Audio recordings and transcripts from focus groups will remain confidential and will have identifying information removed at the time of transcription. Original audio files will be destroyed once transcription has been completed. All data will be collected and maintained securely as outlined in the data monitoring section. Information will be stored on password protected computers and servers. No information will be shared outside the research team and all identifying information in original audio files will be destroyed once the audio files have been transcribed and checked for accuracy, no earlier than 6 years after study completion.

Clinicians Participating in Intervention: The study risks include a breach of confidentiality of survey answers, audio and video recordings from family meetings, and/or audio and video recordings of didactic CST sessions. This presents no more than minimal risk of everyday life. Participation in the study will not be required for employment and others outside the research team will not be notified of an individual provider's participation in this study, including the CST program. Results of all surveys and audio coding will remain confidential. If subjects indicate that they would like additional emotional or professional support after completion of survey questions assessing confidence in performance of skills, referral to the employee assistance program will be suggested by the research team. There are multiple research studies and QI projects conducted in the CICU which assess clinician competency, therefore clinicians are accustomed to being interrogated about their comfort level and clinical skills and even having those skills tested as part of research. All data will be collected and maintained securely as outlined in the data

monitoring section. Information will be held on password protected computers and servers. No information will be shared outside the research team, and all identifying information will be destroyed once the study is completed and analyses are submitted and accepted into peer-reviewed journals, no earlier than 6 years after study completion.

Clinicians Not Participating in Intervention: The study risks include a breach of confidentiality of the audio and video recordings from family meetings. This presents no more than minimal risk of everyday life. These clinicians were already planning to participate in the family meetings. Participation in the study will not be required for employment and others outside the research team will not be notified of an individual provider's participation in this study, including the CST program. Results of all surveys, and audio coding will remain confidential. All data will be collected and maintained securely as outlined in the data monitoring section. Information will be held on password protected computers and servers. No information will be shared outside the research team, and all identifiable information will be destroyed once the study is completed and analyses are submitted and accepted into peer-reviewed journals, no earlier than 6 years after study completion.

Parent-patient Dyads Participating in the Survey or Interview: The study risks include a breach of confidentiality of the parent-patient dyad's survey and/or audio or video recordings from interviews. This presents no more than minimal risk of everyday life to participants. Participants should not require medical or psychological care for their participation in the survey. If they need to end participation at any time, this will not affect their child's care in any way, and they will be allowed to end participation. Results of all surveys, interviews, and audio coding will remain confidential. All data will be collected and maintained securely as outlined in the data monitoring section. Information will be held on password protected computers and servers. No information will be shared outside the research team and all identifiable information will be destroyed once the study is completed and analyses submitted and accepted into peer-reviewed journals, no earlier than 6 years after study completion.

8.4.3 Potential Benefits of Trial Participation

Subjects Participating in Co-design

Participating clinician and parent subjects may benefit directly from participation in the study because they will learn about communication skills training based on adult learning theory, best practices in communication theory, and best practices in team functioning. We hypothesize that exposure to this training will enhance their ability to interact with their colleagues, their patients, and their patients' families, ultimately positively impacting health outcomes.

The knowledge gained from this research will provide important information for improving communication skills and team function for clinical teams in the CICU.

Clinicians Participating in Intervention

Participating clinician subjects may benefit directly from participation in the study because they will undergo additional communication skills training based on adult learning theory,

best practices in communication theory, and best practices in team functioning. We hypothesize this training will enhance their ability to interact with their colleagues, their patients, and their patients' families, ultimately positively impacting health outcomes.

The knowledge gained from this research will provide important information for improving communication skills and team function for clinical teams in the CICU.

Clinicians Not Participating in Intervention

Non-participating clinicians will not benefit directly from participation in the study. However, the knowledge gained from this research will provide important information for improving communication skills and team function for clinical teams in the CICU.

Parent-patient Dyads Participating in the Survey or Interview

There will be no direct benefit to parents or patients for taking part in this study. However, the knowledge gained from this study may help doctors improve their teamwork and communication skills. Knowledge gained from this study may also help teams and families better prepare families for family meetings.

8.4.4 Risk-Benefit Assessment

Data collected from this study could contribute to further strides in the field of health communications, where both patients and providers will benefit from more awareness of their communication needs, and more empowerment to engage in effective communication. This strengthened patient-provider communication has implications across many disciplines within medicine but particularly in the CICU, where medical decision-making is very complex and stressful for families. As a minimal risk study, the risk to subjects is reasonable given the potential benefit to subjects, future studies, and society at large. The knowledge gained from this research will provide important information for improving interprofessional teams' engagement with families when giving them bad news and eliciting goals of care in the pediatric CICU. This CST may also improve team functioning and collaboration in patient care.

8.5 Recruitment Strategy

Subjects Participating in Co-Design: Members of clinical teams will be recruited into the study through an open announcement of the study by the study team at faculty meetings and via a faculty and staff listserv that will give them contact information to follow up with a study team member if they are interested in participating (See Appendix 11.1 for recruitment email). Parents will be offered the opportunity to participate in an open call via the Parent Family Advisory Council listserve and emails to families that meet enrollment critieria. Approximately 15 clinicians and 5 parents will be enrolled for the co-design.

Clinicians Participating in Intervention: CICU clinicians will be recruited into the study through an open announcement of the study by the study team at faculty meetings and via a faculty and staff listserv that will give them contact information to follow up with a study team member if they are interested in participating (See Appendix 11.2 for recruitment email). At least 20 clinicians will be consented and enrolled for the intervention, survey and

interview. Block randomization will be done based on study ID number to select which clinicians will be asked to participate in an acceptability interview.

Clinicians Not Participating in Intervention: Working with several CICU team members, we will identify family meetings that are scheduled and will include at least 2 clinicians who are participating in the intervention. We will confirm with the primary team who the other clinicians are that are likely to be present in the meeting and we will contact them either via email or in person to discuss enrollment into the study.

Parent-patient Dyads Participating in the Survey or Interview Prior to Intervention: We will identify via medical record screening patients who have been admitted to the CICU for at least 7 days and are expected to stay for at least another 7 days and whose parents are therefore eligible for participation in a complex care family meeting. Parent-patient dyads will be approached in person by a member of the research team to consent to participate in the study or will be called to determine when they will next be present in the CICU for further discussion of the study. Up to 100 parent-patient dyads for the survey and 30 parent-patient dyads for the interview will be consented and enrolled with the expectation that we will achieve 95 evaluable parent-patient dyads for surveys and 23 evaluable parent-patient dyads for interviews.

Parent-patient Dyads Participating in the Survey or Interview After Intervention: We will identify via medical record screening patients who have been admitted to the CICU for at least 7 days and are expected to stay for at least another 7 days,or the patient has already been admitted to the CICU 14 days and whose parents are therefore eligible for participation in a complex care family meeting. Parent-patient dyads will be approached in person, over the phone or via e-mail by a member of the research team to consent to participate in the study or will be called to determine when they will next be present in the CICU for further discussion of the study. Up to 50 parent-patient dyads will be enrolled for, with a goal of 30 evaluable patient-parent dyads for the survey. Up to 25 parent-patient dyads (of the 50 enrolled for the survey) will be invited to be interviewed in the post-intervention, with a goal of 15 evaluable parent-patient dyads.

8.6 Informed Consent/Assent and HIPAA Authorization

Subjects Participating in Co-design

For participating subjects, a member of the study team will obtain written informed consent, or eConsent, and will explain the rationale, risks, and benefits of the study prior to any study related procedures being performed, including training and data collection. The clinicians will be given a thorough explanation of the study as provided in the consent document. These include the purpose, procedures, risks and benefits of participation, confidentiality, procedures for withdrawal, and contact information for study personnel. After receiving the written consent or eConsent from participating clinician subjects, they will be given a copy of the consent form for their records. In the event that eConsent is used, the document will be logically associated with each subject and will be able to be printed or saved to fulfill requirements related to electronic signatures. They will also be informed that their employment at CHOP will not be jeopardized if they choose not to participate in the proposed research.

Clinicians Participating in Intervention

For clinician subjects participating in the intervention, a member of the study team will obtain written informed consent, or eConsent, and will explain the rationale, risks, and benefits of the study prior to any study related procedures being performed, including training and data collection. The clinicians will be given a thorough explanation of the study as provided in the consent document. These include the purpose, procedures, risks and benefits of participation, confidentiality, procedures for withdrawal, and contact information for study personnel. After receiving written consent or eConsent from participating clinician subjects, they will be given a copy of the consent form for their records. In the event that eConsent is used, the document will be logically associated with each subject and will be able to be printed or saved to fulfill requirements related to electronic signatures. We have worked with REDCap administrators to build eConsent and will utilize only IRB approved documents in the eConsent process with the help of REDCap administrators. They will also be informed that their employment at CHOP will not be jeopardized if they choose not to participate in the proposed research.

Clinicians Not Participating in Intervention

For clinicians not participating in the intervention, a member of the study team will obtain written informed consent or consent via email and will explain the rationale, risks, and benefits of the study prior to any study related procedures being performed, including data collection. The clinicians will be given a thorough explanation of the study as provided in the consent document. These include the purpose, procedures, risks and benefits of participation, confidentiality, procedures for withdrawal, compensation, and contact information for study personnel. After receiving consent from the clinicians, we will give them a copy of the consent form for their records or they will receive a copy of the consent form via email. They will also be informed that their employment at CHOP will not be jeopardized if they choose not to participate in the proposed research.

Parent-patient Dyads Participating in the Survey Prior to the Intervention

For participating parent-patient dyads, a member of the study team will obtain written informed consent,consent via the phone and will explain the rationale, risks, and benefits of the study prior to any study related procedures being performed, including data collection. The parent-patient dyads will be given a thorough explanation of the study as provided in the consent document. These include the purpose, procedures, risks and benefits of participation, confidentiality, procedures for withdrawal, financial information, and contact information for study personnel. After receiving consent from participating parent-patient dyads, they will be given a copy of the consent form for their records. They will also be informed that their choice to participate or not will not impact how the clinical team cares for their family.

This study requests a waiver of assent for child subjects. Given that child subjects will be recruited from the ICU, many of them may be sedated or too ill to comprehend the study purposes and procedures and assent to participation. However, the use of child subject medical records will be clearly outlined in the consent form provided to parents/legal guardians.

Parent-patient Dyads Participating in the Interview Prior to the Intervention

For participating parent-patient dyads, a member of the study team will obtain written informed consent or consent via the phone and will explain the rationale, risks, and benefits of the study prior to any study related procedures being performed, including data collection. The parent-patient dyads will be given a thorough explanation of the study as provided in the consent document. These include the purpose, procedures, risks and benefits of participation, confidentiality, procedures for withdrawal, financial information, and contact information for study personnel. After receiving consent from participating parent-patient dyads, they will be given a copy of the consent form for their records. They will also be informed that their choice to participate or not will not impact how the clinical team cares for their family.

Parent-patient Dyads Participating in the Survey and Interview After the Intervention

For participating parent-patient dyads, a member of the study team will obtain written informed consent, consent via the phone, or eConsent and will explain the rationale, risks, and benefits of the study prior to any study related procedures being performed, including data collection. The parent-patient dyads will be given a thorough explanation of the study as provided in the consent document. These include the purpose, procedures, risks and benefits of participation, confidentiality, procedures for withdrawal, financial information, and contact information for study personnel. After receiving consent from participating parent-patient dyads, they will be given a copy of the consent form for their records. In the event that eConsent is used, the document will be logically associated with each subject and will be able to be printed or saved to fulfill requirements related to electronic signatures. We have worked with REDCap administrators to build eConsent and will utilize only IRB approved documents in the eConsent process with the help of REDCap administrators. They will also be informed that their choice to participate or not will not impact how the clinical team cares for their family.

This study requests a waiver of assent for child subjects. Given that child subjects will be recruited from the ICU, many of them may be sedated or too ill to comprehend the study purposes and procedures and assent to participation. However, the use of child subject medical records will be clearly outlined in the consent form provided to parents/legal guardians.

8.6.1 Selecting Family Meetings

Working with several CICU team members, we will identify family meetings that are scheduled. We will confirm with the primary team planning the family meeting which family members are likely to be present and we will contact them either via phone,in person or via e-mail to discuss the study. We will also confirm with the primary team who the other clinicians are that are likely to be present in the meeting and we will contact them either via email or in person to discuss the study.

When audio or video recording participating clinicians during actual family meetings, others present at the meeting will be recorded as well. This will include parents, patients, and

clinician team members participating in an observed family meeting who did not undergo the CST (because they were not eligible, did not wish to participate in the study, or were not approached because sufficient clinicians were already enrolled).

Parent-Patient Dyads Prior to the Intervention

During recruitment within the CICU in-patient units, a member of the research team will approach parents and patients who will be participating in an observed family meeting in the patient room, or over the phone if the parents will not be in the CICU prior to the family meeting and provide information about the study. A member of the study team will present a one-page explanation of the study to the parents. The explanation will cover the purpose of the study, procedures, risks and benefits of participation, what information will be collected, contact information for study personnel, that their private information will not be written down or used, and that parents can opt-out at any time.

Patients who are 18 years old and will be present in the audio recorded family meeting will be allowed to opt-out as adults if they are medically and cognitively capable of comprehending study purposes and can decline participation.

Parent-Patient Dyads After the Intervention

During recruitment within the CICU in-patient units, a member of the research team will approach parents and patients who will be participating in an observed family meeting in the patient room, or over the phone, or via email if the parents will not be in the CICU prior to the family meeting and provide information about the study. A member of the study team will consent the parents prior to study procedures would begin. The explanation will cover the purpose of the study, procedures, risks and benefits of participation, what information will be collected, contact information for study personnel, that their private information will not be written down or used, and that parents can opt-out at any time.

Patients who are 18 years old and will be present in the audio or video recorded family meeting will be allowed to opt-out as adults if they are medically and cognitively capable of comprehending study purposes and can decline participation.

8.7 Payment to Subjects/Families

Clinicians and parents participating in the co-design will be given $25 per hour session, totaling $275 for all 11 sessions in the form of a debit card or gift card. Clinicians participating in the intervention will be given $100 for the entirety of the intervention participation. Parent subjects will be given $10 in the form of a debit card or gift card upon completion of either the survey or the interview in the pre-intervention. Parent subjects will be given $20 in form of a debit card or gift card upon completion of the survey or the interview in the post-intervention. Patient subjects will not receive any payment for their participation.

9 PUBLICATION

We aim to publish findings of this study in peer-reviewed articles in leading medical journals. We will also present findings at professional meetings.

10 REFERENCES

1. Blume E, Morell Balkin E, Aiyagari R, et al. Parental Perspectives on Suffering and Quality of Life at End-of-Life in Children With Advanced Heart Disease: An Exploratory Study. *Pediatric critical care medicine*. 2014;15(4):336-342.

2. Contro N, Larson J, Scofield S, Sourkes B, Cohen H. Family perspectives on the quality of pediatric palliative care. *Arch Pediatr Adolesc Med*. Jan 2002;156(1):14-19.

3. Meert KL, Eggly S, Pollack M, et al. Parents' perspectives on physician-parent communication near the time of a child's death in the pediatric intensive care unit. *Pediatr Crit Care Med*. Jan 2008;9(1):2-7. doi:10.1097/01.PCC.0000298644.13882.88

4. Studdert DM, Burns JP, Mello MM, Puopolo AL, Truog RD, Brennan TA. Nature of conflict in the care of pediatric intensive care patients with prolonged stay. *Pediatrics*. Sep 2003;112(3 Pt 1):553-8.

5. Meyer E, Ritholz M, Burns J, Truog R. Improving the quality of end-of-life care in the pediatric intensive care unit: Parents' priorities and recommendations. *Pediatrics*. 2006;117:649-657.

6. Needle JS, O'Riordan M, Smith PG. Parental anxiety and medical comprehension within 24 hrs of a child's admission to the pediatric intensive care unit. *Pediatr Crit Care Med*. Nov 2009;10(6):668-74; quiz 674. doi:10.1097/PCC.0b013e3181a706c9

7. Fauman KR, Pituch KJ, Han YY, Niedner MF, Reske J, Levine AM. Predictors of depressive symptoms in parents of chronically ill children admitted to the pediatric intensive care unit. *Am J Hosp Palliat Care*. Dec 2011;28(8):556-63. doi:10.1177/1049909111403465

8. Nuss SL, Hinds PS, LaFond DA. Collaborative clinical research on end-of-life care in pediatric oncology. *Semin Oncol Nurs*. May 2005;21(2):125-34; discussion 134-44.

9. Pochard F, Darmon M, Fassier T, et al. Symptoms of anxiety and depression in family members of intensive care unit patients before discharge or death. A prospective multicenter study. *J Crit Care*. Mar 2005;20(1):90-6.

10. Diaz-Caneja A, Gledhill J, Weaver T, Nadel S, Garralda E. A child's admission to hospital: a qualitative study examining the experiences of parents. *Intensive Care Med*. Sep 2005;31(9):1248-54. doi:10.1007/s00134-005-2728-8

11. Azoulay E, Pochard F, Kentish-Barnes N, et al. Risk of post-traumatic stress symptoms in family members of itensive care unit patients. *Am J Respir Crit Care Med*. 2005;171(9):987-94.

12. Balluffi A, Kassam-Adams N, Kazak A, Tucker M, Dominguez T, Helfaer M. Traumatic stress in parents of children admitted to the pediatric intensive care unit. *Pediatr Crit Care Med*. 2004;5(6):547-53.

13. Colville G, Darkins J, Hesketh J, Bennett V, Alcock J, Noyes J. The impact on parents of a child's admission to intensive care: integration of qualitative findings from a

cross-sectional study. *Intensive Crit Care Nurs*. Apr 2009;25(2):72-9. doi:10.1016/j.iccn.2008.10.002

14. Board R, Ryan-Wenger N. Long-term effects of pediatric intensive care unit hospitalization on families with young children. *Heart & Lung*. 2002;31(1):53-66.

15. Meert KL, Thurston CS, Thomas R. Parental coping and bereavement outcome after the death of a child in the pediatric intensive care unit. *Pediatric critical care medicine*. 2001;2(4):324-8.

16. van der Geest IM, Darlington AS, Streng IC, Michiels EM, Pieters R, van den Heuvel-Eibrink MM. Parents' experiences of pediatric palliative care and the impact on long-term parental grief. *J Pain Symptom Manage*. 2014;47(6):1043-53.

17. Hexem KR, Mollen C, Carroll K, Lanctot D, Feudtner C. How Parents of Children Receiving Pediatric Palliative Care Use Relgion, Spirituality, or Life Philosophy in Tough Times. *Journal of Pallliative Medicine*. 2011;14:39-44.

18. Mack JW, Wolfe J, Grier HE, Cleary PD, Weeks JC. Communication about prognosis between parents and physicians of children with cancer: parent preferences and the impact of prognostic information. *J Clin Oncol*. 2006;24(33):5265-70.

19. Maurer SH, Hinds PS, Spunt SL, Furman WL, Kane JR, Baker JN. Decision making by parents of children with incurable cancer who opt for enrollment on a phase I trial compared with choosing a do not resuscitate/terminal care option. *J Clin Oncol*. Jul 10 2010;28(20):3292-8. doi:JCO.2009.26.6502 [pii]

10.1200/JCO.2009.26.6502

20. Tomlinson D, Bartels U, Hendershot E, Maloney AM, Ethier MC, Sung L. Factors affecting treatment choices in paediatric palliative care: comparing parents and health professionals. *Eur J Cancer*. 2011;47(14):2182-7.

21. Institute of Medicine. *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*. 2014.

22. Mathews T, CMinino A, Osterman M. Annual summary of vital statistics. *Pediatrics*. 2008;127:146-157.

23. Morell E, Wolfe J, Scheurer M. Patterns of care at end of life in children with advanced heart disease. *Archives of pediatrics & adolescent medicine*. 2012;166:745-748.

24. Ullrich CK, Dussel V, Hilden JM, Sheaffer JW, Lehmann LE, Wolfe J. End-of-Life Experience of Children Undergoing Stem Cell Transplantation: Parent and Provider Perspectives and Patterns of Care. *Blood*. Nov 20 2009;114(22):332-333.

25. Wolfe J, Grier HE, Klar N, et al. Symptoms and suffering at the end of life in children with cancer. *N Engl J Med*. Feb 3 2000;342(5):326-33. doi:10.1056/NEJM200002033420506

26. Dussel V, Joffe S, Hilden J, Watterson-Schaeffer J, Weeks J, Wolfe J. Considerations about hastening death among parents of children who die of cancer. *Archives of pediatrics & adolescent medicine*. 2010;164(3):231-237.

27. Hays R, Valentine J, Haynes G, et al. The Seatlle Pediatric Palliative Care Project: Effects of Family Satisfaction and Health Related Quality of Life. *Journal of Palliative Medicine*. 2006;9(3):716-728.

28. Zhukovsky DS, Herzog CE, Kaur G, Palmer JL, Bruera E. The impact of palliative care consultation on symptom assessment, communication needs, and palliative

interventions in pediatric patients with cancer. *J Palliat Med*. Apr 2009;12(4):343-9. doi:10.1089/jpm.2008.0152

29. Back AL, Arnold RM, Baile WF, et al. Efficacy of communication skills training for giving bad news and discussing transitions to palliative care. *Archives of Internal Medicine*. 2007;167(5):453.

30. Barth J, Lannen P. Efficacy of communication skills training courses in oncology: a systematic review and meta-analysis. Meta-Analysis

Research Support, Non-U.S. Gov't

Review. *Ann Oncol*. May 2011;22(5):1030-40. doi:10.1093/annonc/mdq441

31. Bylund CL, Brown R, Gueguen JA, Diamond C, Bianculli J, Kissane DW. The implementation and assessment of a comprehensive communication skills training curriculum for oncologists. *Psycho-oncology*. 2010;19(6):583-593.

32. Shilling V, Jenkins V, Fallowfield L. Factors affecting patient and clinician satisfaction with the clinical consultation: Can communication skills training for clinicians improve satisfaction? *Psycho-Oncology*. 2003;12(6):599-611. doi:10.1002/pon.731

33. Curtis JR, Back AL, Ford DW, et al. Effect of commnication skills training for residents and nurse practitioners on quality of communication with patients with serious illness: a randomized trial. *JAMA*. 2013;310(21):2271-81.

34. Johnson L, Gorman C, Morse R, Firth M, Rushbrooke S. Does communication skills training make a difference to patients' experiences of consultations in oncology and palliative care services? *Eur J Cancer Care (Engl)*. 2013;22:202-209. doi:10.1111/ecc.12014

35. Shaw DJ, Davidson JE, Smilde RI, Sondoozi T, Agan D. Multidisciplinary team training to enhance family communication in the ICU. *Crit Care Med*. Feb 2014;42(2):265-71. doi:10.1097/CCM.0b013e3182a26ea5

36. Back AL, Arnold R, Tulsky J, Edwards K. Vitaltalk.org. Accessed 2/12/15, 2014.

37. Prsa M, Holly C, Carnevale F, Justino H, Rohlicek C. Attitudes and Practices of Cardiologists and Surgeons Who Manage HLHS. *Pediatrics*. 2010;125(3):e625-e630.

38. Kon AA, Prsa M, Rohlicek C. Choices Doctors Would Make If Their Infant Had Hypoplastic Left Heart Syndrome: Comparison of Survey Data From 1999 and 2007. *Pediatric Cardiology*. 2013;34:348-53.

39. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med*. Mar 1997;44(5):681-92.

40. American Academy of Pediatrics Committee on Hospital Care. Family-centered care and the pediatrician's role. *Pediatrics*. Sep 2003;112(3 Pt 1):691-7.

41. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. National Academies Press; 2001:364.

42. Davidson J, Powers K, Hedayat K, et al. Clinical practice guidelines for support of the family in the patient-centered intensive care unit: American College of Critical Care Medicine Task Force 2004-2005. *Crit Care Med*. 2007;35(2):605-22.

43. Meert KL, Clark J, Eggly S. Family-centered care in the pediatric intensive care unit. *Pediatr Clin North Am*. 2013;60(3):761-72. doi:10.1016/j.pcl.2013.02.011

44. Lautrette A, Darmon M, Megarbane B, et al. A communication strategy and brochure for relatives of patients dying in the ICU. Multicenter Study

Randomized Controlled Trial

Research Support, N.I.H., Extramural

Research Support, Non-U.S. Gov't. *The New England journal of medicine*. Feb 1 2007;356(5):469-78. doi:10.1056/NEJMoa063446

45. Kodali S, Stametz RA, Bengier AC, Clarke DN, Layon AJ, Darer JD. Family experience with intensive care unit care: association of self-reported family conferences and family satisfaction. *J Crit Care*. 2014;29(4):641-4.

46. Powazki R, Walsh D, Hauser K, Davis MP. Communication in Palliative Medicine: A Clinical Review of Family Conferences. *J Palliat Med*. Jul 3 2014;doi:10.1089/jpm.2013.0538

47. Fineberg IC, Kawashima M, Asch SM. Communication with families facing life-threatening illness: a research-based model for family conferences. *J Palliat Med*. 2011;14(4):421-7.

48. Curtis JR, Engelberg RA, Wenrich MD, et al. Studying communication about end-of-life care during the ICU family conference: Development of a framework. *Journal of Critical Care*. 2002;17(3):147-160. doi:http://dx.doi.org/10.1053/jcrc.2002.35929

49. Feudtner C. Collaborative Communication in Pediatric Palliative Care: A Foundation for Problem-Solving and Decision-Making. *Pediatric Clin N Am*. 2007;54(5):583-xi.

50. Curtis JR, White DB. Practical guidance for evidence-based ICU family conferences. *Chest journal*. 2008;134(4):835-843.

51. Billings JA, Block SD. The end-of-life family meeting in intensive care part III: A guide for structured discussions. Research Support, Non-U.S. Gov't. *Journal of Palliative Medicine*. Sep 2011;14(9):1058-64. doi:10.1089/jpm.2011.0038-c

52. Michelson K, Emanuel L, Carter A, Brinkman P, Clayman M, Frader J. Pediatric intensive care unit family conferences: One mode of communication for discussing end-of-life care decisions. *Pediatric critical care medicine*. 2011;epub ahead of print April 7

53. Michelson KN, Clayman ML, Haber-Barker N, et al. The Use of Family Conferences in the Pediatric Intensive Care Unit. *J Palliat Med*. 2013;

54. Walter JK, Benneyworth BD, Housey M, Davis MM. The factors associated with high-quality communication for critically ill children. *Pediatrics*. 2013;131(Suppl 1):S90-5.

55. Curtis JR, Engelberg RA, Wenrich MD, Shannon SE, Treece PD, Rubenfeld GD. Missed opportunities during family conferences about end-of-life care in the intensive care unit. *American Journal of Respiratory and Critical Care Medicine*. 2005;171(8):844-849.

56. Selph RB, Shiang J, Engelberg R, Curtis JR, White DB. Empathy and life support decisions in intensive care units. *Journal of General Internal Medicine*. 2008;23(9):1311-1317.

57. McDonagh JR, Elliott TB, Engelberg RA, et al. Family satisfaction with family conferences about end-of-life care in the intensive care unit: increased proportion of family speech is associated with increased satisfaction. *Crit Care Med*. Jul 2004;32(7):1484-8. doi:00003246-200407000-00005 [pii]

58. Boss R, Nelson J, Weissman D, et al. Integrating Palliative Care Into the PICU: A Report From the Improving Palliative Care in the ICU Advisory Board. *Pediatr Crit Care Med*. 2014;30:30.

59. Doorenbos A, Lindhorst T, Starks H, Aisenberg E, Curtis JR, Hays R. Palliative Care in the Pediatric ICU: Challenges and Opportunities for Family-Centered Practice. *Journal of Social Work in End-Of-Life & Palliative Care*. 2012;8(4):297-315.

60. Hudson P, Thomas T, Quinn K, Aranda S. Family meetings in palliative care: are they effective? *Palliat Med*. 2009;23(2):150-7.

61. Hannon B, O'Reilly V, Bennett K, Breen K, Lawlor PG. Meeting the family: measuring effectiveness of family meetings in a specialist inpatient palliative care unit. *Palliat Support Care*. 2012;10(1):43-9.

62. Kolarik RC, Walker G, Arnold RM. Pediatric resident education in palliative care: a needs assessment. *Pediatrics*. Jun 2006;117(6):1949-54. doi:117/6/1949 [pii]

10.1542/peds.2005-1111

63. Liben S, Papdatou D, Wolfe J. Paediatric palliaite care: Challenges and emerging ideas. *Lancet*. 2008;371(9615):852-864.

64. Rapoport A, Obwanga C, Sirianni G, Librach SL, Husain A. Not just little adults: palliative care physician attitudes toward pediatric patients. *J Palliat Med*. June 2013 2013;16(6):675-9. doi:10.1089/jpm.2012.0393

65. Serwint JR, Rutherford L, Hutton N. Personal and professional experiences of pediatric residents concerning death. *Journal of Palliative Medicine*. 2006;9(1):70-81.

66. Lupu D, Force AAoHaPMWT. Estimate of current hospice and palliative medicine physician workforce shortage. *Journal of Pain and Symptom Management*. 2010;40(6):899-911.

67. Hebert HD, Butera JN, Castillo J, Mega AE. Are we training our fellows adequately in delivering bad news to patients? A survey of hematology/oncology program directors. *J Palliat Med*. Dec 2009;12(12):1119-24. doi:10.1089/jpm.2009.0074

68. Kersun L, Gyi L, Morrison WE. Training in difficult conversations: a national survey of pediatric hematology-oncology and pediatric critical care physicians. *J Palliat Med*. Jun 2009;12(6):525-30. doi:10.1089/jpm.2008.0251

69. Turner D, Mink R, Lee K, et al. Are pediatric critical care medicine fellowships teaching and evaluating communication and professionalism? *Pediatric critical care medicine*. 2013;14(5):454-61.

70. File W, Bylund CL, Kesselheim J, Leonard D, Leavey P. Do pediatric hematology/oncology (PHO) fellows receive communication training? *Pediatric blood & cancer*. 2014;61(3):502-506. doi:10.1002/pbc.24742

71. Boss RD, Hutton N, Donohue P, Arnold R. Neonatologist training to guide family decision making for critically ill infants. *Arch Pediatric Adolescent Medicine*. 2009;163(9):783-8.

72. Back AL, Arnold RM, Tulsky JA, Baile WF, Fryer-Edwards KA. Teaching communication skills to medical oncology fellows. *Journal of clinical oncology*. 2003;21(12):2433-2436.

73. Back AL, Arnold RM, Baile WF, et al. Faculty development to change the paradigm of communication skills teaching in oncology. *Journal of clinical oncology*. 2009;27(7):1137-1141.

74. Fallowfield L, Jenkins V, Farewell V, Saul J, Duffy A, Eves R. Efficacy of a Cancer Research UK communication skills training model for oncologists: a randomised controlled trial. *Lancet*. 2002;359(9307):650-656.

75. Fallowfield L, Jenkins V, Farewell V, Solis-Trapala I. Enduring impact of communication skills training: results of a 12-month follow-up. *British Journal of Cancer*. 2003;89(8):1445-1449.

76. Fallowfield LJ, Lipkin M, Hall A. Teaching senior oncologists communication skills: results from phase 1 of a comprehensive longitudinal program in the UK. *J Clin Oncol*. 1998;16(5):1961-68.

77. Clayton JM, Butow PM, Waters A, et al. Evaluation of a novel individualised communication-skills training intervention to improve doctors' confidence and skills in end-of-life communication. *Palliative Medicine*. Jun 18 2013;doi:10.1177/0269216312449683

78. Meyer EC, Sellers DE, Browning D, McGuffie K, Solomon MZ, Truog R. Difficult conversations: Improving communication skills and relational abilities in health care. *Pediatric critical care medicine*. 2009;10(3):352-359.

79. Boss R, Urban A, Barnett M, Arnold R. Neonatal Critical Care Communication (NC3): training NICU physicians and nurse practitioners. *J Perinatology*. 2013;33(8):642-6.

80. Ford S, Hall A, Ratcliffe D, Fallowfield L. The Medical Interaction Process System (MIPS): an instrument for analysing interviews of oncologists and patients with cancer. *Soc Sci Med*. 2000;50(4):553-66.

81. Bonvicini KA, Perlin MJ, Bylund CL, Carroll G, Rouse RA, Goldstein MG. Impact of communication training on physician expression of empathy in patient encounters. *Patient Education and Counseling*. 2009;75:3-10.

82. Uitterhoeve R, Bensing J, RP G, Demulder P, Van Achterberg T. The effect of communication skills training on patient outcomes in cancer care: a systematic review of the literature. *Eur J Cancer Care (Engl)*. 2010;19:442-457.

83. Moore PM, Rivera Mercado S, Grez Artigues M, Lawrie TA. Communication skills training for healthcare professionals working with people who have cancer. Meta-Analysis

Research Support, Non-U.S. Gov't

Review. *The Cochrane database of systematic reviews*. 2013;3:CD003751. doi:10.1002/14651858.CD003751.pub3

84. Wilkinson S, Perry R, Blanchard K, Linsell L. Effectiveness of a three day communication skills course in changing nurses' communication skills with cancer/palliative care patients: a randomised controlled trial. *Palliative Medicine*. 2008;22(4):365-375. doi:10.1177/0269216308090770

85. Weiner JS, Arnold RM, Curtis JR, Back AL, Rounsaville B, Tulsky JA. Manualized communication interventions to enhance palliative care research and training: rigorous, testable approaches. *Journal of Palliative Medicine*. 2006;9(2):371-381.

86. Mosser G, Begun J. *Understanding Teamwork in Health Care*. McGraw-Hill Education; 2014.

87. Harris KT, Treanor CM, Salisbury ML. Improving patient safety with team coordination: challenges and strategies of implementation. *Journal of obstetric, gynecologic, and neonatal nursing : JOGNN / NAACOG*. Jul-Aug 2006;35(4):557-66. doi:10.1111/j.1552-6909.2006.00073.x

88. Panel IECE. *Core Competencies for Interprofessional Collaborative Practice: Report of an Expert Panel*. 2011. Accessed 1/12/15. http://www.aacn.nche.edu/education-resources/IPECReport.pdf

89. Weaver SJ, Dy SM, Rosen MA. Team-training in healthcare: a narrative synthesis of the literature. *BMJ quality & safety*. May 2014;23(5):359-72. doi:10.1136/bmjqs-2013-001848

90. Medicine Io. *Establishing transdisciplinary professionalism for improving health outcomes: Workshop summary*. The National Academies Press; 2013.

91. Medicine Io. *Measuring the Impact of Interprofessional Education on Collaborative Practice and Patient Outcomes*. Outcomes CoMtIoIEoCPaP; 2015.

92. Nathanson BH, Henneman EA, Blonaisz ER, Doubleday ND, Lusardi P, Jodka PG. How much teamwork exists between nurses and junior doctors in the intensive care unit? *Journal of Advanced Nursing*. 2011;67(8):1817-1823. doi:10.1111/j.1365-2648.2011.05616.x

93. Baggs JG, Schmitt MH, Mushlin A. Association between nurse-physician collaboration and patient outcomes in three intensive care units. *Critical Care Medicine*. 1999;27:1991-98.

94. Dechairo-Marino AE, Jordan-Marsh M, Traiger G, Saulo M. Nurse/physician collaboration: action research and the lessons learned. *The Journal of nursing administration*. May 2001;31(5):223-32.

95. Maxson PM, Dozois EJ, Holubar SD, et al. Enhancing nurse and physician collaboration in clinical decision making through high-fidelity interdisciplinary simulation training. *Mayo Clin Proc*. Jan 2011;86(1):31-6. doi:10.4065/mcp.2010.0282

96. Bruner P, Waite R, Davey MP. Providers' perspectives on collaboration. *International journal of integrated care*. Jul 2011;11:e123.

97. Fineberg IC. Preparing Professionals for Family Conferences in Palliative Care: Evaluation Results of an Interdisciplinary Approach. Article. *Journal of Palliative Medicine*. 2005;8(4):857-866. doi:10.1089/jpm.2005.8.857

98. Curtis JR, Ciechanowski PS, Downey L, et al. Development and evaluation of an interprofessional communication intervention to improve family outcomes in the ICU. *Contemporary Clinical Trials*. 2012;

99. Truog R, Meyer E, Burns J. Towards interventions to improve end-of-life care in the pediatric intensive care unit. *Critical care medicine*. 2006;34(11):S373-9.

100. Meert K, Eggly S, Pollack M, et al. Parents' perspectives on physician-parent communication near the time of a child's death in the pediatric intensive care unit. *Pediatr Crit Care Med*. 2008;9(1):2-7.

101. Hill D, Miller V, Walter JK, et al. Regoaling: a conceptual model of how parents of children with serious illness change medical care goals *BMC Palliative Care*. 2014;13:9.

102. Feudtner C, Walter JK, Faerber J, et al. Good Parent Beliefs of Parents of Seriously Ill Children. *JAMA Pediatrics*. forthcoming;

103. Maslach C, Jackson SE, Leiter MP. Maslach burnout inventory. 1986;

104. Bate S, Robert G. *Bringing user experience to healthcare improvement: the concepts, methods and practices of experience-based design*. Radcliffe; 2007.

105. née Blackwell RW, Lowton K, Robert G, Grudzen C, Grocott P. Using Experience-based Co-design with older patients, their families and staff to improve palliative care experiences in the Emergency Department: A reflective critique on the process and outcomes. *International Journal of Nursing Studies*. 2017;68:83-94.

106. Robert G, Cornwell J, Locock L, Purushotham A, Sturmey G, Gager M. Patients and staff as codesigners of healthcare services. *BMJ*. 2015;350:g7714.

107. Arnold R, Nelson J, Predergast T, et al. Educational Modules for the Critical Care Communication (C3) Course: A Communication Skills Training Program for Intensive Care Fellows. Creative Common2010.

108. Hudson P, Quinn K, O'Hanlon B, Aranda S. Family meetings in palliative care: Multidisciplinary clinical practice guidelines. *BMC Palliat Care*. 2008;7(12):7-12.

109. Stapleton RD, Engelberg RA, Wenrich MD, Goss CH, Curtis JR. Clinician statements and family satisfaction with family conferences in the intensive care unit*. *Critical care medicine*. 2006;34(6):1679-1685.

110. Butterfoss FD, Goodman RM, Wandersman A. Community coalitions for prevention and health promotion: factors predicting satisfaction, participation, and planning. *Health Educ Q*. Feb 1996;23(1):65-79. doi:10.1177/109019819602300105

111. Goldstein SM. Community coalitions: a self-assessment tool. *Am J Health Promot*. 1997 Jul-Aug 1997;11(6):430-5. doi:10.4278/0890-1171-11.6.430

112. Butterfoss FD. The coalition technical assistance and training framework: helping community coalitions help themselves. *Health Promot Pract*. Apr 2004;5(2):118-26. doi:10.1177/1524839903257262

113. Pyke-Grimm K, Degner LF, Small A, Mueller B. Preferences for participation in treatment decision making and information needs of parents of children with cancer: A pilot study. *Journal of Pediatric Oncology Nursing*. 1998;15(2):108. doi:10.1016/s1043-4542(98)90022-4

114. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand*. 1983;67(6):361-70.

115. Creamer M BR, Failla S. Psychometric properties of the Impact of Event Scale - Revised. *Behaviour Research and Therapy*. 2003;41(12):1489-1496.

116. Anderson LA, Dedrick RF. Development of the Trust in Physician scale: a measure to assess interpersonal trust in patient-physician relationships. *Psychol Rep*. 1990;67(3 Pt 2):1091-100.

117. Epstein D, Unger JB, Ornelas B, et al. Psychometric evaluation of a modified version of the family satisfaction in the ICU survey in parents/caregivers of critically ill children*. *Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies*. Oct 2013;14(8):e350-6. doi:10.1097/PCC.0b013e3182917705

118. Mercer LM TP, Pang PS, et al. Patient perspectives on communication with the medical team: Pilot study using the communication assessment tool-team (CAT-T). . *Patient education and counseling*. 2008;73(2):220-223.

119. Bell SK, Roche SD, Mueller A, et al. Speaking up about care concerns in the ICU: patient and family experiences, attitudes and perceived barriers. *BMJ Qual Saf*. 2018;27(11):928-936.

120. Barry M, Fowler F, Mulley A, Henderson J, Wennberg J. Patient Reactions to a Program Designed to Facilitate Patient Participation in Treatment Decision for Benign Prostatic Hyperplasia. *Medical Care*. 1995;33(8):771-782.

121. Tulsky JA, Arnold RM, Alexander SC, et al. Enhancing communication between oncologists and patients with a computer-based training program: a randomized trial. *Annals of Internal Medicine*. 2011;155(9):593.

122. Bays AM, Engelberg RA, Back AL, et al. Interprofessional communication skills training for serious illness: evaluation of a small-group, simulated patient intervention. *J Palliat Med*. 2014;17(2):159-66.

123. Rosenberg AR. Close to Home. *JAMA Pediatr*. Jan 26 2015;doi:10.1001/jamapediatrics.2014.3449

124. Chiu CJ, Brock, D., Abu-Rish, E., Vorvick, L., Wilson, S., Hammer, D., Schaad, D., Blondon, K., and Zierler, B. (u.d.). . Performance Assessment of Communication and Teamwork (PACT) Tool Set. http://collaborate.uw.edu/educators-toolkit/tools-for-evaluation/performance-assessment-of-communication-and-teamwork-pact-too

125. Chiu C-J. *Development and Validation of Performance Assessment Tools for Interprofessional Communication and Teamwork (PACT)*. University of Washington; 2014.

126. Bruce CR, Newell AD, Brewer JH, et al. Developing and testing a comprehensive tool to assess family meetings: Empirical distinctions between high-and low-quality meetings. *Journal of critical care*. 2017;42:223-230.

127. Rafferty JP, Lemkau JP, Purdy RR, Rudisill JR. Validity of the Maslach Burnout Inventory for Family Practice Physicians. Article. *Journal of Clinical Psychology*. 1986;42(3):488-492.

128. Baggs JG. Development of an instrument to measure collaboration and satisfaction about care decisions. *J Adv Nurs*. 1994;20(1):176-82.

129. Becker CL, Arnold RM, Park SY, et al. A cluster randomized trial of a primary palliative care intervention (CONNECT) for patients with advanced cancer: Protocol and key design considerations. *Contemp Clin Trials*. Mar 2017;54:98-104. doi:10.1016/j.cct.2017.01.005

130. Cox CE, Hough CL, Carson SS, et al. Effects of a Telephone- and Web-based Coping Skills Training Program Compared with an Education Program for Survivors of Critical Illness and Their Family Members. A Randomized Clinical Trial. *Am J Respir Crit Care Med*. Jan 1 2018;197(1):66-78. doi:10.1164/rccm.201704-0720OC

131. Cocks K, Torgerson DJ. Sample size calculations for pilot randomized trials: a confidence interval approach. *J Clin Epidemiol*. Feb 2013;66(2):197-201. doi:10.1016/j.jclinepi.2012.09.002