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

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The Children's Hospital of Philadelphia®

Informed Consent Form and HIPAA Authorization

Study Title:	**Communication Skills Training for Interprofessional Teams in Pediatric Cardiac Intensive Care Unit**
Version Date:	June 17, 2020
Consent Name:	Clinicians Participating in Intervention Consent

Principal Investigator: Jennifer Walter, MD PhD MS Telephone: (267) 426-7466

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are a clinician in the at the Children's Hospital of Philadelphia (CHOP) who may participate in the CICU's chronic care meetings this year.

What is the purpose of this research study?

The purpose of this research study is to learn more about the way that clinician teams communicate with families and each other in the CICU. This study also aims to determine the impact of a communication skills training program on the communication skills and collaboration of clinician teams in the CICU. Finally, the study aims to gather information about clinician burnout and changes in family meeting practices related to the 2020 COVID-19 pandemic.

How many people will take part?

Approximately 20 CICU clinicians will take part in this study. This includes attending intensivists, cardiologists, cardiac surgeons, front line clinicians, nurses, and social workers.

What is involved in the study?

If you agree to take part in this study, you will participate in a 10-hour communication training program that 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. After the training, you will be observed during one or more actual family meetings.

Throughout your participation, you will be asked to complete surveys that will ask you about your satisfaction and perception of team collaboration, your evaluation of the communication training program, and your retention of communication skills learned. You may also be asked to take part in 15-30 minute interview regarding your participation in the communication training program.

How long will you be in this study?

If you agree to take part, your participation will last for approximately 4 years and will involve at least 21 study visits. Visits that involve training sessions will take approximately 30 minutes-5 hours. Visits that involve an acceptability interview will last 15-30 minutes. Visits that involve family meetings will take 30-120 minutes. Visits that involve only surveys will take 5-10 minutes.

What are the study procedures?

The study involves the following procedures.

Communication Skills Training Program

You will participate in a communication skills training program adapted for interprofessional teams. The training sessions will last for 10 hours over the course of several months. They will include short didactic sessions around giving bad news, eliciting parental goals, team collaboration building, and review of the CHOP family meeting resources. These 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.

Acceptability Interview

_____A random sample of 8 participants will be asked to take part in an acceptability interview after the communication skills training program has been completed.

Observed actual family meetings

One or more actual family meetings you were planning to participate in will be audio recorded after the communication training program. You will not be observed more than 24 times after the training.

Surveys

Online surveys will be given to you after actual family meetings and at the conclusion of the training program. They will assess the following:

- Basic demographic information
- Your perception and satisfaction with team collaboration during actual family meetings
- Your evaluation of the training program
- Job satisfaction and level of burnout as described by a validated measure
- Changes in practice due to the COVID-19 pandemic

Visit Schedule

The table below provides a brief description of the purpose and duration of each study visit.

Visit	Purpose	Main Procedures	Duration
Visit 1, Day 1	Enrollment	Informed consent Review Inclusion/ Exclusion Criteria	20 minutes
Visit 2-11, Days 2-200	Intervention	10-hour communication skills training program Post-training course evaluation survey	30 minutes-5 hours per day; 5-10 minutes
Visits 5-30, Days 9-500	Follow-Up	Follow-Up actual family meetings Online survey	30-120 minutes each; 5-10 minutes
Visit 6-21, Day 36-310	Follow-Up	Acceptability interview	15-30 minutes

What are the risks of this study?

Taking part in a research study involves inconveniences and risks.

While in this study, you are at risk of a breach of confidentiality of your survey answers,audio recordings from family meetings, and/or audio and video recordings of didactic intervention sessions.. Participation in the study will not be required for employment, and others outside research staff will not be notified of an individual provider's participation in this study including the training program. Results of all surveys and audio coding will remain confidential.

If you have any questions about any of the possible risks, please contact the Principle investigator of this study.

Are there any benefits to taking part in this study?

You may benefit directly from participation in this study because you will undergo communication skills training on adult learning theory, best practices in communication theory, and best practices in team functioning.

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

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this consent form. A copy will be given to you to keep as a record. Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. Your decision to participate or results of the study will not have any effect of your performance evaluation or employment status.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What about privacy and confidentiality?

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. People from oversight agencies and organizations such as the Department of Health and Human Services, and Office for Human Research Protections may also look at your study records.

The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation about the study.

By law, CHOP is required to protect your private information. The investigator and staff involved with the study will keep your private information collected for the study strictly confidential. All audio recordings of family meetings will be kept secure on CHOP protected computers and servers. Once the research is complete, original audio files will be destroyed to reduce the risk of breach of confidentiality. Responses to surveys will be kept confidential from other members of the medical team and from patients and families that you care for.

Certificates of Confidentiality (CoC)

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

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

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

If you consent, your 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.
- You can still share information about yourself. You can also freely discuss your involvement in this research.

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

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your personal information at any time. To take back your permission, it is preferred that you tell the investigator in writing.

Dr. Jennifer Walter
The Children's Hospital of Philadelphia
34th Street and Civic Center Blvd.
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In the letter, state that you changed your mind and do not want any more of your information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal information, you will be withdrawn from the study.

Financial Information

Will there be any additional costs?

There will be no additional costs to you for taking part in this study.

Will you be paid for taking part in this study?

You will be compensated $100 for participating in this study.

Who is funding this research study?

The National Heart, Lung, And Blood Institute of the National Institutes of Health under Award Number K23HL141700 is providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Jennifer Walter at 267-426-7466.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study. You are also agreeing to let CHOP use and share your health information as explained above.

Name of Subject	
Signature of Subject	Date