Understanding Paramedic, Trial Network, and Patient's Family Experiences in Emergency Research Clinical Trials

PROJECT 1: EMS PROJECT – PARAMEDIC TRAINING AND SCOPE OF INVOLVEMENT IN CLINICAL TRIALS

January 31, 2020

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Executive Summary

Overview

There is tremendous opportunity to learn from researchers and emergency medical services (EMS) personnel about approaches for implementing prehospital clinical trials, and for developing and delivering research training for paramedics. Under the leadership of the Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN), paramedics and other EMS professionals were invited to participate in a mixed methods study to better understand how EMS paramedics are prepared for their role and to capture their experiences related to prehospital clinical trials.

Methods

The study followed an exploratory sequential mixed methods strategy with three phases of research (focus group and interview data collection, member checking, and integration of findings). Westat, a Maryland-based research organization, independently completed data collection, analytic, and reporting responsibilities in consultation with the SIREN project team. A total of 51 individuals (22 paramedics and 29 others participated in either a focus group or interview, and, of these, 33 (70.2%) responded to the member checking survey.

Results

Several factors were found to be associated with the context in which the trial is implemented, specifically institutional support and leadership, availability of resources, and strategies to involve paramedics throughout the research process. Paramedics' prior exposure and attitudes regarding the perceived value of research were indicated as influencing their experiences. Training delivery methods identified as effective in building skills and confidence include in-person and hands-on training activities focused primarily on the specific trial protocol, refresher trainings, and access to reference materials and informed trial leaders and champions. Institutional support to augment training and motivation include recognition of the role of paramedics, providing incentives and support, using templates that can be tailored to participating sites, and providing ongoing feedback on enrollment and other trial progress.

Recommendations for Next Steps

Specific recommendations for training design and conduct are summarized. These findings and recommendations can be considered by researchers and others to address some of the barriers or challenges to paramedic involvement in prehospital clinical trials.

1. Introduction

1.1 Background

There is tremendous opportunity to learn from researchers and emergency medical services (EMS) personnel about approaches for designing and implementing prehospital clinical trials, and for developing and delivering research training for paramedics. Participation in clinical research presents special challenges for paramedics and EMS agency personnel due to the unique nature of the prehospital environment. Under an administrative supplement awarded to the Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN), paramedics and other EMS professionals were invited to participate in interviews and focus groups to better understand how EMS paramedics are prepared for their role and to capture their experiences related to prehospital clinical trials. Information collected from this endeavor will help EMS researchers identify best practices for involving and preparing EMS paramedics for their role in emergency care research and will contribute to shaping clinical practice in the emergency setting.

The research was conducted in three phases[1]: 1) qualitative data collection (focus groups and interviews), 2) member checking, and 3) integration of findings and completion of analysis. This report provides a summary of the research phases and results, describes development of a conceptual model, and presents recommendations for future research.

1.2 Research Questions

The research questions went through several iterations over the course of discussion among members of the research team. Revisions to the questions were made to ensure that the data collection activities elicited findings that are useful, applicable, and that contribute to advances in the field of prehospital clinical research. The final research questions were:

- What factors and strategies are associated with paramedic engagement in prehospital clinical trials?
- What methods and strategies have been used for paramedic training for prehospital clinical trials?
- What are the challenges and barriers associated with paramedic engagement and training for prehospital clinical trials?
- What are the recommendations to optimize methods and strategies to engage and train paramedics for prehospital clinical trials?

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[1] Westat, a research organization headquartered in Rockville, Maryland, provided qualitative services under subcontract. Westat independently completed data collection, analytic, and reporting responsibilities in consultation with the SIREN project team.

2. Methods

2.1 Protocol Design

The study followed an exploratory sequential mixed methods strategy that included three phases of research (Figure 1). In Phase 1 (Qualitative data collection), focus groups were first conducted for initial exploration of topics and themes, followed by collection of data through individual interviews.   Focus group and interview participants were subsequently invited to provide feedback on select preliminary findings through a member checking survey (Phase 2), and results of both data collections were integrated in the final analysis (Phase 3).

These phases are described in more detail below.

Figure 1. **Phases of data collection and analysis**

Phase 1
- Qualitative data collection
  - Focus groups
  - Interviews

Phase 2
- Member checking

Phase 3
- Integration of findings
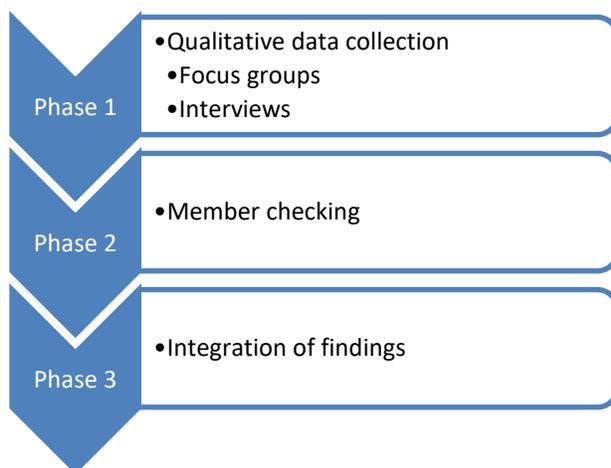
2.1.1   Qualitative Data Collection. Focus groups and interviews were conducted with individuals in one of two role classifications: (1) current paramedics and (2) other roles associated with clinical trials such as investigators, EMS medical directors and educators, and operational chiefs. The purpose of the data collection was to assess attitudes, beliefs, and experiences associated with preparation for and conduct of prehospital clinical trials. Focus groups were conducted initially, and findings helped to inform the content for the subsequent interviews.

Sampling Method. The qualitative sampling strategy – homogenous sampling – was intended to identify information-rich sources relative to their experience with prehospital clinical trials and with training of paramedics in particular. The SIREN team used various methods to recruit an intentional group of focus group and interview participants perceived to represent key stakeholders based on their experience with clinical trials. This process included identifying investigators from the two prior networks (ROC - Resuscitation Outcomes Consortium and NETT - Neurological Emergencies Treatment Trials Network), email blasts, snowball (referral) sampling, and announcements at the 2019 National Association of EMS Physicians (NAEMSP) annual meeting. The research team used a participant screener to confirm eligibility and identify focus group/interview times that were convenient for participants. The screener included questions regarding name, participant background, trial experience, and network affiliation. For the interviews, the team aimed to recruit a greater proportion of paramedics relative to non-

paramedics to gain a deeper understanding of the paramedic experience and sought to recruit an overall participant pool with balanced representation of ROC and NETT trials.

Focus Group Approach. Three in-person facilitated focus groups were conducted with key stakeholders at the 2019 NAEMSP annual meeting (January, Austin TX). Constructed with an intent to capture perspectives relevant to the major steps of conceptualizing, designing and implementing prehospital clinical trials, participants were asked a series of questions to understand their experiences and to assess their perspectives on challenges paramedics face with protocol development and implementation, participant consent and enrollment, and training for prehospital clinical trials. See Appendix A for the focus group guide.

Focus group discussions were led by two trained facilitators who are members of the Westat research team. A member of the research team was also present during all groups to manage logistics, honoraria, and the consent process. All participants provided consent before the start of the session. The discussion was audio-recorded with permission of all focus group participants. Focus groups were held in a private conference room and lasted two hours. All participants were provided a $100 Visa gift card.

Interview Approach. Preliminary findings from the focus groups were used to develop a tailored interview guide (Appendix B) which addressed paramedics' experiences with prehospital clinical trials, comfort and skills related to research, experiences with training and conducting specific trials, and environmental factors influencing paramedics' engagement and participation in research.

Interviews were co-led by two members of the Westat research team. The purpose of the interview was reiterated, and all participants provided verbal assent and permission to record the discussion before the interviews were conducted. Interviews were conducted and recorded via WebEx. All participants were offered a $100 as honoraria.

2.1.2 Member Checking Survey Methods.
A member checking process (Phase 2) was conducted as a means to determine the resonance of preliminary themes identified through analysis of interviews and focus groups. Member checking enhances trustworthiness of data and enables triangulation of data to enhance understanding of the phenomena in question, leading to more valid and nuanced interpretations. Specifically, the research team conducted a Synthesized Member Checking method (Birt et al., 2016), which summarizes themes across the data, and provides participants the opportunity to confirm or dispute and add clarifying comments to these themes.

Twenty statements were selected that synthesized key thematic findings from the preliminary analysis, representing the following: organizational context for trial implementation; paramedic characteristics related to attitudes, beliefs, and experiences pertaining to clinical trials; and training approaches for clinical trials. The statements were included in a mixed data survey instrument (Creswell & Hirose, 2019) that was administered to interview and focus group participants using a mixed methods integration strategy of *connecting* such that the respondents surveyed were those that participated in earlier data collection activities (Fetters et al., 2013). Respondents were instructed to review each statement and indicate whether they agreed, disagreed, or had no opinion; and were also encouraged to provide comments, particularly if they disagreed or felt strongly about the finding. At the close of the survey, participants were asked to provide their first and last names to enable tracking of survey responses and linking of the dataset with role (i.e., paramedic or other) and participant type (i.e., interview or focus group). See Appendix C for final Member Checking instrument.

Completing the survey was estimated to take no more than fifteen minutes. The survey was mobile optimized and programmed using SurveyMonkey®. After excluding three participants because of missing or invalid email addresses, forty-eight participants were sent an initial email from SIREN@westat.com on November 18, 2019 that described the purpose of the data collection and included a URL to access the survey. An additional participant was excluded because of an invalid email address, resulting in an analytic sample size of 47. A reminder email was sent to non-respondents eight days after the initial email. Survey data collection closed on December 2, 2019.

2.1.3   Participant Characteristics. A total of 51 individuals (22 paramedics and 29 individuals in other roles, including investigators, EMS medical directors and educators, and operational chiefs [hereafter referred to as "Others"]) others) participated in either a focus group or an interview during the Phase 1 qualitative data collection (Table 1). From these participants, 47 received an invitation to complete the member-checking survey and 33 participants responded to the survey, for an overall response rate (RR) of 70.2%. One survey response was considered incomplete because the name of the respondent was missing, and therefore, was not included in the analysis. Table 2 presents the Member Checking survey response rates, by role and Phase 1 participant type.

Table 1. Number and Role of Phase 1 Participants (Focus Groups and Interviews)

	Focus Group	**Interview**	**Total**
Overall	32	19	51
By Role			
Paramedic	11	11	22
Other	21	8	29

Table 2. Member Checking Survey Response Rates, Overall and by Respondent Role and Participant Type

	# Receiving Survey	**# Completing Survey**	**Response Rate (%)**
Overall	47	33	70.2%
Response By Role			
Paramedic	18	13	72.2%
Other	29	20	69.0%
Response by Phase 1 Participant Type			
Interview	19	11	57.9%
Focus Group	28	22	78.6%

Note: Four paramedics were excluded from the member checking survey because of missing or invalid email addresses.

2.2   Integration of Findings

The analysts used a mixed data analytic strategy to examine the qualitative data and assess resonance of the findings quantitatively. The integration strategy for the member checking survey involved the process of *building*, that is, construction of items based on the qualitative results (Phase 1), and *matching*, the strategy of creating items to reflect the qualitative themes (Phase 2) (Fetters et al., 2013;

Fetters, 2020a). To provide a comprehensive understanding of the findings, the team used joint display analysis and presentation procedures (Phase 3) (Fetters, 2020b).

2.2.1 Data Sources. Multiple data sources were included in the analysis, as described in Table 3.

Table 3. Qualitative Data Collection and Member Checking Survey Data Sources

Source	Description	How used in analysis
Facilitator/co-facilitator notes/interview notes	• Notes taken by the interviewer or co-facilitator during the interviews/focus groups	• Notes were used to develop the codebook and preliminary coding discussions with facilitators and co-facilitator • Notes provided additional context and insights to coded text
Focus group and interview transcripts	• Transcriptions based on focus group and interview recordings	• Transcripts were imported into NVivo® 11 • Text was coded per the codebook (Appendix D)
Member checking survey	• Quantitative and open text data from online survey	• Endorsement of items were used to confirm themes, ensure that themes accurately represented participants' views

2.2.2 Data Management. For focus groups and interviews, all discussions were audio recorded with the consent of participants and were professionally transcribed verbatim. Co-facilitators and interviewers also took notes.[2] All transcripts were anonymous and any names of individuals, facilities, or other descriptors that could compromise confidentiality were removed from the transcripts. Once validated, transcripts were posted on a secured drive where members of the research team could access the data for analysis. Using standardized procedures, transcripts were formatted and imported into NVivo® 11 for analysis. For the member checking exercise, data from SurveyMonkey® were exported to an Excel spreadsheet. The spreadsheet was saved on a secured drive, only accessible by the research team. Frequencies and percentages were calculated in Excel.

2.2.3 Data Analysis. Broad content areas and themes of interest based on focus group and interview data were explored. The broad content areas initially identified included Research Operations and Logistics; Research Training; Attitudes towards Research; EMS and Other Systems; and Other Relevant Discussion.   The initial identification of content areas and themes was meant to be as expansive and inclusive as possible so that the analysis would capture the breadth and depth of issues discussed. In this manner, the content areas and themes emerged and evolved during data collection. Throughout the process, the research team met to discuss analysis progress, leading to the development of a codebook (Appendix D) to document the emergent concepts and themes. Throughout the coding process, the codebook was refined as codes were merged, expanded, deleted, or divided. Previously coded text was recoded to reconcile variability. Research team members trained in qualitative data analysis methods utilized NVivo® 11 (NVivo, 2015) to code the transcripts and retrieve text segments for the analysis.

Coding Rules and Meetings. Prior to the start of analysis, all coders met to discuss and agree on specific coding rules. NVivo® 11 is organized around nodes that are defined by emergent content areas and themes. Rules included how much text surrounding each node to code (e.g., coding at the beginning of a

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[2] Detailed notes were used for analysis of three interviews in which the audio-recording technology failed.

sentence or paragraph, coding interviewer questions) in order to provide sufficient context to derive meaning. Coders also came to consensus on the organization and use of the codebook. These rules allowed the research team to standardize the coding process. Coders met regularly to discuss the status of coding and triangulation of interpretations. Inconsistencies in coding were discussed and resolved through consensus.

Coders collaborated with the research team to analyze and refine the coding process as follows:
- *Step 1.* Draft Codebook – based on high-level themes from the focus groups.
- *Step 2.* Confirm Codebook – select research team members reviewed the codebook against a set of focus group and interview transcripts to ensure that the codebook captured the breadth and depth of concepts in the transcripts.
- *Step 3.* Test and Refine Codebook – a subset of the research team reviewed a coded interview to assess the application of codes. Inconsistencies or inaccurate application of codes were resolved and the codebook was further refined.
- *Step 4.* Active Coding – coded text was generated and distributed to the research team for review. This process ensured that coded text accurately and consistently represented assigned codes.

3. Development of Conceptual Model

During preliminary analysis, emergent themes were organized into a conceptual model to understand the contributors that influence the implementation and conduct of prehospital clinical trials. The model posits that there are multiple and bidirectional interactions among the domains and also accounts for external factors in the larger environment, all of which likely contribute to institution and learner level outcomes.

The scope of this study was not to test the relationships among the domains, but to generate a model to organize the findings and to potentially guide future projects exploring topics pertaining to implementation of prehospital clinical trials. Figure 2 illustrates this model, which includes domains identified through the analysis process, and which incorporates potential outcomes at the level of the individual (the learner) as well as the institution. Results are presented by domain in the following section (Section 4).

- **Implementation Context** – Organizational factors existing in the immediate environment where the prehospital clinical trial is being trained on and implemented.
- **Learner Factors** – Paramedic characteristics including personal attitudes, beliefs, experiences, and skills in conducting prehospital clinical trials.
- **Training Approaches** – Different methods and strategies to encourage successful uptake of clinical trial training goals.
- **Environmental Factors** – Variables that influence the prehospital clinical trial environment overall but that are not likely to be directly impacted by training programs.
- **Potential Outcomes** – Possible benefits of training approaches to both the individual learner and the institutional environment.

Figure 2. Organization of Domains Associated with EMS Participation in Prehospital Clinical Trials
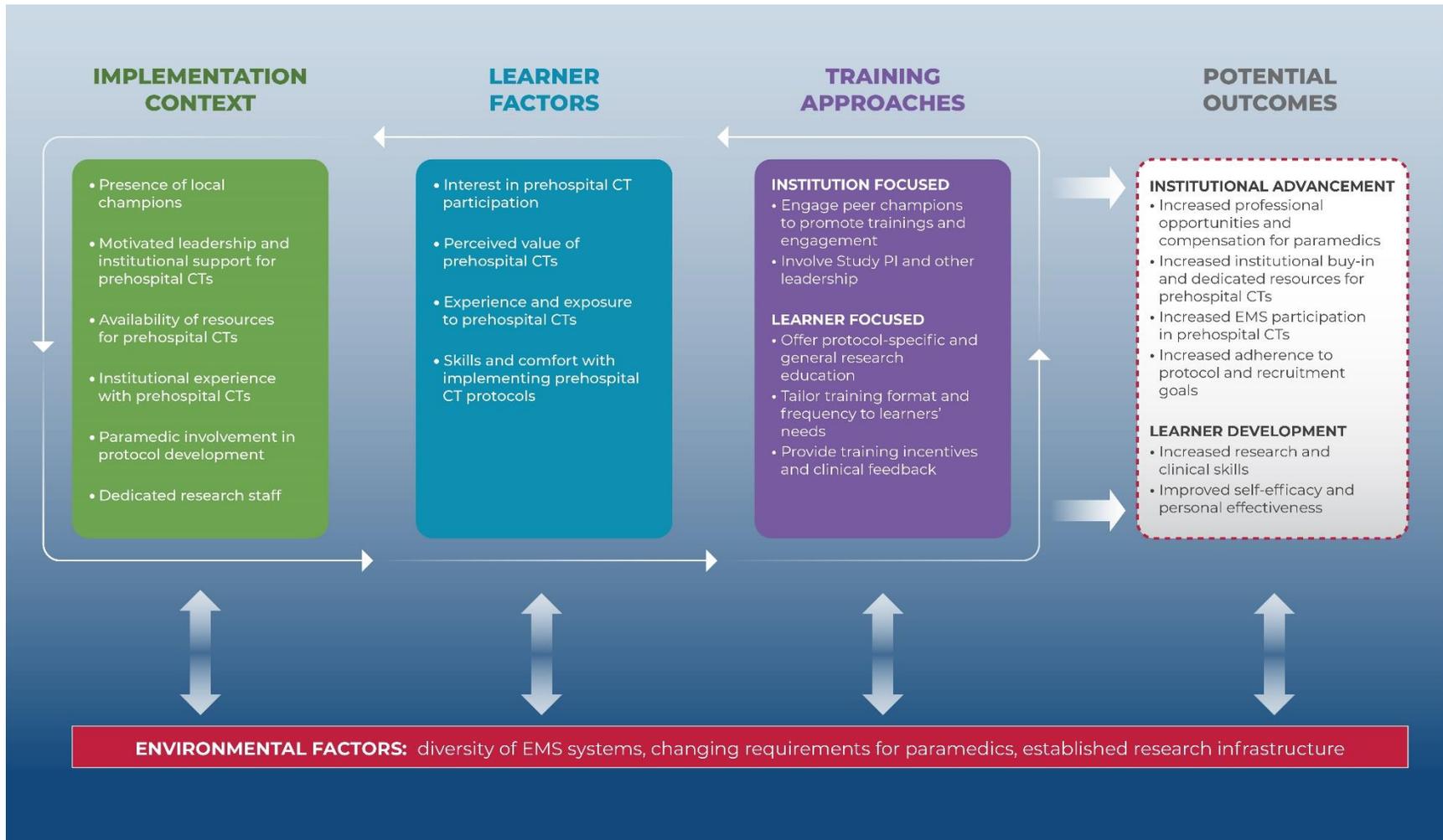
4.   Results

Member Checking Results. The member checking data, organized to reflect the attitudinal responses and related qualitative comments, were a data source for the analysis (Section 2.2.1, Table 3). Percent agreement for each of the 20 statements on the Member Checking Survey was calculated and was found to range from 52% to 100%. Respondents agreed with the majority of the findings. Fifteen statements resulted in 90% or greater agreement among respondents (presented in Appendix Table E.1); of these, eight statements received 100% agreement. For items with less than 90% agreement, the percent disagreement overall and by role was calculated, which confirmed general consistency in perspective, irrespective of role. The mixed methods joint display of Appendix Table E.2 presents these five statements and illustrative comments. All qualitative comments provided by respondents for these five statements were incorporated in the final results (Section 4).

Results are presented by model domain, with illustrative quotes presented in italics in tables accompanying the findings. Subthemes, where found, are presented in bold text in the tables. Illustrative quotes add background and richness to the findings and sources are identified by data collection mode *(Interview = I, Focus Group = FG, Member Check = MC)* and attributable participant role. As themes in the analysis are interrelated, cross-references to other relevant sections are provided.

4.1   Implementation Context

The Implementation Context domain pertains to the *organizational context in which the clinical trial is conducted that influences paramedics' experiences and attitudes, and directly or indirectly impacts training and support for the anticipated or implemented trial*. The focus group and interview discussions identified a range of factors pertaining to the organizational context in which clinical trials are conducted. These factors in the implementation context are likely associated with the conduct of successful trials and may function to reduce reluctance of paramedics to participate in specific trials, as well as to reinforce interest and skills needed to be fully engaged in research more generally. Many of these comments were the result of reflections on what participants thought affected paramedics' comfort and skills with regard to participation in prehospital clinical trials. Training, a critical element in building the skillset and level of comfort for trial participation, is addressed in Section 4.3, with themes pertaining to the institution-level found in 4.3.2.

Broad and interrelated themes in this domain include the importance of institutional support and leadership (4.1.1), availability of resources (4.1.2) and presence of dedicated research staff or those who serve as study champions at the local level (4.1.3). Participants also expressed the value of incorporating paramedics' input in both the development of the trial protocol and modifications following implementation (4.1.4), as well as on providing feedback on the progress of the trial to keep paramedics informed and motivated (4.1.5). Finally, the broader context of the prehospital setting and the challenges of conducting trials under those circumstances were also discussed (4.1.6).

4.1.1   Institutional Support and Leadership (Table 4). Participants discussed how stakeholders in the EMS system in which the trial takes place demonstrated their support for prehospital clinical trials. This theme, particularly voiced by participants who were in leadership and education roles, suggests that institutional efforts to communicate with paramedics to keep them informed and to have visible leadership with regard to the conduct of clinical research at the agency level is believed to impact

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paramedics' experience and intentions. These efforts, which typically include key individuals such as medical directors, set the stage by recognizing the complexities of clinical research and by creating a culture in which paramedics are expected and encouraged to support research.

This concept was explored in the Member Checking exercise with the following statement: *"Informing paramedics of a possible pending trial is more likely to engender interest and engagement."* The additional information provided through member checking qualitative feedback suggests that timing of this information is critical, as in "*It is important not to get them excited and then not deliver. The deflation they feel at missing an opportunity is worse than them not knowing they almost got the opportunity" (MC- Other),* and "*Wait until the trial is funded and at least 90% ready for implementation to inform them about it. I don't inform them until it is ready to deploy, as it really doesn't matter to line providers until that point" (MC- Other).*   However, timing of the announcement is also related to the opportunity for paramedics to potentially participate in trial design (see Section 4.1.4), as demonstrated by *"earlier contact allows them to have a voice and hopefully help with buy-in" (MC- Other).*

Table 4. Institutional Support and Leadership

Importance of EMS agency support in building a culture for research.   Perspectives on the value of agency support for the implementation of a prehospital clinical trial were expressed particularly by individuals in the non-paramedic group, which included medical directors and paramedic educators. Efforts at the broader agency level can take different forms depending on the agency, but should reflect the agency's genuine commitment to research.   *We probably failed the trial on our side by not doing enough promotion of the trial internally. And I think that's probably a disconnect between our medical director and the organization, because I think there was a few of us that were, for lack of a better term, really trial champions…really ensuring that esprit de corps on the research exists and it stays with the project I think is probably very important. (I- Other)*   *So it does create that – creating that culture is – takes a lot of sort of commitment, which also means that, you know, you've got to have dedicated academic folks who have got projects going and basically continuing to engage them, because they do like to be on the cutting edge. I will agree that systems that really like research, part of what drives it is they like to be on the novel edge of what you're doing. (FG- Other)*   *So what's happened is because of my role as an EMS commissioner, I've been able to leverage my – you know, my interest in doing research along with, you know, the connections I've made, the relationships I've had. I've been able to leverage those to get pre-hospital research kind of more higher visibility within the EMS agency. So I'm always a champion for research. (I- Other)*
Leadership buy-in and presence is a critical element of the implementation context. Often the commitment of the EMS agency is expressed by individuals in leadership roles who promote or represent the particular trial and the value of building the evidence base more generally. Thus, an important element of the implementation context is the presence of visible and committed leadership, a role often played by the medical director or study PI.   *So it's very clear, if you want to do research within the – you need to, number one, have the EMS medical director as your advocate. If the EMS medical director is not your advocate, you're going to get nowhere. And then next it does EMS medical director have the clout to get the different battalion chiefs and the different infrastructure to move up to do a study. (I- Other)*

> *I think it falls upon the medical director and the administrators just to kind of make the case for why the participation is important, and once you provide that up front education, you do get a little more buy in. It just may not come as naturally, say like a doctor, they know, you know, research is part of their job. (I- Other)*
>
> *I think when there's enthusiasm coming from their leadership [paramedics are] always on board… (I- Other)*

4.1.2 Availability of Resources for Prehospital Clinical Trials (Table 5).

Limited resources at EMS agencies often restrict opportunities to conduct prehospital clinical trials, or complicate efforts to sustain a successful trial. Participants expressed that EMS leadership are often unable to commit to implementing prehospital clinical trials due to limited budgets, staffing, timelines, and competing priorities. Additionally, EMS agencies may be required to pay for paramedics' time to participate in protocol trainings, placing more strain on limited resources. Thus, for some EMS agencies, research is often not viewed as a priority.   Subthemes identified in the focus groups and interviews include challenges associated with lack of resources and the benefit of having access to resources throughout the duration of the trial. Also, see Training Approaches (Section 4.3) regarding additional discussion related to resources and training.

Table 5. Availability of Resources

> **Challenges created by lack of resources for research.** Lack of resources at the agency level impacts the continued investment required to conduct the trial, as well as capacity to provide sufficient training for paramedics. This theme was particularly captured during the focus group discussions from the perspective of non-paramedics, who expressed frustration with the range of resource requirements for research (e.g., time, equipment, training funds).
>
> *It also takes resources. That's like – I mean, honestly, most EMS managers are bogged down by the day to day fires that are created by a lot of different variables. And then to have – To say like okay, well, we're going to take some of your time, and your resources, and your paramedics' like focus, and say we're going to do a live trial, not everyone has that ability. You also usually need an academic center pretty near the hub too…Like I mean, the task of doing a rural study, I can't even imagine what that would be for the EMS agency on that side. (FG- Paramedic)*
>
> *Every study I've been involved in, this is like universally under budgeted and underrepresented. And it's very hard when you're – particularly when your budget constraints are tight and your – you need the equipment and you need the – you need to pay for the regulatory investment, and you need to pay for your investigators and for your research infrastructure, like your RAs who are doing the consents and obtaining the data in the ED, EMS becomes an afterthought, and you know, maybe there's a little money in there for training, but it's very difficult to – Very difficult to sell that as part of the grant. (FG- Other)*
>
> *If you're trying to do a study on a skeleton research staff, it's going to be hard, because then you have to ask more from the EMS program. (FG- Other)*
>
> *So for our side [the challenge] is getting the EMS agencies to participate, finding time, because training time is training dollars, you know, so we provided the training but they provided the people, which meant that the agencies were paying for them to go to this training. And whenever you're talking about training, you're talking about dollars out of someone's budget. (I- Other)*
>
> **Access to resources throughout the trial supports implementation.**   Given that patient enrollment in a prehospital trial is often a relatively rare event, it is especially critical that resources be allocated to provide the tools and information throughout the trial, to supplement any trainings offered and to provide support for the paramedics. These can be incorporated into the study protocol or materials

to assist with recollection of the procedures, or can be in the form of reliable access to real-time support. This is also related to themes addressed in Training Approaches (4.3).

So using those prompts, that's what they'd do. And many of them thanked me over and over again because they don't remember all the steps. So everybody carries a pocket card, if they don't like the pocket card, they carry their app on their phone. (I- Other)

We have 24/7 hotline that the paramedics, we give them that number at the training. So at any point at any time if they have a question about the protocol or inclusion, or exclusion, or anything, they can call us at 2:00 in the morning, and any human being highly trained in the protocol will answer the phone and answer their question. (I- Other)

4.1.3   Dedicated Research Staff and Champions (Table 6).
Leadership and agency commitment to research is often evidenced by the presence of dedicated research staff or study champions. Respondents stated that EMS agencies that have been successful with conducting research often utilize dedicated staff devoted to research studies, research training, and quality improvement (QI) studies. These staff can include research assistants, nurses, or study coordinators, who function to simplify the research environment and paramedic experience during the conduct of the trial. The presence of study champions, in addition to other factors, has an impact on paramedics' comfort and skills with research participation.

Table 6. Dedicated Research Staff and Champions

One approach to facilitating trial implementation is to provide staff, such as nurses or administrators, who can be a resource to the paramedics and others over the course of the study. However, providing this infrastructure can be both challenging and costly. Also valuable are the individuals either within the EMS agency or among the paramedic team who either opt to be advocates for the trial or are encouraged to do so by investigators and others. Study champions in particular can provide paramedics with informal access to information pertaining to the trial and motivate trial participation.

Also, what hasn't gotten discussed yet is the trial came in, and they hired a study nurse, and they actually hired two of them, so they could, you know, -- There would always be one available. They had to get credentialed into the hospitals to be able to come in, access the facility, go into the ED, and then ultimately access the patient charting. (I- Paramedic)

I've got my daily operations to worry about. So having like dedicated staff that's not being paid by the EMS agency is actually a good way to separate those things. And when you look at the successful EMS agencies and research…they pour most of their resources into QI and training, and they have dedicated staff that cannot be pulled from their trucks for other things. That doesn't happen in a lot of other agencies (FG- Paramedic)

We were successful because we had nurses contacting the paramedics regularly and so having the research infrastructure…when we had our nurses doing regular visits with cookies and donuts and just forming relationships, paramedics were much more open to the on the fly education, and got more buy in. (I- Other)

So if a paramedic gets befuddled – and this happens throughout our province, they simply call in and this – we call them almost champions too, but they're not – it's not their job. They're there to try and remedy this. So they simply problem solve any issues that the paramedic might be happening. (I- Other)

…find a few champions in your organization that are into it, and will listen, and understand what [inaudible 20:36] for, and then they go to their peers and say this is why this should be important to you. And they're more willing to listen to their peers than they are the guy sitting in the glass palace, right? So you find those few people that are really into it…then they tend to come around because they're listening to each other. (FG-Paramedic)

4.1.4 Paramedic Involvement in Protocol Development or Modification (Table 7).

Participants also emphasized the value of considering the paramedic role throughout trial design and implementation.   Engaging paramedics at all phases of the research not only impacts their commitment to the trial but also can ensure that the design is pragmatic and approximates the standard of care (see related theme in 4.1.6). Paramedics with research experience may be engaged as the trial is being designed, and trial monitoring approaches can incorporate constructive feedback from participants which may lead to protocol modification. However, successful uptake of these strategies requires agency commitment and vigilance, as well as resources.

Table 7. Paramedic Involvement in Protocol Development or Modification

The value of engaging paramedics was recognized as critical when planning the protocol. Methods to solicit ongoing feedback, mostly informal check-ins or encouragement to report on what is or is not working in the field, were also components of effective trial implementation. These efforts help to ensure that the expectations for the trial are aligned as closely as possible with standard EMS routines to minimize the burden on the paramedics.

…in our area, the paramedics are the authors of protocol… We had people from around the country that are like how did you get this protocol written like this where it's aggressive over here, but very simplistic and kind of, you know, cautious on this end? And it was – It's paramedic driven. (I- Paramedic)

I personally think that EMS personnel need to be involved with the genesis of any research idea pretty much at step one – step two if not step one, and a bunch of us have followed that lead. You've got to treat [paramedics] like part of your investigative team, and they will identify all sorts of problems with your protocol before you even get started. (FG- Other)

We even went so far as to making sure that the control medication, if you will, was the same type of control medication as what we carry on the unit. So even though it's the same medicine, and it's labeled the same, there was no difference in those two vials, and those guys are used to seeing, oh, that's the blue vial with the red top. Yep, same one. And it becomes a muscle memory thing, and they're not worried about screwing something up. (I- Paramedic)

So we actually changed our approach to our next study. A couple things. One is paramedics don't want to spend time on the phone doing a formal consent process. They want to go, go, go. So we found a compromise, which is we no longer do the 10 minute on the phone going through the consent form with the paramedics. That really got on their nerves. They really gave us a lot of flack for that. (I- Other)

He [one of the medical directors] will actually step in [and say] hey, you guys know who I am. I have a question. What problems are we running into? And just to every paramedic that's sitting here, what issues do we have, and if there's an issue we can address it. Say, hey, there was a shoulder strap that came with it. That needs to go. It's in the way. Okay, perfect. Those are now coming off. So he basically can kind of do an intermittent kind of meeting with all the paramedics that are at continuing education and say are we running into issues? (I-Paramedic)

4.1.5 Motivating Paramedics by Providing Feedback on the Trial (Table 8). Monitoring of the
trial can provide useful information to share with participants to keep them informed of trial progress, as discussed above. Furthermore, in addition to reinforcing the agency's commitment to the trial, information on recruitment and other key trial milestones can educate paramedics about the process and outcomes of research.

However, some participants observed that paramedics are more inclined to remain engaged and invested in the trial if they believe that efforts to monitor compliance with the protocol are not punitive. This was explored during Member Checking with the following statement: *"Some paramedics may be less inclined to participate in research due to concerns about making mistakes."* Comments from respondents qualified this statement, as per the following which emphasizes the importance of training: *"They'll be more likely to participate willingly when they're trained-and feel the trial is well organized, optimized clinically and procedurally-and they understand the purpose" (Paramedic)* and *"Maybe in some trials at other departments but our department makes sure that instructions are on hand and practice has been* provided." *(Paramedic).* Other comments suggest awareness of this issue and approaches to address it, including: *"…and that is a management responsibility to understand their employees and manage them when implementing a trial." (Other)* and *"If properly educated of their role, this is not a concern for the majority of paramedics involved in clinical trials." (Other).*

Table 8. Motivating Paramedics by Providing Feedback on the Trial

Participants in both roles provided specific feedback on useful information to share and on the importance of keeping paramedics informed of the progress of the trial. Often an underlying theme of these strategies is the provision of ongoing appreciation for paramedics' efforts and an emphasis on how critical they are to the success of the trial (see 4.2.2). Appropriately crafted messages can also help alleviate concerns about making "mistakes" in the field by emphasizing how investigators appreciate the input and can learn from these challenges, thereby reinforcing a non-punitive culture for the conduct of research.

Here's how many patients we have enrolled. Here's how many patients were screened and did not get enrolled. You know, you guys are doing a great job. Here's kind of where we are in the grand scheme of numbers. So he keeps everybody pretty abreast of …where the study is. (I- Paramedic)

So it is easy for me to get up there and say you guys are rock stars…You have already changed medicine and how we care for our patients and improved patient outcomes across this country. You have. Every one of you that has enrolled a patient into a trial or helped to, you have impacted the way we care for patients and have improved outcomes. (I- Other)

And if they make a mistake, we never scold them. We simply say thank you. We'll learn from that. They're usually horribly embarrassed….I mean, it's a blaming game where they're always worried they're going to make a mistake, and we're saying no, you did your best. Everybody makes mistakes. We just learn from that. (I- Other)

…when the research team makes it clear that this is not going to be a discipline process. So hey guys, yes, we really can't have you making like, you know, errors that are very, you know, deliberate, and we can't have you doing unsafe acts on patients, and here's how we're going to mitigate that. But if for some reason something happens or you drop the box, and it shatters, or you drop the medication and it shatters, no big deal, we'll just get you another one. (I- Paramedic)

4.1.6 Conducting Trials in the Prehospital Setting (Table 9).

As introduced above, there are challenges with conducting research in the prehospital setting that influence the strategies and methods that can be implemented within the agency to support and conduct trials. These immutable influences in the broader implementation context, expressed particularly in the focus groups, include challenges to conducting research in the prehospital setting that impact paramedics' comfort level and may be challenging to address in typical training strategies and approaches.

Table 9. Conducting Trials in the Prehospital Setting

Adding a research protocol to the context of emergency are in the prehospital setting, which is typically unpredictable and chaotic by nature, can impact the standard work flow and negatively impact paramedics' comfort and intentions. Keeping research protocols as close to routine practice as possible, and promoting a positive culture, which acknowledges these challenges (as described above), can positively impact learner and institutional outcomes.

You got familiarized with it yourself and say, hey, I think this may fit the criteria…and you're sitting there and you're second guessing it, and sometimes you can miss the window of opportunity to deliver something that someone needs, you know? … these are not frequent events and they're a little bit different from what you're familiar with and maybe a different work flow. (Paramedic)

Maybe something as simple as wording. Some of the studies we've done, they have very specific wording in the protocol that's written because it's very clear and it makes a great deal of sense, which you then try to translate at 3:00 in the morning in the dark, doesn't translate nearly as well [inaudible 11:38] what does that mean?... And you do something different. (FG- Paramedic)

You know, there's so much variability in the pre-hospital setting or even in the emergency setting. I mean, you can't think of every situation. You can't have a script for everything that's going to come up. (FG- Paramedic)

The things that improve the buy in is the more pragmatic the study is, the more the study is in keeping with our normal practice, the more likely they're going to buy in. When you design a study that has multiple interventions to be done, the likelihood of that going well is really poor….if you have a whole bunch of new procedures that are specific to this particular study, your compliance is going to be way lower than it would normally. (FG- Other)

And I think it has to be simple. It has to be very clear and straight forward. The thing you ask them to do has to be very limited and very well defined. And it can't be onerous. (FG- Other)

4.2 Learner Factors

Participants were asked to reflect on how *paramedic characteristics, including personal attitudes, beliefs, experiences, and skills, may affect their experiences and comfort with the conduct of prehospital clinical trials*. In addition to the two broad themes discussed below, the model incorporates prior experience with clinical trials as a relevant factor. However, as all participants in this study had experience with prehospital clinical trials, this theme was not explicitly explored. Two broad themes were identified in focus groups and interviews pertaining to paramedics' characteristics associated with general interest in research (4.2.1), and specifically how paramedics perceive the value of prehospital clinical trials as a factor influencing their attitudes, interests, and behaviors (4.2.2).

4.2.1 Characteristics of Paramedics in Relation to their Field of Practice (Table 10).

All participants contributed to the discussion of how typical traits, inclinations, and backgrounds of individuals currently in the field of paramedicine may influence factors associated with participation in research. These were often expressed in the context of understanding why a paramedic may or may not be interested in research or inclined to view it as a component of his or her profession, which can be useful in the design of training approaches to maximize paramedics' comfort and skills with participation. Characteristics identified include general predisposition that may have led individuals to the practice of paramedicine, enthusiasm for new or novel experiences, and the impact of generational or cohort differences.

Table 10. Characteristics of Paramedics in Relation to their Field of Practice

Influence of prior experience and predisposition on attitudes toward research. Participants described perceived traits of paramedics that either drew them to paramedicine, or were relevant to having an understanding of or interest in research. Some of these comments, expressed by both groups, may reflect traits of more typical paramedics that are perceived to impact attitudes toward research, such as interest in helping others, and expectations for understanding the rationale behind protocols.
In my opinion, a good paramedic embraces the aspect of helping people. You know, and anything that you can do is a plus, so if we can give them pain medication or I mean, you have to have an attitude of service, in my opinion, to make a good paramedic, you know? The attitude of service, and not the attitude of, you know, being bothered. (I- Paramedic)
Paramedics are generally willing to do – a bigger workload or a difficult challenge if they understand it and it makes sense…if it doesn't make sense, or it's poorly deployed, or it's just stupid, they'll break it or they'll kill it. (I- Paramedic)
…they're really not sophisticated in understanding the depth of how research is done…I mean, a lot of EMTs and folks will move mountains and do really complex, you know, almost unthinkable work…and they will do it well and very accurately if they understand the why. (I- Other)
I think most paramedics are very mechanical in their thinking. They're not very analytical as far as trying to look at analyzing what the reasons that they're doing things, so I think it really – the most important thing is just learning that [inaudible 14:53] expectation specifically. If that makes sense. (I- Other)
Interest and preference for new experiences may be relevant to the conduct of prehospital clinical trials. There were several themes pertaining to whether or not paramedics' predisposition for change and new experiences is related to participation in research. The data suggest that some paramedics are driven by preference for novel or new experience, whereas other are more protocol-driven. In some cases, general disinterest in one's job, or "burnout," was also discussed as a factor which can impact paramedics' inclination toward the additional expectations regarding a clinical trial.
It's like a change almost, like you know, sometimes people fight change, so they've got the attitude of well, why am I doing this, why is it up to me, right. So there's the odd person like that. It's not as many, but I just think on a personal level, we're just – want to try new things and be involved in things and it's learning as well. (I- Paramedic)
…that's totally new to them, but they love it, because they say they're doing something different. They're now doing something that might help somebody's brain, and they're getting to do something that's hands on. Paramedics like things that are hands on. (I- Other)

They're a really unique group that foundationally are protocol driven. So they're very much driven by specific step by step protocols. So as a whole, you're dealing with a workgroup that is very scripted, and if you leave it for too much interpretation, then you can end up corrupting the project, right? Does that make sense? (I- Other)

…they view participation in these studies as a change in work environment, where now there's a new skill that I have to perform where there's this new thing that I have to do, and they balk at that almost unanimously… because that's a change in our environment. (FG- Paramedic)

There is a small group that is not interested in taking the extra few minutes or whatever it takes to do the training, and extra few questions, so there is – that can be tough to get buy in from those. (FG- Other)

I have found a lot of people, because of burnout and whatnot that just comes along with the job, they – you know, they're like I don't want to participate in those things, I don't get paid any extra money…and I'm just a puppet and I'm just tired of doing trials, because you're kind of tired of doing the job too, so. That affects some people's attitude toward these things. (I- Paramedic)

Paramedic cohort as a potential factor influencing trial interest and experience. Some of the comments linked paramedic age and job seniority to interest in participating in clinical trials. Participants explained that younger cohorts are more likely to have received education on research methods as part of their training, which they felt contributes to a culture change in some EMS systems; also see related discussion on changes to the field of paramedicine in Environmental Factors (Section 4.4).

The only thing I can think of for the handful of studies where, you know, four or five studies where we've gotten pushback from specific individuals is they're closer to retirement, and they tend to be older or have longer tenure there. (I- Other)

I think you've got to remember most paramedics, especially the older ones, received no education or very little education in research methodologies, and so as the profession moves more towards an evidence based medicine sort of model, getting more paramedics hands on experience with doing research gets them to understand that process better. (FG- Paramedic)

…We're turning over. We're an older service. We've got a lot of 40 year old people retiring, a lot of young kids coming straight out of college, and they're more invested in research, and they're chomping at the bit to get involved in some of this stuff, so I think there's a little bit of a cultural change with the education for medics coming up. (FG- Other)

4.2.2   Interest in and Perceived Value of Prehospital Clinical Trials (Table 11). Focus groups and interview participants were asked to elaborate on what paramedics found interesting or rewarding about research. Paramedics especially stressed the relationship between research and advances in patient care, and also the general importance of prehospital clinical research to ensure that the most evidence-based approaches are practiced.

Table 11. Interest in and Perceived Value of Prehospital Clinical Trials

Research in the context of improving patient care.   Many participants appreciated that research can lead to advances in the treatment of patients by providing evidence that may lead to protocol changes in the field. This understanding of the longer-term goal of research was described as a potential factor motivating paramedics and others to participate in clinical trials.

As a professional paramedic, as a practitioner of paramedicine, we all want to advance the field. We want to do the most correct, best practices out there…So I think participating in these studies where we find the kind of – the old way is not necessarily the best way anymore helps us advance our field and gain knowledge and make it better for our patients out there. (I- Other)

I think it's an important part to see the future of where we're going and what we're going to be doing. Most of the paramedics want more tools to help our patients, so participating in trials is a good way for us to shape our own future. (I- Paramedic)

…from my perspective it makes us better to participate in these. We're getting information on kind of the cutting edge stuff a lot earlier than it's getting published, so I think it's important for our people to participate just because it makes us better at providing clinical care. (FG- Other)

It's important to us because we feel like we're part of a group that's learning or trialing things that are going to hopefully improve patient outcome and I think we all want that in the long run. So it's kind of fun also to be like hey, I was part of that study and you know, help make a difference maybe, or maybe not... (I- Paramedic)

We really think this is going to make a difference in patient outcomes and patient care or we wouldn't be doing it. (I- Paramedic)

Importance of paramedicine research in the prehospital setting. There were several themes related to the recognition that, in order to improve patient outcomes, potentially life-saving emergency medicine techniques need to be tested specifically in the prehospital setting. Awareness of the importance of this setting for clinical trials will increase buy-in from all stakeholders (e.g., hospitals in particular) and help to advance the field of paramedicine as a whole.

It also creates buy in from the field perspective that they're an active participant in, you know, changes in care or protocol changes that are coming up, whereas before it's things that maybe extrapolated from in hospital studies that, you know, doesn't work in the pre-hospital environment. We don't know unless we try it. (FG- Paramedic)

…if it's all done in the hospital and it's not employed or evaluated in the field, we're missing a real critical piece. (I- Other)

It helps the average paramedic, average EMS provider to understand that there's more to it than just providing the care on the vehicle, or like at the patient side. You know, it shows that there's career development options, there's different ways that they can advance and work up through the ranks. I think it's kind of an opportunity. (FG- Other)

4.3   Training Approaches

Drawing on the conceptual model, the domain of Training Approaches addresses the *methods and strategies to encourage successful uptake of clinical trial training goals.* Participants were asked to reflect on their experiences to address a series of questions about training practices and recommended strategies for developing and implementing successful training programs for prehospital clinical trials. Topics raised by the participants align with the conceptual model domain, Training Approaches, as they describe different methods and strategies focused on the learner's needs and influences (4.3.1) and on those strategies aimed at promoting institutional uptake of clinical trial training goals (4.3.2). Many of the themes that emerged relate to those described in the Implementation Context (Section 4.1) and Learner Factors (Section 4.2) domains, but are distinguished as actionable approaches that may

influence factors within those domains. As posited by the conceptual model (Figure 1), the interplay of these three domains (Implementation Context, Learner Factors, and Training Approaches), in addition to the influence of the environment, may ultimately affect prehospital clinical trial training outcomes.

4.3.1 Training Approaches addressing Learner-level Factors

4.3.1.1 Training Delivery Methods (Table 12). During focus groups and interviews, participants described training methods that support learners' mastery of competencies for successful prehospital clinical trial participation. Useful methods include delivery of the training in person (versus web-based), incorporating hands-on activities and other interactive approaches that promote active learning, and repetitive training to impress new skills and protocols in learners' minds.

Table 12. Training Delivery Methods

In-person training is important for gaining buy-in and engaging learners. Participants noted the value of in-person training, either alone or as a complement to web-based training, to gain buy-in from paramedics and stimulate learning. Compared to remote or asynchronous training approaches, in-person training encourages paramedic participation in training. Classroom-style discussion and in-person group activities can help solidify training material, while providing opportunities for learners to ask questions and raise concerns. *Oh, I guess the biggest thing would be face to face service. I mean, that's the best thing, because when you do it online, or you know, have it as a continuing education that, you know, people say do on a computer, they're just going to ignore it. I mean, they're just going to say, excuse me, even if it's mandatory, they're going to just cook through it, you know, just to get it done. (I- Paramedic)* *I think that the initial training can be online, but if there isn't that in person follow up component of it the paramedics will either lose interest or not follow through. (I- Other)*
Hands-on training activities help build learners' confidence. Participants noted that hands-on training experiences engage learners while improving their skills and self-efficacy with clinical trial protocols. Although hands-on training is generally preferred among paramedics, participants in other roles reported that available resources often drive selection of training methods. *Face to face and tactile is the best way to go to get to EMS providers. (FG- Paramedic)* *What do they value? They all like hands on. They all like operating something that they haven't done before using a pump. (I- Other)* *Yeah, the training was…only half the day. It was really good and to the point when we were learning how to use the pump. Again, the pump was easy and they made us do it with our eyes closed, so we could just do it by feel so we were really comfortable with it, which was great. (I- Paramedic)* *Actually, he came to each firehouse …and…told us how to administer it, told us about the protocols, told us about the study. You know, he opened it up. He let us touch it. You know, because to me, most firemen learn best by actually being hands on. So he actually, you know, let us touch it, let us see it, you know, let us have our understanding of what it was going to be, and you know, that was it. (I- Paramedic)* *If we could have had them actually work a patient that was a simulation of a traumatic brain injured patient, I think that would have done wonders as well. It would have just helped set it in their minds a little bit more…you*

know, they saw what we wanted them to do, then they actually did it. I think that would have helped…We would have needed two hours, so it's that balance between how much time do you have, how much time are they willing to give and do you have the facilities, the equipment to do that kind of training. (I- Other)   *I think it depends on the complexity of what it is, but I know when we were rolling out like high performance CPR, and obviously even like teaching it, I find that unless – by doing it, it was like totally – you had to go and do it a couple times and stuff, so I mean, certain things I think are really critical to do the simulation for. (FG- Other)*
Repetition of training material supports learning retention and learners' comfort with the protocol. Focus group and interview participants discussed the role of repetition during training to impress new protocols upon paramedics and improve their comfort. Particularly for complex protocols, it is important to provide sufficient protocol training and repetition of critical components so paramedics feel comfortable implementing the protocol in the field.   *This is what you need to focus on, and when you went through the video training or the PowerPoint training, those were the three things that were continually hit on over and over that repetitive, that repetition makes a big, big difference. (I- Other)*   *… the more training somebody has, the more comfortable they're going to be giving the medication or dealing with that medication…if you come in and do kind of repetitive training on that and keep like pounding it into their heads a little bit of this is when you give it, this is why we're doing it, then you know, they'll be a lot more comfortable doing it. (I- Paramedic)*

4.3.1.2 Prehospital Clinical Trial Training Content (Table 13). Participants reported that prehospital clinical trial trainings generally focus on the information essential to paramedics, with an overview of the trial's purpose and research concepts briefly covered as part of the overall training curriculum. Tailoring training content to the learner's clinical knowledge base and using familiar language can help gain the attention of learners and support their grasp of new concepts.

Table 13. Prehospital Clinical Trial Training Content

Prehospital clinical trial trainings focus largely on the specific protocol. Prehospital clinical trial trainings emphasize what paramedics need to know to take part in the study, including the protocol and the rationale for the study. Research methods and ethics are often included in the training at some level, although non-paramedic participants reported that paramedics' appetite for detailed research education is generally low.   *So it was a package, a curriculum package. It was designed to introduce the trial, the logic for the trial, patho physiology of stroke. We added also stroke prevention in there. Some of the – Well, obviously most of the researchers are heavy into public health also. And then the mechanics of the trial. Here's the protocol. (I- Other)*   *About 300 medics are going to carry out the protocol. I just want them to know the basics. This is why. This is how you do it. (FG- Other)*   *He kind of gave us what we call like a 10,000 foot view of the study, and then he said but I want to talk about the – like this is the moral and ethical considerations and kind of how clinical trials worked, so that was in the same continuing education session that he went into that first. (I- Paramedic)*   *Other than sometimes the more advanced paramedics want more literature, more understanding of what actually this drug does, but I don't think that's critical, as long as they can conduct the trial effectively. So I give*

> *them references that they can go to to read up on more information. But as far as undertaking the trial, I give them what's necessary with some handouts. (I- Other)*
>
> *Oh, I had to do EFIC training for all 400 paramedics, which is doing it 35 times, the Belmont report, beneficence. (laughs) We've all done that every year training. That was really a lot of work, and no one liked it. (FG- Other)*

Tailoring trainings to paramedics' clinical knowledge base and delivering the training in "their language" supports paramedic understanding and engagement. Paramedics' training uptake may be improved when the training content takes into account the language, experiences, and learning style of paramedics.   *And one of the girls who was there training us, I know that she's really quite smart (laughs) and she said I was reading this and I know it was put together by a neurologist, but I didn't understand any of it, so here's the meat and potatoes of it. And they just dumbed it down to our level, which was great. (I- Paramedic)*   *So the training has to be directed towards the type of individual and you know, it's – well, I'm that type of individual. I need to see images. Words kind of don't sync in as well. (I- Other)*   *I'm out there all the time. I'm interacting with paramedics, answering their questions, and when they talk to me, they know they're talking to somebody they can speak the same language. (I- Other)*   *The other thing that we found was that paramedics doing the training was far superior to – Nurses or docs doing the training. We involved paramedics very early in our training curriculum, and got their input and incorporated it into our program, and that made all the difference in the world, because the medics just – a medic speaks the language to another medic that a physician or a nurse just doesn't, so that worked really well for us. (FG- Other)*

4.3.1.3 Refresher Training and Ongoing Learner Support Strategies (Table 14). Prehospital clinical trial refresher trainings and ongoing instructional strategies were key discussion topics in the focus groups and interviews. Although refresher trainings are not uniform, participants communicated the importance of continually refreshing paramedics on the trial for successful protocol implementation over time. Participants also reported additional strategies to provide paramedics with ongoing trial assistance and motivate their continued participation. These strategies include providing paramedics with trial reference material and access to telephonic assistance for trial-related questions.

Table 14. Refresher Training and Ongoing Learner Support Strategies

Refresher/booster training sessions can improve protocol implementation (e.g., protocol deviations, low enrollment) and motivate paramedics. Focus group and interview participants discussed the importance of refresher or booster training sessions on protocol implementation and sustained paramedic participation. When the volume of cases is low, refresher trainings may be especially useful to maintain paramedic awareness of the trial.   *We've found that refresher training is very, very important in terms of protocol adherence and keeping them on track… (I- Other)*   *…data was now becoming instantaneous for us for the first time so we could see the trends and we could get instant follow up, so if a crew was out of protocol or outside of the… guidelines, for one, we had the follow up from the hospital right away, and now I could go back, look at the chart and say, hey, this is where there are mistakes. And once we saw trending mistakes, we would block out a next training of EMS training would go specifically to those mistakes to the whole department. Hey, this is what we're seeing. (I- Other)*

> *And it's also dependent on how frequently they actually do the calls. So hey, if I've done four [Trial name] calls, I may not need retraining. I haven't done a [Trial name] call for a year or two. Probably be a good idea. (I- Other)*

Reference material and access to trial-informed individuals (e.g., investigators, nurse educators) for assistance can help paramedics overcome uncertainties and address training gaps. Participants reported various strategies to support paramedics in their ongoing implementation of the protocol, including reference cards and placards, online resources, and access to PI and/or others for questions. Non-paramedics described the intent of these strategies to remind paramedics of the protocol and help them through uncertainties, especially if the paramedic lacked training for the prehospital clinical trial. Some paramedic participants noted that strategically placed protocol reference cards can help trigger their recall of the trial, and appreciated having access to PIs and/or other trial-informed individuals for questions.

I think for the most part once we got our little reference cards it had parameters as far as what you need to do, as far as you know, the blood pressure or this or that. Once we had those available, I mean, in most cases I remember the reference cards either being on the monitor thing…so you can look at it and say, hey, we're doing this. They either had that there or if it was a drug trial they had something on the drug box so when you went to get a drug out of the drug box you could remember, you know, which trial you're doing it. I mean, I think that helps. (I- Paramedic)

The difficulty of course, as I've say, is maintenance of competency, as every six months we have to review it, but we've got placards that hang beneath the pump. I call them 3:00am cards. When it's 3:00am in the morning this tells you step by step what you're supposed to do. (I- Other)

And then there are certainly those that don't get the training that they should, and that's why we have all of these, you know, pocket cards and EPOS physicians and paramedic specialists and all of that. Paramedic specialists are the ones that sit in dispatch working on single response vehicles or are there to answer calls from the field. (I- Other)

The other thing that I think was vital…is that accessibility to the PI or somebody that they can call to say when those gray area situations come up that they don't have an answer for, what do I do. Can I call somebody, can I get in contact with somebody to get an answer to that question? (FG- Paramedic)

4.3.1.4 Training Rollout (Table 15).

In focus groups and interviews, participants commented on challenges that arise when there is a significant time lag between the prehospital clinical trial training and initiation of the trial, and when there are varying levels of training exposure among paramedics within an organization.

Table 15. Training Rollout

Time lags between training and trial initiation may negatively affect paramedics' ability to recall and implement the protocol effectively. Participants discussed the impact of time lags on paramedics' implementation of the protocol. Significant time lags between the training and trial initiation can negatively affect learners' retention of training information, affecting their ability and confidence to implement the protocol effectively. With regard to impact on training specifically, non-paramedic participants discussed the budgetary implications when a second training is necessary to re-train participants because of extended time gaps between the initial training and the trial. Relevant themes are also presented in the context of resources under Implementation Context (4.1.2).

> *What affects their comfort? Hm. Well, again, it's length of time between training and rolling out what we will be doing. (I- Paramedic)*
>
> *But the problem is we do a lot of planning and ramping up and say, okay, we're ready to start on September first, so we're going to do our training in October or August. And then we get everybody trained, and then…two weeks goes by, a month goes by, 12 weeks goes by, 16 weeks goes by, everyone's forgot about everything. We burned through all the money for overtime for the initial training, and now we've got – So sometimes that is unavoidable, but it creates a complete nightmare. (FG- Other)*

> **Non-uniform paramedic training for specific clinical trials within organizations can create challenges for paramedics in the field and affect the trial.** Participants reported that inadequate prehospital clinical trial training among paramedics and organizational training gaps can result in protocol implementation issues, and may place burden on paramedics who have received the training.
>
> *I think the one super failure that we realized, I think it was just because we had so many other things going on, and there was probably a two or three year break in our training specifically for [Study name], and we'd actually like – through QI we noticed that there was, hey, why aren't these guys doing this, and we brought it back in and some of the guys had never had the initial training. Some guys didn't even know we were still doing the study at all, and that – that was the huge kind of breakdown… they realized if you're not continuing education every 18 months your members completely lose track of everything. (I- Other)*
>
> *I guess the drilling that we get in the classroom, it helps, but it's just one time a month until the trial goes in or actually goes, you know, into effect, but like I said, if you don't go to those classes, that could be the challenge of it all. (I- Paramedic)*
>
> *…so all of a sudden, they get scheduled to work on your car and they don't have the training. So it makes it a little more difficult because you're running the whole show, whereas if I'm with my partner who's trained, she could be getting the [trial equipment] set up while I'm on the phone… (I- Paramedic)*

4.3.1.5 Training Incentives (Table 16). Focus group and interview participants discussed the use and effectiveness of training incentives. Specifically, non-paramedic participants commented on the use of incentives to help drive learner engagement in training activities; however, respondents to the Member Checking Survey indicated that incentives may not be the most essential element for motivating paramedics. Respondents clarified that paramedics appreciate food and money provided, but training incentives are generally not necessary.

Table 16. Training Incentives

> Providing paramedics with food at trainings and monetary tokens of gratitude are appreciated but not critical to garner paramedic participation. Non-paramedic participants noted the benefit of providing food at in-person trainings and using other types of incentives as a strategy to boost paramedic engagement. In Member Checking, however, paramedics commented that providing food is a nice touch, but other types of prizes (e.g., gift cards) are not necessary for motivating paramedic participation.
>
> *So you know, every quarter we would have somebody from [the network], [inaudible 57:34] would come down, bring pizza, or doughnuts, or food, or whatever, because that is an excellent way to – Attract our folks. (FG-Other)*

Paramedics really like food. You have to bring food to every training if you want them to be your friend. I mean, that's like on a check list. It's really important that you feed them. (I- Other)

So at the end of the month when everybody had replied and we had a whole bunch of different agencies – EMS agencies participating, we drew a name from each agency, and they got something kind of cool, like an iPod shuffle or a $50 gift card – Visa gift card or something that would up the ante for them to respond and read that message, and I think it was really, really, really helpful. Protocol deviations went down for the first two weeks always after we sent that message. (I- Other)

I think there will always be some that are motivated through various incentives, however, I don't think they are critical to garner participation. (MC- Paramedic)

Food is always good. Prizes, much less so. If they need to be compensated to participate, that negates the altruistic aspect of research. (MC- Other)

4.3.2 Training Approaches addressing Institution-level Factors

4.3.2.1 Institutional Resources to Strengthen Trainings and Support for Prehospital Clinical Trials (Table 17).

Interview and focus group participants described how EMS institutional resources can be leveraged to promote successful training programs using approaches that endorse collaboration with internal agency leadership and external stakeholders, such as hospital and fire systems, institutional review boards (IRBs), and unions. Participants described benefits of the multi-system approach including the prevention of knowledge and communication gaps and consistency of protocol implementation across sites. As expected, most of the responses about the use of institutional resources were made by participants who serve in roles other than paramedics, given that many in the sample, such as training managers and principal investigators, have experience coordinating and implementing successful training programs.

Table 17. Institutional Resources to Strengthen Trainings and Support for Prehospital Clinical Trials

Involve peer champions in the trainings. Staff members within the EMS organization who are motivated and/or experienced in conducting prehospital clinical trials can be engaged to promote trainings and research study participation or be trained to train others (i.e., used in a train-the-trainer model).

I know who my champions are, my paramedic champions. So I talk to them before I go into that first day of training and say, "You guys, what do you think? How is this going to be received? There's this really cool study we've got an opportunity to participate in. Your leadership wants to do it, but I really wanted your opinion." So if you feel like you're empowering the champions…, they also have influence and can get excited. And sometimes we train the trainer with those champions so it's peer to peer training instead of me. (I- Other)

There's kind of two ways I think of getting things done in an EMS agency or a fire department, and one is getting the administration's buy in and the medical director's buy in. But sometimes they have other things going on and they're just like I can't add one more thing to my plate. So sometimes it's easier to find some paramedics in the organization that you know, that you're comfortable with, that you can kind of sell them, and then they become the champion for you to work it through the system. (I- Other)

Demonstrate leadership buy-in and support for training. Training programs for prehospital clinical trials can be more successful when the managers and other leaders of EMS organizations are supportive of research.

In my experience I think training is absolutely critical to the paramedics, and certainly in our situation I do all the training, mainly because I'm the PI, and what I've learned over the years with paramedics is they like to hear it from the horse's mouth. You send in a coordinator. You send in someone else. They're not going to buy in, and they've really enjoyed that, and they commented specifically on the fact that that's why they're doing research, because you're engaged enough to actually speak to us about it. (FG- Other)

I had an in-service training which is basically all of the members go to our central training locations at our training bureau, and then [the PI] came in. He led the training and then he had fellows…there to say, "We're on board. We know what you're doing."…They did a great job of saying we're all on board. …Any question that we had, we could ask him directly. We had plenty of ed opportunities. Our supervisors, you could call them and say, "I've got a question about this trial." (I- Paramedic)

So for our side, [the challenge] is getting the EMS agencies to participate, finding time, because … whenever you're talking about training, you're talking about dollars out of someone's budget. …So trying to get a big organization…to come on board, it took us a while to get that to happen, almost I want to say close to a year, because they've got… 2,000 practitioners out there that we needed to talk to. So it was getting them on board and then getting into their training cycle was a little bit difficult. (I- Other)

Use standardized templates that can be tailored to site training needs. Trainings for prehospital clinical trials should include common methods, messages, implementation format and frequency to encourage a system-wide approach, and include templates for tools that can be tailored to site specifics. When asked to comment on this theme during the member-checking exercise, only 82% of the respondents agreed. Member Checking respondents provided comments stressing the importance of tailoring training programs to local needs.

You can have some messages or key points that everybody needs to be trained on, but how those are delivered I think needs to – you need to have trust in people that are doing the training, that they know their agencies, they know their medics, and they know what's going to be best and what will work. Everybody does it a little different. (I- Other)

How can you replicate studies when no system is the same? It's very difficult to get some of those replication when logistically or the way that systems set each other up organizationally, culturally, the structure of it, it's all different. Who are they funded by? Municipality, county, the fire department, public health department. I mean, that creates different organizational behaviors and structures that also create a lot of barriers for research in EMS and drive different cultures, because they have different goals. I mean, they're different missions. I mean, a fire based EMS system has a way different mission than a public health like funded EMS system. (FG- Paramedic)

You know, there's so much variability in the pre-hospital setting or even in the emergency setting. I mean, you can't think of every situation. You can't have a script for everything that's going to come up. We kind of tried to think of as many things for this trial, and there's been a few things come up that we never imagined were going to happen, so I think you just have to teach … what are the core values of the study and then kind of give them the freedom to you know, make a common sense decision and always err on the side of, you know, being ethical. (FG- Paramedic)

Training needs to be tailored to local expectations, approaches, languages and culture. (MC- Other)

Give contemporaneous feedback to motivate paramedic engagement with the study. As discussed above as part of the Implementation Context (4.1.5), institutional resources should be allocated to provide study updates (e.g., enrollment). This theme was particularly endorsed by the non-paramedic participants.

…I think face time was important, ongoing, and just sort of keeping them informed of how things are going or where the opportunities lie. (FG- Other)

But yeah, annually there would be an update, and along with the update would be well, you know, here's how many cases we've enrolled right now and we haven't had any problems or anything like that. (I- Other)

So – and the other problem too with the research is there's not that instant gratification, like the [Name] Trial, we didn't have any kind of information back for, boy, I think a year maybe. (I- Other)

…things that came from the research group that were meant to be as kind of like token 'thank yous' for participation … a lot of that wasn't necessary from the line providers' perspective as much as maybe seeing how getting a better insight and recognition that individual providers were contributing to the development of sciences probably would have been more important and gave more buy-in than the stipends for participating in the training. (I- Other)

And also, if you kind of followed up and said, 'Hey, this is where the trial's at. This is how it's going. This many people have shown improvement. … and the people that haven't shown improvement, here's why.' If you keep people more involved, I think they'd be more willing to do it. (I- Paramedic)

4.4   Environmental Factors

As per the model, Environmental Factors are *variables that influence the prehospital clinical trial environment overall but that are not likely to be directly impacted by training programs*. A range of environmental factors may influence the success of prehospital clinical trial training programs. These factors intersect with paramedicine and research at a community and societal level, and as such, paramedics and EMS leadership do not necessarily have actionable control of them. Focus group and interview discussions uncovered two factors within the larger setting of the prehospital environment that may indirectly influence paramedic participation in research - the evolution of the paramedicine profession (4.4.1), and the role of stakeholders in advancing research within the field (4.4.2). Respondents of both role types (paramedics and others) provided feedback related to this domain.

4.4.1   Evolution of the Paramedicine Profession (Table 18). The impact of the movement toward a license/degree-based profession was discussed, including the potential influence on newer cohort's research knowledge and the conduct of prehospital clinical trials (see 4.2.1 for discussion of cohort differences). For example, requiring paramedics to obtain a bachelor's degree is likely to create opportunities for paramedics to learn about research methods, research design, data collection, public health, behavioral health, and to internalize their role in research prior to entering the paramedic profession. The majority of these sentiments were expressed by participants representing "other" roles, several of whom were originally trained in paramedicine.

Table 18. Evolution of the Paramedicine Profession

The field is advancing the scope of paramedicine training to include advanced education.
Participants (particularly non-paramedics participating in interview data collection) reported that

paramedics are increasingly joining the field with advanced education and skills, and that their increased role in research demonstrates a general acceptance that the field is expanding.

We are developing an advisory for [EMS councils] right now that talks about elevating the credentialing for paramedics to a more formalized university-level degree program for moving from certification to licensure in the paramedic field. So a paramedic would need to have a bachelor's degree to be able to practice. (I- Other)

The traditional concept was …that the medical director practices the medicine and that the paramedics and EMTs basically carry out the protocols. It's actually [the EMTs and paramedics who] practice the medicine, and I think that's where the mindset is changing. That they actually are independent practitioners. They independently treat patients. They function under a set of standing orders, but they have their own licenses. They have their own training, their own certifications, and I think that's the mindset that we've been trying to change for the last at least five, ten years, and I think so that's probably this technician-clinician difference is making them more of a clinician than they think they at least – and getting that mindset into their thinking. (I- Other)

One of the things that we've been trying in my career to do is elevate the paramedic to a level of being a professional – considered a medical professional in the same level as a, you know, physician, nurse, dentist, pharmacist, and you know, basically bring them in to that realm of healthcare provider. And I think we've done a good job and honestly, the paramedics that are out there now, almost all of them have advanced education…I think the current cohort very much considers themselves…a part of the medical healthcare profession. (I- Other)

Added value of advanced education and research experience. Participants described how the benefits of more extensive training programs leads to better quality of research and improved patient health outcomes. Participants (particularly paramedics) expressed their beliefs that employers will expect paramedics to have degrees and other indicators of advanced education, and in return, paramedics will expect to be compensated commensurate with their increased skills and knowledge.

I think paramedicine is a very, very new profession, and I think certainly when I teach our paramedics, the buy in in terms of moving the profession forward I think is very, very key. There's very little evidence for so much of what we do in paramedicine early on, and I think with the randomized trials you add science to the profession, and you move that profession forward. And I think that gets a lot of buy in from the paramedics, for sure. (I- Other)

So when I got a graduate degree in education I was one, if not the only advanced graduate-degree paramedic in our system. It helped – It opened a bunch of doors for me, and it makes me appreciate research. It makes me appreciate everything so much better. …So we would like to get more of that. (I- Other)

So when …we elevate the entire practice of paramedicine to be more in line with nursing and the doctors out there…there is room in the curriculum to be able to talk about studies and data and what our role is in those studies. (I- Other)

I know one time here … they were trying to make the paramedic like an associate's degree or something, make it even like pre-requisites as far as anatomy, physiology, and all this other stuff. That's all fine and well and everything, but I mean, you could go to school same amount of time it is for all that and get your medic or you could go to nursing and make, you know, twice the money. So I mean, it's kind of a money thing on that. (I- Paramedic)

Well, in the near future, we are going – moving away from like a one year program to a two year program for paramedics, so it's going to be a longer and broader education. And I think once you do that, you get people who are more used to a learning environment…. But I think there will be buy-in and I think at that time, people might be interested in how the research is done, because they may have taken that stats course or something like that, that they would understand it more. (I- Paramedic)

4.4.2 Stakeholder Engagement to Advance Research (Table 19).
EMS agencies work alongside a variety of organizations to implement prehospital clinical trials, with varying levels of experience, interest, and resources available for research. These variations across settings impact the implementation context directly or indirectly and can make implementation difficult when priorities or resources conflict, or when organizations have differing needs and goals for their involvement in research. Themes related to stakeholder engagement include demonstrating commitment to working across different agencies and institutions, and to guidance for developing networks of institutions committed to research that can potentially reduce barriers to engagement for all relevant partners.

Table 19. Stakeholder Engagement to Advance Research

Work with and across diverse EMS systems. Participants described the range of characteristics across EMS agencies and other organizations involved in implementing clinical trials that must be considered when developing training programs and determining how to standardize training information while maintaining flexibility for site-specific needs; see Training (Section 4.3).

I would say just having many, many points of view or input, having different departments with different structures like – Just coming at it from different points of view as far as, you know, size, amount of medics, utilization of medics in the department, you know, I guess you need to take all that into account when you're doing a study like that. (I- Paramedic)

It would be really easy to roll out the same training for every single agency. But if you don't individualize that to the agency or the group of paramedics you're talking to based on their previous experience in clinical trials or maybe they have none. An agency who has never participated in research at all is going to have to be trained very differently than an agency who has participated in three exception trials. …You can have some messages or key points that everybody needs to be trained on, but how those are delivered I think needs to – you need to have trust in people that are doing the training, that they know their agencies, they know their medics, and they know what's going to be best and what will work. Everybody does it a little different. (I- Other)

How can you replicate studies when no system is the same? Like you know, it's very difficult to get some of those replication when logistically or the way that systems set each other up organizationally, culturally, the structure of it, it's all different. Who are they funded by? Municipality, county, the fire department, public health department. I mean, that creates different organizational behaviors and structures that also create a lot of barriers for research in EMS and drive different cultures, because they have different goals. I mean, they're different missions. I mean, a fire based EMS system has a way different mission than a public health like funded EMS system. Or a private company… Continuity is different, especially like on these multi-site pre-hospital trials. It's very difficult to try to make those generalizations between those sites. (FG- Paramedic)

From a creative sort of standpoint from the get-go would be developing the trainings. I was able to … create the program in such a way … that information translates across all those [sites]. When I say A, does that mean A in Idaho or no, because they use Z there. So I mean, even before it even gets rolled out to the people, there are challenges that you have to sort of think about and be able to overcome those as well. (I- Other)

Develop, engage, and train networks of institutions committed to research. Participants described the importance of having an established research infrastructure in place before beginning clinical trial implementation and for garnering support from leaders of all key institutions. Participants in leadership and educational roles who are more actively engaged in institutional-level collaboration also described communication gaps and other frustrations dealing with organizations (e.g., unions, fire departments, and city councils) collaborating on clinical trials who are not aware or were not trained to carry out the trials.

I think the first step to avoid any political conflict when you're introducing a trial to an EMS agency is to sit down with the leaders first and say, 'Here's what we want to do. This is what it's like to be involved. This is how much time it's going to take. This is what we can compensate you. This is how long it's going to last.' And just be really transparent with that leader and have that leader make a decision, yes we want to participate or no, we don't. (I- Other)

The unions are important, but one thing we've been really successful with in getting buy-in is so fire chiefs report to a mayor and city council, so we were heavily involved in the rescue trial. When that publication came out, you know, we went before the city council and really – 'Thanks to the leadership of the fire chief. We were able to do this study here, and these are the results.' And 'Thank you, Mr. Mayor. Thank you, City Council.' And so we go right to the politicians and get buy in from them, and I think when we did that several years ago now, that set a great foundation to … encourage the fire chief to value research and that stuck a little bit. (FG- Other)

I worked in other systems around the country where you're getting a lot of private systems, and those open up lots of different things. You know, union contracts, and labor constraints for how people are trained, and how people are paid, and all of these stratified layers of restriction, that it comes down to you just want to get good training. …I think one of the early challenges is really getting in earlier with the administration, understanding good MOUs on what timeline looks like…those were challenges that were not recognized as fully by the line providers, but it was certainly a challenge that was recognized by management that you run into these labor agreement challenges that are just frustrating when you try to just do the research. (I- Other)

Our system is that all patients are transported by ambulances. There is the fire department too. We get along with all of them. But [if] we can't get there fast enough, the fire department responds first. So … we needed their engagement. We needed their help. We needed them not to do things or to do things. So we had to make sure everybody's engaged. … So we've got to make sure that everybody is on the same page and they all know what each other's responsibilities are. (I- Other)

To do these types of trials it takes someone who knows the intricacies of EMS and knows their system well, … It probably took about a year and a half just to get buy in from the community, so at the same time we're talking to paramedics, we're talking to the hospitals, the critical care physicians...we needed to get all the neurologists and those individuals on board so they would support it because it – yeah, it only takes one prominent physician or nurse saying this is not good to really derail a study. (I- Other)

5.   Discussion

In this section, limitations of the study are presented, followed by a summary of key findings organized by research question (1.2). Note that the final research question explicitly addresses recommendations to optimize methods and strategies to engage and train paramedics for prehospital clinical trials.

5.1.   Study Limitations

There are several limitations of this study that impact interpretation of the findings. First, and by design, the study was largely exploratory and required drawing on prior experiences with training for and implementation of clinical trials. Given the emphasis on identification of lessons learned, all individuals have had prior experience with clinical trials in the prehospital setting. This criterion for involvement has the potential to emphasize the perspective regarding, for example, factors that may or may not contribute to paramedics' interest in research. Paramedics who have not participated in trials, and who are not included in this study, may have different or other emphases relative to barriers to participation.

Future research exploring barriers to participation or perceived barriers should consider recruiting paramedics who have declined, or have not yet been invited to participate in a trial, or those known to be disinterested. Second, this qualitative study employed an intentional sampling strategy designed to identify information-rich sources with relevant prehospital clinical trial experience. It is not intended to be representative of the entire population of stakeholders, but this approach is appropriate for generating transferrable findings. That is, the findings would likely have relevance broadly without making any specific claims about the full details or any particular emphasis across the findings. Third, there is some potential for recall bias. Participants were asked to reflect on their training and trial implementation experiences from trials that may have concluded several years prior to data collection. However, the information that they retained, regardless of whether it represented the full breadth of their experiences, may be the most important relative to their current views about participation in research and likely has little impact on the themes under discussion. Finally, as this information is self-reported, social desirability may have filtered participants' reports. Steps taken to mitigate this risk included taking precautions to avoid expressing any particular view by the researchers in the construction of the interview guide, the efforts to explore the full range of opinions, and the use of an independent data collection entity (Westat) which has no particular stake in the study findings.

The conceptual model provided is a preliminary attempt to represent factors influencing participation in and success of prehospital clinical trials, with an emphasis on paramedic training. While appropriate for examining the breadth of opinions relative to the participants in the study, the sampling approach used does not allow for stratification on variables (e.g., type of EMS agency, type of trial, etc.) which may have relevance to the setting in which the trial takes place. Due to these limitations, further exploration of contextual factors, coupled with a quantitative approach to assess the generalizability and importance of specific factors, could enhance understanding about factors and strategies associated with paramedic engagement in and training for prehospital clinical trials.

5.2.   Discussion of Findings

The findings provide information to address the research questions underlying this qualitative study, namely:

- What factors and strategies are associated with paramedic engagement in prehospital clinical trials?
- What methods and strategies have been used for paramedic training for prehospital clinical trials?
- What are the challenges and barriers associated with paramedic engagement and training for prehospital clinical trials?
- What are the recommendations to optimize methods and strategies to engage and train paramedics for prehospital clinical trials?

These findings have been organized through a conceptual model (Figure 1) to comprehensively illustrate the overarching domains of relevance, and the breadth of relevant factors. Many of the themes from this study pertained to the organizational context in which the trial is conducted and the training for the trial takes place. Participants, particularly those in leadership and educational roles with personal experience facing some of the challenges, emphasized the importance of agency support for prehospital clinical trials, which is evidenced by visible **leadership** and which uses a range of strategies to reflect the agency's genuine commitment to building and sustaining a culture for research. Also critical for

supporting trials is **availability of resources**, which is often a challenge for EMS agencies due to limited budgets and competing priorities. Lack of resources at the agency level impacts the continued investment required to conduct the trial, as well as capacity to provide sufficient training for paramedics. Given that enrollment in prehospital trials is often a relatively rare event, it is especially critical that resources be allocated to provide the tools and information throughout the trial, to supplement any trainings offered and to provide support for paramedics. Another contextual factor associated with trial success is the presence of **dedicated research staff or study champions,** who function to simplify the research environment and paramedic experience during the conduct of the trial. The presence of study champions, in addition to other factors, has an impact on paramedics' comfort and skills with research participation by providing informal access to information pertaining to the trial and motivating trial participation.

To advance the field of prehospital research, it is critical that the contexts in which trials take place are prepared to **engage paramedics in all phases** of the research. Consideration of the paramedic role throughout trial design and implementation not only impacts commitment to the trial but also can ensure that the design is pragmatic. Employing methods to solicit ongoing input on what is or is not working in the field, and providing periodic updates on trial enrollment, were also recommended. A positive culture for research more broadly and adequate training for specific trials, can reinforce paramedic engagement, as per this comment from a paramedic who provided this feedback during the member checking exercise, "*[Paramedics are] more likely to participate willingly when they're trained-and feel the trial is well organized, optimized clinically and procedurally -- and they understand the purpose.*" Given the challenges of conducting trials in the prehospital setting, efforts to monitor paramedics' compliance with the protocol should be conducted using non-punitive approaches that incorporate ongoing appreciation for paramedics' efforts.

The findings also reflect observations on how paramedic characteristics (learner factors), including **personal attitudes, beliefs, experiences, and skills**, may affect their experiences and comfort with the conduct of prehospital clinical trials. These characteristics include the general predisposition that led individuals to the practice of paramedicine, enthusiasm for new or novel experiences, and the impact of generational or cohort differences. Paramedics, the findings show, perceive research in the prehospital setting to be valuable because it can identify evidence-based approaches to patient care that advance the field of paramedicine.

Awareness of important learner factors, such as the perception that paramedics are motivated by helping others and by understanding the purpose and goals of the trial, can contribute to more effective design of training curricula for clinical research conducted by EMS agencies. Focus group and interview participants were asked to draw on their own experience to reflect on **training methods and strategies** that support learners' mastery of competencies for successful prehospital clinical trial participation. Those in the non-paramedic group were more likely to emphasize that training options and opportunities are impacted by availability of resources, and to observe that current cohorts of paramedics are typically disinterested in learning about research methodology. The timing of training relative to implementation, combined with refresher trainings and ongoing learner support strategies, were considered critical for successful protocol implementation over time. Although incentives are typically offered and can help drive learner engagement, additional feedback from the member checking exercise indicated that they are appreciated but not essential, as per this comment from a paramedic, "*I think there will always be some [paramedics] that are motivated through various incentives, however, I don't think they are critical to garner participation.*"

The findings also reflect variables that are part of the larger prehospital clinical trial environment, which may influence the paramedic experience as well as the success of training programs. These topics were discussed chiefly by participants in leadership and educational roles. In particular, the **evolution of the paramedicine profession** was acknowledged as a potential factor influencing future cohorts' knowledge and experiences with clinical research methods. Paramedics are increasingly joining the field with advanced education and skills, and with an enhanced expectation that they will be involved in clinical research in the prehospital setting. Recommendations to encourage **institutional and stakeholder engagement** were also identified, including working with and across diverse EMS systems to build a network of institutions committed to and capable of conducting research successfully in the prehospital setting.

Specific recommendations for training design and conduct are presented in Table 20.   Framed by the preliminary conceptual model (Section 3), these findings and recommendations can be considered by researchers and others to address some of the barriers or challenges to paramedic involvement in prehospital clinical trials.

Table 20. Recommendations for Training

To the extent possible, provide trainings for prehospital clinical trials in person
Incorporate hands-on activities into the training program
Ensure the prehospital clinical trial training is commensurate to the complexity or newness of the protocol
Engage paramedics in the development of the training program
Tailor the style and content of trainings to the paramedic audience
Conduct ongoing refresher training sessions, especially for trials with low volumes of cases
Provide paramedics with easy access to protocol reference material and trial experts
Aim to minimize the time lag between initial training and trial initiation
Provide adequate training to all paramedics who may have an opportunity to enroll patients
Involve peer champions
Provide feedback to paramedics on enrollment and study outcomes
Show leadership support for training and appreciation for paramedics' role

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Appendices

Appendix A
Focus Group Guide

EMS Project Focus Group: Paramedic Training and Scope of Involvement in Clinical Trials
SIREN Subproject #1

Focus Group Preamble

Thank you for taking part in this focus group. We are delighted that you have agreed to join us. I am [FACILITATOR NAME] and will be facilitating today's discussion. This is [CO-FACILITATOR NAME], who will be taking notes so we can refer to them later if we have any questions. We are part of a team of researchers led by Dr. Robert Silbergleit at the University of Michigan and others involved in the SIREN Network.

[CO-FACILITATOR] and I are from a research organization, Westat, located in Rockville, MD. We are working with SIREN to better understand the range of research practices currently used to involve and prepare EMS paramedics for their roles in clinical trials that enroll subjects in the prehospital setting. The goal of today's focus group is to get your thoughts and opinions about the experiences of paramedics and EMS directors involved in these trials. We recognize that many of you are not paramedics, so we will be asking for your thoughts on their experiences. We will also, however, be asking for your own experiences and perspectives based on your role in prehospital research. Information collected from this discussion and others will help SIREN identify best practices of involving and preparing EMS paramedics for their roles in emergency care research, and help to identify challenges, unanswered questions, and clarify what needs to be studied empirically.

Before we continue, I want to stop and see if you have any questions about what I have said so far. *Answer any questions.*

Okay, now I'd like to go over a few "housekeeping" guidelines.

In a focus group, it is really important that you express yourself openly. There are no right or wrong answers. We want to know what you think. I am here to guide you, but you should feel free to express your opinion and discuss among yourselves. If you would like to add to an idea, or if you have an idea that is different from someone else, feel free to jump in. You do not need to wait for me to call on you to talk, but of course, only one person should speak at a time.

I want to remind you that your participation in this discussion is *voluntary* and you can choose *not* to respond to any question for any reason. Do I have everyone's consent to participate? Obtain verbal agreement.

Also, we ask you to keep what will be discussed today within this group and not share it with others who are not participating. This is to make everyone feel comfortable sharing their honest opinions with the group.

We will be recording this discussion today as a back-up to make sure our notes are correct. Your input will be kept confidential, and what you say will *not* be linked to your name in any report. The recording will be destroyed after we have analyzed the discussions. If at any time you do not want your comment to be recorded, please let [NAME] know and we will turn off the recorders while you are speaking.

Do I have your permission to record our discussion? *Obtain a verbal agreement.*

Please silence your cell phones and other electronic devices. You might also notice that I may repeat or ask questions about some of the comments that you make throughout the discussion today. I will do this not only to ensure that we capture everything that is said in the group but also to confirm that I understand what you have said.

Are there any questions before we get started? *Answer any questions.*

Introduction

Let's first go around the room and have each of you state your first name and role (e.g., paramedic, EMS director, research investigator. When you introduce yourself, briefly please tell us about your experience doing clinical trials in the pre-hospital setting and what types of pre-hospital studies you've been involved in.

1. In what ways is participating in clinical trials something you think is an important part of paramedics' jobs?

    Probes:

    - To your knowledge, have paramedics participated or heard about how the results of a prehospital trial have impacted or led to a change in the care provided in the prehospital setting?

2. From your perspective, what about participating in trials do you think paramedics find most difficult in terms of protocol implementation and other procedures?

    Probes:

    - Logistical challenges (executing key steps, communicating with hospital/study staff, ensuring consistency)?

    - Lack of EMS voice/perspective during protocol development?

    - Protocol implementation (e.g. confirming eligibility, a particular procedure?)

    - Enrollment (e.g., recognizing that a patient is eligible, identifying which study to enroll patient if there are multiple studies)

    - Consenting

- For those of who you are not paramedics, what do you find most difficult about participating in prehospital trials?

3. Can you tell us about a time when it was uncomfortable to enroll a patient into a prehospital trial and what made it uncomfortable?

Probes:

- Ethical considerations (e.g. audio recording, protecting patient confidentiality, concerns about the study)?

- Consenting

- Determining eligibility

- Family/LAR communications

- Have you heard about whether some medics avoid enrolling people because they are uncomfortable with it?

EFIC Studies

4. In EFIC trials, where consent is not required prospectively, how are decisions made about when consent may be feasible versus when it is not?

Probes:

- Describe a time when consent feasibility in an EFIC trial needed to be determined.

- Describe a time when "no objection to research" needed to be obtained from a family member available prior to enrolling a patient into an EFIC research study? How was it done?

5. Can you tell us about any particular experiences (positive or negative) you have had with patients or families in EFIC studies?

Probes:

- When you/paramedics are enrolling a patient in an EFIC trial, how do you/they communicate with the family member/others present?

- In what ways do you/paramedics adjust how you act because family members or other people are observing you*?*

- For those negative experiences you described, what do you think could have prevented them (e.g., changes in training/your own behavior, changes in the protocol, changes in EFIC status or process*)?*

Non-EFIC Studies

Now I'm going to ask you some questions about exception from informed consent or EFIC studies.

6. When you have been involved in prehospital studies that require consent, tell us about the consent process for these studies.

   Probes:

   - How is this different than the screening and enrollment process for EFIC studies?

   - What do you think matters most about doing consent processes in the prehospital setting (e.g. keys to success, biggest areas for failure/problems)?

   - What are people's (patients' or families') reactions to being asked for consent?

   - Are there particular types of studies that you think cause problems/challenges from the perspective of consent?

   - Are there challenges to the consent process specific to non-EFIC studies that we haven't already talked about?

General

7. What would you like the researchers developing prehospital protocols to know or take more into consideration?

   Probes:

   - Challenges with enrollment, consent, etc.

   - Need to consider paramedics' competing priorities.

   - Impediments to clinical roles.

Training to be involved in Clinical Trials

Now that we've heard about the challenges of conducting clinical trials in the prehospital setting, let's discuss the types of training and tools that would help mitigate those challenges. We'd also like to hear about any topics you'd like training on that are not currently available.

8. Can you tell us about the kinds of training you/paramedics have received to be involved in a clinical trial? What are your thoughts about these trainings (e.g. strengths, weaknesses, gaps)?

   Probes:

- Protocol implementation (e.g., enrollment procedures, inclusion/exclusion criteria, consenting process)?

- Communicating with family members/others?

- Research ethics (e.g., GCP/HSP)?

- General research (e.g. design, studies)?

9. Thinking back to some of the negative or uncomfortable situations you experienced in prehospital research, were you provided with adequate/appropriate training for circumstances such as these?

   Probe:

   - What recommendations do you have to improve or create trainings that would prevent or mitigate these occurrences?

10. What would make the clinical trial training experience better for you/for paramedics from your perspective?

    Probes:

    - Involve paramedics in training design?

    - More/better training tools (e.g., scripts, reminder cards)?

    - More/better training formats (e.g., web-based, hardcopy, instructor-led)?

    - Realistic training expectations (e.g., time commitments, compensation) and refresher sessions (e.g., frequency, duration)?

11. Have there been training tools you found especially helpful to paramedics and what about these tools were so helpful?

    Probe:

    - Content

    - Format (e.g.

    - Logistics, mode of delivery

    - If you/your organization has developed training tools for clinical trials, are you willing to share your tools with SIREN? We can speak more about this after the focus group.

Closing Statement

Thinking back to our discussion, does anything else come to mind that you think might be important?

> ➢ Dr. Silbergleit, do you have any follow-up questions you would like to ask or clarifications you'd like to make at this time?

Thank you for participating. You have all worked hard and we have learned a great deal from you. We appreciate your help with this important topic.

[NAME] will distribute your gift card and ask that you sign the form to document that you received this gift from us.

Appendix B
Interview Guide

EMS Experience Project/Aim 1
INTERVIEW GUIDE (MASTER)
Paramedic Training and Scope of Involvement in Clinical Trials (SIREN Subproject #1)

Thank you for agreeing to participate in this interview. I am [INTERVIEWER NAME] and will be facilitating today's discussion. This is [CO-INTERVIEWER NAME], who will be taking notes so we can refer to them later if we have any questions. She may also ask questions to ensure all the necessary topics are covered. As you are aware, we are from Westat, a research organization headquartered in Rockville, MD, and are part of the team of researchers led by Dr. Robert Silbergleit at the University of Michigan and others involved in the SIREN Network. [Add brief description of SIREN Network here and in introductory email from Westat. May also add detail about gift card here and in introductory email from Westat.]

We are talking with you and others to better understand how EMS paramedics are prepared for their role in clinical trials in the prehospital setting. The goal of today's interview is to learn your thoughts and opinions about the experiences of paramedics involved in these trials. We will be asking you to reflect on your own experiences and provide your perspective based on your role in this type of research. Information collected from this discussion will help EMS researchers identify best practices for involving and preparing EMS paramedics for their role in emergency care research.

Before we continue, I want to stop and see if you have any questions about what I have said so far. ***Answer any questions.***

Okay, now I'd like to go over a few "housekeeping" guidelines.

We hope that you are comfortable expressing yourself openly, as there are no right or wrong answers. I want to remind you that your participation in this discussion is *voluntary* and you can choose *not* to respond to any question for any reason. Do I have your consent to participate? ***Obtain verbal agreement.***

We will be recording this discussion today as a back-up to make sure our notes are correct. Your input will be kept confidential, and what you say will *not* be linked to your name in any report. The recording will be destroyed after we have analyzed the data. If at any time you do not want your comment to be recorded, please let me know and we will turn off the recorder.

Do I have your permission to record our discussion? ***Obtain a verbal agreement.***

Are there any questions before we get started? ***Answer any questions. Turn on recorder.***

Introduction

In today's discussion we are going to address several topics, including your own experience, and your perspective on paramedic training. Some of our questions are informed by focus groups,

conducted in January at the NAEMSP Conference, in which you or your colleagues may have participated. We will also be asking you some targeted questions pertaining to your experience and perspectives regarding [Trial name here].

First, I would like to understand your personal experience with clinical trials research more generally. I understand that your role is [paramedic, EMS director, research investigator, research coordinator].

1. Please briefly describe your clinical trial experience in the pre-hospital setting and the studies you've been involved in. We are interested in experiences that you would consider either positive or negative.
   Probes:
     ● In your experience, what makes a pre-hospital clinical trial go well (i.e., what is the "secret sauce?" (e.g., previous positive experiences, leadership, team chemistry, motivators/incentives)
2. What do you consider to be the challenges or barriers to clinical research in the pre-hospital setting? Have you encountered these barriers?

   Probes:
     ● Lack of resources (e.g., time for training and for protocol development, staffing)

     ● Protocol complexity

     ● Lack of/low involvement of trial champion

     ● Regulatory challenges

     ● Insufficient training (EMS or otherwise)

     ● Lack of EMS voice/perspective during protocol development

Paramedic Experience

Now I'd like to move to a focus on the experience of paramedics.

3. In what ways is participating in clinical trials an important part of your job/a paramedic's job? What do you find/think paramedics find interesting or valuable about participating in research?

   Probes:
     ● Knowing that trial results lead to change in care provided in the prehospital setting

     ● Requirements/expectations (e.g., of EMS directors/managers)

     ● Wanting to feel "part of something bigger"

     ● More opportunities for advancement

4. What do you think affects your/paramedics' comfort and skills with regard to clinical trials?

   Probes:
   - *Individual-level:* Years of experience, prior background, educational background, understanding of research methods, appreciation of the value of trials in improving emergency care

   - *Patient-level:* e.g., mistrust, language/health literacy, social conflict

   - *Institutional-level*: Type of institution (e.g., fire department, etc.) in which trial is taking place, presence of a champion, effective leadership, shifting priorities, earmarked funds

   - *System-level:* EMS systems, change in public awareness, advances in the profession

   - Nature and complexity of the trial, including adequacy of training and other support

5. What approaches or strategies can help with these issues [regarding comfort and skills]? You can speak from your own experiences, from what you've heard from others in the field, or from what you have read.

   Probes:
   - More engagement of the EMS director [requires resources, more like for a multi-site?]

   - Reduce complexity of protocol, if possible

   - Design protocol to mediate conflict or "hesitation" between providing acute care and enrolling the patient

   - Availability/accessing of research coordinator

   - Stronger foundation in research methods; different educational requirements

   - More participation of EMS in protocol development

   - Additional training (both "soft" skills re: dealing with LAR, and technical/methods skills), including refresher training

   - More recognition of paramedics' role

Targeted Trial [FRONTIER, IMMEDIATE, Ketamine]

6. Now I am going to ask questions that pertain more directly to your experience and role on XXX trial. I understand that this trial was conducted from [xx date to xx date] and focused on xxx. Please describe your role in this research.

7. I understand that on the XXX trial, paramedics were required to:
FRONTIER:

IMMEDIATE:

McMullan-Ketamine:

Can you tell me anymore about this? Is anything incorrect or missing?

> *Probes:*
>
> - Was there any step that you found to be particularly critical or less critical?

8. It is my understanding that this trial was particularly unique because [**FOCUS**]. Can you describe more about this [if haven't already]?

9. What was the most difficult situation for you/for the paramedics in this trial? Can you describe a situation that worked well?

10. What training did you/paramedics receive for the XXX trial? Please describe the training or resources that were provided.
    Probes:

    - How were you/are paramedics prepared for this types of [difficult and positive] situations [described above]?
    - What did you think you/paramedics were or weren't prepared for?

11. Can you tell me [more} about how the training or resources were delivered or provided to you/to paramedics?

    Probe:

    - Were you/paramedics able to complete the training as planned? Did you/they have any particular challenges (e.g., timing, your schedule, etc.)?
    - What aspect of the training worked best for you/paramedics?

12. If you have received/developed training for other pre-hospital trials, how did the training for XXX trial compare?

13. What would you recommend to improve paramedics' training for clinical research? Can you think of anything else we haven't covered that would make the EMS training experience better?   This could be related to content, format, or delivery.

Environment and Context

For our last topic I'd like to ask you to think about organizational or policy-level issues that may influence the future of EMS participation in research, or emergency care clinical research more generally.   Several of these topics came up during our focus group discussions.

14. How does the often-complex structure or politics of EMS systems impact research?

15. Among your colleagues, have you noticed any movement toward professionalization in the field of paramedics (i.e., licensed/degree, paramedicine) and, if so, how may this impact the role of paramedics in research?

16. Are there any other circumstances in the broader environment that may influence the future of EMS participation in research, e.g., public awareness of the value of this type of research for trauma care?

17. As a final question, do you have any thoughts on how a research network such as SIREN can help address the issues we've discussed today? (e.g., accumulating and disseminating best practices, communicating with policy makers and other decision leaders, etc.)

Thank you for participating. We appreciate that you have taken the time to discuss your perspectives on this important topic. We will be developing a summary report that will be shared with you via email for additional input and feedback.

Appendix C
Member Checking Survey

PAGE 1

The NIH would like to know about paramedics' experiences with prehospital clinical trials.

This survey asks for your feedback on preliminary findings from focus groups and phone interviews conducted with EMS professionals. Your participation in this survey is requested because you participated in either a phone interview or focus group. It should take 15 minutes or less to complete.

Your responses are confidential and all results will be reported in the aggregate. We will ask for your name for survey tracking purposes. Your participation and responses will have no bearing on your EMS agency, work on prehospital clinical trials, or NIH funding. If you have any questions or concerns about this exercise, please contact Dr. Paula Darby Lipman at PaulaLipman@Westat.com (301-279-4555).

We thank you for your assistance!

SECTION 1: Important Methods or Strategies Associated with Paramedics' Engagement in Prehospital Clinical Trials

Please review each statement and indicate if you agree as to whether the statement fits with your experience in the field, disagree or have no opinion. If you feel strongly about any statement (especially if you disagree), please add your thoughts in the Comments field for the relevant statement(s).

1. Paramedics generally like participating in procedures that will benefit patients and improve clinical care.

__Agree

__Disagree

__No opinion

Comments:

2. Paramedics are motivated when they understand the clinical relevance of the trial, rather than by the research process per se.

__Agree

__Disagree

__No opinion

Comments:

3. Paramedics may like clinical trials that offer opportunities to try something new, particularly if it's "hands on."

__Agree

__Disagree

__No opinion

Comments:

4. Paramedic input on trial design, or feedback on existing protocols, improves the quality of the study and ensures the protocol will be feasible to implement in the field.

__Agree

__Disagree

__No opinion

Comments:

5. Informing paramedics of a possible or pending trial is more likely to engender interest and engagement.

__Agree

__Disagree

__No opinion

Comments:

6. Paramedics may be more willing to be engaged in research when there is evidence of buy-in from all stakeholders, and when there is a clear trial champion.

__Agree

__Disagree

__No opinion

Comments:

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7. Attitudes about the value of research in general among EMS providers may impact implementation of the prehospital clinical trial.

__Agree

__Disagree

__No opinion

Comments:

8. Some paramedics may be less inclined to participate in research due to concerns about making mistakes.

__Agree

__Disagree

__No opinion

Comments:

9. Paramedics are less willing to complete clinical trial tasks if they think that it will interfere with patient care.

__Agree

__Disagree

__No opinion

Comments:

10. Engaging stakeholders including EMS medical directors, union leaders, and other agency leaders mitigates potential challenges in implementing prehospital clinical trials.

__Agree

__Disagree

__No opinion

Comments:

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SECTION II: Important Methods or Strategies Used for Paramedic Training in Prehospital Clinical Trials

11. In-person training is critical for gaining buy-in and engaging paramedics.

__Agree

__Disagree

__No opinion

Comments:

12. Training methods that support active learning (e.g., simulations, scenarios, and hands-on training) generally work better at engaging paramedics than methods relying more on passive learning.

__Agree

__Disagree

__No opinion

Comments:

13. Incentives (such as food at trainings, gift cards, and lottery-based prizes) help promote paramedic participation in training activities.

__Agree

__Disagree

__No opinion

Comments:

14. Tailoring the content of trainings to paramedics' clinical knowledge base and delivering the training in "their language" supports paramedic understanding and engagement.

__Agree

__Disagree

__No opinion

Comments:

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15. Peer champions can be engaged to promote trainings and engagement in the research study or be trained to train others.
__Agree

__Disagree

__No opinion

Comments:

16. Leadership buy-in or a culture supportive of research helps to improve the success of training uptake.

__Agree

__Disagree

__No opinion

Comments:

17. Trainings should be standardized across sites, include a system-wide approach, and include templates for tools that can be tailored to site specifics.

__Agree

__Disagree

__No opinion

Comments:

18. Time lags between training and trial initiation may negatively impact paramedics' ability to remember and implement the protocol effectively.

__Agree

__Disagree

__No opinion

Comments:

19. In-person refresher/booster training sessions can improve protocol implementation (e.g., protocol deviations, low enrollment) and motivate paramedics.

__Agree

__Disagree

__No opinion

Comments:

20. Research training should be included as part of paramedic continuing education, should piggy back on existing trainings, and should offer continuing education credits.

__Agree

__Disagree

__No opinion

Comments:

SECTION III. About You

We are requesting your name for survey tracking purposes. We will keep your responses confidential and only report aggregated results.

21. Please provide your name

First Name _____

Last Name _____

22. Thank you for your input on this topic. Please let us know if you have any additional comments or feedback.

Comments:

Appendix D
Focus Group and Interview Codebook

Parent code	Child code	Grandchild code	When to use code	Comments
Research Operations & Logistics	Paramedic involvement		Discussion of including EMS when developing protocols at the beginning or throughout the development process; EMS provider involvement improves design/implementation	Includes the idea of "buy-in" of the process, relying on EMS expertise
		Strategies	Examples of strategies to ensure EMS involvement when developing protocols	
	Protocol design		Discussion of designing protocols that are simple, limited deviation from routine care processes, feasible process and equipment, integrating protocol in workflow, EMS provider reference for simple protocols, also during discussion of EMS "style" and that they are used to step-by-step procedures and little deviation, use of scripts	
		Role in consent	Discussion of EMS obtaining consent in protocol, challenges of obtaining consent, and enrollment	Includes discussions of EFIC, teleconsenting
	Research personnel		Comments about dedicated research staff (e.g., site coordinators), can include discussion of need or cost of having dedicated staff, difficulty with training several staff but enrollment is low or sporadic	
	Other		Include other discussion related to research operations and logistics	Includes discussions of community consultation, recruiting from registries, QI versus research
Research Training	Paramedic involvement		Discussion of including EMS when developing trainings at the beginning or throughout the development process	
		Strategies	Examples of strategies to ensure EMS involvement when developing trainings	

Parent code	Child code	Grandchild code	When to use code	Comments
	Basic protocol training		Comments about protocol-specific trainings, strategies to assist EMS providers in navigating protocol/protocol knowledge	
	Research methods training		Comments about training for research methods, research design	
	Ethics training		Discussion about ethics trainings, human subjects protection	
	Training format		Discussion of types of training formats, modes, delivery	
	Training topics		Comments about including topics beyond protocol-specific trainings, including obtaining consent, communication	
	Training schedule		Discussion of timing of training (closer to protocol implementation), booster sessions, timing of training affecting motivation, bureaucratic delays	
	Standardized training		Discussion of the need for standardized trainings across sites	
	Challenges to participating in trainings		Comments about difficulties with participating in trainings, timing, competing priorities	
	Lack of training resources		Discussion of challenges faced due to a lack of training resources or discussion of the resource deficit itself	
	Other		Include other discussion related to research training	Involve the PI and leadership in trainings
Attitudes Towards Research	General interest in research		Discussion about interest in conducting research in general or theoretically, participating in journal clubs, buy-in and understanding contribution of research	Includes discussion of generating study ideas, equipoise between clinical care and research, considered an honor to be included in research; Also includes the negative (the feeling that research is burdensome, that EMS resist participating in

Parent code	Child code	Grandchild code	When to use code	Comments
				research); may need to parse out grandchild codes
		Generational differences	Examples of how generational differences affect interest in conducting research	
		Level of experience	Examples of how level of experience in the field affects interest in conducting research	
		Level of exposure to research	Examples of how level of exposure to research affects interest in conducting research	
	Comfort with research		Discussion about comfort and skills with conducting research	
	Value of participating in research		Includes discussion of how EMS research makes translation more relevant to the EMS providers, improvement of EMS provider skills, strategies to improve EMS provider participation	
		Improvement in care	Discussion of how research, results of studies can improve care, patients in studies get better care, engaging EMS providers in research will improve care, research improves EMS systems and how these are a valuable incentive to participating in research, discussion of outcomes (patients' clinical outcomes, EMS proficiency outcomes)	
		Strategies	Discussion of strategies to increase EMS' buy-in for participating in research, such as research education, providing clinical feedback, feedback on status on project	
	Reluctance for EMS to participate in research		Includes comments about challenges with obtaining informed consent, delays in implementation, difficulty staying current on research protocols, alternative engagement in research (e.g., QI)	
	Other		Include other discussion related to attitudes toward research	

Parent code	Child code	Grandchild code	When to use code	Comments
				Includes discussion of general EMS traits (e.g., those who are "good" and want to help patients however they can including doing research; those who are "bad" and just want the thrill of the fire/emergency) – See also "Interesting Quotes" for general EMS attitude.
EMS and Other Systems	Standardized certifications		Comments about the need for standardization of EMS systems, certifications	
	Diversity of EMS systems		Discussion of various types of EMS systems with different funding mechanisms, priorities	
	Stakeholders		Comments about the importance of champions, motivated leadership, institutional support for EMS, hospital staff, includes reverse of no buy-in from institution	Could include positive feedback to paramedics from hospital staff
	Resources		Discussion of resources in EMS systems (opportunities or resources available within the system)	
	Barriers		Discussion of challenges or barriers in EMS systems	
	Engaging paramedics		Discussion of importance of engaging paramedics in research endeavors, respecting paramedics (beyond including them in protocol development and design)	Includes discussion of leadership, infrastructure that supports research
	Move toward professionalization		Discussion about professional opportunities and/or movement toward developing a licensed/degree-required field of study	
	Other		Include other discussion related to EMS systems	
Parking Lot	EFIC		Any discussion of EFIC studies	Code comments to these codes, but we may not analyze
	Regulatory		Any discussion of regulatory processes, challenges, especially in relation to EFIC studies	
	Community Awareness		Discussion re: community awareness of trial, community consultation	

Parent code	Child code	Grandchild code	When to use code	Comments
Interesting Quotes			Code any interesting quotes, can be double-coded with above quotes	Give EMS credit for their skills; Discussion of general EMS traits (e.g., bad vs good attitudes about the job)

Appendix E
Member Checking Results

Appendix Table E.1. Member Checking Results – Theme Statements with Greater than 90% Agreement, Overall (N=33)

Conceptual Model Domain	Theme Statement	% Agree
Implementation Context	Paramedic input on trial design, or feedback on existing protocols, improves the quality of the study and ensures the protocol will be feasible to implement in the field.	100%
	Paramedics may be more willing to be engaged in research when there is evidence of buy-in from all stakeholders, and when there is a clear trial champion.	97%
	Engaging stakeholders including EMS medical directors, union leaders, and other agency leaders mitigates potential challenges in implementing prehospital clinical trials.	94%
Learner Factors	Paramedics generally like participating in procedures that will benefit patients and improve clinical care	100%
	Paramedics are motivated when they understand the clinical relevance of the trial, rather than by the research process per se.	100%
	Attitudes about the value of research in general among EMS providers may impact implementation of the prehospital clinical trial.	100%
	Paramedics are less willing to complete clinical trial tasks if they think that it will interfere with patient care.	97%
	Paramedics may like clinical trials that offer opportunities to try something new, particularly if it's "hands on."	97%
Training Approaches – *Institution Focused*	Leadership buy-in or a culture supportive of research helps to improve the success of training uptake.	100%
	Peer champions can be engaged to promote trainings and engagement in the research study or be trained to train others.	97%
Training Approaches – *Learner Focused*	In-person training is critical for gaining buy-in and engaging paramedics.	100%
	Time lags between training and trial initiation may negatively impact paramedics' ability to remember and implement the protocol effectively.	100%
	In-person refresher/booster training sessions can improve protocol implementation (e.g., protocol deviations, low enrollment) and motivate paramedics.	100%
	Training methods that support active learning (e.g., simulations, scenarios, and hands-on training) generally work better at engaging paramedics than methods relying more on passive learning.	97%
	Tailoring the content of trainings to paramedics' clinical knowledge base and delivering the training in "their language" supports paramedic understanding and engagement.	94%

Note: Missing data and "no opinion" are not included in percentages.

Appendix Table E.2. Member Checking Results - Theme Statements with Less than 90% Agreement and Illustrative Comments

Conceptual Model Domain	Theme Statement	N (%) Disagree			Respondent Comments
		PM N=13	Other N=20	**Overall** N= 33	
Learner Factors	Some paramedics may be less inclined to participate in research due to concerns about making mistakes.	5 (42%)	7 (44%)	12 (43%)	*They'll be more likely to participate willingly when they're trained-and feel the trial is well organized, optimized clinically and procedurally-and they understand the purpose (Paramedic- agree)* *But there are a hundred other reasons they may be less inclined....fear of retribution for a mistake; fear of liability, resistance to change, etc. There will be a variety of interest levels, and that is a management responsibility to understand their employees and manage them when implementing a trial. (Other- agree)*
Training Approaches – *Learner Focused*	Incentives help promote paramedic participation in training activities.	2 (29%)	3 (18%)	5 (21%)	*Incentives are good for showing appreciation but do not offset the time commitment (Other- disagree)* *Food is always good. Prizes, much less so. If they need to be compensated to participate, that negates the altruistic aspect of research. (Other- agree)*
Training Approaches – *Institution Focused*	Research training should be included as part of paramedic continuing education, should piggy back on existing trainings.	2 (18%)	3 (18%)	5 (18%)	*Depends on the EMS agency, many paramedics do not care about research and will tune this out. May be good for some interested individuals. (Other- disagree)* *Paramedics should be regularly engaged with the importance of research and clinical trials in CME offerings. If the research training is part of a current trial the paramedics are involved in, regular refreshers will help reinforce important concepts and benchmarks for the trial. (Other- agree)* *Key word is piggy back - separate the trial and procedural training from the research education/training Don't exceed attention spans! (Paramedic- agree)*
	Trainings should be standardized across sites, include a system-wide approach, and include templates for tools that can be tailored to	1 (8%)	3 (17%)	4 (13%)	*Consistency is important but tailoring is needed since EMS systems in the US are not uniform (Other- agree)* *As with any clinical research, there will be variability in clinical practice and operations across sites which may hinder standardization. Prior to training, it is important to explore these differences. (Other- agree)*

Conceptual Model Domain	Theme Statement	N (%) Disagree			Respondent Comments
		PM N=13	Other N=20	**Overall** N= 33	
	site specifics.				
Implementation Context	Informing paramedics of a possible or pending trial is more likely to engender interest and engagement.	1 (11%)	2 (11%)	3 (11%)	*It is important not to get them excited and then not deliver. The deflation they feel at missing an opportunity is worse than them not knowing they almost got the opportunity (Other-disagree)* *Wait until the trial is funded and at least 90% ready for implementation to inform them about it. I don't inform them until it is ready to deploy, as it really doesn't matter to line providers until that point. (Other- agree)*

Notes: Missing data and "no opinion" are not included in percentages. PM= paramedic

Understanding Paramedic, Trial Network, and Patient's Family Experiences in Emergency Research Clinical Trials

PROJECT 2: ACCUMULATED ROC/NETT EXPERIENCES AND FINDINGS RELATED TO EFIC

March 13, 2020

Table of Contents

1.   Introduction

1.1   Background

Over the past decade, investigators associated with the Resuscitation Outcomes Consortium (ROC), a network of regional clinical centers that conducted experimental and observational studies of out-of-hospital treatments of cardiac arrest and trauma, and the Neurological Emergencies Treatment Trials (NETT) Network, which aimed to improve outcomes of patients with acute neurologic problems through research focused on the emergent phase of patient care, have accumulated a wide range of experiences with regard to the ethics and conduct of exception from informed consent (EFIC) trials, including implementation of strategies for community consultation and public disclosure, and other aspects of transparency and compliance. Synthesizing these experiences and developing a model operational procedures document for the implementation of EFIC can provide a valuable resource for investigators conducting emergency care research, can be used to inform future EFIC studies conducted by the Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) investigators, and may serve as a foundational document for broader use in NIH-funded research.

1.2   Purpose

The overall project focuses on the policies, practices, and accumulated experiences related to EFIC, with a particular emphasis on goals and methods for community consultation and public notification.   An **expert panel method** was used to gather specialized input and perspectives on the topics introduced through two documents developed by the SIREN team. The sample of experts was invited to provide written feedback on the draft documents and to participate in a facilitated expert panel discussion to provide additional insights into topics pertaining to EFIC. The expert panel, comprised of individuals representing the expertise and knowledge that exists through ROC, NETT and SIREN experiences, was convened via a web conference to help illuminate and explore the range of opinions, to identify gaps, and to provide critical feedback regarding possible recommendations and future courses of action.

This report details the process and results of the expert panel method, conducted in three research phases[1]: 1) written feedback on two documents which were prepared by members of the SIREN team, 2) participation in a facilitated panel discussion to discuss the utility of the documents and the specific topics pertaining to EFIC, and 3) integration of findings to provide actionable feedback for document revision and to identify gaps for further exploration.

1.3   Description of the SIREN Deliverables

In response to the passage of the EFIC regulations, the U.S. Food and Drug Administration (FDA) developed and disseminated the Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors EFIC Requirements for Emergency Research. The guidance is intended to determine the safety

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[1] Westat, a research organization headquartered in Rockville, Maryland, provided qualitative services under subcontract. Westat independently completed data collection and analysis, in consultation with the SIREN project team, which included developing procedures for data management, development of the expert panel discussion guide, and facilitation of the panel discussion.

and effectiveness of FDA-regulated products (e.g., drugs, including biological drug products, devices) in emergency setting EFIC trials. EFIC investigators and IRBs, however, have found that the regulatory intent and specific goals of community consultation (CC) and public disclosure (PD) are difficult to interpret and implement.   EFIC researchers employ a variety of methods to define and engage with communities and have varied perspectives on the best ways to report on and determine adequacy of CC and PD activities. SIREN was charged with developing two documents that identify best practices or clarify areas where further debate or research is needed.

The first document was a scoping review of the literature on **implementation of community consultation and public disclosure for emergency research using EFIC** [lead author: Neal Dickert, MD]. The purpose of the scoping review was to:

> *"...review the published empirical, conceptual, and policy literature related to community consultation and public disclosure for EFIC. Where possible, the goal is to identify best practices that can be communicated to the emergency research community in order to improve both the efficiency and quality of the conduct and review of community consultation and public disclosure. Where best practices cannot be identified, the aim is to clarify areas where further debate or research could help to develop them."* (Scoping Review, p. 1)

The second document presents **model operational procedures (MOP) for the implementation and review of NIH sponsored multicenter clinical trials with EFIC for emergency research** [lead author: Robert Silbergleit, MD]. The document is intended to:

> *"...provide a model process and procedures that can be used as starting point for implementation of clinical trials using Exception from Informed Consent for Emergency Research (EFIC) in NIH funded multicenter clinical trials. The process and procedures described can and must be adapted to the specific needs and details of any future trials. The materials provided were developed and informed by both thorough review of the accumulated scholarship related to EFIC, and other lessons learned through practical shared experiences of prior NIH funded emergency care researchers."* (MOP, p. 1)

2   Methods

The project used a sequential strategy with three phases of research (Figure 1). In Phase 1 (expert panel review of documents), experts were sent two documents with instructions to complete the review. Feedback from this phase was used to identify topics for the subsequent facilitated expert panel discussion (Phase 2). Results of both data collections were integrated in the final analysis (Phase 3). These phases are described in more detail below.

Figure 1. Phases of data collection and analysis

Phase 1	• Expert Panel Document Review
Phase 2	• Expert Panel Facilitated Discussion
Phase 3	• Integration of Findings
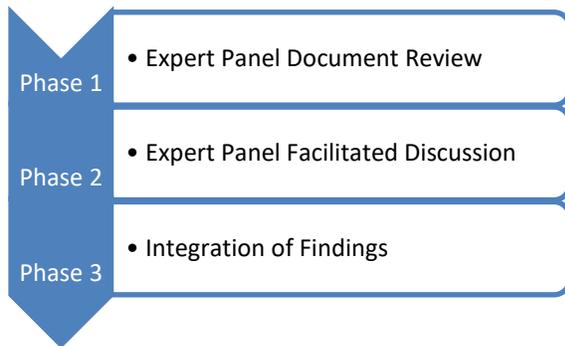
2.1   Sample

Expert sampling was used to identify a group of individuals with relevant experience, expertise and familiarity with the fundamentals of EFIC. The sample was composed of experts representing at least one of three key stakeholder perspectives: (i) EFIC investigator or researcher, (ii) Bioethicist/Ethicist, and/or (iii) Central Institutional Review Board (CIRB)/IRB affiliate. There were no honoraria for participation in either the document review or facilitated expert panel discussion activities.

Appendix A provides the list of invited experts, their affiliations, the perspective they represented, and their participation in the project.

2.2   Phase 1: Expert Panel Document Review

The first phase of the project was to invite the expert panel to review the two draft documents and provide written comments on specific sections of the documents and in general.

Data collection. The SIREN team confirmed that the goal of the review was for the experts to consider whether the findings or interpretations expressed in the documents accurately reflected their expertise and experience with EFIC and their familiarity with the literature.   As Document Authors (Drs. Dickert and Silbergleit) were interested in capturing feedback on specific sections of text using a low-burden approach, each document was formatted with editable text boxes corresponding to sections for which feedback was requested. The original text of the documents was protected from editing.

All experts invited to participate in the panel were sent an email with both documents attached and detailed instructions on how to provide feedback (see Appendix B: Scoping Review and Appendix C: MOP). In particular, experts were asked to provide input on sections where they felt revisions or more detailed explanations were required or where they saw gaps in descriptions of EFIC procedures and interpretations. The experts were also invited to provide general comments at the end of each document.

Experts were instructed to return their written feedback (i.e., draft documents containing their feedback in text boxes, saved with their initials) via email within two (2) weeks. A reminder was sent three days prior to the due date.

Data Management. The Westat team developed an Excel spreadsheet and assigned a number to each document's comment box and a unique ID for each respondent. As documents were received, the Westat team extracted statements from comment boxes and entered them into the applicable cell in the Excel spreadsheet. The reviewed documents were also saved on the secure project drive as source materials. The Excel spreadsheet containing all reviewer comments was uploaded to the SIREN project drive for access by Document Authors and other SIREN team members.

The Westat team summarized the key points from the Excel spreadsheet and created summary tables for review with the SIREN team. The summary tables included feedback that offered new aspects of a concept or divergent points of view, as well as suggestions considered "actionable" (e.g., revised words, suggested restructuring). Duplicative feedback was combined (and not weighted by amount), and feedback that indicated agreement with the text or concept was not included. The SIREN team used the summary tables to guide decisions regarding topics for further exploration in Phase 2.

2.3   Phase 2: Facilitated Expert Panel Discussion

The second phase of the project was to convene a facilitated expert panel discussion to explore a selected set of topics generated from the Phase 1 document review feedback. The discussion was conducted via web conference and hosted by Westat.

Data Collection. A link to a scheduling poll for the facilitated discussion was included in the initial email to the expert panel when requesting the document review. The email explained that the facilitated expert panel discussion was intended to be an opportunity to further explore the topics presented in the documents.

The SIREN working group identified topics for discussion based on the Phase 1 document review and developed a semi-structured guide to facilitate the discussion (Appendix D: Facilitated Expert Panel Discussion Guide). Westat generated an agenda and distributed an Outlook meeting invitation with a WebEx session link to everyone who was invited to participate in the expert panel, including those who did not submit document reviews.

The 2-hour facilitated expert panel discussion was led by a trained facilitator from the Westat team. Three other members of the Westat team and several SIREN working group members were in attendance to take notes and provide technical and content-specific assistance, as needed. All participants were notified that the facilitated expert panel discussion was being recorded to which participants verbally agreed. Participants were reminded that the purpose of the discussion was not to reach consensus or to discuss the basics of EFIC, but to explore the challenges and lessons learned of EFIC research.

Data Management. Two members of the team from Westat independently took detailed notes during the web conference, which were compared subsequently to reconcile any inconsistencies. The notes were then compared against the list of facilitated discussion attendees and the recording, to fill in any missed discussion and speaker names. The notes were not formally transcribed but capture the majority of what was said by participants.

The Westat team created a tracking sheet to identify expected facilitated discussion attendees and monitor their participation in the web-based discussion. The tracking sheet was updated after the

facilitated expert panel discussion to revise attendee list and update affiliations, as needed. The Westat team shared the tracking sheet with the SIREN team for review and confirmation of panel member details (see Appendix A: Expert Panel List).

2.4   Phase 3: Integration of Findings

The SIREN team, and Document Authors in particular, used multiple sources from the Phase 1 document review to develop the discussion guide for the Phase 2 facilitated expert panel discussion. As described in Section 2.3 above, the SIREN team used the summary of feedback from each document review to decide which topics to address in the expert panel discussion. The Document Authors then reviewed the complete set of reviewer comments in the Excel spreadsheet and selected four topics that required further discussion and clarity from the panel.

The Westat team created a first draft of the facilitated expert panel discussion guide, including main questions and probes for the four topics selected from the Phase 1 document review results. The Document Authors reviewed and provided input on the draft guide, honing the probes to address the heart of the challenges and how to provide guidance. The guide was finalized and a notes document was developed to capture comments under all relevant questions.

To expedite the document revision process (to be conducted by Document Authors subsequent to this report), the Westat team conducted a secondary level of review of the Phase 1 Expert Panel Document Review Summary Tables. Comments were classified to reflect instructions to reviewers to identify where revision or clarification is needed, and where there are gaps, as follows.

- **Revision** - refers to comments about edits, wording, terms used, or reorganization of sections of the document.
- **Clarification** - specific suggestions for elaboration or different information about a topic introduced in the document
- **Gap** - refers to the absence of a relevant, substantive topic or information missing from the document

The Phase 2 Facilitated Expert Panel Discussion Notes were also reviewed and analyzed independently to capture the main themes and related nuances expressed by the experts during the discussion. In particular, text related to engaging diverse communities, FDA EFIC guidelines, and methods and goals of community consultation and public disclosure were reviewed and coded.

3   Results

3.1   Participant Characteristics

Eleven of the 29 experts (38%) invited to participate in the document review submitted written comments on at least one of the two documents (one expert only provided feedback on the MOP).

Sixteen experts[2] (of the 22 invited) attended the Phase 2 facilitated expert panel discussion (via WebEx)—seven of whom had also submitted written comments on the documents in advance. There was vigorous discussion among attendees, with seventy-five percent of participants (12/16) contributing at least one comment. See Appendix A for details about expert panel participation.

3.2   Summary of Phase 1 Expert Panel Document Review Feedback

This section summarizes the feedback specific to each document, particularly pertaining to feedback classified as *clarifications* on information provided in the review, or possible *gaps* reflecting a topic or concept that is either absent or not fully addressed. See Appendix E: Phase 1 Expert Panel Document Review Summary Table for all feedback on both documents, including suggestions for revisions.

Scoping Review. As described in Section 1.3 above, this document reflected a review of published literature related to CC and PD activities for EFIC.   One expert reported having no revisions to this document, and a second expert only returned feedback on the MOP. Thus, the assembled feedback represents input from a total of nine experts. Several highlights were identified, with the majority focusing on CC:

- Clarify that CC and PD should occur during protocol development.
- Address how and when CC and PD activities occur at national vs. local levels.
- Describe whether CC results vary by trial focus (e.g., cardiac arrest, TBI).
- Emphasize that community consultation is intended to reflect the importance of establishing trust and respect within the community.
- Include data on how and whether protocols are amended based on CC results.
- Include additional detail on acceptance rates by CC method and rates of opt-out use.
- Address challenges with PD, including the inability to reach entire communities.
- Include more information on how to define the "community," how to incorporate both qualitative and quantitative approaches for CC, and improve definitions of the purpose of each method.
- Add text pertaining to transparency in CC and PD and consider restructuring the paper to align with FDA regulations.

MOP. Also described in Section 1.3, this document is intended to provide a model process and procedures helpful for implementing clinical trials using EFIC. Based on review of accumulated knowledge and lessons learned through experience of NIH funded emergency care researchers, and using a specific trial on TBI as illustration, the information is intended to be adapted based on the specifics of the trial. Feedback was received from all eleven experts; however, there were no comments associated with two sections of the document - "Reporting public disclosure activities" and "Data safety monitoring board." General feedback on the MOP included the following:

- There is not enough information for the document to be a study protocol, but it is too specific to TBI studies to be a general guidance document about EFIC.
- The flow of the document is unclear.

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[2] Several of the experts were unable to participate in the project.   Two web conference attendees, who joined the discussion in place of invited experts unable to attend, are included in the total count of experts present during the facilitated expert panel discussion.

- Additional language is needed regarding historical racism, effect on research ethics, and the need for more inclusion in community consultation activities.

The majority of the feedback on sections addressing regulatory criteria and protections for EFIC reflect suggestions for revision or clarification. A higher volume of substantive feedback was accumulated in sections pertaining to CC and PD principles and the associated "menus" of methods and approaches. Highlights of this feedback are summarized below:

- *Community consultation and public disclosure principles:*
  - Include historical context of racism and patient enrollment without consent.
  - Balance discussion of geographic communities vs. racial/ethnic/age composition of patient population.
  - Include recommendations on the appropriate persons to conduct CC and PD activities.
  - Address expectations regarding intended reach of methods and other outcomes.
  - Emphasize value of continuous engagement throughout the trial, and address how feedback is captured and its potential impact on the conduct of the trial.
- *Menu of methods:*
  - Improve integration and cohesion of these sections with the associated sections discussing principles.
  - Clarify the basis for recommendations, e.g., mix or number of activities.
  - Consider incorporating methods to leverage social media and public relations expertise and methods.
  - Elaborate on advantages and disadvantages of each approach, including measures of impact (consider including a grid of pros and cons for each method).

3.3   Summary of Phase 2 Facilitated Expert Panel Discussion

The following section presents findings from the EFIC Facilitated Expert Panel Discussion. As previously stated, the purpose of the web conference was to expand on the expert document reviews on the Scoping Review and MOP. Given the ambiguity of the FDA guidance for EFIC requirements, the goal of the discussion was not to reach consensus among experts, but rather to identify the range of perspectives, experiences, and understanding of the goals, methods, and guidance to develop and implement CC and PD activities. In addition, a number of comments specifically targeted advice for improvements to the MOP.

The range of themes and subthemes expressed during the facilitated discussion (See Appendix F: Phase 2 Expert Panel Facilitated Discussion Notes) are presented in the following sections. Each section represents larger categories of discussion that either emerged from the facilitated discussion or were specifically queried. Subthemes, a description of these subthemes, and participant comments[3] are also included to provide context.

Engaging Diverse Communities

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[3] As proceedings of the EFIC Facilitated Expert Panel Discussion were not formally transcribed, these are considered "comments" rather than "quotes."

The FDA EFIC guidance document describes "'the community in which the research will be conducted' to mean the geographic area, e.g., hospital or other facility, or city or region, where the hospital or clinical investigator study site is located" (pg. 25). Several comments from the Phase 1 document review indicate that researchers are also interested in ensuring that diverse communities are engaged in the community consultation and public disclosure process. Other feedback addressed the need to include language on the importance of protecting patients' rights and the historical context of racism and patient enrollment without consent. Several participants stated that engagement of diverse groups should be proportional to the community demographics; an alternative suggestion emphasized that outreach should reflect the demographics affected by the disease/condition of interest. Others suggested that diverse groups should be specifically engaged to address injustices that these groups have faced. In order to expound on these recommendations, questions asked during the web conference focused on the topics of engaging diverse communities, definitions of "community" and which communities to include.

Table 1. Engaging Diverse Communities

Subtheme: *Description*	Participant Comment
Mirror diversity of community: *Emphasis on outreach to diverse groups that are reflected in the community*	It is more important to mirror the community in which you are doing consent…some people do a blanket approach to include all minorities, but if that doesn't mirror the local community, and one can put in a lot of effort, it doesn't really make sense. You need to start with the study you are doing and understand your expected ethnic distribution of the population that will participate in the study and address those groups within your community accordingly.
Mirror diversity of community affected by disease or condition: *Emphasis on outreach to diverse groups that are affected by the disease/condition*	I think it depends on the scientific goals of the research and what the disease or condition is of study, which minority groups will be most affected. It is essential that minority communities in fact be sought out. Investigators do not know their own blind spots…From BOOST study experience with Advarra, we found that we targeted people accessible to us, we reached a largely educated African-American community. When we gave education levels to Advarra, the IRB asked us to target an uneducated African American cohort because that is actually a huge portion of the population that was likely to be enrolled in study. We were not aware of that blind spot.

FDA Guidance for EFIC Requirements for Emergency Research

Although there were no specific questions asked during the facilitated expert panel discussion regarding the FDA guidance for EFIC requirements, several experts discussed this document from both the investigator and IRB perspectives. Comments suggested that the FDA guidance was difficult for IRBs and investigators to interpret and execute. Additionally, CIRBs may not have enough understanding of the local community to tailor the guidance as needed. Others implied that although the guidance is ambiguous, they cautioned against proscriptive regulations that are difficult to implement in various communities.

Table 2. Guidance for IRBs and Investigators to Implement Community Consultation and Public Disclosure Activities

Subtheme: *Description*	Participant Comment
Explicit regulatory guidance: *Comments regarding challenges for IRBs and CIRBs to follow and implement the FDA guidance*	Challenge with articulating what we ought to be doing with no regulatory guidance on this…it would be very helpful for IRB for there to be some sort of guidance, because the FDA regulations are understandably extremely vague. Central IRB, may not know the local community, may not be able to provide guidance. It's a challenge for IRBs to walk the line between telling the community that they may not be doing an optimal job and respecting the local knowledge.
Flexible, broad regulatory guidance: *Comments regarding ensuring that the FDA guidance is flexible and broad to apply to various communities*	The challenge in writing guidance on broad regulations is to allow a broad array of different options that are suitable for particular studies. FDA regulations and guidance are largely permissible for a large array of community consultation and public disclosure activities, which I think is advantageous. They've identified certain principles that are important to guiding those activities, but they are not proscriptive. I think it's a double-edged award. In 1995, FDA specifically didn't mandate certain approaches because every community is different, and there are different approaches that are most appropriate for that local population. So, they were intentionally vague. I raise consciousness of group to be careful re: what is mandated or said about what people have to do—it's a wide world and every community is different. What is optimal for one community might not be optimal for another community.
Guidance on modifying protocols after community consultation: *Discussion of how and when to modify IRB-approved protocols after receiving feedback from community consultations*	In the era of CIRBs (e.g., BOOST 3 trial), it feels disingenuous to do CC when protocol is IRB approved and essentially fixed in local context. Conducting CC when there is no means to radically change the protocol or impact the CIRB's broad assessment of the protocol. There should be some element of CC done centrally before going to local communities, or it could be done in a number of representative local communities as part of IRB deliberations. The 2nd issue is the IRB's protocol approval before communities seeing it. FDA says that IRB has authority to change protocol based on CC feedback data, but not sure how that is handled. My concern is when we have a protocol through IRB, the community decides they don't like something and we change it. Do we go back to community and let them know it's been changed. They may have more opinions about that [change]. Do you go back to them a second time? We have to expect any protocol will be modified down the road-- it's the nature of research. CC is different from the ongoing responsibility

Subtheme: *Description*	Participant Comment
	for PD, you need to look at it with common sense perspective. If initially you describe the protocol in a certain way, and modifications don't change fundamental nature of the research, then I don't think you need to go do another CC or look to re-consent people, depending on how the whole thing is framed.

Community Consultation Goals, Methods and Metrics

During Phase 1, expert reviewers provided comments on the MOP and Scoping Review documents pertaining to methods used for CC. Reviewers, however, did not elucidate their thoughts about the reasons for employing specific methods, or the goals of CC. As these goals are not clearly described in the FDA guidance and clinical trial investigators may not have experience conducting CC methods or reporting metrics, participants were queried on these topics during the facilitated expert panel discussion.   Participants stated that the goals of community consultation include improving the study protocol, promoting transparency, and building trust. In terms of CC methods, experts suggested several activities to engage key stakeholders, stressed the importance of conducting activities in the community setting, emphasized the value of using multiple methods, and pointed to the need for adequate metrics on CC activities.

Table 3. Community Consultation Goals, Methods and Metrics

Subtheme: *Description*	Participant Comment
Community Consultation Goals	
Improve study protocol: *Community consultations can provide invaluable suggestions to improve the protocol and communication to the public*	In literature… the ability to potentially modify materials based on community feedback. The community may offer suggestions regarding what is clear or it's important to understand this or that aspect. Which is valuable. We are into our science; the communication piece to the public sometimes needs adjustment.
Promote transparency: *Community consultations can be conducted to ensure transparency between the research team and community members*	One of the goals of both CC and PD is promotion of transparency. Another is promotion of trust between research institution and research community/catchment area - those potentially part of research, where subjects will be drawn…One reason to drill down further into diverse/minority communities is the promotion of trust and the promotion of transparency. These two are potentially linked.
Build trust: *Community consultations can be conducted to promote trust between the research team and community members, particularly among groups that have been disenfranchised by research*	Another [goal] is promotion of trust between research institution and research community/catchment area - those potentially part of research, where subjects will be drawn.

Making the decision to reach out to communities that don't have a voice typically in our public square, and who are less likely to be the ones to go look at a website about health care issues or fill out survey on a website, is a way to build trust for future by meeting with those communities-- maybe even disproportionately to their overall presence in the community-- is a good way of addressing past oversights. Jeremy Sugarman calls it research justice. How to |

Subtheme: *Description*	Participant Comment
	make up for past behavior? Respectfully make this effort to drill down into communities that have been abused. Another advantage to think about with targeting African-American groups or other ethnic minorities, it gives people safe space to think through their opinions, deep ethical questions, what type of trials should we do without consent…it's hard to think through all of the nuances. A lot of people don't have well-formed views. Think through in your mind with others that look like you and share some of your values from the same community.
Community Consultation Methods	
Collaborate with community leaders: *Identify and collaborate with key leaders and stakeholders in the community; important to receive their buy-in*	Once we've identified the community we need to engage, then it's important to identify leaders of those communities and start there…It's important to identify the leaders of those communities. We have seen really engaging and creative ways to reach out to communities, from meeting with chaplains and going out to religious groups. One site talked to Spanish interpreters at hospitals to figure out how to reach community, they said here is a community leader- go for a walk with him. PI went for a walk in the community and met with leaders.
Meet community members where they live: *Conduct community consultations outside of the academic setting, and where the target population frequents*	It's important to go into the community—and not expect minorities or individuals to come to CC activities but to go into their communities in a way that reflects the importance of certain sites or community events for them, e.g., barbershops in Black communities and maybe churches, and so forth.
Continuous engagement with community partners: *Establish relationships with community partners prior to research conduct to build trust; relationships can be continued after study ends to ensure strong partnerships for future studies*	When research is being done, it's typically done through an academic institution. It's important to have good relationships with patients in clinical and therapeutic settings, before researchers wants to "enroll patients in study in this way…" Some of the way has to be paved with the institution's relationship already with the community.
Utilize community research advisory panels: *Seek guidance from patient and community advisory panels to inform community consultation methods, as well as to assist with public disclosure methods*	Through our CTSA, there are research advisory panels. One is based in African-American neighborhood. Couple EFIC studies used that group as part of community consultation. One question we are asking folks in CC, we have patient advisory councils – ask them how can we do PD better? Having the first step of in-depth panel on how you can do the broad outreach. Have a panel guide you on your broad outreach. Can guide you on how to do it better. E.g., one member is on the board of previous

Subtheme: *Description*	Participant Comment
	TBI survivors and she will connect us to that group to publicize about the study. CC can set up your PD.
Importance of multiple methods: *Utilize multiple methods to maximize the strengths and balance out weaknesses of approaches. Examples include focus groups and other face-to-face approaches (which provide rich, interpersonal data and may be used to build trust) versus surveys and other broader methods (which provide more diverse data, but less depth and opportunities to develop trust).*	Each approach has strengths and weaknesses. One-on-one interactions with community are terrific, but Personal [approaches] only reach so many people. RDD [random digit dialing] has a strength. Black community is 26% but only 20% responded in RDD, you can weight to assure 100% ethnic coverage, and weighted samples that directly reflect the ethnic distribution you are targeting, and no other approaches can do that, but there are downsides – e.g., no one-on-one interactions. I'd advocate for multiple approaches to maximize the strengths of all the different kinds of the approaches.
Community Consultation Metrics	
Need to develop adequate metrics: *Determine the most effective ways to demonstrate that CC activities have achieved CC goals.*	Metrics, make sure that it's not institution based but community based How to ensure receiving high quality community data that leads to positive changes, better quality data in protocols

Public Disclosure Goals, Methods, and Metrics

During Phase 1, expert reviewers provided feedback on the MOP in terms of the methods of public disclosure, but were less informative about the goals and metrics of this process. Similar to the CC topic, facilitated expert panel discussion participants were asked to expand on their perspectives about feasible, realistic goals for PD and best practices to implement PD announcements.

Table 4. Public Disclosure Goals, Methods and Metrics

Subtheme: *Description*	Participant Comment
Public Disclosure Goals	
Promote transparency: *Public disclosures can be conducted to ensure transparency between the research team and community members*	Easier to say what is NOT the goal, than what is the goal. State the goal is not community informed consent. It's not a referendum on the study. Explicitly state that – it was in document. Be transparent. Not possible to disclose every possible risk and have everyone see it or understand it, given what everyone is paying attention to in the media. It wouldn't be feasible. Can't reach everyone or document that you have reached them.
Build trust: *Public disclosures can be conducted to promote trust between the research team and community members, particularly among groups that*	One of the goals of both CC and PD is promotion of transparency. Another is promotion of trust between research institution and research community/catchment area - those potentially part of research, where subjects will be drawn.

Subtheme: *Description*	Participant Comment
have been disenfranchised by research	
Public Disclosure Methods	
Centralized public disclosure mechanism: *Utilize the centralized study infrastructure to disseminate public disclosure on a national level; infrastructure and resources are not readily available to investigators*	Most [studies] have a central coordinating center with website for local sites…Seems like our national organization could have EFIC general info that is patient and media friendly so not such a foreign concept…normalize it, so people see that it has been tried nationally for 30 years and is not a foreign concept. Compared to CC, which should be done locally, it seems there is opportunity to emphasize central PD a bit more. The NIH sponsors EFIC studies – they are excellent at disseminating info about health, seems good way to have central resources in general for EFIC that could be leveraged for all EFIC studies. Surgeon General disseminates information on health. A resource that could be there but is not for local investigators.
Develop feedback mechanism: *There is a gap in feedback mechanisms for public disclosure methods to address questions or concerns from community*	"CYA" – there is no feedback loop, maybe a radio or newspaper ad. Like a checkbox. There is a need for delineated mechanism for feedback -- phone number, email, probably several different mechanisms. Gotta be multiple mechanisms for feedback, may not have access to email.
Public Disclosure Metrics	
Difficult to demonstrate public disclosure outcomes: *Efforts to conduct public disclosure should be documented and are more important than measuring outcomes of disclosure activities as it is not possible to reach everyone in the community*	The process is what is important rather than trying to measure an outcome. I think it's about a good faith effort. I think it's more about the process than trying to measure the outcome. Not possible to disclose every possible risk and have everyone see it or understand it, given what everyone is paying attention to in the media. It wouldn't be feasible. Can't reach everyone or document that you have reached them.
Measure public disclosure activities with social media metrics: *Social media metrics can be easily assessed to understand the reach of public disclosure announcements*	Two thoughts re: metrics. Modern age with social media, it is much easier now, e.g., Twitter account can see how many people viewed tweet. Through other social media platforms, it's much more feasible to get a sense of how many eyes have seen your PD announcement. Opportunity to start collecting data on what is common or the norm for PD activities.

General Comments on the MOP Document

Although participants were not explicitly asked for feedback on the MOP during the facilitated expert panel discussion, several experts provided comments on how the MOP can be used to provide guidance to IRBs and investigators. Other comments addressed how the MOP can be improved upon to increase its utility and advance the EFIC field.

Table 5. General Comments on the MOP Document

Subtheme: *Description*	Participant Comment
Adaptable EFIC guidance document: *Advantage that the document provides guidance that can be tailored to the local community*	FDA guidance identifies reaching out to community leaders might be a good idea when doing CC. I'll echo what others have said-- the challenge in writing guidance on broad regulations is to allow a broad array of different options that are suitable for particular studies. FDA regulations and guidance are largely permissible for a large array of CC and PD activities, which I think is advantageous. They've identified certain principles that are important to guiding those activities, but they are not proscriptive. That is one of the advantage of docs such as the MOP, and including a wide array of activities. It's a real strength of the document. It can be a resource for IRBs and investigators.
Clarify the role and responsibilities of the CIRB and local site: *Suggestion to elucidate the roles and responsibilities of the CIRB and local sites, particularly when the CIRB may not understand the community's needs*	CIRB does not abrogate needs of local communities. There are people who are trying to lay this out. But, this would be a great document to do that. The local sites' responsibilities isn't well articulated in many places.
Expand the table of community consultation and public disclosure methods: *Expand on the community consultation and public disclosure method tables so that IRBs and investigators are able to select from these "menus"*	These menus [reference to MOP document] should push not just 2—but maybe 3 or 4 from each "column" – so there is wide spread of activity even though it may challenge the sites and address complementarity people are mentioning. Also the menu - credit to Rob et al., good effort – is a superb shortcut but needs to be fleshed out regarding what the options mean. Even within each section, here is what we think the best way to do it… Maybe language that says, this just isn't aspirational, describe floor and ceiling. Increasing the variety of activities that sites use can address the comments about each method having strengths and weakness.

4.   Conclusion

Although it has been over 20 years since enactment of the EFIC regulations, investigators, study teams and IRBs continue to find it a challenge to interpret and implement the requirements for CC and PD. The purpose of the SIREN project is to develop and disseminate two documents – a scoping review and a model operations procedures document – to advance the field's understanding of these important topics. Experts (EFIC investigators/researchers, ethicists, and CIRB/IRB affiliates) provided feedback on these documents (Phase 1) and participated in a facilitated discussion (Phase 2) to further elucidate the goals, challenges, and best practices of CC and PD.

The following sections present recommendations for the MOP (Section 4.1) and future research considerations (Section 4.2) based on synthesis of findings from Phase 1 and Phase 2.

4.1   Recommendations for the MOP

The expert panel provided several suggestions for refinement of the MOP based on their past experiences and knowledge of community consultation and public disclosure. Themes that are potentially actionable and appropriate for inclusion in the MOP are presented in Table 6.

Table 6. Phase 1 and 2 Recommendations for the MOP

Consider providing options on engaging diverse communities; consultation with community can help determine which recruitment options are most appropriate for the local environment • Mirror diversity of community • Mirror diversity of community affected by disease or condition
Provide guidance on modifying protocols after community consultation
Include description of best practices for authentic community engagement • Collaborate with community leaders • Meet community members where they live • Continuous engagement with community partners • Utilize community research advisory panels • Importance of multiple methods
Develop feedback mechanisms for all types of public disclosure announcements
Measure public disclosure activities via social media metrics
Clarify the role and responsibilities of the CIRB and local site
Expand the table of community consultation and public disclosure methods
Leverage public relations expertise to package and disseminate the documents, to ensure researcher awareness and use in the field

4.2   Considerations for Future EFIC Research

The most common observation expressed by the expert panel was the important contribution this project will make to the field of EFIC research. Members of the expert panel described challenges they experience interpreting and implementing clinical research through the EFIC regulatory pathway and the gaps that the FDA guidance does not address, leading to areas of uncertainty among researchers, CIRBs, and local sites. The experts explained that the solutions to the challenges they describe, which require collaboration of stakeholders representing a variety of social, organizational, scientific, and other communities, will not be achieved overnight. The following themes represent areas for EFIC researchers and other stakeholders to consider as they embark on future studies:

- **Defining community.** Experts expressed the continued need for the field overall to explain how to define and target the communities related to the EFIC trial being implemented; how to best

collect feedback from these communities; how to present feedback to local and central IRBs; and how to incorporate CC feedback into trial design and implementation.

- **Clarifying goals for public disclosure**. Experts noted that the goals of PD still remain ambiguous, but suggested that methods include broad and expansive efforts at the national level as well as targeted and in-depth strategies at the local level. Details for how these two-pronged strategies are operationalized will require additional examples from researchers and their experiences.
- **Addressing historical racism.** Experts gave feedback in both phases of the project to acknowledge historical racism in relation to research ethics, and the need for efforts to improve inclusion in CC and PD activities.
- **Assessing effectiveness of methods.** Experts described the need for more detail in applying and measuring impact of the varied methods used for CC and PD activities. Some suggested the use of a grid of pros and cons for each type of consultation method or other ways to guide researchers in selecting the most useful methods to achieve CC and PD goals.

Appendices

Appendix A:
Expert Panel List

Individuals recruited to participate in the review of documents and facilitated expert panel discussion, and their participation.

Name/Affiliation	Perspective	Reviewed Documents	Attended Web Conference
Benjamin Abella, MD, MPhil University of Pennsylvania	**EFIC Investigator**		✓
Opeolu Adeoye, MD University of Cincinnati	**EFIC Investigator**		✓
Tom Aufderheide, MD Medical College of Wisconsin	**EFIC Investigator**	✓	✓
Jill Baren, MD, MBE MBA University of Pennsylvania	**EFIC Investigator, Ethicist**	✓	
Michelle Biros, MD, FACEP University of Minnesota	**EFIC Investigator**	✓	
Katie Blackburn Leidos Biomedical Research, Inc.	**EFIC Investigator (former)**		
Judith Carrithers, JD Advarra	**IRB**		✓
Arthur Derse, MD, JD, FACEP Medical College of Wisconsin	**Ethicist, IRB**		✓
Sara DiFiore University of Pittsburgh	**EFIC Researcher**		
William Feldman, MD, DPhil Brigham and Women's Hospital and Harvard Medical School	**Ethicist**	✓	✓
Luke Gelinas, PhD* Advarra	**IRB, Ethicist**	N/A	✓
Sara Goldkind, MD, MA Goldkind Consulting	**Ethicist**	✓	✓
Paula Knudson The University of Texas	**IRB**		
Alexander Limkakeng, MD, MHS Duke University	**EFIC Investigator**	✓	✓
Michael Linke, PhD, CIP University of Cincinnati	**IRB**	✓	✓
Holly Fernandez Lynch, JD, MBE University of Pennsylvania	**Ethicist**		
Laurie Morrison, MD, FRCPC, MSc St. Michael's Hospital	**EFIC Investigator**		
Joseph Ornato, MD, FACP, FACC, FACEP Virginia Commonwealth University	**EFIC Investigator**		✓
Marisha Palm, PhD[a] Tufts Medical Center	**EFIC Researcher**	N/A	✓

James Paxton, MD, MBA, FACEP Wayne State University	**IRB**	✓	✓
Gail Povar, MD, PhD Advarra	**IRB**	✓	✓
Lynne Richardson, MD Mount Sinai School of Medicine	**EFIC Investigator**	✓	
Michele Russell-Einhorn, JD Advarra	**IRB**		✓
Nerses Sanossian, MD University of Southern California	**EFIC Investigator**		
Terri Schmidt, MD Oregon Health Sciences University	**EFIC Investigator**	✓ (MOP only)	
Victoria Sciluna, MD, MPH University of Michigan	**Ethicist**		
Harry Selker, MD, MSPH Tufts Medical Center	**EFIC Investigator**		✓
Jeremy Sugarman, MD, MPH Johns Hopkins University	**Ethicist**		
Henry Wang, MD, MPH, MS The University of Texas	**EFIC Investigator**		

[a] Individual was not invited to participate in Phase 1 (document review).

Appendix B:
Draft Scoping Review Document distributed to Expert Panel

Reviewer Instructions:

1. Save this document to your local computer with your last name at the end of the file name.
2. Read through each section of the document and consider whether the findings or interpretations reflect your expertise and experience with EFIC and your existing familiarity with the literature. **Particularly, please provide input on sections you feel require revisions, more detailed explanations, or where you see gaps**.
3. Enter your comments in the closest text box to the right of the corresponding section. Make observations and comments only where you feel you have something of value to add. You do not need to comment if you think the relevant concept has been well captured.
4. Save this document with your comments and email it to LizJansky@westat by January 31, 2020.

Thank you for your help!

Scoping review of literature on Implementation of Community Consultation and Public Disclosure for Research Using Exception from Informed Consent for Emergency Research.

Introduction

United States regulations that allow an exception from the requirement for informed consent (EFIC) for certain clinical trials in the context of emergency settings are central to advancement of care for acutely ill, incapacitated patients. Prior to the passage of these regulations in 1996 (21 CFR 50.24), there was no clear regulatory provision to allow clinical trials in emergency settings where consent is impracticable. The EFIC regulations contain a number of important provisions. Most obviously, they require that it be impracticable to conduct the proposed trial by only enrolling individuals who can provided informed consent or who have a legally authorized representative (LAR). In addition, the regulations place restrictions on approvable risk, require a prospect of direct benefit for enrolled subjects, and limit the use of EFIC to life-threatening conditions for which existing therapy is unsatisfactory or unproven. They are also notable for requiring two forms of community engagement; community consultation prior to approval and initiation of a study; and public notification or disclosure prior to and during the study. To date, the EFIC regulations are the only U.S. research regulations to require community engagement.

In the more than 20 years since passage of the EFIC regulations, investigators, IRBs, and regulators have gained substantial experience interpreting and implementing this regulatory structure. Determining precisely which studies qualify for EFIC, what constitutes an "unsatisfactory or unproven" standard of care, and what constitutes impracticability of informed consent can all be difficult. However, the most well-recognized challenge for IRBs, investigators, and study teams has been interpreting and implementing the requirements for community consultation and public disclosure. As noted previously, this is the only type of research for which these activities are required by regulation. In this context, a heterogeneous set of practices have emerged. There are different methods of defining and engaging with communities, different definitions of adequacy, and different views of how to report and interpret community consultation feedback. This can be especially intimidating for investigators and IRBs who lack experience with EFIC. On the other end of the spectrum, IRBs and investigators with substantial experience conducting EFIC have settled into practices that may or may not be grounded in evidence or informed by the work of other groups.

The purpose of this scoping review is to review the published empirical, conceptual, and policy literature related to community consultation and public disclosure for EFIC. Where possible, the goal is to identify best practices that can be communicated to the emergency research community in order to improve both the efficiency and quality of the conduct and review of community consultation and public disclosure. Where best practices cannot be identified, the aim is to clarify areas where further debate or research could help to develop them.

Methods

We used a structured search, in collaboration with an informationist, in order to identify literature related to the conduct of EFIC research. We used scoping review methodology, which aims to synthesize and characterize relevant literature around a topic.[1] This approach was chosen, because this is a heterogeneous body of literature incorporating both conceptual and empirical work and highly-variable methods. The complete initial list of search terms is provided in Box 1. Terms were designed to capture literature related to consent in emergency research, EFIC research, and the conduct of community consultation and public disclosure for emergency research. We also included terms that covered several common conditions or clinical contexts for which EFIC research is commonly conducted; these include resuscitation, cardiac arrest, and traumatic brain injury.

Box 1- Search Terms

efic OR 'exception from informed consent' OR 'final rule' OR 'waived informed consent' OR 'waiver of informed consent' OR 'waiver of consent' OR 'waived consent' OR 'delayed consent' OR 'deferred consent' OR 'community consultation' OR 'community consent' OR 'public disclosure' OR 'public notification' OR 'public deliberation'
AND
'emergency'/de OR emergency OR 'emergencies'/de OR emergencies OR 'consciousness'/de OR consciousness OR conscious OR 'unconscious'/de OR unconscious OR 'unconsciousness'/de OR unconsciousness OR 'resuscitation' OR trauma OR 'brain injury' OR tbi OR 'traumatic brain injury' OR 'coma' OR comatose OR 'heart arrest' OR 'cardiac arrest' OR 'emergency treatment' OR 'emergency medical services' OR 'emergency health service' OR 'brain injuries' OR 'research in emergency settings'

In order to capture relevant aspects of the academic literature, our search included EMBASE, HEIN Online (a source for legal materials and legislative pieces), PubMed, and Web of Science. As displayed in Figure 1, the initial search identified 1719 references, including 995 duplicates. After removing duplicates, there were 446 articles from EMBASE, 30 from HEIN online, 470 from PubMed, and 180 from Web of Science.

Figure 1- PRISMA Chart
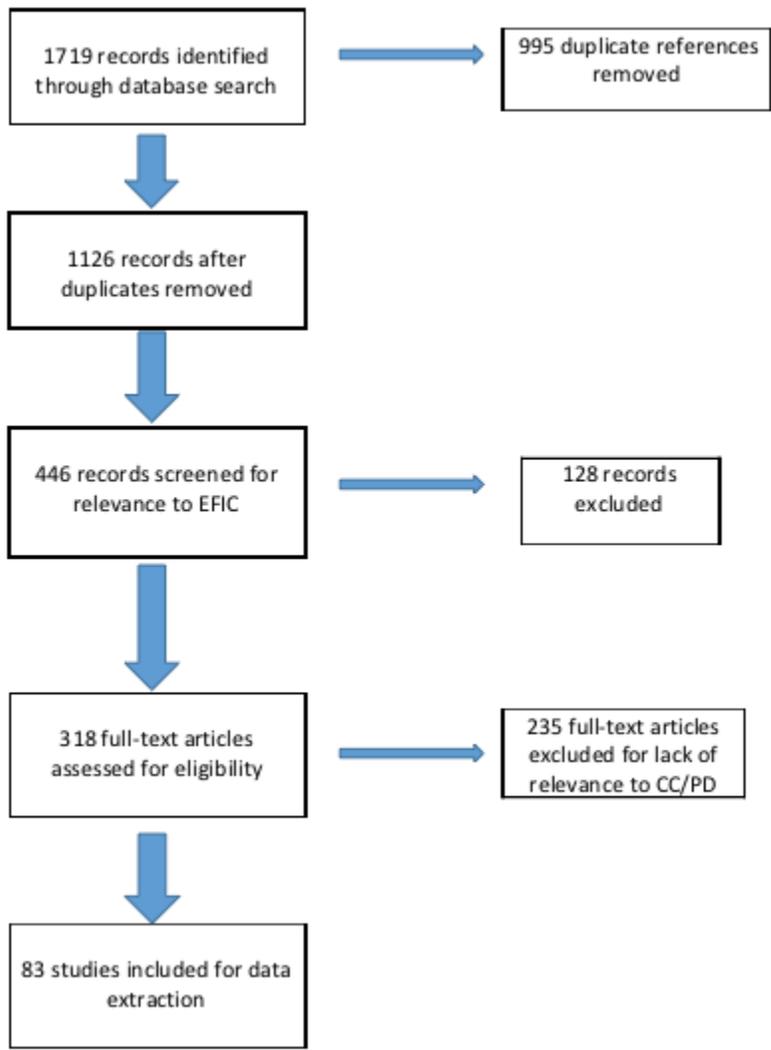
Titles and abstracts of the full sample were screened initially by KM, with additional screening by CS and ND, resulting in 318 articles related to EFIC for full text review. From these 318, we selected articles with content specifically focusing on Community Consultation or Public Disclosure. These articles represented the following categories of primary content: empirical reports, descriptions of process/approach, opinions/policy/ethics pieces, and attitudes of IRBs, investigators, and providers. These categories simply represent primary "types" of articles; there was overlapping content across categories. Empirical reports of CC results, for example, frequently included descriptions of processes and approach for the conduct of CC. A total of 83 papers were ultimately eligible for data extraction.

A standardized data extraction tool was developed iteratively by the 3 reviewers and reviewed by the entire research team. The extraction tool was built using Google forms and captured key domains within each category of article. For example, in empirical reports of community consultation activities, information extracted included method of consultation, type of study for which consultation was conducted, form of assessment conducted and key questions or domains of assessments, population targeted, and key insights or implications described. Among ethics and policy papers, we extracted key content such as views of the value and purpose of community consultation, views regarding definitions of "community," and views of particular methods of community consultation or public disclosure. In each category, there were open-ended fields for extraction of relevant findings outside the of pre-determined extraction questions.

Results

We grouped findings from this review under three main themes, Community Consultation Reports, Public Disclosure, and Conceptual or Policy-Focused Literature on Community Consultation and Public Disclosure,

Community Consultation Reports
In all, 31 articles reported results of community consultation processes conducted for EFIC trials. Among these, the most common consultation process used was meetings with existing groups, followed by town-hall meetings, in-person surveys and interviews, and random-digit dialing (Table 1). The most frequent population involved in reported community consultation activities was the general public (59% of activities from 18 articles). This was followed by current/former patients with the condition under study, patients in emergency departments, neighborhood/geographic groups, and members of support groups.

Survey Data
The most frequently used form of assessment reported as part of community consultation was a survey. Surveys were sometimes administered as stand-alone consultation activities (e.g. at a community event) or at the end of a group meeting or interview. Qualitative reports and summaries were often not provided in detail within published reports. Because they are typically provided to the IRB by investigators, these methods of assessment are likely under-represented in published literature. Among surveys, a variety of types of questions were asked to elicit views of participants. The four most common questions focused on personal acceptance of being included in the proposed EFIC trial, personal willingness to enroll/be included in the proposed trial (without specific reference to EFIC), general acceptance of the proposed EFIC trial, and acceptance of the conduct of the trial in the community (without specific reference to EFIC). Samples of each type of question are included in Table 2.

Personal Acceptance of EFIC Enrollment
Reported acceptance of personal EFIC enrollment was generally in the range of 64-85%, consistent with a previously published systematic review (Table 3). There were outliers, including one study that reported an acceptance rate of 51%[2] and one that reported a 92.5% acceptance rate.[3] Because this domain was the most commonly and most consistently assessed, it provides the most helpful cross-study comparison. Other domains utilized more heterogeneous wording across reports, making cross-report comparisons difficult. Moreover, some questions in other domains lack clear validity or focus.[4] For example, answers about willingness to be enrolled in a proposed trial without specific reference to EFIC

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are challenging to interpret, because it is not clear whether respondents understand that enrollment would occur without prospective consent. Similarly, small variations in wording related to acceptance of trial conduct within a "community" appear to result in substantially discordant answers without a clear difference in content.[5,6]

Across the range of reported studies, several patterns were observed of note regarding predictors of acceptance (Table 3). There was variable impact based on demographic factors. Some studies reported slightly increased support among respondents who were younger and reported higher income. Some studies also reported decreased personal EFIC acceptance among minority respondents as compared to Caucasian respondents. In some reports, there was increased acceptance among respondents with personal connections to the condition under study (such as a patient or a family member of a patient affected by the condition under study), though this was not uniform. One report found the reverse association,[7] and another suggested that this relationship was modulated by race, with African-American respondents' views not demonstrating this relationship.[8]

Range and Impact of Consultation Method
Several subthemes were observed across reports in terms of experiences with particular methods of community consultation. Meeting-based and other more interactive methods were observed to be associated with higher rates of personal acceptance (though more variable) than survey-based or other less interactive methods, such as random-digit dialing.[4,6,9-11] It has been commonly reported that open public meetings or "town hall" meetings have very low attendance; this was less commonly reported in community consultation efforts involving attendance at meetings of existing groups.[12] Focus groups and interviews, not surprisingly, involve more dialogue and interaction.

In addition to a variety of ways to conduct the consultation itself, multiple approaches were reported for selection and recruitment of community consultation participants. As mentioned previously, some reported consultation focused specifically on individuals with specific connections to or risk for the condition under study. Even within more population-based, quantitatively-focused consultation efforts, there were a variety of strategies reported that were designed to selectively involve individuals felt to be important target populations (e.g. those who represent likely enrollees). These strategies include,

for example, survey administration within emergency departments and zip code-based sampling based on incidence of the condition under study.[3,13,14]

Inconsistent Metrics

Some reports included assessments of efforts and resources necessary to conduct community consultation. These were not, however, routinely reported or reported using consistent metrics across studies. It was commonly reported that the yield of town hall meetings, relative to the efforts of the study team, was very low. Numbers of respondents were, not surprisingly, substantially higher among more quantitatively-focused efforts. Some reports cited the rapidity with which strategies such as random-digit dialing could be conducted; this method was also reported to involve appreciable expense, due to the need to contract with a survey firm.[11,15] More interactive efforts were reported, on the other hand, to require more time on the part of the research team.[2,16]

Public Disclosure Reports

A broad range of public disclosure methods was reported. Traditional approaches include the use of press releases, public service announcements, and media appearances (not associated with cost to the team), paid advertisements in print, broadcast media, or other forms (purchased by the team), use of in-hospital posters, flyers, study websites, and brochures, and personal letters and emails. Less commonly reported methods (though more common recently) included use of social media ads and posts using platforms such as Facebook and Twitter. Importantly, some methods were described as serving both consultative and disclosure functions. For example, social media posts often allow for feedback, but interaction with ads or pages is often quite brief and primarily "one-way."[17-19]

Defining Populations

Intended populations for public disclosure efforts were typically geographically-defined; efforts were most commonly directed toward the general public in the geographic area where the proposed study would take place. There were reported attempts at notifying more focused populations. For example, some teams utilized in-hospital notification methods (such as posters or flyers) to reach a population of patients or notifications directed to disease-related support groups whose members were familiar with the condition being studied.[20-23] Similar to strategies employed for consultation, there are also reports of focusing on high-incidence zip codes or other approaches that try to notify individuals more likely to be enrolled in a study.[16-18,24,25]

Estimates of Effort and Inconsistent Metrics

Across the studies, there were not uniform methods for reporting or assessing effectiveness of public disclosure activities. Commonly reported metrics included process measures such as number of activities or venues and the diversity of audiences sought. Other reports described the content of the disclosures. Other measures included the number of people exposed to, or aware of, a public

disclosure message. Actual "penetration" of such messaging is difficult to estimate and were not often reported. Metrics of this kind that were sometimes reported include number of website views, time spent on websites, numbers of surveyed individuals and patients/families who were aware of the study, and estimates of readership or listenership of common media outlets. Web-based or social media disclosure do allow for more precise reporting of metrics such as hit rates, but time spent was often quite low, making real exposure difficult to assess. Furthermore, estimates of viewership or readership may not reflect awareness. Published estimates of awareness, both within communities in which research was conducted and among individuals ultimately enrolled in a particular study after a public disclosure effort, were very low (with the exception of very focused notifications within a particular hospital unit, for example)[22], rates of opt-out requests received were also invariably low.[2,22,24,26,27]

Conceptual or Policy-Focused Literature on Community Consultation and Public Disclosure
There were 30 articles that focused on conceptual ethical or policy issues related to community consultation and/or public disclosure. These pieces focused more often on community consultation than on public disclosure. Some empirical reports also contained substantive discussion about these issues.

Value and Purpose of Community Consultation
One major focus of some articles was the value of community consultation. Two forms of value were identified relatively frequently. One form of value (more intrinsic in nature) highlighted the ability of community consultation to clarify the impact of trial enrollment on potential enrollees and potential ways to refine the study. A second form of value (more extrinsic) was the potential for community consultation to promote trust within relevant communities, to provide transparency and education, and to demonstrate respect. There were questions raised about the extent to which community consultation, as commonly conducted, accomplishes these goals, especially the more intrinsic form. Another key theme regarding the value of community consultation was the reiteration that community consultation is not intended to be a "consent" process or vote. The EFIC regulations, for example, emphasize that it is meant to be primarily a public comment and feedback process rather than a deliberative process. There was less robust endorsement of the value of public disclosure. Some authors did highlight the potential of public disclosure to facilitate transparency (and avoid secrecy) to increase trust and education about research. Others highlighted its potential to facilitate opt-out for individuals who may wish not to be included in a study.

Views on Consultation and Disclosure Methods

There were a variety of views expressed regarding specific consultation and disclosure methods, and several sub-themes emerged. First, there was an emphasis that community consultation activities should be context-specific and tailored to the audience. One specific way in which context-sensitivity was emphasized was an argument that the extent and nature of required community consultation may be related to the risk level of the study.[28,29] Second, many commentators emphasized the "two-way" nature of community consultation.[30] These commentators frequently argued against the use of more quantitatively-oriented, less interactive forms of consultation on multiple grounds. They emphasized the ability of more interactive methods to facilitate more substantive input, for example, and the fact that views often change over the course of discussion.[29,31] Third, in contrast to the emphasis on interaction and dialogue, some commentators did ground support for more quantitatively-oriented methods on the extent to which they involved "representative" samples.[11,15] Finally, some commentators emphasized the importance of attempting to focus consultation efforts on persons at risk for or with connections to the disease under study.[32]

Challenges Related to Community Consultation

Two clear challenges emerged in the literature on community consultation specifically. First, many commentators reiterated difficulties that teams often face defining the relevant community for consultation.[33,34] Second, there is an acknowledgement of the challenge of interpreting data related to acceptance or objection to the proposed study.[6,29,31] Though a rate of acceptance around 70% seems to be the norm and is high relative to typical rates of consent to clinical trials, others have emphasized that this still indicates that an important portion of the population has concerns about the use of EFIC for the proposed study.[35] Moreover, in most contexts, individuals who do not want to participate can simply decline; in EFIC trials, they often do not have that opportunity.

Views on public disclosure

Public disclosure was a less common focus. One key theme that runs through the published literature was an emphasis on the need to ensure that it be recognized that public disclosure and community consultation serve different functions.[19,32] This is clear in the regulations and guidance document.[36] A second theme was uncertainty regarding the value or "return on investment" from public

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disclosure activities. Finally, related to both of the prior challenges, it was clear in review of this literature that there is an absence of any established metric regarding how to assess whether public disclosure is adequate.

Discussion

The requirement for community consultation and public disclosure is one of the more novel elements of the EFIC regulations. Because they are not required in any other context by federal regulation, emergency researchers and IRBs have had to develop approaches to their implementation and evaluation. More than 20 years after the passage of these regulations, there has now been substantial experience accumulated, and there is a valuable body of literature that helps to demonstrate areas of some consensus that may help to clarify best practices; there are also remaining questions on which there may be an opportunity to develop greater clarity.

One area on which there appears to be consensus is that community consultation efforts such as town hall meetings and other open public forums have fallen out of favor. These types of efforts were used in many early EFIC studies and appear to have been characterized by low attendance and viewed by research teams as inefficient.[37] Related, though the frequency with which descriptive reports of how community consultation is executed has decreased within the literature, there appears to be some consensus that effective community consultation often involves multiple methods for a particular project.[33] This matches our impression as active researchers engaged in EFIC research over many years. Different methods clearly serve different goals and require different types of resources.

Another area of broad agreement within the emergency research community is the general recognition that that community consultation should be a two-way exchange and does not represent a referendum or vote on a study. This view is validated by the fact that very few cases appear to exist in which community consultation has led to a proposed EFIC trial not being conducted.[30] As articulated previously, there have been important questions raised regarding what, if any threshold of acceptance, ought to be met before a study is allowed to go forward, and there is an important sense in which asking for input from the community should imply a

willingness to listen and heed to strong objections.[38] However, there is a general emphasis on substance of input over frequency of particular responses.[39]

Much has been written within the literature on two central, and connected, issues. First, is there a need to focus community consultation efforts on individuals with connections to the condition under study, as a function of having had the condition, being at risk for the condition, or being involved in treatment of that condition? And is there a need specifically to involve members of the general public in the geographic area in which the study will be performed? The second question relates to whether community consultation should be a quantitatively-driven, survey-based process design to ensure numeric representation of key demographic categories or stakeholder types, or whether it is should principally be a qualitative, interpersonal and interactive process between a research team and relevant community members.[4,29,31-33,39]

Regarding the priority population or community for community consultation, the published literature reflects heterogeneity in focus. The empirical literature frequently reports geographically-focused consultation efforts, often involving the general public. However, there is a theme in the conceptual and policy-focused literature that the feedback obtained from individuals with various connections to the conditions under study may be more meaningful and higher yield. There is also some evidence to suggest that patients enrolled in trials find the fact that investigators talked to "people like them" more meaningful than investigators' talking with members of the general public.[40] Regarding the "type" of community to be consulted, it is important to recognize that there is a false dichotomy that can easily be reified in discussions about geographic versus condition-related communities. The EFIC regulations and associated guidance documents do not require that these two be considered separate communities, and the geographic requirement seems primarily intended to ensure that community consultation is conducted in the area where the study will be conducted and not to require involvement of the general public.[36] The real question, then, relates to the value of consulting the general public.

The literature also clearly demonstrates heterogeneity in approaches to community consultation. Stand-alone surveys are common among published empirical reports, but they may be over-represented due to the extent to which they may be viewed as more

publishable. This is particular important because there is also a theme in the conceptual and policy literature that the primary goal of community consultation is to achieve a two-way process involving feedback. The ability of less interactive, more quantitatively-focused methods to achieve this goal has been questioned.[4,31,32,39] Moreover, there appears to be relative consistency in acceptance across geographic areas and across different types of studies.[4,11] In this respect, there have been questions raised regarding the incremental value, particularly given the associated expense, of further quantitative efforts at community consultation. It may be that these large-scale, population-based efforts served a very important role earlier in the EFIC experience. At that time, background attitudes toward EFIC research were not well understood. Now over 20 years after the EFIC regulations were created, and particularly in institutions where a substantial number of EFIC trials have been conducted, the role of these efforts may be reduced.

A relatively focused finding within this review is that there are multiple ways that attitudes toward EFIC trials have been assessed. One of the most common methods is the use of a survey. It has been previously documented that different ways of asking questions about acceptance of EFIC studies may have very different results, a finding that is not surprising given the importance of survey design.[5,6,9] While there may be good reasons for wanting to get feedback from community consultation participants on domains other than their personal acceptance of EFIC enrollment in the proposed trial, we do think there are important reasons to prioritize this type of question over others. It is the question that most naturally lends itself to comparison with other studies, is relatively straightforward for participants to understand, and is a question we believe most participants feel more confident and comfortable answering.

Ultimately, there may be a role for further guidance to clarify the value of various forms of community consultation and engagement of different types of people. Defining what is meaningful in different contexts may help investigators and IRBs to make determinations of when community consultation efforts are sufficient and how to most effectively elicit feedback.

Public disclosure has been much less a focus of both the empirical and conceptual literature. The clearest themes within the literature are that there are multiple ways to conduct public disclosure and that

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awareness of EFIC studies tends to be low in cases where penetration of disclosure efforts have been assessed.[2,24,26] It is also clear that many teams have undertaken extensive, resource-intensive public disclosure campaigns. However, the literature also does not reflect a particularly well-developed sense of the key goals of public disclosure. As a result, there are no clear standards or benchmarks by which investigators or IRBs can assess the adequacy of disclosure efforts.

Given what we consider to be unavoidably low rates of penetration or awareness, it seems unreasonable to expect public disclosure efforts to have a substantial role in helping people who do not want to participate in an EFIC trial to identify that they would want to opt out of participation, for example. In this sense, it seems unlikely to play any meaningful justificatory role in terms of assessing or indicating acceptance on the part of a community. Rather, it seems more appropriate to treat the requirement as requiring a "good faith effort" on the part of a research team to be transparent with the community in which they are conducting a study. It avoids secrecy and may help to facilitate trust and educate the community about research, both the specific study and the process more generally. It also may serve as a sort of mirror for research teams by forcing them to think through how trials they are proposing may be received in the community. Because many disclosure efforts can be highly resource-intensive, however, we do believe greater clarification regarding what constitutes a "good faith effort" may be helpful for investigators and IRBs.

The EFIC regulations were foundational in creating a structure within which to conduct clinical trials in emergency settings. The accumulated experience with and reflection on the requirements for community consultation and public disclosure within the literature offer important lessons and provide a body of limited evidence to guide this field moving forward. In particular, there is a recognition that neither public disclosure nor community consultation poses an insurmountable barrier to conduct of important EFIC trials. Available literature and accumulated experience also clarify that there are multiple ways to accomplish both of these activities and that they serve multiple purposes. Investigators and IRBs will, appropriately, need to continue to consider each protocol and setting in order to assess the most suitable approach to both forms of public engagement. There are also notable areas where uncertainty remains. Given that further guidance at the federal level is unlikely, clarification of norms and consensus among experts in this space could be helpful. Two areas specifically emerge where such

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clarification could be helpful. First, there are not settled norms regarding assessments of adequacy

and extensiveness of public disclosure efforts. Second, there has been a lingering debate about the needed "reach" and the role of more targeted community consultation efforts given the fact that background attitudes among the general public, in particular, are relatively well understood. Clarity on each of these issues will be especially important in the context of migration to central IRB review for multi-site studies.

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Tables for Scoping Review

Table 1- CC Methods (can talk about how to order, etc.)

Method	Type of Interaction	Described Advantages	Described Limitations	References
Existing group meetings	In-person presentation by investigator or other study team member	-Face-to-face interaction -opportunities for feedback and discussion -increased attendance relative to town hall-style meetings -ability for IRB to observe -Can be tailored to most relevant groups -can pair with survey.	-Variable attendance -Possible selection bias/reduced generalizability based on groups - May be difficult to schedule -labor-intensive to summarize.	Chin 2015 Dickert 2014 Galbraith 2014 Govindarajan 2013 Holsti 2015 Longfield 2008 Nelson 2008 Tisherman 2008
Town hall-style meetings	In-person presentation	-Face-to-face interaction -Opportunities for open feedback and discussion -Ability for IRB to observe -Can pair with survey -Opportunity for interested people not in targeted groups to be included	-Lower attendance than at existing group meetings -Possible response bias from those choosing to attend meetings -Significant effort for few participants -Labor-intensive to summarize.	Holsti 2015 Kremers 1999 McClure 2003 Nelson 2008 Salzman 2007 Santora 1998 Tisherman 2008

Telephone or electronic surveys	Survey administered over the phone or internet	-Large numbers are achievable -Can capture more representative population (geographically) -Time-efficient	-Lack of interactivity and discussion -Heavily dependent on framing (both the study and the questions) -Response bias based on method (landline, internet access) -Expensive, requires expertise -Tends to represent general public rather than more focused communities	Beshansky 2014 Bulger 2009 Contant 2006 Henry 2017 Nelson 2008 Tisherman 2008
Surveys at community events	In-person distribution of survey at sporting event, fair, etc.	-Potential for capturing large numbers in a geographic area -Avoids expense of RDD -Avoids landline/internet selection bias -Time-efficient; some opportunity for interaction and discussion with staff present	-Potential responder bias -Selection bias based on type of event -Relatively minimal or brief interaction -Focus on geographic community	Biros 2009 Dickert 2014 Eubank 2018
Surveys in hospital/clinic	In-person administration of survey in a medical setting (written, electronic, or verbal), often ED or inpatient	-More focused population -Potential for significant number of respondents -Level of interaction and discussion depends on method and personnel	-Labor-intensive -May afford little interaction and discussion depending on who does it/how it is designed	Clark 2013 Eubank 2018 Morris 2004 O'Malley 2017 Raymond 2010 Triner 2007

In-person interviews or focus groups	In-person discussion and interview with individual or small groups	-Opportunity for open discussion and dialogue -Ability to ensure greater understanding of the study among respondents than some other methods -Can focus on target population (often with condition-relevant experience) -Higher level of recall of study information among respondents -Can pair with survey	-Small sample size -Labor-intensive and potentially expensive -Concerns about generalizability of feedback/selection bias -Can be labor-intensive to summarize	Fehr 2017 Govindarajan 2013 Holsti 2015 Kasner 2011 Scicluna 2017

Table 2- Assessment questions in community consultation

Content	Examples	Potential Advantages/Disadvantages
Personal acceptance of EFIC enrollment in proposed trial	- "My own EFIC enrollment in this study would be acceptable."[6] - "If you were having a heart attack and were to be treated by paramedics, would you object to participating in this study?"[3]	-Face validity -Epistemically more valid (people can know the answer for themselves)
Willingness to enroll in proposed trial	- "If today your child had been in a coma as a result of a serious head injury, would you agree to enroll him/her in this study?"[1] - "Would you agree to participate in this study?"[27]	-Face validity -Does not specifically address EFIC (attitude toward study and not EFIC enrollment)
General acceptance of EFIC for proposed trial	- "Do you object to the enrollment of someone in this research study without their individual consent before the study begins?"[43] - "Sometimes no family member can be found to make medical decisions for patients with traumatic brain injury. It is okay to include those patients in the ProTECT study without consent."[71]	-May avoid idiosyncratic preferences -Difficult to answer for others -Potential bias toward more negative response
Acceptance of EFIC in community	- "EFIC is acceptable for emergency research in our community."[6] - "Would you be willing to allow us to do this study in your community?"[3]	-Lacks face and content validity/hard to know what is being asked -Heavily dependent on phrasing
Importance of proposed trial	- "Do you feel there is potential benefit from receiving the experimental blood substitute, PolyHeme?"[43] - "The COMBAT study is an important study to do."[10]	-Straightforward -Ceiling effect and lack of understanding on respondents' part - Does not address enrollment/EFIC

Acceptance of enrollment in proposed trial with surrogate consent	- "If you are confused or drowsy, you might not be able to make such a decision for yourself. Would you be happy for your next of kin/relative (or other representative) to take this decision for you?"[72] - "If I had a traumatic injury and a family member agreed to include me in the COMBAT study, I would be okay with being included."[10]	-Face validity is a strength -Does not specifically address EFIC

Table 3- Acceptance rates of Personal EFIC enrollment

Study	Type of Consultation	Parti-cipants	Rate of Accept ance	Other Key Findings
PROPPR (Henry, 2017)	RDD survey	500	76%	-Even though they used zip code targeting, the population had lower representation of minorities and men than the enrolled population
RAMPART (Vohra, 2014)	Meetings with existing groups	105	85%	-Used audience-response technology (ARS) -Increased engagement through the use of ARS during CC may lead to more understanding and willingness to participate.
STEP-UP CSDH (Scotton, 2014)	In-person surveys	215	74%	-A previous history of CSDH and age greater than or equal to 66 years showed a non-significant trend towards increased willingness
AVERT Shock Trial (Sims, 2013)	Interviews; Focus groups	309	77%	-One of the only studies to show higher acceptance of general EFIC (84% than personal (77%). -Community members were more accepting of general and person al EFIC compared to trauma patients and their family members.

ProTECT (Dickert, 2014)	Multi-site: Town Hall meetings; Meetings with existing groups; Interviews; Focus groups, emails, community events	2612	71%	-Increased acceptance with interactive methods, more connection to condition (cite other)
IMMEDIATE (Beshansky, 2014)*	RDD survey	2,079	68%	-Trial involve pre-hospital assent in an ambulance
Out-of-hospital hypertonic saline resuscitation (Bulger, 2009)	RDD survey	2418	64-79%	-inverse relationship between age and desire to enroll in study -limitation: survey questions and order of questions varied among sites – -willingness to enroll decreased from 77% to 64% between 2 survey administrations in Portland due to negative press coverage of an unrelated EFIC study
RESCUE-ASDH (Clark, 2013)	In-person surveys	171	91%	-UK study -Exact questions were not published -84% said they would be willing to participate - 91% Acceptability of surrogate consent by a doctor independent to the trial
TBI/management of brain trauma (Dix, 2004)	Meetings with existing groups	137	93%	-100% of participants were okay with the study being done in community -"Would you be willing to participate in this study?"
PolyHeme (Longfeld, 2008)	Town Hall meetings	150	64%	-pre-survey projection of 68% trial enrollment; actual enrollment in trial was 79%
Hypertonic saline resuscitation for brain injury or traumatic shock	Random Digit Dialing/Telephone Survey; Town Hall meetings; Meetings with existing groups; website	361	78%	-community meeting respondents more willing to receive experimental treatment themselves or for family member than phone or web respondents -In-person meetings had greatest acceptance of EFIC

(Nelson, 2008)				
Endotracheal intubation techniques (O'Malley, 2017)	In-person surveys	6,936	74%	-29 were subjects in the intubation study; 22 had been notified of the study prior to the intubation/enrollment; the other 7 were notified of the study weeks or months after being enrolled, -of the 22 who had been notified prior to enrollment, 13 had agreed to participate; of the 7 notified after, 5 agreed to participate
PolyHeme (Triner 2007)**	In-person surveys	497	51%	-Attitudes in community where CC was done rather than with true CC participants

**Attitudes of general public, not true CC

Table 4- Public Disclosure Methods

Method	Described Advantages (include reach and cost)	Described Limitations (include reach and cost)	References
Print Media (Newspapers, press releases)	-Can reach large audiences -Can approximate reach	-Expensive -Passive approach –People don't always read them -Often not targeted to specific communities	Sazlman (2007) Jacoby (2008) Chin (2015)
Broadcast Media (Radio, TV, PSA Press Conferences,)	-Can reach large audiences -Can approximate reach	-Expensive -Often not targeted to specific communities	Sazlman (2007) Jacoby (2008) Galbraith (2014) Chin (2015) Holsti (2015)
Social Media ads	-Geographic targeting (Facebook ads) -Cheaper than traditional advertising, can increase website traffic	-May only reach certain demographics (younger) -Very little engagement (time spent on websites)	Stephens (2013) Stephens (2016) Matchett (2018) Harvin (2019)
Individual communication (letters, emails, phone calls)	-Can target specific communities and/or community leaders -Better opportunities to opt out	-Calls and postage can be expensive	Galbraith (2014) Holsti (2015) Matchett (2018)
In-person disclosure	-Can target specific communities (parents for peds studies) -Better opportunities to opt out	-Smaller scale	Raymond (2010) Holsti (2015)
In-Hospital materials – posters, brochures	-Can target specific communities (i.e. patients with a specific disease) -Reaches people in the healthcare system	-Passive method -People often don't notice posters or read brochures	Kremers (1999) Morris (2004) Raymond (2010) O'Malley (2017)
Websites	-Can measure hit rates -Can facilitate opt-outs -Can provide more detail, multi-media options	-Often short interactions with people who land on sites -Have to drive traffic to sites -Limited to individuals with internet access	Chin (2015) Holsti (2015)

Meetings (presentations, focus groups with hospital staff)	-Inform staff members likely to be involved	-Personnel time and cost	Raymond (2010)

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Appendix C:
Draft Model of EFIC Procedures (MOP)
Document distributed to Expert Panel

Reviewer Instructions:

5. Save this document on your local computer with your last name at the end of the file name.
6. Read through each section of the document and consider whether the findings or interpretations reflect your expertise and experience with EFIC and your existing familiarity with the literature. **Particularly, please provide input on sections you feel require revisions, more detailed explanations, or where you see gaps**.
7. Enter your comments in the closest text box to the right of the corresponding section. Make observations and comments only where you feel you have something of value to add. You do not need to comment if you think the relevant concept has been well captured.
8. Save the document with your comments and email it to LizJansky@westat by January 31, 2020.

Thank you for your help!

Model Operational Procedures for the Implementation and Review of NIH Sponsored Multicenter Clinical Trials with Exception from Informed Consent (EFIC) for Emergency Research

A. Introduction

B. Investigator's EFIC Implementation Plan

C. Application for Single Institutional Review Board Review

D. Guidelines for Centralized Review of Community Consultation and Public Disclosure

A. Introduction

The purpose of this document is to provide a model process and procedures that can be used as starting point for implementation of clinical trials using Exception from Informed Consent for Emergency Research (EFIC) in NIH funded multicenter clinical trials. The process and procedures described can and must be adapted to the specific needs and details of any future trials. The materials provided were developed and informed by both thorough review of the accumulated scholarship related to EFIC, and other lessons learned through practical shared experiences of prior NIH funded emergency care researchers.

This document <u>is</u> intended to be a useful, practical, and tested tool for future investigators in this field. It <u>is not</u> intended to be a definitive guideline for application of the EFIC regulations, and should not be interpreted as any form of regulatory guidance. This document does not represent the only way to implement Exception from Informed Consent, and may not be applicable or optimal for EFIC studies that differ from those for which this document was created.

B. Investigator's EFIC Implementation Plan

This "Investigator's EFIC Implementation Plan" is a sample procedure based upon a trial enrolling participants with acute severe traumatic brain injury (TBI). This is intended to be used as a model or template for trials involving patients with any qualifying emergency condition. For trials involving patients with other conditions, the elements in this example that refer to TBI must be modified as appropriate to the clinical trial for which this is being adapted. The plan also sometimes refers to specific elements of the sample trial's protocol, which should also be disregarded when adapting this procedure for a future trial.

This model plan has the following components. An introduction and overview lay out the anticipated use of EFIC and informed consent in the trial. The following section explains how the trial qualifies for EFIC by explicitly addressing all criteria of the regulations point-by-point. Subsequent sections describe the underlying goals and principles upon which the proposed plans for community consultation and public disclosure are based, followed by specific menus and descriptions of the types, numbers, and mix of events in which sites are required to engage, and how the results of these should be reported.

INTRODUCTION

Please Comment Here

1

The goal of this document is to describe the implementation of the protections associated with 21 CFR 50.24, Exception from Informed Consent (EFIC) Requirements for Emergency Research in a specific clinical trial. Implementation of this plan is the first phase of conducting the proposed trial. The findings acquired from planned activities will be presented to the Central IRB (CIRB) to help the IRB assess community attitudes related to the study.

Research involving the acute care of patients with emergencies such as severe Traumatic Brain Injury (TBI) presents ethical challenges. Respecting participants and their autonomy through the informed consent process is a cornerstone of ethical research, but patients with severe TBI are comatose and unable to participate in an informed consent process. When available a legally authorized representative (LAR) may act as a surrogate decision maker for a comatose

patient. The LAR can decide if the patient will participate in the research study, even though the wishes of the patient may not be known. However, for many patients with severe TBI, no LAR is readily available during the patient's resuscitation and emergency care. Excluding patients without capacity or an available LAR from TBI research does not necessarily defend patient autonomy since the patient's actual wishes are unknown. In fact, when they can be asked, patients and their representatives choose to participate more often than not. Excluding patients without capacity, however, limits the ability to ever scientifically improve care, and makes enrollment in the emergency setting impracticable. Therefore, this study will enroll participants for whom an LAR is unavailable with EFIC.

OVERVIEW

All patients meeting eligibility criteria for this trial will be obtunded or comatose and unable to give informed consent to participate. Participants will be enrolled in this trial either with the informed consent of a LAR or with exception from informed consent (EFIC) for emergency research under the conditions established at 21CFR50.24 and pursuant to 45CFR46.101(i) and the HHS Secretarial Waiver at FR Doc. 96–24968 .

Upon hospital arrival of a potentially eligible subject, study teams will diligently attempt to determine the patient's identity and the availability of an LAR. If an LAR is available at any time prior to the routine emergent placement of intracranial probes for standard clinical management of severe TBI, the patient may only be enrolled with prospective informed consent from the LAR, as documented by a signed informed consent document. If an LAR is not available prior to the routine emergent placement of intracranial probes, eligible patients will be enrolled with EFIC. When enrolling with EFIC, enrollment and randomization take place immediately after probe placement. Subsequent to an

EFIC enrollment, attempts will be made to notify an LAR at the earliest opportunity, and consent to continue in the study will be sought.

<u>Enrollment with Consent</u>

If an LAR is available prior to the routine emergent placement of intracranial probes, the patient will only be enrolled with the prospective informed consent of the LAR. Informed consent is a process involving a meaningful and compassionate exchange of information, questions, and answers between an LAR and a study team member delegated to obtain informed consent. The study team member will discuss the opportunity to participate in a balanced and noncoercive manner and will review the informed consent document with the LAR. The informed consent document provides a record of the informed consent process. The LAR signature on the consent document indicates permission for the patient's participation and acknowledges this consent.

<u>Enrollment with EFIC</u>

Upon hospital arrival of a potentially eligible subject, study teams will diligently try to determine the patient's identity and the availability of an LAR. Both routine hospital and study team resources and processes should contribute to these efforts. The steps undertaken to identify the patient and find the LAR should be documented on the informed consent log case report form. If an LAR is not available prior to the routine emergent placement of intracranial probes, eligible subjects will be enrolled with EFIC. After EFIC enrollment, efforts to contact an LAR will continue. Once the LAR is available and as soon as it is feasible, the LAR will be informed of the subject's enrollment in the study. Details of the study, the potential risks and potential benefits of participating in the study will be explained to the LAR. After discussing the study with the LAR, the LAR will be given the option of allowing the subject to continue study participation, or to withdraw from the study. The LAR will be informed that the decision to continue participation in the study may be withdrawn at anytime throughout the course of the study. If the LAR wants to continue the subject's participation, the LAR will sign the informed consent form.

The informed consent log case report form is used to document the continuing efforts to locate an LAR, the notification of the LAR, the consent process, and the decision of the LAR. This log will include the types of attempts made, the number and times of those attempts, and the outcome of each attempt. If the subject regains decision-making capacity, the patient will be notified of the study and will be asked if he or she wants to continue the study. If no LAR is found and the subject never regains decision-making capacity, the subject will remain enrolled under EFIC. For subjects who expire prior to identification of an LAR, consent is not obtained. If an LAR is eventually located, they

should be notified of the subject's participation. In the rare case where an LAR cannot be found and the subject remains incapable of consent at 6 months, attempts to find an LAR will be discontinued, but documentation of the LAR search process until that time, and the subject's decisional capacity, will be documented.

<u>Withdrawal from Participation</u>

Regardless of whether a subject was initially enrolled with informed consent or EFIC, an LAR may withdraw the subject from further participation at any time and for any reason. If the subject regains consciousness and decision making capacity, subjects may also withdraw from further participation. Whenever possible, the reason for wishing to withdraw should be determined. Those wishing to withdraw the study intervention should be aware that the intervention can be discontinued (i.e. request that the PbtO2 probe be removed, or that ICU staff be unblinded to PbtO2 values) without withdrawing from the trial and further data collection. Discontinuation of the study intervention itself does not constitute withdrawal from further participation in the study. After withdrawing from either the intervention or any further participation in the study, the participant's care should revert to usual care based upon patient characteristics, treating physician preference, and institutional practice. Consistent with OHRP and FDA guidance, participant data collected prior to withdrawal from the study is maintained in the study database, but no additional participant data will be collected from the participant or their medical record following withdrawal from the study.

REGULATORY CRITERIA FOR USE OF EFIC

FDA regulations identify the specific circumstances in which EFIC is appropriate even when performed under the secretarial waiver rather than an IND or IDE. This trial fulfills these requirements for emergency research. In the following section. The components of the regulation are reproduced (in italics), along with an explanation of how this trial will comply with each requirement.

TBI is life-threatening and available treatments are unsatisfactory or unproven.

> *21 CFR 50.24(a)(1) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.*

TBI is a major cause of death and disability in modern industrialized societies, the scope of which is described in section 2.1 of the study protocol. Despite 52,000 deaths from TBI annually in the US, and years of clinical investigation, there are still no proven specific treatments available. Although both ICP guided and PbtO2 guided goal-directed therapy are used in the care of patients with severe TBI, neither is proven to be effective. The Cochrane Library (http://www.cochranelibrary.com/) contains numerous systematic reviews of various unsuccessful or persistently unproven interventions. Further clinical trials are needed. TBI has been recognized as a condition qualifying for EFIC in several prior studies.

Obtaining prospective informed consent is often not feasible.

> *21 CFR 50.24(a)(2) Obtaining informed consent is not feasible because: (i) the subjects will not be able to give their informed consent as a result of their medical condition; (ii) the intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and (iii) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.*

Potential subjects with severe TBI are unconscious and unable to provide informed consent due to their medical condition. Critical care of patients with TBI, however, must be initiated rapidly after hospital arrival. The hypothesized benefit of reducing tissue hypoxia in this trial relies upon early detection and correction. The BOOST 2 trial demonstrated that brain tissue hypoxia is already present in many patients

at the time that their monitoring was initiated.

In ProTECT 3, a trial which treated 882 participants with moderate to severe TBI within 4 hours of injury, an LAR was available to provide consent within 6 hours for 427 participants (48%). An LAR was not available to provide consent within 6 hours for 52% of participants. When an LAR did not arrive within 6 hours, the time lag until an LAR did become available rapidly increased, with a median value of about 30 hours. In this previous TBI trial, the consent for continued participation after EFIC enrollment and retention rates were very high. Without EFIC, half of the TBI patients potentially desiring participation may be denied access to the trial, making the trial impracticable. Since TBI is accidental and unpredictable, there is no reasonable way to prospectively identify the individuals who will become eligible for participation in the research.

Participation holds prospect of direct benefit to subjects

> *21 CFR 50.24(a)(3) Participation in the research holds out the prospect of direct benefit to the subjects because: (i) subjects are facing a life-threatening situation that necessitates intervention; (ii) appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and (iii) risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.*

Participation in sample TBI trial offers the prospect of direct benefit to subjects. Subjects may directly benefit from participation because TBI is a life-threatening condition and the PbtO2 goal directed interventions used in this study may be more effective than the ICP goal directed therapies alone. In particular, risks associated with the intervention, comparison of two goal-oriented strategies of care, are reasonable in relation to what is known about severe TBI and its treatment. The risks of intervention align with the range of risks of standard care as both strategies themselves are variations of standard care. Some participants report comfort and appreciation from the attention and follow up from the study team that is inherent to their participation.

The trial can not be practicably carried out without exception from informed consent

> *21 CFR 50.24(a)(4) The clinical investigation could not practicably be carried out without the waiver.*

This research could not be carried out without EFIC because treatment for TBI (including placement of probes and care driven by these measurements) needs to begin rapidly after hospital arrival. Since TBI patients are unable to consent for themselves and there often is no LAR available within the therapeutic window of the proposed intervention, we expect that approximately half of the participants in this trial will be enrolled under EFIC. In TBI, time to treatment is critical. Inability to obtain informed consent in the absence of EFIC can limit the ability to discover better treatments for this critical and life-threatening condition.

Need for rapid treatment of TBI often precludes consent from an LAR

> *21 CFR 50.24 (a)(5) The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator*

The narrow therapeutic window described above, the inability of patients with TBI to communicate, and the lack of an LAR available to provide surrogate consent in more than half of potential subjects precludes the possibility of obtaining informed consent for many eligible patients in sample TBI trial. Attempts to contact LAR for notification and consent to continue participation will be tracked and summarized at continuing reviews.

REGULATORY PROTECTIONS FOR IMPLEMENTING EFIC

4

The regulations for EFIC research mandate additional requirements for the implementation of this kind of clinical trial. Each of these additional protections and components of the regulation are reproduced (in italics) here, followed by an explanation of how the sample TBI trial will comply with the requirement. Further details about implementation will follow in a subsequent section.

Provision of an informed consent document

> *21 CFR 50.24(a)(6) The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with Sec. 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with paragraph (a)(7)(v) of this section.*

A written informed consent document for this study will be reviewed and approved by the study CIRB. Subjects enrolled in sample TBI trial, or their LAR, are approached for consent prior to enrollment or informed of the subject's inclusion in the clinical investigation at the earliest possible opportunity. The study team is immediately notified of the arrival of all potential subjects. An on-call study team member quickly responds to the hospital to enroll subjects or to complete the subject enrollment under EFIC. For the latter, the subject (or LAR or family) is approached, and an informed consent process initiated as soon as feasible. The study team notifies the subject or LAR/family about the subject's enrollment, provides information about the study, the subject's rights, and the responsibilities of the investigators. The study team answers any questions about the study and further participation. A written informed consent document is used to reinforce the information provided in the consent discussion, and to document the decision to continue in the study or to not participate any further. A copy of this form is provided to the subject and another copy is placed in the research record.

Community Consultation

> *21 CFR 50.24(a)(7) Additional protections of the rights and welfare of subjects will be provided, including, at least: (i) consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn*

The community will be consulted prior to the initiation of research. The community will be asked to give their opinions about the research and the need for EFIC in order to complete this trial.   A detailed menu of acceptable options for community consultation is included later in this plan. The site will choose from this menu and perform sufficient consultations to ensure the CIRB that community consultation has been satisfactorily completed at each site. Reporting of community consultation results will be standardized across the sample TBI trial sites.

Public Disclosure

> *21 CFR 50.24(a)(7) Additional protections of the rights and welfare of subjects will be provided, including, at least: ….(ii) Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits; (iii) Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results*

Public disclosure is the primary element in making certain that sample TBI trial is conducted in an entirely transparent manner. Methods of announcing information about the trial, and the development of advertising and other materials about the trial, will take place both locally and nationally. Public disclosure will be initiated prior to approval of the trial, may continue during enrollment, and will conclude with dissemination of study results after the trial is completed. A menu and discussion of many public disclosure methods and procedures is included later in this plan. The CIRB will approve the types and forms of public disclosure. Reporting of public disclosure efforts will be standardized. Summaries of public disclosure will be reported to the CIRB, and made publically available.

Data Monitoring Committee

> *21 CFR 50.24(a)(7) Additional protections of the rights and welfare of subjects will be provided, including, at least: ….(iv) Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation;*

A Data and Safety Monitoring Board (DSMB) is appointed by the NINDS to provide ongoing evaluation of safety data as well as the overall conduct of the trial, per institute guidelines. The members will meet with the study team prior to study commencement to discuss the protocol as well as content and format of the DSMB reports. The DCC will prepare requested reports at specified time intervals. Data and safety monitoring will be performed consistent with the guidance provided by the NIH notices 98-084 "Policy for data and safety monitoring" and OD-00-038 "Further guidance on data and safety monitoring for phase I and phase II trials", and by the NINDS document based on these notices "NINDS Guidelines for Data and Safety Monitoring in Clinical Trials".

Contacting Other Family

> *21 CFR 50.24(a)(7) Additional protections of the rights and welfare of subjects will be provided, including, at least: …. (v) If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.*

Whenever possible, informed consent will be used in lieu of EFIC enrollment. EFIC enrollment will also not proceed if an LAR or any other surrogate present either at the bedside or remotely declines participation on behalf of the potential subject. A provision of the protocol has been made to allow subjects who learn of the trial through public disclosure efforts or other means, and who, if treated in the hospital for TBI, would not want to participate, to communicate that decision to the ED without causing any delay in treatment. As part of the primary assessment of any TBI patient, ED providers already check for medical alert jewelry to ascertain emergent medical information about the patient. If the words "sample TBI trial declined," or similar alternative designation, are listed on the medical alert tag, the patient will not be enrolled in the clinical investigation. A hypoallergenic silicone bracelet may also be provided by the study team to members of the public if requested to indicate their wishes to decline study participation. Use of this enrollment exclusion will be tracked and this information will be provided to the CIRB at the time of continuing review.

Post Enrollment Notification and Consent to Continue

> *21 CFR 50.24(b) The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.*

Subjects enrolled in sample TBI trial, or their LAR, are informed of the subject's inclusion in the clinical investigation at the earliest possible opportunity as detailed above. It is anticipated that the notification of subjects, or their families or LAR, will most commonly take place in the ED within hours of subject enrollment. Attempts to notify the subject or an LAR are repeated until successful. All notification attempts are logged and recorded in the subjects' online case report form in CTMS. Reports of these attempts will be available for inclusion in annual reports to the CIRB.

Record Keeping

> *21 CFR 50.24(c) Like other IRB records, records of the determinations above must be kept for a minimum of three years after the completion of the clinical investigation. Again, like other IRB records, these are subject to inspection and copying by FDA.*

Records documenting the enrollment of participants using EFIC, procedures for notification of enrollment, and informed consent forms will be kept for a minimum of three years after completion of the clinical investigation.

IND Requirement

> *21 CFR 50.24(d) Protocols involving an exception to the informed consent requirement*

under this section must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for investigations under this section may not be submitted as amendments under Secs. 312.30 or 812.35 of this chapter.

This trial has been reviewed by FDA, including intent to enroll with EFIC, and the Agency has determined that an IDE is not required for this trial. The Agency has pointed out that this finding is consistent with their latest guidance on EFIC specifically for device trials.

Communication of IRB Determination

21 CFR 50.24(e) If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided under paragraph (a) of this section or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation. The sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRBs that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

Pursuant to the NIH single IRB policy for multicenter clinical trials, sample TBI trial will be reviewed and approved by a single CIRB. If the CIRB does not approve the trial, no subjects will be enrolled at any site, and all stakeholders will be informed. Because of a single IRB of record, there will be no opportunity for discordant IRB findings, and no other reporting of disapprovals.

COMMUNITY CONSULTATION PRINCIPLES

Implementation of community consultation in this trial is based on the applicable regulatory language, applicable FDA guidance documents (from March 2011, updated April 2013), and the investigators own empirical ethics research and experience in developing best network practices.

Goals

5

The regulatory intent and specific goals of community consultation are not explicit in the regulations, and have been the subject of academic disagreement. As described in the FDA guidance, the goals of community consultation include:

- To **show respect for persons** by informing the community about the study in advance;

- To inform community members about the trial in advance and provide a means for **affected communities to provide meaningful input to the IRB** before its decision to approve, require modifications to, or disapprove the study;

- To show respect for the community by allowing **representatives of the community** to identify potential community-level concerns and effects of the research; and

- To show respect for subjects' autonomy. Respect may be shown by including in community consultation activities **individuals who may have, or be at risk for, the condition under study** (and thereby obtain input from a group that is expected to be similar to the eventual study subjects).

This EFIC plan incorporates and interprets these goals into the following specific actionable elements.

To **show respect for persons**, we require CC events that include going out into the community to talk to people where they already gather, rather than simply

asking them to come to us at events that we originate. Showing respect also involves CC events that specifically engage the investigators responsible for the research with the members of the community, rather than only allowing consultations that can be outsourced or delegated.

To create effective opportunities for the **affected communities to provide meaningful input to the IRB**, we train for and promote event formats that ensure that study teams listen as much as they talk. Simply giving a presentation about the trial and then asking if there are any questions is not effective CC. Deliberately brief descriptions of the trial, preferably with few or no slides, are followed by probing the community members for what additional information is important to them, and by soliciting the values and experiences of the community members that are most relevant to the research and to TBI. Community members are experts about themselves. How their own narratives intersect with the proposed research and the way in which it will be carried out (under EFIC) is the most useful input the community can provide to the IRB.

To show respect for the community, CC activities explicitly reach out both to individuals in the community without specific roles, and to **representatives of the community**. Representative of the community may be religious leaders, community organizers, patient or disease advocates, local political leaders, or others best equipped to identify group-level concerns.

Demonstrating respect for the autonomy of a group of **individuals who may have, or be at risk for, the condition under study** is particularly challenging in TBI research because traumatic injuries can happen to anyone. We meet this goal by asking sites to describe the breadth and depth of the communities they serve, and then asking that they complete CC activities that reflect a sufficient portion of that spectrum. In past TBI trials we have specifically sought out communities that are high risk of TBI, but that may be hard to engage in CC, such as Motorcycle or ATV Clubs and young adult males playing basketball or football. Sites have historically accessed TBI support groups to speak to TBI victims and their caretakers as well. These groups are keenly aware of possible treatments and the cost a traumatic TBI can have on one's quality of life.

It is also important to explicitly reinforce the FDA guidance by stating the goal of CC is **not** intended to represent community consent. Consent to participate in research is meaningful only as an individual decision; community support of the research does not reflect consent for all members of the entire community. Community consultation is therefore not intended to be a form of unbiased voting, deliberative democracy, or other purely quantitative activity, but rather an opportunity for open discussion and commentary. The IRB makes the final determination on study approval based on information obtained from the community consultation.

Definition of Community

For the purposes of EFIC, the definition of community includes "the community in which research will take place" and the "community from which subjects will be drawn." In other words, the community includes the geographical area from which patients will be drawn and the group of patients with, or at risk for, the disease of interest. Communities have many subgroups that can be defined by innumerable characteristics such as race, ethnicity, religion, age, gender, wealth, education, employment, neighborhood and other factors. Community consultation should consider the heterogeneity of the community and seek diverse input. It is understood, however, that it is impracticable to reach every possible subgroup, but each site will complete activities that reflect a sufficient portion of the spectrum of their relevant communities.

Content

The content of community consultation will inform the community participants that informed consent will be obtained for any research subjects prior to enrollment whenever possible, and will not be obtained when no LAR is available. Informational materials developed for sample TBI trial CC activities are included in the appendix of this plan and are subject to IRB approval. Additional materials developed later will be submitted to the IRB for approval before being used in any CC/PD activities. Specifically, the content of all CC activities will:

- Tell the community about the most relevant aspects of the trial including its potential risks and potential benefits, and the therapeutic window (based on timing of probe placement, but generally within about 2-10 hours of injury).

- Hear the perspective of the community on the proposed research, elicit values and experiences

- Explain how individuals wishing to be excluded may indicate this preference

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<u>Types of Events</u>

Based on our interpretation of the regulations and their proposed ethical basis, we have prepared a menu of the types of events and activities that sample TBI trial sites may use to meet their requirements for CC. Sites will prepare a site plan that lists all the events and activities that they will use to engage the community. Each site plan will:

- Provide opportunities for broad community discussion

- Ensure that representatives from relevant communities participate in the consultation process

- Include more than one type of event or activity to provide for effective community consultation

- Consider multiple factors including, but not limited to, the size of the communities, the languages spoken within those communities, the heterogeneity of the population

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COMMUNITY CONSULTATION MENU

A (Interactive - Direct)	B (Asynchronous - Delegated)
A presentation and discussion by an investigator visiting a meeting of an existing group (visits to existing meetings)	Telephone survey (random digit dialing)
Focus group (moderated small group session)	Web-based survey
In-person individual interviews or meetings	Social media messaging
A booth or table at community events involving interactive discussions (not just surveys)	In person solicited survey e.g., waiting room survey, booth survey without other interaction
Meetings convened by the investigators inviting the targeted audience (preferably with RSVP)	

Required mix is at least 6 total CC events or activities. Among these 6 events or activities, at least 2 events or activities must be of a type in column A, and at least 1 event or activity must be of a type in column B. The 2 events of a type in column A may be of the same type, for example, they could both be focus groups or visits to existing groups. Events should include participants representing a sufficient breadth of the diversity of both the geographic community primarily served by the enrolling sites' institution, and the community either at-risk for, or familiar with, TBI. There is no expectation that all of the subgroups of either community can be engaged.

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Visits to existing meetings or existing groups

In this method of community consultation, members of the study team, sometimes accompanied by representatives of their participating institutional research leadership, ask to present the study and lead a discussion about the study at a regularly scheduled meeting of a relevant community group. Sometimes, the existing group may hold a special meeting for this purpose, but the study team still goes to the group

(rather than asking members of the group to come to the study team).

Existing groups that might be consulted using this method may include, but are not limited to: disease-related support or interest groups, civic groups, neighborhood groups, service organizations, athletic groups (inclusive of athletes, coaches, and trainers at any level of competition from high school to professional), parent-teacher associations, faith-based organizations, political or governmental bodies, business groups, social clubs, retiree groups, and college fraternities or others. Examples of disease-related support groups include TBI support networks of parents of children and young adults with TBI. Examples of governmental bodies include law enforcement and fire department groups, city councils, and community boards. This approach may also include study team visits to senior centers or rehabilitation facilities. Participation in an existing meeting shows respect for community by bringing the information to the community, reduces inconvenience to the community and exposes the study to a diverse audience. Community members may be more comfortable expressing their opinions in a known setting. Investigators may have to travel, attend multiple meetings and conform to the community group's schedule. Using this method can encourage more involvement by co-investigators and other members of the study team, which can be advantageous.

Prior to and during the visit, the study team must clearly communicate that being allowed to attend the meeting does not imply any implicit approval or endorsement by the group being visited.

Best Practices:
- An investigator should be present to take and answer questions from the community.
- Presentation should be brief (i.e., 10 to 15 minutes).

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- If a presentation is longer than 15 minutes, it should be interactive throughout the presentation.
- The presenter should be knowledgeable about the study and comfortable with the group.
- Allow ample time for community discussion (at least 15-30 minutes).
- Often best to ask for 30 minutes on an existing meeting agenda to allow 10 minutes to present, 15 minutes for discussion, and 5 minutes to hand-out and get back evaluation surveys. Insufficient time for solicitation of feedback greatly reduces the utility of this method.
- Probe for discussion using open-end questions. Ask participants about their experiences and what they care about.
- Ensure that the discussion includes feedback from the participants on EFIC.
- Light refreshments may be sponsored; direct monetary incentives are uncommon.
- An anonymous survey for group participants to indicate their thoughts, feelings, and opinions about the EFIC regulations and the study is typically collected at the end of the event. The survey template is available on the sample TBI trial website in the toolbox under EFIC.

<u>Focus groups</u>

In this approach, a trained facilitator interviews and moderates a discussion in several small groups (generally about 8 to 12 participants). This method can be conducted with or without an investigator present, but the former is favored. Unlike focus groups designed for other research purposes, these focus groups are performed as community consultations. They are an opportunity for investigators to directly listen to community members, and to show their respect by listening humbly. An investigator may often start the session by briefly presenting information about the trial or may elect to allow the facilitator to proceed, and listen and be available to clarify issues and answer questions. The facilitator runs the discussion using an explicit guide prepared by or reviewed beforehand by the investigative team. The facilitator elicits the group's views, questions, concerns and comments about the study. The interaction is generally audio-taped (and possibly videotaped) for review by the investigative team and the facilitator to allow subsequent analysis and reporting of the session. Focus groups could solicit

feedback from any relevant focus of the community, including: the general public, individuals affiliated with particular organizations or subgroups, or specific patient populations.

Recruitment methods for focus group participants will depend on the targeted population. Participants may be recruited by mail or telephone, at random from volunteer banks or public data sets or from special populations (such as patients with prior brain injury or their families, advocacy group representatives or other vested interest groups).

Compared to other methods of community consultation, focus groups may allow for more in-depth discussion of the study because of their small size. They also allow for interaction not only between the facilitator and participant but between participants. For these reasons, focus groups offer a rich set of information and have often been found by investigators and IRB members to be a high-quality source of information.

Best Practices:
- The meeting should be at an accessible location and time for the population included.
- The session should generally be run by a trained facilitator; sometimes it is helpful if it is someone who is also demographically concordant with the focus group participants (experience, race, ethnicity, or gender).
- Sessions should be small, generally including 8 -12 participants.
- Focus groups generally run 1 to 2 hours in length.
- Refreshments should be provided.
- Participants are generally paid for participation in focus group sessions in an amount and form appropriate to the participant population.
- An anonymous written survey for group participants to indicate their thoughts, feelings, and opinions about the study and the focus group session should be conducted at the end of the event.

Convened (invited) meeting

Sometimes called a "Town Hall Meeting", this type of CC uses the same structure and best practices as visits to regularly scheduled meeting, but invites a target audience to a meeting convened by the study team. The potential advantage of this method is that

multiple groups of attendees can be invited to the meeting, and have a chance to interact with each other and the investigator. Because the meetings are typically open to the public, there is the potential to involve everyone. The disadvantage with this method is that organizing such a meeting and attaining adequate attendance can be burdensome and difficult. To be successful, however, an intensive effort to diligently invite several potential attendees and secure their commitment to participate is needed. Merely advertising a public meeting and seeing who shows up leads to events with very few community members. Such low attendance events have been commonly held in prior EFIC trials, but are not acceptable for sample TBI trial. The use of invited meetings, therefore, is discouraged unless the site has a track record of successfully using this method in the past.

<u>Community events - interactive or survey</u>

In this type of event, the study team and investigator typically set up a booth or table at an existing community event and interact with individuals one at a time as they browse or stop by the booth. Events of this kind have occurred at State Fairs, Fire and Emergency Services Open Houses, Farmers Markets, Art Festivals, Music Concerts, Health Fairs, Ice Cream Socials, Disease-related Fundraising Events, Tailgates and other Sporting Events. This kind of event often allows exposure to a large number of community members. Depending on the kind of event it may allow investigators to reach a focused or very diverse group and a large number of participants. Because conversations are typically one on one, this method often allows more intimate and revealing opportunities for the investigator and members of the public to interact. Disadvantages of this approach is that most of the contacts are very brief, usually limiting the opportunity to exchange information. Also, the time commitment from the study team to staff the booth for the duration of the event may be significant, making this potentially inefficient. This type of event can be conducted in a way that is more interactive (a column A event), in which an investigator or other study team member primarily engages participants in conversations, often concluding with having the participant fill out a survey either through an interview or by completing a written tool. The event can also be conducted in a way that is primarily driven by just giving out written information about the study and

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asking participants to fill out a written survey (a column B event). In this case, the booth can be staffed without an investigator present, which can be more efficient for the study team.

Best Practices:
- Booths should have good signage that attracts passers-by.
- Have small treats or "swag" to attract participants and thank them for taking time to talk to you.
- Have enough staff at the booth to engage with anyone who wants to talk.
- Have enough clipboards and pens to make certain no one has to wait to complete written feedback.
- It is often effective to make this kind of event a fun social team-building exercise for the study team.

<u>Telephone (random digit dialing) survey</u>

Large telephone surveys can provide the most statistically representative description of community responses to questions about the study and EFIC. This approach also has the potential to access the views of members of the community that are unlikely to attend other types of community consultation activities. This kind of survey is often outsourced to a vendor. Vendors are often costly, but because they can deliver rapid, predictable data, and consume relatively little study team time, this approach can still be efficient. Interviewers should be trained by the study team about sample TBI trial. Telephone surveyors are trained to read information verbatim provided to them by the study team about the study and EFIC. They then ask close-ended questions and solicit open-ended comments and questions. This information is then summarized and reported back to the investigators and the CIRB. It is important that the survey and accompanying guide used by the interviewers should be carefully written and tested by the study team. Vendors can potentially perform large online surveys that are akin to these large random digit dialing surveys.

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There are several limitations to this method. Telephone surveys can be intrusive and unwelcomed. Also, because they are delegated rather than conducted directly by the investigators, they do not allow investigators to demonstrate the same level of interpersonal respect for persons or communities as other methods. Questions are

typically narrow and closed ended in this approach. Professional surveyors are also not generally equipped to answer clarifying questions about the trial or EFIC. To achieve a reasonable sample size, telephone surveys have to be short. The presentation of EFIC and BOOST3 is therefore necessarily very limited, so responses may not be as well informed or may be less reflective than responses solicited in more interactive methods. The extent to which this method produces systematically different responses is unknown.

Simple solicited surveys like those performed online, in waiting rooms, or at booths

Simple individual surveys, whether performed on-line or in person, can also be used to solicit community questions and views. This method can be used to reach large numbers and a wide variety of respondents. Online surveys can be linked to social media platforms or can be easily solicited by email. Respondents can also be recruited to complete surveys distributed in-person in relevant clinical settings like emergency department or clinic waiting rooms. These simple survey methods may not be as statistically representative as telephone surveys, but can be potentially provide more background information and are much less expensive. Internet and paper surveys also allow respondents to see visual aids and diagrams not possible with telephone surveys. Waiting room surveys may allow focus on populations with particular health care or TBI experience. Online and waiting room surveys otherwise have the same limitations as telephone surveys. Careful writing and testing of surveys remains critically important. If surveys are distributed in person, surveyors need to be well trained in the study protocol and in the EFIC regulations.

Best Practices:

Whenever possible, these surveys should be conducted by members of the study team, and or delegated surveyors with medical knowledge and training in the protocol and EFIC. Medical students and residents can sometimes be recruited as surrogates for the investigative team.

Other social media

Social media offers a low cost, potentially far reaching, and potentially interactive method to exchange information with members of a community. Recent data suggest that the penetrance of social media is very high with 80% of adults in the US accessing Facebook, Youtube, Instagram, Pinterest, Snapchat, LInkedin, Twitter, or WhatsApp daily (while only 29% read print newspapers daily). Social media may also allow messages to be directed to selected subgroups and demographics. However, investigators should still be aware that despite the high prevalence of social media overall, that use is still somewhat weighted toward younger adults, those living in suburbs, those with higher incomes, and those with more education. Also different platforms are favored by different demographics. Social media is a medium that blurs the line between one way communication (as used in public disclosure) and dialog (as used in community consultation). The former type of use is probably more common, but truly interactive social media communications are also possible. If chosen as a CC activity, the content of the presentation, the methods to allow interaction, and gaps in the available population should be clearly described.

REPORTING COMMUNITY CONSULTATION RESULTS

All community consultation activities must be reported to the CCC via the Community Consultation (CC) Form in CTMS. Here, study site personnel will data enter the aggregate data of their community consultation activities, by event. Data captured includes: information about the participants, the presentation, participant questions and comments, and responses to closed- and open-ended survey questions. A complete list of CC Form data fields is available on the sample TBI trial website in the toolbox under CTMS. The

results will be further collated to produce individual site or trial-level reports.

PUBLIC DISCLOSURE PRINCIPLES

Public disclosure is defined in guidance as the "dissemination of information about the research sufficient to allow a reasonable assumption that communities are aware of the plans for the investigation, its risks and expected benefits and the fact that the study will be conducted". It also includes "dissemination of information after the investigation is completed so that communities and scientific researchers are aware of the study's results".

Goals

The regulatory intent and specific goals of public disclosure are not explicit in the regulations, and have been the subject of academic disagreement. This plan is based on the presumption that the primary goal of public disclosure is transparency.

Transparency is achieved when information about the study is broadly and publicly disseminated through multiple channels. We note that transparency has a protective effect because investigators will not propose anything that they would not be willing to announce and defend openly.

Adequacy of public disclosure and transparency is best measured like advertising, by the size of the potential audience of the disclosure, rather than by knowledge or recollection of the audience. In fact, the more benign and acceptable the content of a public disclosure is, the less likely it will be internalized and recalled.

Content

The content of public disclosure materials will vary with the media used. Advertisements (whether signs, print media, broadcast, or electronic) may have limited space. These disclosures may convey short messages and how the audience can obtain more detail. Follow up examples may include ways to talk to the study team, or a link to the study website. Short messages should at a minimum emphasize:

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- That a research study of patients with traumatic brain injury is being conducted locally.

- That the study will enroll patients with injuries that prevent them from participating in informed consent.

- Who to contact or where to find additional information.

Other forms of disclosure, such as press releases, websites, or brochures for example, allow for greater detail and should, depending on available space, also include:

- Information about TBI and how it is treated

- The purpose of the research

- Who will be included in the study

- A description of the two treatment strategies being compared

- A balanced description of the potential clinical and research risks and benefits

- Synopsis of the research protocol and study design

- Participating sites/institutions

- Description of the attempts to contact a LAR

- Information about opting out of the study

After the clinical trial is completed, further public disclosure should include:

- The findings of the trial

- Impact of what was learned on patient care

- Where to find resources for further information

- Gratitude and thanks to the study subjects, their families, and their communities.

PUBLIC DISCLOSURE MENU - PRE-TRIAL

A (networking)	B (paid advertising)	C (conventional outlets)
National or local study website	Newspaper advertisement (and similar print advertising)	Press release
Social media postings	Television and radio ads (broadcast advertising)	News stories, interviews (print, radio, or TV)
Mailings (including email circulars/bursts and direct paper mailings)	Outdoor advertising (placards, bus ads, billboards, etc.)	Newsletters (articles or informational ads, print or electronic)
Booth/Table Community event	Paid online advertisements (banner, block, or video ads purchased from Google, Facebook, Youtube, etc.)	Brochures, flyers, handouts, bulletin boards
		Radio or TV PSA (public service announcements)

Many different channels of public disclosure should be used. This will increase the depth and breadth of market penetration. The required mix is at least 6 total PD activities including at least 2 of a type in column A, and at least 1 of a type in column B or column C. Distribution of activities should be cognizant of the anticipated audiences, and should include audiences representing a sufficient breadth of the diversity of both the geographic community primarily served by the enrollment site, and the community either at-risk for, or familiar with, TBI. There is no expectation that all potential audiences will be reached. It is expected that PD efforts will represent a good faith effort to provide transparency across the relevant communities.

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Networking

Electronic platforms can provide a passive or interactive approach to disseminating information that has benefits and challenges. Measurement of the audience reached by these methods may be elusive. Access may be limited to those segments of the population with regular computer access, although internet access through cell phones is rapidly becoming common in all parts of society. Despite these minor concerns, electronic social media and other e-platforms are inexpensive to develop,

are wide-reaching and can be relatively democratic, and can even permit continuous and anonymous input from the public. Hospitals and community based organizations often host and curate websites, social media accounts (Facebook, Twitter, etc) and listservs, that can be efficiently leveraged to disseminate a message broadly.

Paid advertising

Purchased advertising in broadcast and print media ensures dissemination of accurate materials to a wide audience. Advertisement of the study may occur on a major news radio station serving the area surrounding the study hospitals. A 30 to 60 second sound bite should include a general description of the study, the website address, and contact information where more information can be provided if desired. Printed materials, including advertisements for publication in newspapers and magazines, brochures, and flyer, are available electronically on the sample TBI website. Advertisements should be placed in both English language and foreign language newspapers as appropriate to the local community. Printed advertisements should provide a general description of the study, the national and/or local website address, as well as site contact information.

Conventional informational outlets

Press releases leading to newspaper and periodical articles are an effective form of public dissemination. Investigator appearances on local news, radio or television call-in talk shows can accomplish both public disclosure and community consultation. In addition to traditional news outlets, it is often possible to obtain coverage in local health focused newsletters, in direct mail advertisements and educational materials sent out by health care organizations and in newsletters of TBI advocacy and support groups. A video on emergency medicine trials and EFIC research in general will be available for use in public service announcements and for dissemination to media outlets. Local community access cable stations may be

accessible to investigators. Cable access channels may offer appearances on shows presenting issues of local interest or may offer to broadcast prepared materials.

Brochures and flyers may be disseminated in locations including:

- Medical sites (e.g., emergency department waiting rooms, medical clinics, dentist offices, etc.)
- Health fairs (community, employer, school, etc.)
- Support groups and other existing community groups
- Schools, universities,
- Churches and other religious affiliates
- Grocery & laundry-mat bulletin boards
- Through large employers (i.e., hospitals, universities, etc.)

Local flyers and brochures distributed should reference the trial website as an additional resource for patients, families, and healthcare providers to get information as well as ask questions about the trial.

PUBLIC DISCLOSURE ACTIVITIES - POST-TRIAL

Post-trial public disclosure activities may include any of the methods used pre-trial, especially press releases because results of trials can be especially newsworthy. Post-trial public disclosure also includes a number of more specific additional methods. Post-trial disclosure includes publication of the trial results in a major scientific journal and presentation of the results at scientific meetings. Through these publications and presentations, it usually possible to leverage the existing public relations machinery of the journals and the meeting to amplify the message through broader media outlets as well. Another specific post-trial public disclosure method is return-of-results to the study participants and their families.

REPORTING PUBLIC DISCLOSURE ACTIVITIES

All public disclosure activities must be reported to the CCC via the sample TBI trial Public Disclosure (PD) Form in CTMS. Study site personnel will data enter data on each activity including: name and type of activity, size of anticipated audience, and characteristics of the intended audience, and timing and duration when relevant. A complete list of PD Form data fields is available on the sample TBI trial website in the toolbox under CTMS. Activity data will be further collated to produce individual site or trial-level reports.

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CONTACTING A LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The definition and hierarchy of LAR is determined by local state regulations.

When more than one LAR are present, the LAR highest in the local hierarchy should give consent. However, unless otherwise stated in local or state regulations, any LAR may consent if others are not promptly available.

EFIC does not obviate the need to seek an LAR to provide consent prior to enrollment if possible, and to seek patient or LAR consent to continue participation after EFIC enrollment. Potential subjects are also not enrolled under EFIC if any family contacted prior to enrollment objects to enrollment, even if they are not an LAR or are only available by telephone. Subjects enrolled in sample TBI trial, or their LAR or family, are informed of the subject's inclusion in the clinical investigation at the earliest feasible opportunity. The study team is immediately notified of the arrival of potentially eligible patients in the emergency department (ED). An on call study team member quickly responds to the ED to determine eligibility, seek an LAR for consent, and enroll the subject if consent is obtained or enroll under EFIC when appropriate. The subject (or LAR or family) is approached, and an informed consent process initiated as soon as possible.

LAR identification and tracking will typically be a shared responsibility between the onsite social workers (or equivalent) and the study team. Each site PI and team will meet with their social workers (or equivalent) before the trial initiation to inform them of the trial protocol and need for intensive LAR search. The site team should review the local protocol for an LAR search and assure that it is sufficient (multiple methods for locating LAR and multiple attempts), and if not, recommend additional steps be put in place.

Once available after an EFIC enrollment, an LAR will be informed of the patient's enrollment into the study and of the study details and potential risks and potential benefits of study participation. At that time, the LAR will be given the option to continue participation in the study, or to cease participation then or at any time throughout the course of the study. If the LAR wants to continue participation, an informed consent process is performed and an informed consent form signed by the LAR will be obtained. If an established LAR has given consent for the participant to be enrolled, other family members' objections to inclusion will not result in the participant's removal from the study. If the participant regains decision making capacity, the participant will be asked to consent to or decline continued participation in the study. If the participant wishes to continue and an LAR has not already provided consent and signed a consent form, the participant will sign an informed consent form. If the LAR has already signed a consent form, an additional form signed by the participant is not required.

Using the Informed Consent CRF, the study team will document efforts to find the LAR. This will include contact person (Subject, LAR, Other), number of attempts, date and time and outcome of attempts. The tracking process should continue until consent or withdrawal is obtained. The tracking process is complete once the LAR or participant has provided consent or has withdrawn. It is expected that LAR consent or withdrawal be obtained within the first 24 hours, except in rare circumstances (no LAR identified, LAR not available, participant identification is unknown, participant expires prior to consent being obtained, etc.).

For participants who expire prior to identifying an LAR or before LAR consent is obtained, consent should not be pursued further. However, once an LAR is located, they should be informed of the subject's participation. The study team should document the notification conversation. If it is not possible to have this notification conversation with the LAR or family of a deceased subject in the hospital, a "family notification letter for a deceased subject" should be used to notify the LAR or other family. The template for this letter can be found in the "Toolbox" section of the sample TBI trial website. A copy of the family notification letter (with return receipt) should be kept with the study documents.

In the rare case where no LAR consent is obtained, the LAR is never available, and the participant remains incapable of consent at six months, documentation of the attempt process and condition of the participant will be recorded on the Informed Consent Log CRF. In these cases, the final outcome will be discussed and approved by trial leadership.

DESCRIPTION OF REFUSAL OF PARTICIPATION PROCEDURES (OPT-OUT)

Individuals who learn about sample TBI trial and do not wish to participate may contact the trial investigators through the trial website, or by otherwise contacting a site study team or the CCC. At their request, their name will be put on a list of those declining to participate. Prior to the start of the study they will be provided an opt-out medical alert silicone bracelet that says "sample TBI trial declined" at no expense. Members of the public may also obtain and may wear this medical alert bracelet, or any other medical alert notification with the same message and be excluded from the trial without providing their name. Wearing the provided bracelet or any other medical alert notification that says the name of the trial and the words "trial declined" is how the individual can communicate to the care team or study team, her/his wishes to opt out of the study in the event of a severe TBI. The presence of a medical alert with the statement "sample TBI trial declined" is the metric for those with prior knowledge of the study to indicate their desire to opt out, which is an enrollment eligibility exclusion.

DATA SAFETY MONITORING BOARD

An independent Data Safety Monitoring Board (DSMB) has been established and has reviewed and approved the trial protocol. The DSMB will oversee the course of the clinical trial. The DSMB will provide ongoing evaluation of safety data as well as the overall conduct of the trial, as per institute guidelines.

APPENDIX

This appendix lists the kinds of trial specific community consultation and public disclosure materials that are created and provided as central resources for all participating sites. This would be pre-approved by the CIRB at the time of protocol review, and the unmodified content of these used by sites without further approval. If sites develop additional new and valuable materials, the CCC would send these to the CIRB for review prior to their use by the site. When approved, new materials are added to the list for subsequent use by any site.

Because these materials can be dynamic, the links on this page have been disabled. The list is included here only as an example of the kinds of materials that the study could provide.

CC Material
    Suggestions for Community Consultation Opportunities

    Meeting recruitment flyer
    Focus group moderator guide
    CC slide set - Full
    CC slide set - Reduced

    Letter to community physicians
    Letter to community members

    Survey Instruments
    Self-Administered Survey
    Self-Administered Survey – Additional languages
    Group Evaluation Survey
    Telephone Survey

PD Material
    Suggestions for Public Disclosure Opportunities

    Website and Video Content
    Trial-specific Video/Public Service Announcement (6 seconds)
    Trial-specific Video/Public Service Announcement (15 seconds)
    Emergency Research Video Scripts – Non-trial specific
    Emergency Research Video Links - Non-trial specific

    Print copy/advertisement
    Brochure
    Brochure – Additional languages
    AD/Flyer/Poster
    AD/Flyer/Poster – Additional languages

    Opt-out Material
    Opt-out bracelet request form
    Opt-out bracelet mailing letter

Additional EFIC Material

[Letter to notify families or LAR about EFIC enrollment in subjects who die prior to consent opportunity](#)

C. Standard Operating Procedure for Trial Applications involving Exception from Informed Consent (EFIC) to a Single/Central Institutional Review Board

Purpose

Our goals for this procedure are to protect the interests of human research participants to be enrolled in emergency research trials with EFIC, to respect the communities from which participants will be enrolled, to comply with applicable regulations and their intent, and to create efficiencies for both the IRB and the applicants.

Definitions

The following are operational definitions for the purposes of this procedure

CC/PD   refers to Community Consultation and Public Disclosure activities as described at 21 CFR 50.24

CCC   refers to the investigators' Clinical Coordinating Center for the trial

IRB-IS   refers to the web based IRB information system

DCC   refers to the investigators' Data Coordinating Center for the trial

DSMB   refers to the trial-specific Data Safety Monitoring Board

EFIC   refers to emergency research conducted with exception from informed consent as regulated primarily under FDA regulations 21 CFR 50.24. EFIC also refers to research conducted under 45 CFR 46.101(i) when consistent with the HHS Secretarial Waiver from October 2, 1996 -- Notice, HHS, Informed Consent Exemption for Emergency Research

CIRB   refers to the Central Institutional Review Board reviewing the application

FDA   the United States Food and Drug Administration

IND   Investigational New Drug application

IDE   Investigational Device Exemption application

CTMS   refers to a comprehensive Clinical Trial Management System

Procedures

A. FDA approval of IND or IDE identifying the plan to conduct a trial using EFIC.
For EFIC research regulated by FDA, the

sponsor will obtain approval for an IND or IDE prior to submitting an IRB application. For EFIC research not regulated by FDA, the investigators should typically provide documentation of this, such as a letter from FDA concordant with this determination. An application may proceed while the IND/IDE is on clinical hold if the reasons for the clinical hold do not contain concerns related to the protection of human research participants.

B. DSMB approval.
The applicants will present the study protocol and consent form to the study DSMB for comment, suggestions, and approval before submission to the ER-CIRB.

C. Protocol (Parent) application submission to ER-CIRB.
The applicant will submit an IRB protocol application that also includes an EFIC plan into IRB-IS. The EFIC plan will be submitted as "Additional Documentation". The EFIC plan will include the following;

a. Itemized descriptions of how the trial meets each required qualification for EFIC described at 21 CFR 50.24

b. Menu of community consultation event types and a plan for a minimum required mix of events

c. Menu of public disclosure activities and a plan for a minimum required mix of activities

d. Check off list for disease-based and geographic-based communities of special interest that will be engaged

e. Templates for materials to be used for community consultation and public disclosure

D. ER-CIRB review of protocol application.
The ER-CIRB will review the study protocol,

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consent form, and EFIC plan. If the ER-CIRB identifies concerns or requires modifications, the investigators will revise the application as needed. If the protocol, consent form, and EFIC plans are acceptable, the ER-CIRB will approve the protocol application. No CC/PD will be conducted until approval of the protocol application and EFIC plan.

E. Sites prepare individual CC/PD plans.
Sites use the IRB approved menus and the IRB approved required mix of events (from the protocol application) to develop lists of proposed individual CC/PD events and activities. The CCC oversees and assists sites throughout this site development process.

a. The site plan includes a log of proposed CC/PD events and activities, including planned dates and intended communities to be engaged. These events and activities are entered into CTMS. The ER-CIRB will also have access to these event logs in the CTMS.

b. The site plan includes a supplemental EFIC local context form that will also be completed in the CTMS with additional information about communities served by the institution.

c. If sites develop new materials for use in CC/PD these must be submitted to the sponsor, via the CCC. The CCC will submit any additional sponsor approved material to the ER-CIRB through IRB-IS via an amendment to the protocol application for review and approval prior to their use.

d. The ER-CIRB will have continuous access to the site plan (the CC/PD event logs and supplemental EFIC local context form) in CTMS throughout the conduct of CC/PD.

F. Sites perform CC/PD activities and events.

a. Sites commence the CC/PD activities and events they have listed in the log. As activities and events are completed, event forms are completed in CTMS.

b. If activities and events are rescheduled or replaced with new events, these changes are immediately logged in CTMS. In this way, site progress may be checked by the CCC or the ER-CIRB at any time.

c. Representatives of the CCC or the ER-CIRB may also use the log to plan their own visits to site CC/PD activities and events at their discretion.

G. Site application submission to the ER-CIRB.
Sites submit all information for their site CIRB
applications in CTMS, including any revisions to the
EFIC local context form. After a site has completed
its CC/PD and submitted all findings and summaries
to CTMS, these are reviewed by the CCC and a
report of findings is prepared to include as additional
documents with the site ER-CIRB application. The
CCC then submits the site application to the ER-
CIRB through IRB-IS. Click for example of a site-
specific CCC activities report.

H. ER-CIRB review of site applications.
The ER-CIRB does an explicit review of each site
application including discussion of each site-
specific CC/PD report. The ER-CIRB may use a
checklist to aid in the review of each site.
Specifically, the IRB will check if the site's
completed activities complied with the menu and
requirements in the IRB approved EFIC plan in
the protocol application, if the completed
activities reflect a sufficient portion of the
spectrum of community described in the sites
local context form, if the CC/PD performed
represent sufficient engagement and notification
of the communities, and if any of the findings
reported indicate a need for additional follow up
CC/PD. If the site application and EFIC reports are
acceptable, the site may be approved by the ER-CIRB and
permitted to begin enrollment. Site applications may be
reviewed as rapidly as submitted or may be batched at the
discretion of the ER-CIRB.

I. Reporting to the public.
Cumulative reports of CC/PD will be assembled by the CCC
and reported to the FDA docket at least annually until all pre-
trial CC/PD are completed. An additional report of post-trial
public disclosure activities will be assembled by the CCC and
to the FDA docket after the trial is completed. If the trial is not
FDA regulated, the same materials will be posted on another
public facing web-page.

J. Reporting to relying institutions.
   Sites will be able to download their own CC/PD findings report from CTMS and
   may use these to report to their own relying institution if their institution requests
   to review these internally, but this is not required. Similarly, the ER-CIRB will
   provide minutes of the review of the site application to the CCC to provide to the
   relying site if requested.

K. Protocol application close out.
   At the end of the clinical trial, all sites will report all required post-trial public
   disclosure activities in CTMS. The CCC will prepare a cumulative report of all
   post trial public disclosure activities at all sites, which will be submitted to the ER-
   CIRB with the protocol application's close out.

D. Process Guideline for Central IRB Review of Site Applications for EFIC Trials: How to Review Local Community Consultation and Public Disclosure Findings

This document is intended to provide advice to central IRB panels on potential processes they might use to guide and manage deliberations related to local context for site applications of clinical trials involving exception from informed consent (EFIC) for emergency research. The document is informed by observations of IRB deliberations of EFIC-related community consultations and public disclosure and a related stakeholder workshop conducted as part of an empirical ethics grant from the NIH Office of the Director. In addition to this qualitative research, this document is also informed by the cumulative experiences and views of the investigators. The document is meant to suggest a framework to aid in efficiency and effectiveness of the review, but is not intended to constrain IRB consideration or discussion in any way.

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Review of the trial EFIC plan in the protocol application

Prior to review of site applications for a trial involving EFIC, the IRB should briefly re-cap the trial-specific EFIC plan proposed with the previously approved protocol application. This allows the panel members to re-familiarize themselves with the quantitative and qualitative expectations of sites. These expectations describe the site self-assessments and reporting of important elements of their own local context, and the number and types of community consultation and public disclosure activities to be completed. The plan also describes the underlying goals of community consultation and public disclosure as contextualized for the application. At the IRB meeting, the IRB chair or other designated reviewer or member should be assigned to present the key elements of the plan to the full board.

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Community consultation / public disclosure site report format

Site applications for clinical trials involving EFIC will be accompanied by a consistently formatted report summarizing the community consultation and public disclosure activities performed by the site. The report format presents a brief narrative

summary and aggregated data at the front, and then many more pages of granular listings of individual comments in the rest of the report. At the time of the first site application to be reviewed by the panel, prior to deliberation of the reports content and the site application, the IRB chair or other designated reviewer or member should briefly orient the full board to the sections and structure of the report format.

Deliberation - quantitative consideration

During the discussion and deliberation of each site application, a systematic approach to the review of local context requirements may start with quantitative aspects of the site community consultation / public disclosure report. The trial EFIC plan requires a specific number of activities in more than one category of activity types. The IRB should confirm that these requirements have been met. Site applications failing to meet these criteria may be tabled and the site queried prior to further review, or the review may continue but the site application not approved until the deficiency is addressed.

The panel may also want to consider quantitative aspects of the community consultation / public disclosure report that do not have pre-defined requirements, but may be salient. The IRB may wish to consider the number of activities performed at each site, the number of participants in each event, and the number of open-ended comments or closed-ended responses collected and reported. There are no required numerical criteria for these aspects because they are expected to differ from site to site based on the nature of the activities performed. For example, sites performing in depth focus groups may have fewer participants but more feedback, while those hosting a booth at the state fair may have far more participants but briefer contact and fewer recorded responses from each. In the absence of objective criteria, the panel members should evaluate these quantitative aspects subjectively. Panel members may consider these metrics in the context of the numbers they might expect based on the type of activities reported, or in comparison to the numbers reported at other sites. In comparing to other sites, the panel should keep in mind that there will always be a range and that all sites cannot be above average.

Deliberation – qualitative considerations

The panel then should consider qualitative aspects of the community consultation / public disclosure report. First, the panel should consider whether the activities performed by the site are appropriately aligned with, and sufficiently address, the principals and goals established for community consultation and public disclosure in the trial-specific EFIC plan. For example, is there evidence for respect for community, for two-way communication in consultations, for transparency in public disclosures? The site report should be demonstrative of how principals and goals were considered.

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Consideration may be given to whether a variety of types of stakeholders participated in the site's activities. Were both geographic and disease-related communities consulted? While it is impracticable to reach all demographics in a representative manner, the panel should consider the diversity achieved in the events conducted. The panel may consider whether any parts of the community with increased stakes or special interest in the research have been adequately consulted. The diversity of community may be considered by the IRB in the context of the site's self-reported local context report, or by comparison with other sites.

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Other qualitative assessments of the community consultation / public disclosure findings include consideration of the closed-ended and open-ended feedback from participants in the site's activities. While EFIC is explicitly not a community consent process, the degree of support or concern expressed in these responses can be considered in the context of similar findings from the literature and the FDA EFIC docket for previous EFIC trials, or comparing different communities. The IRB may also consider the nature of specific concerns and any of these should preclude site participation or be otherwise addressed.

Other elements of local context review

Before completing the deliberation of community consultation and public disclosure the panel should

review and consider other elements of local context review. Site self-reporting of local context issues related to the community served, past relevant experiences with EFIC or emergency research at the site, local regulations or laws impacting the research, local medical practice patterns intersecting with the trial should all be considered if they may affect the protection of human subjects. Local IRB or other elements of the local institutional research administration also have the option of submitting information relating to local context as well. If submitted, such optional information should be considered and discussed at this point in the site review.

Board actions

These considerations of site applications for clinical trials involving EFIC are supplemental to the standard elements of site application review by the IRB. Approval based on deliberation of community consultation and public disclosure is incorporated into the IRB approval of the site application.

Queries, contingencies, or non-approval based on review of community consultation / public disclosure activities should be reported back to the sites as specifically as possible. Clear and explicit descriptions of any additional activities desired, or modifications of the application required, are necessary to rapidly providing the panel with any necessary corrective actions.

Process refinement

Centralized review of clinical trials involving EFIC is new. It is expected that the IRB and the investigators at both the Clinical Coordinating Center and the sites will identify ways to improve the content and the process over time. Mechanisms for incorporating these lessons back into systematic improvements will be pursed and supported by all parties.

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Please use this space to provide any other additional overarching comments or suggestions not previously captured.

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Appendix D:
Phase 2 Facilitated Expert Panel
Discussion Guide

Network EFIC project - Accumulated ROC/NETT experiences and findings related to EFIC: SIREN Subproject #2

Discussion Guide Preamble [OPENING SLIDE]

Thank you for taking part in this expert panel discussion. We are delighted that you have agreed to join us. My name is [FACILITATOR NAME]. I am from Westat, a research organization headquartered in Rockville Maryland, and will be facilitating the discussion on behalf of the team of researchers led by Dr. Robert Silbergleit at the University of Michigan and others involved in the SIREN Network. I am joined by my colleague, Carl Riley, who is Westat's technical expert and will be running the WebEx for us today.

As you know, the purpose of this project is to collect, share, and consolidate the experiences and scholarship of emergency care clinical trials researchers relative to implementation of **exception from informed consent (EFIC)**. You have been invited to participate because of your **experience and expertise.** We are not here to discuss the basics of EFIC, but want to take advantage of your familiarity with the fundamentals of EFIC and to build on them so we can discuss the heart of the controversies and tough challenges. We will not have time to solve any of the challenges today, but we want to make sure that we hear a range of your opinions on this topic.

Prior to this web conference, some of you were able to review and provide written comments on two documents: a draft of a scoping review of the literature on EFIC implementation, and a draft of a model operational process manual for EFIC implementation. Now we are conducting this expert panel discussion to explore and better understand areas in which experts expressed differing views or interpretations. Everyone, even those who did not provide written feedback, is invited to equally participate in today's discussion.

Before we continue, I want to stop and see if you have any questions about what I have said so far. *Answer any questions.*

Housekeeping/Ground Rules [SLIDE]

Okay, now I'd like to go over a few guidelines for our conversation today.   I'm here to guide the discussion, but I encourage you to converse among yourselves. If you would like to add to an idea, or if you have an idea that is different from someone else, feel free to speak up or use the "hand icon" in the WebEx features so I know to call on you. I may also ask to hear from individuals who haven't yet provided their perspectives.

My role is also to ensure that we do not exceed our allotted time. Since we have several concepts to discuss, I may suggest that we curtail comments if the conversation veers off course or if we need to move on to the next topic. We will aim to spend about 15 minutes on each topic.

As we are on a web conference, when you are NOT speaking please mute your line. When you do speak, unmute your line and first state your name prior to making your comment. This session will

be recorded and detailed notes taken so please speak clearly and one at a time so we can capture your input. If you are experiencing any technical issues, please use the chat function to explain the problem, and Carl and I will resolve the issue.

I wanted to note that there are others on the line from the SIREN project team, most of whom will be observers. However, the primary authors of the two documents, Dr. Robert Silbergleit and Dr. Neal Dickert, may also be engaged in the discussion to keep us on topic or to ask clarifying questions.

Are there any questions before we get started? *Answer any questions.*

Roll Call [SLIDE WITH NAMES AND AFFILIATIONS OF PARTICIPANTS]

Before we begin the discussion, I would like to confirm who is on the call. Several of you may be colleagues or have worked together on past projects and trials. When I read your name, please confirm you are on the line. [FACILITATOR READS LIST] I know that some of you indicated you will not be available for the complete 90 minutes. If you need to leave the call and/or rejoin, you do not need to say anything. We should be able to track who is with us using the participant list on the WebEx dashboard.

Set Up [SLIDE WITH NAMES OF DOCUMENTS AND LIST OF THEMES]

As a general frame to the discussion, we will be focusing on three themes that arose from the synthesis of your feedback on the draft EFIC documents. The two documents are shown on this slide:

1. Scoping Review of Literature on Implementation of Community Consultation and Public Disclosure for Research Using Exception from Informed Consent (EFIC) for Emergency Research

2. Model Operational Procedures for the Implementation and Review of NIH Sponsored Multicenter Clinical Trials with Exception from Informed Consent (EFIC) for Emergency Research.

Reviewers were instructed to provide feedback in targeted sections, specifically reflecting topics that need revision or clarification, and where there may be gaps. This information across both documents has been reviewed by the project team, and the following themes have been distilled for further discussion:

1. Theme 1: Engaging Diverse Communities
2. Theme 2: Exploring Potential Goals, Methods and Metrics of Community Consultation (CC)
3. Theme 3: Exploring Potential Goals, Methods and Metrics of Public Disclosure (PD)

We'll review each theme individually, and I will have some general and specific questions to obtain further clarification on these themes. We are not looking to gain consensus from the group, but your feedback will help ensure that these documents are useful and applicable to EFIC researchers.

Discussion

THEME 1: ENGAGING DIVERSE COMMUNITIES

1. The first theme we'd like to discuss is engaging minority communities or other communities affected by discrimination or vulnerability. **From your experience and knowledge of the literature, how do you recommend we provide guidance for researchers to ensure they include members of diverse groups in community consultation and public disclosure activities?**

    Probes:
    - Do you recommend researchers conduct community consultation and public disclosure events that target the general population? Or reach out to minority communities on their own as separate special interest groups? Or should they allow the diversity of experiences in the community to be heard without attempts at proportionality?
    - How do plans for CC and PD interact with the burden of the disease, or the burden or benefit of the research among different minority groups?
    - Should representation in CC and PD resemble that in the geographic community, or the demographics of the disease of interest, or of patients enrolled in a particular hospital?
    - What are the best ways to build trust through community consultation and public disclosure activities that target specific ethnic, racial, socio-economic, or other groups?

THEME 2: EXPLORING POTENTIAL GOALS, METHODS AND METRICS OF COMMUNITY CONSULTATION

2. The next theme we'd like to discuss is related to community consultation. **From your perspective, what does the literature tell us about the kind of goals researchers should aim to achieve from their community consultation activities** (e.g., to get meaningful input on the protocol, to demonstrate respect for persons)**?**

    Probes:
    - Describe examples of how the CC strategies or methods might differ depending on the CC goal the researcher is aiming to achieve. How feasible are these strategies/methods? How effective are these strategies/methods?
    - Should researchers prioritize the breadth of community discussions so as to increase "representation," or prioritize the quality of community discussions and other interactions (i.e., the depth of message dissemination)?
    - Should researchers target their community discussions to a geographic area, to specific underrepresented groups, or to patients with trial-specific conditions?
    - How, if at all, does the adequacy of CC activities depend on the risk of the intervention? What recommendations can you make to help researchers determine whether their CC activities will be adequate in relation to their intervention?

2b. As the next step after researchers design and implement their CC activities, **what recommendations do you have for demonstrating that they have achieved their goals**?

Probes:
- How do you recommend researchers provide evidence that their CC goals have been achieved?
- In what format should researchers report the output of their CC activities (e.g., description of CC events and attendees, protocol revisions made based on CC input)?

THEME 3: EXPLORING POTENTIAL GOALS, METHODS AND METRICS OF PUBLIC DISCLOSURE

3. Now I'd like to discuss the same set of questions but in thinking about the goals of public disclosure. **From your perspective, what does the literature tell us about the kind of goals researchers should aim to achieve from their public disclosure activities** (e.g., creating transparency, creating awareness, ensuring an understanding of the trial)?

   Probes:
   - Describe examples of how the PD strategies or methods might differ depending on the PD goal the researcher is aiming to achieve. How feasible are these strategies/methods? How effective are these strategies/methods?
     Probe for recommended methods to achieve specific goals:
       - Create transparency
       - Create awareness
       - Ensure knowledge, recall or understanding of the trial
   - Does the literature and you past experience support a recommendation that researchers aim for large numbers of respondents like what one can achieve using random-digit dialing or certain types of social media, OR do we emphasize smaller numbers of more human face-to-face interactions directly with investigators?
   - How, if at all, does the adequacy of PD activities depend on the risk of the intervention? What recommendations can you make to help researchers determine whether their PD activities will be adequate in relation to their intervention?

3b. As the next step after researchers design and implement their PD strategies, **what recommendations do you have for demonstrating that they have achieved their goals**?

   Probes:
   - How do you recommend researchers provide evidence that their PD goals have been achieved?
   - In what format should researchers report the output of their PD activities (e.g., in metrics, in qualitative summary, some other demonstration of success)?

Closing Statement

Thinking back to our discussion, does anything else come to mind that you think might be important?

- ➢ Drs. Silbergleit and Dickert, do you have any follow-up questions you would like to ask or clarifications you'd like to make at this time?

Thank you for participating. You have all worked hard and we have learned a great deal from you. We appreciate your help with this important topic.

Appendix E:
Phase 1 Expert Panel Document Review
Summary Tables

Scoping Review of Literature on Implementation of Community Consultation and Public Disclosure for Research Using Exception from Informed Consent for Emergency Research

Summary of Phase I – Feedback from Reviewers[4]

SECTION	FEEDBACK	TYPE[5]	DETAIL
Community Consultation Reports (boxes 1-5)	Restructure or relabel this section	Revision	e.g., section can be called "Forms of Assessment" and include Surveys, Qualitative Reports, etc. under this section; change "Inconsistent Metrics" to strategies
	Detail results from each method as sub-sections	Revision	
	Add more description of surveys	Clarification	Include type of format (in-person, anonymous, electronic, paper), type of question (Likert scales, open-ended questions), strength of random digit dialing and electronic surveys, and reference FDA Docket 955-1058 re: survey sample size and community consultation
	Add more description of community consultation	Clarification	e.g., includes two-way communication, focused on community impact and not individual acceptance
	Include information on how to interpret the meaning of each type of result	Clarification	
	Provide more definition of "community" in the studies reviewed	Clarification	e.g., US only; did studies make individual-level or group-level comparisons; definition of 'relationships;' describe community where research will be performed and community where participants will be drawn
	Add more description about focus groups and meetings	Clarification	e.g., presence of a trained facilitator; open to the public; town hall

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[4] Feedback is not verbatim but summarized for presentation. Excluded: Duplicative feedback re: content, general positive comments, and indications of agreement

[5] Feedback type classification: **Revision** (refers to comments about edits, wording, terms used, or reorganization of sections of the document; **Clarification** (specific suggestion for elaboration or different information about a topic introduced in the document); **Gap** (refers to the absence of a relevant, substantive topic or something identified that is missing from the document)

	Describe whether results vary by trial/topic (e.g., cardiac arrest, TBI)	Gap	
Public Disclosure Reports (boxes 6-8)	Add detail about opt-out rate frequency	Clarification	
	Specify that public disclosure occurs before, during and after the study	Clarification	
	Specify that "pre-consenting" an entire community may not be possible	Gap	Text expresses well the criticism that distribution metrics do not translate to public awareness
	Specify that ethnic distribution of the expected patient population should be targeted	Gap	target and actual audiences are not always the same
Conceptual or Policy-Focused Literature on Community Consultation and Public Disclosure (boxes 9-13)	Move this section up to the Community Consultation and Public Disclosure sections	Revision	they describe the analysis of CC/PD and the value of different methods
	Add data on how often CC concerns are raised, if protocols have been modified based as a result, and how often IRBs participate in CC activities	Gap	
	Differentiate between the purpose/intent of CC versus its value	Gap	terms like "intrinsic" and "extrinsic" are not helpful
	Address the idea that PD and CC should occur while the protocol is being developed and at a national level, but still have local sites do PD to allow for output	Gap	
	Add detail about reported acceptance rates by CC method and rates of opt-out use	Gap	
	Describe problem of poor community comprehension of research-related concepts	Gap	consider adding that PD communications are reviewed and edited for health literacy
Discussion (Boxes 14-25)	Suggest revising the description of regulations from "novel" to "challenging and subject to vast interpretation"	Revision	
	Insert a grid of method by goals and resources	Revision	Agree with value of multiple methods
	Clarify whether there is evidence besides select publications to support that CC efforts have fallen out of favor	Clarification	

Clarify why there are questions about whether CC should be qualitatively or quantitatively focused when the regulations require both	Clarification	suggest adding that it might depend on the generalizability of the condition under study	
Clarify that the regulations require both the geographic and targeted communities be involved in CC (and that targeted community members can be part of the geographic community);	Clarification	suggest reviewing Kahn, Mastroianni, and Sugarman, Beyond Consent Seeking Justice in Researc	
Clarify that the reduction in value of large-scale population-based efforts is a matter of opinion	Clarification	there could be confounding factors (e.g., benefit of random digit dialing, challenge of community comprehension)	
Clarify that individual acceptance is not the goal of CC	Clarification	but to ensure that the respondents understand the reasons why IC cannot be obtained and if the study should be conducted in their community, and to ensure the respondents understand the difference between research and treatment	
Emphasize that the regulations allow for variation in methods	Clarification	suggest surveying patients/families part of EFIC studies	
Clarify that penetration/awareness is the issue with PD coverage versus the amount of coverage	Clarification		
Emphasize that two-way CC exchange reflects the importance researchers place on establishing trust/respect with the community	Gap		
Emphasize that surveys are easier to complete but there is an issue with community comprehension; consult FDA docket for other forms of CC and PD	Gap		
Add discussion of post-study public disclosure	Gap	including a report of who was enrolled in the EFIC study	
Add use of marketing professionals (vs research staff) to improve CC/P	Gap		
Specify that CIRBs and PIs should ensure mutual agreement on expectations	Gap	an emerging model is for the CIRB to decide if the study qualifies for EFIC	

General Feedback (Box 26)	Suggest restructuring paper to start with conceptual material/normative basis for EFIC regulations and for judging whether activities reflect reason for the regulations	Revision	
	Reference #s34 and 59 are the same	Revision	
	Add to the conceptual literature list: Smirnoff M, Wilets I, Ragin DF, Adams R, Holohan J, Rhodes R, Winkel G, Ricci EM, Clesca C, Richardson LD. *A Paradigm for Understanding Trust and Mistrust in Medical Research: The Community VOICES Study* (PMID: 29368998)	Gap	
	Add text re transparency in CC and PD, given that regulations require evidence of PD in FDA docket	Gap	
	Add text re non-mandatory but strongly recommended FDA regulation	Gap	

Model Operational Procedures for the Implementation and Review of NIH Sponsored Multicenter Clinical Trials with Exception from Informed Consent (EFIC) for Emergency Research

Summary of Phase I - Feedback from Reviewers[6]

SECTION	FEEDBACK	TYPE[7]
Introduction (box 1)	Use language consistent with FDA guidance	Revision
	Reframe the document so that it serves as a general EFIC guidance document that can be used for various types of conditions	Revision
	Clarify the enrollment process and the LAR's role	Clarification
	Include language on the importance of protecting patients' rights, informed consent, situations when informed consent cannot be obtained	Gap
Overview (box 2)	Clarify the purpose of the document, include background of the TBI study, EFIC and decision points	Clarification
	Clarify language about participant data collection following withdrawal of the study	Clarification
	Revise language to explain that enrollment in EFIC studies does not preclude the LAR consent	Clarification
	Revise language re: procedures to provide information about the emergency research per 21 CFR 50.24	Clarification
	Include language about therapeutic window, key decision points for searching for LAR and enrollment into trial per FDA guidance	Gap
Regulatory criteria for use of EFIC (box 3)	Include a transition to describe the focus on EFIC	Revision
	Streamline specific discussion on TBI	Revision
	Describe if patients in this study meet the HHS/FDA guidance definition of life-threatening?	Clarification

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[6] Feedback is not verbatim but summarized for presentation. Excluded: Duplicative feedback re: content, general positive comments, and indications of agreement

[7] Feedback type classification: **Revision** (refers to comments about edits, wording, terms used, or reorganization of sections of the document; **Clarification** (specific suggestion for elaboration or different information about a topic introduced in the document); **Gap** (refers to the absence of a relevant, substantive topic or something identified that is missing from the document)

	Clarify what is meant by "sample" trial and if this refers to a proposed or actual trial	Clarification
	Provide justification on why it would be impractical to conduct the trial as a non-EFIC study	Gap
	Include language about therapeutic window	Gap
Regulatory protections for implementing EFIC (box 4)	Rename section title	Revision
	Clarify acronyms (e.g., CIRB)	Revision
	Clarify how this study is conducted without an IDE, which contradicts 21 CFR 50.24(d) which indicates these studies must be conducted under a separated IND/IDE	Clarification
	Clarify mention of NINDS in document, how this relates to all EFIC studies	Clarification
	Clarify that EFIC enrollment is not an alternative to LAR/Family consent, as stated in the document	Clarification
	Describe the process if e-consent is used rather than paper consent	Gap
	Explain how a non-LAR relative can refuse consent to participate	Gap
	Describe under what circumstances public disclosure would occur during enrollment	Gap
	Mention FDA's guidance on data monitoring committees	Gap
Community consultation principles (boxes 5-8)	Clearly distinguish between public disclosure/informing vs. community consultation informing	Clarification
	Describe that there is a significant degree of agreement re: CC forms through network research structures	Gap
	Include historical context of racism and patient enrollment without consent, need for CC to include members of minority groups	Gap
	Address the detailed discussion on geographic community. Discussion of racial, ethnic, and age community of patient population should be emphasized instead.	Gap
	Include sentence that encourages exploration of the definition of the community between the investigator and the IRB of record	Gap
	Increase emphasis that certain communities (the poor, people of color, or ethnic minorities) should especially be included if appropriate for condition and location of study	Gap
	Consider including recommendation on who is appropriate to conduct CC activities	Gap

	Include mention of importance of translated materials	Gap
Community consultation menu (boxes 9-16)	Ensure that this section is cohesive with rest of document, as this section is more general and not trial specific	Revision
	Consider including the following in the survey described (in "Visits to existing meetings or existing groups" section): age, race/ethnicity, gender, education, and experience with the condition being studied; and brief knowledge check questions	Revision
	Reference the source for the 80% statistic (adults accessing social media)	Revision
	Replace BOOST3 with "sample TBI study"?	Revision
	Clarify why there should be a mix of at least 6 required activities and how this number was derived, evidence of this number of activities	Clarification
	Consider providing basis for the recommended presentation length of 10-15 minutes (in "Visits to existing meetings or existing groups" section)	Clarification
	Note the role of observer/note-taker at the meetings, i.e., to observe and create record of the interactions and document questions/concerns raised by attendee	Clarification
	Partnering with community leaders who can encourage community participation has been a valuable approach	Clarification
	Consider providing the basis for why an investigator should be present for a meeting but may or may not be present at focus groups	Clarification
	Comment on any anecdotal reports of meetings that were highly attended	Clarification
	Reviewers agreed there are limitations to RDD; one reviewer commented that their IRB determined that RDD is not an appropriate CC activity	Clarification
	Mention that the strength of RDD is that responses can be weighted to match the age, gender, race, and ethnic distribution expected in the study	Clarification
	One reviewer disagreed with the statement "Large telephone surveys can provide the most statistically representative description of community responses to questions about the study and EFIC"	Clarification
	Note that, to make valid comparisons, the same survey should be used across sites	Clarification
	Provide specifics on monitoring reach of CC activities	Gap
	Consider mentioning the need to have 2-way communication if using a survey	Gap

	Consider describing ways to measure the impact of community events (e.g., the number of conversations)	Gap
	Consider adding recommendations to leverage institutional social media accounts and PR interfaces, and engaging professional organizations in social media efforts	Gap
	Consider describing ways to measure impact of social media approaches	Gap
Reporting community consultation results (box 17)	Demographics of the study area should also be included in the report	Clarification
	Discuss how the results of CC shape the conduct of trials	Gap
Public disclosure principles (boxes 18-20)	Delete "In fact, the more benign and acceptable the content of a public disclosure is, the less likely it will be internalized and recalled" because it is unclear how it can be operationalized	Revision
	Consider including that the messages need to be consistent and IRB approved	Clarification
	Gratitude may not be appropriate in all cases and could be misinterpreted	Clarification
	Gratitude to subjects and their families should be done on a personal level, in addition to other broader approaches	Clarification
	Press releases, alone, might not be considered a public disclosure method	Clarification
	State whether "at least 6 total PD activities" is an NIH policy	Clarification
	One reviewer thinks the best measure would be the number of people aware that a trial is taking place	Gap
Public disclosure menu – Pre-trial (boxes 21-23)	Engaging professional organizations might boost reach	Clarification
	Number of website hits can help determine impact	Clarification
	Include specific disease-community websites and neighborhood specific websites/listservs	Clarification
Public disclosure menu – Post-trial (box 24)	Note that post-trial PD must include the demographics of the participants in the trial	Clarification
	Consider sending summary letters to partner organizations	Clarification

Contacting a legally authorized representative (LAR) (box 26)	Provide references to the federal regulations re: how a non-LAR relative can refuse consent	Revision
	Recommend changing "… the LAR highest in the local hierarchy should give consent" to "…the LAR highest in the local hierarchy should be asked to provide consent"	Revision
	Revisit the sentence stating "informed consent process is performed"—revise to "discuss risks and benefits"?	Revision
	Clarify the intent of "the LAR highest in the local hierarchy" (e.g., the LAR highest in the jurisdiction's legal hierarchy?	Clarification
	Clarify whether or not NIH requires obtaining informed consent for continued participation in the study	Clarification
	Include the concept of "continuous" public notification throughout the trial	Gap
Refusal of participation procedures (Opt-out) (box 27)	Consider commenting on the response if subject carries a DNR/DNI card/bracelet or has DNR/DNI documentation at the institution	Gap
C. SOP for trial applications involving EFIC to a single/ central institutional review board (boxes 29-34)	Clarify what is meant by "an application may proceed" in the context of the IND/IDE being on clinical hold; or delete if inaccurate	Clarification
	Clarify what is meant by "approval of the protocol application" (e.g., by whom?)	Clarification
	Note that CC feedback might lead to important changes in the clinical trial	Gap
D. Process guideline for central IRB review of site applications for EFIC trials (boxes 35-41)	Sites should provide local demographics and any special considerations- similar to local context issues provided for CIRB submissions for non-EFIC studies	Clarification
	CC/PD plans should be fully reviewed before implementation, and IRB expectations should be clear to sites	Clarification

Appendix F:
Phase 2 Facilitated Expert Panel Discussion Notes

Network EFIC project - Accumulated ROC/NETT experiences and findings related to EFIC: SIREN Subproject #2
Expert Panel: FINAL WEB CONFERENCE NOTES – 2020_02_13
Notes: Speaker comments not professionally transcribed. Unasked probes are highlighted below in grey.

Are there any questions before we get started? *Answer any questions.*

NONE.

THEME 1: ENGAGING DIVERSE COMMUNITIES
4. The first theme we'd like to discuss is engaging minority communities or other communities affected by discrimination or vulnerability. **From your experience and knowledge of the literature, how do you recommend we provide guidance for researchers to ensure they include members of diverse groups in community consultation and public disclosure activities?**

   Probes:
   - Do you recommend researchers conduct community consultation and public disclosure events that target the general population? Or reach out to minority communities on their own as separate special interest groups? Or should they allow the diversity of experiences in the community to be heard without attempts at proportionality?

Ben Abella: It's important not to reach out to minorities blindly, but rather try to match your local environment. Equal representation of various minority groups sounds good, but it is more important to mirror the community in which you are doing consent. E.g. if primarily enrolling a Hispanic community, then reflect that. Some people do a blanket approach to include all minorities, but if it doesn't mirror the local community—and one can put it a lot of effort—it doesn't really make sense.

Sara Goldkind: I agree with that. Depends on what the study is and who might be the most affected minority population based on the study itself. It's important to go into the community—and not expect minorities or individuals to come to CC activities but to go into their communities in a way that reflects the importance of certain sites or community events for them, e.g., barbershops in Black communities and maybe churches, and so forth. I think it depends on the scientific goals of the research and what the

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disease or condition is of study, which minority groups will be most affected. CC materials and activities need to be tailored to the important centers within those communities.

Gail Povar: I'm in vigorous agreement with what has been said. Challenge with articulating what we ought to be doing with no regulatory guidance on this. At IRB level, the challenge is to figure out how directive to be and what is acceptable. We have seen really engaging and creative ways to reach out to communities, from meeting with chaplains and going out to religious groups. One site talked to Spanish interpreters at hospitals to figure out how to reach community, they said here is a community leader- go for a walk with him. PI went for a walk in the community and met with leaders. There are a lot of ways of doing this that are important and reflect what's been recommended—i.e., tying it to metrics of specific institution and its community, and making sure it's not institutional based, but community based. It would be very helpful for IRB for there to be some sort of guidance, because the FDA regs are understandably extremely vague. It's possible for IRBs to differ dramatically based on their interpretation.

Tom Aufderheide: I think it's the wrong question. You need to start with the study you are doing and understand what your expected ethnic distribution of the population that will participate in study and address those communities within your own community accordingly. Re: lack of guidance… I think it's a double-edged award. In 1995, FDA specifically didn't mandate certain approaches because every community is different, and there are different approaches that are most appropriate for that local population. So, they were intentionally vague. I raise consciousness of group to be careful re: what is mandated or said about what people have to do—it's a wide world and every community is different. What is optimal for one community might not be optimal for another community.

Opeolu Adeoye: I agree with what a lot of what has been said. Principle that research community expecting each EFIC study to be different is essential because it depends on the study, and depends on the community, so we should expect every single study to be different. Back to the original question – it is essential that minority communities in fact be sought out. Investigators do not know their own blind spots. I can't think of a justification for an EFIC study that says "this particular participant population is not likely to be involved." From BOOST study experience with Advarra, we found that we targeted people accessible to us, we reached a largely educated African-American community. When we gave education levels to Advarra, the IRB asked us to target an uneducated African American cohort because that is actually a huge portion of the population that was likely to be enrolled in study. We were not aware of that blind spot. I differ with Tom on the use of targeted efforts.

Tom Aufderheide: I completely agree. We need to reach out to everybody, but base your focus on what your expected ethnic distribution is.

Harry Selker: First thing to do is, start with the right sites to engage the diverse communities. SIREN has the opportunity to pick diversity of communities to be able to engage diverse communities.

Will Feldman: It seems most agree there needs to be some matching between people engaged and enrolled. One concrete thing we found in our research is the % of AA enrolled in these trials tend to be in high 20% range, whereas % of AAs surveyed is closer to 15%. In as much as surveys are part of CC, that is one concrete way to get more minority voices.

Mike Linke: Once we've identified the community we need to engage, then it's important to identify leaders of those communities and start there. This seems to work best in EFIC in Cincinnati. It's important to identify the leaders of those communities.

Sara Goldkind: FDA guidance identifies reaching out to community leaders might be a good idea when doing CC. I'll echo what others have said-- the challenge in writing guidance on broad regulations is to allow a broad array of different options that are suitable for particular studies. FDA regulations and guidance are largely permissible for a large array of CC and PD activities, which I think is advantageous. They've identified certain principles that are important to guiding those activities, but they are not proscriptive. That is one of the advantage of docs such as the MOP, and including a wide array of activities. It's a real strength of the document. It can be a resource for IRBs and investigators.

Gail Povar: Each site should have a lot of flexibility in how they reach out to their communities. Floor/ceiling issue with regs. I'm hearing people say FDA is being permissive. If IRB is central and doesn't know the local community, its important to have some self-awareness on how to let community know it appears to have blind spot without being too prescriptive. It's challenge for IRBs to walk the line between telling community they may not be doing optimal job and respecting local knowledge.

[LIZ – posed question about historical origins of distrust….]

James Paxton: it should be part of game plan to make efforts of engaging minority communities well known and visible.   Part of building trust that may have been violated in the past. In Detroit, the mostly African American patients are distrustful of research and would be of this technique. Drawing attention through media or otherwise is an important aspect.

[LIZ – posed question about other pathways…]

Art Derse: When research is being done, it's typically done through an academic institution. It's important to have good relationships with patients in clinical and therapeutic settings, before researchers wants to "enroll patients in study in this way…" Some of the way has to be paved with the institution's relationship already with the community.

[LIZ – posed question about pre-engagement…]

Art Derse: Yes, I think that's right.

[LIZ – asked for recommendations for researchers re: pre-engagement…]

Mike Linke: In Cincinnati, through our CTSA/CTSP, there are research advisory panels. One is based in African-American neighborhood. Couple EFIC studies used that group as part of CC.

- How do plans for CC and PD interact with the burden of the disease, or the burden or benefit of the research among different minority groups?
- Should representation in CC and PD resemble that in the geographic community, or the demographics of the disease of interest, or of patients enrolled in a particular hospital?
- What are the best ways to build trust through community consultation and public disclosure activities that target specific ethnic, racial, socio-economic, or other groups?

THEME 2: EXPLORING POTENTIAL GOALS, METHODS AND METRICS OF COMMUNITY CONSULTATION
5. The next theme we'd like to discuss is related to community consultation. **From your perspective, what does the literature tell us about the kind of goals researchers should aim to achieve from their community consultation activities** (e.g., to get meaningful input on the protocol, to demonstrate respect for persons)**?**

Ben Abella: In literature… the ability to potentially modify materials based on community feedback. The community may offer suggestions re: what is clear or it's important to understand this or that aspect. Which is valuable. We are into our science, communication piece to the public sometimes needs adjustment.

[LIZ – ….goal for researchers?]

Ben Abella: Think it is an actionable goal [modifying materials based on community feedback].

Alex Limkakeng: In the era of CIRBs (e.g., BOOST 3 trial), it feels disingenuous to do CC when protocol is IRB approved and essentially fixed in local context. Conducting CC when there is no means to radically change the protocol or impact the CIRB's broad assessment of the protocol. There should be some element of CC done centrally before going to local communities, or it could be done in a number of representative local communities as part of IRB deliberations.

[LIZ – examples?]

Harry Selker: This is not well addressed; CIRB does not abrogate needs of local communities. There are people who are trying to lay this out. But, this would be a great document to do that [reference to MOP?]. The local sites' responsibilities isn't well articulated in many places. Good point.

Tom Aufderheide: Thought what Adavrra did for BOSOT3 was phenomenal. It gave every site a selection of approaches from a table to adapt an optimal approach locally. From an IRB standpoint, I thought that was an excellent way to approach this. Deserves to be included.

Mike Linke: Strokenet CIRB, we reviewed an EFIC study. For grant reasons, they needed protocol approved before CC. They indicated in letters that it may need to be revised based on results of CC...we were aware of that when we approved the protocol.

Gail Povar: Two issues: How to figure out how to do CC? We talked with Mike Linke and other IRB members-- focus groups might be a good place to start before CC fully articulated. FGs can let investigators pilot test materials and plan, and get feedback from community members. I imagine IRB would be happy to see that sort of process. The 2nd issue is the IRB's protocol approval before communities seeing it. FDA says that IRB has authority to change protocol based on CC feedback data, but not sure how that is handled. It will depend on quality of data we get from community. Changing protocols assumes you are getting high quality community data—and I'm not sure we know how to judge that yet.

James Paxton: My concern is when we have a protocol through IRB, the community decides don't like something and we change it. Do we go back to community and let them know it's been changed. They may have more opinions about that [change]. Do you go back to them a second time?

Opeolu Adeoye (uncertain): I'm thinking of the administrative burden and scale of administrative burden. E.g., LA requires a certain protocol change, then NY versus Tallahassee... I scale that quickly in my head, and it becomes untenable and may compromise the quality of the study questions. E.g., if each site wants different protocol modifications.

> **Probes:**
> - Describe examples of how the CC strategies or methods might differ depending on the CC goal the researcher is aiming to achieve. How feasible are these strategies/methods? How effective are these strategies/methods?
> - [LIZ – rephrased this question - Should researchers prioritize the breadth of community discussions so as to increase "representation," or prioritize the quality of community discussions and other interactions (i.e., the depth of message dissemination)?

Michele Russell-Einhorn: Go back to last conversation – we have to expect any protocol will be modified down the road-- it's the nature of research. CC is different from the ongoing responsibility for PD, you need to look at it with common sense perspective. If initially you describe protocol in certain way, and modifications don't change fundamental nature of the research, then I don't think you need to go do another CC or look to re-consent people, depending on how the whole thing is framed. But may play into a need for PD about how the research initially described to the community has changed. I worry about getting too caught up in, if we change protocol we'll have to do this or that. [Want to] thank everybody. But have to agree that we don't want guidance from government because it becomes too proscriptive. I think that local contexts vary, and who knows how that will change down the road. We really need guidance for IRBs and investigators in particular. Is this group putting together guidance to go out to investigators that would help them understand at least general concepts about PD and CC?

[no comments from group]

[LIZ – back to question I asked before, does the panel have any feeling whether researchers should focus on broad representation or more targeted in-depth methods for the community—or might it depend on the research?].

Unknown: Think there should be both [pathways].

Sara Goldkind: I agree as well.

[LIZ – what if both strategies conflict or there's not enough time in the day?]

Opeolu Adeoye (uncertain): Back to Cincinnati example, research advisory panels…we have defacto focus groups. Have overall research expertise but not expertise about each exact study. Sets them apart. Have blind spots just like investigators do. They counsel us in the outreach, and then in the outreach we capture broader opinion. I don't think it doesn't overtly conflict. We have scenarios where we learn from advisory panels and advisory panels learn from community. Suggest that we as investigators and advisory panels or FGs have to be open to learning from community at large.

James Paxton: I would recommend diversity over depth. I'd like to have as many opinions as possible—even if its gut reaction-- if it represents more of the community. It's nice to have in-depth conversations, but I would rather have a broad range of opinion rather than a really deep opinion from one person.

Alex Limkakeng: The way I envision both-- one question we are asking folks in CC, we have patient advisory councils – ask them how can we do PD better? Having the first step of in-depth panel on how you can do the broad outreach. Have a panel guide you on your broad outreach. Can guide you on how to do it better. E.g., one member is on the board of previous TBI survivors and she will connect us to that group to publicize about the study. CC can set up your PD.

- Should researchers target their community discussions to a geographic area, to specific underrepresented groups, or to patients with trial-specific conditions?
- **LIZ** - How, if at all, does the adequacy of CC activities depend on the risk of the intervention? What recommendations can you make to help researchers determine whether their CC activities will be adequate in relation to their intervention?

[Liz rephrased. Do you have any recommendations we can make?]

Gail Povar: Assume [this is] tied to metrics, and interested in benchmarking and I'm mindful of the comment about surveys…Can we hear from people re: whether they think there is such a thing as proportional representation from the community, in terms of number of participants and if should that be correlated to size of the institution in some rough way? And how specifically written surveys collected might be used as a metric in terms of numbers and adequacy for specific responses, in terms of the ns for each response. Don't know the answer, can group address?

Alex Limkakeng: Like Tom from Wisconsin mentioned layout of activities and options from BOOST 3 trial incorporated into the model EFIC procedures document. For BOOST 3, they set out a defined quantitative amount of activities in various categories and recognizing it might not be be-all and end all, but measurable and seems reasonable and feasible. So that's a pretty good source of good guidance for

future IRBs. We could argue about specifics but is reasonable and feasible, and seems to match the goals of CC and PD.

Will Feldman: Comment on surveys. I don't conduct EFIC trials but sifted through surveys done. Surveys are helpful. I noticed a lot of heterogeneity in how questions are worded even within same trial, sites will word things differently. If someone is trying to compare, it becomes difficult to compare across sites or across trials. If surveys continue to be a part of CC, ideally more standardization in terms of the questions and how it all gets reported. There is a tremendous amount of info that's been collected. But can be challenging to access… as we think about metrics, the questions about what is the right threshold for saying people agree is hard, because even looking at questions that can be grouped together e.g., re; willingness to be enrolled, there is lot of variability in wording, so hard to talk about threshold with the heterogeneity.

Robert Silbergleit: There are some real tensions. Is good survey methodology good CC, and vice versa? This comes up with controversial topics like RDD, which is arguably the best surveying method for CC, but a lot of people don't like for CC because not personal, it doesn't give investigators the opportunity to sit across the table and talk to somebody. Tension between depth and quality of survey tends to be there. What IRBs and and sponsors demand will drive what we do. Whether we want to drive toward more face-to-face things or better survey methodology. Survey methods done so far are very limited from survey standpoint. I struggle with this tension. Others?

Tom Aufderheide: Crucially important issue. Personal opinion, each approach has strengths and weaknesses. One on one interactions with community are terrific, but Personal [approaches] only reach so many people. RDD has a strength. Black community 26% but only 20% responded in RDD, you can weight to assure 100% ethnic coverage, and weighed samples that directly reflect the ethnic distribution you are targeting, and no other approaches can do that, but there are downsides – e.g., no one on one interactions. I'd advocate for multiple approaches to maximize the strengths of all the different kinds of the approaches.

Gail Povar: I agree with all of that. These menus [reference to MOP document] should push not just 2— but maybe 3 or 4 from each "column" – so there is wide spread of activity even though it may challenge the sites and address complementarity people are mentioning. Also the menu - credit to Rob et al., good effort – is a superb shortcut but needs to be fleshed out [more] re: what the options mean. Even within each section, here is what we think the best way to do it… Maybe language that says, this just isn't aspirational, describe floor and ceiling. Increasing the variety of activities that sites use can address the comments about each method having strengths and weakness.

[LIZ – advantages and disadvantages of one over other? And other comments re: methods?]

Mike Linke: Random digit dialing. In our last EFIC study, we were asked not to do RDD because of coverage. [muddled] institute for policy research…there are real problems with random digit dialing, especially using auto-dialers… in our consultation with experts, we decided that RDD was NOT a good approach. Other issue, lot of people use cell phones now. Cell phones does not suggest community localization. Discouraged use of RDD for CC.

[LIZ – any other thoughts? - there were NONE]

2b.   As the next step after researchers design and implement their CC activities, **what recommendations do you have for demonstrating that they have achieved their goals**?

Probes:

- How do you recommend researchers provide evidence that their CC goals have been achieved?
- In what format should researchers report the output of their CC activities (e.g., description of CC events and attendees, protocol revisions made based on CC input)?

THEME 3: EXPLORING POTENTIAL GOALS, METHODS AND METRICS OF PUBLIC DISCLOSURE

6. [LIZ - Now I'd like to discuss the same set of questions but in thinking about the goals of public disclosure. **From your perspective, what does the literature tell us about the kind of goals researchers should aim to achieve from their public disclosure activities** (e.g., creating transparency, creating awareness, ensuring an understanding of the trial)?]

Ben Abella: "CYA" – there is no feeback loop, maybe a radio or nerwspaper ad. Like a checkbox. There is a need for delineated mechanism for feedback -- phone number, email, probably several different mechanisms.   Gotta be multiple mechanisms for feedback, may not have access to email.

Alex Limkakeng: Two thoughts re: metrics. Modern age with social media, it is much easier now, e.g., Twitter account can see how many people viewed tweet. Through other social media platforms, it's much more feasible to get a sense of how many eyes have seen your PD announcement.   Opportunity to start collecting data on what is common or the norm for PD activities. Compared to CC, which should be done locally, it seems there is opportunity to emphasize central PD a bit more. The NIH sponsors EFIC studies – they are excellent at disseminating info about health, seems good way to have central resources in general for EFIC that could be leveraged for all EFIC studies. Surgeon General disseminates information on health. A resource that could be there but is not for local investigators.

[LIZ – 2 prongs. Centralized PD to reach broader audience? But also researches should conduct localized face-to-face?]

Alex Limkakeng: Yeah, but even on the central side. Most have a central coordinating center with website for local sites…Seems like our national organization could have EFIC general info that is patient and media friendly so not such a foreign concept…normalize it, so people see that it has been tried nationally for 30 years and is not a foreign concept.

[LIZ – what are the goals of PD? What should they be? What looking to achieve/demonstrate with PD plan?]

Tom Aufderheide: This is a very important question; I don't have an answer. Over the years, we've had people with loved ones enrolled who say I never heard about this, [that] you were inadequate in your PD. So we double up our PD when someone says that. One message is: you can't get into everyone's head no matter how much PD you accomplish. That needs to be said.   I look to group re: goal.

Gail Povar: We had a wonderful image one of our IRB members said, our goal should be that institutions don't shoot themselves in the foot in the public square. Don't demonstrate absence of good faith effort. Trying to figure out outcomes on PD is almost impossible. The process is what is important rather than trying to measure an outcome. I think it's about a good faith effort. I think it's more about the process than trying to measure the outcome. A good faith effort would include some of the same things as CC. Make sure you have reached out to your catchment area. Reach out to your digitial/aural media in that area, use of social media can't be too heavily depended on – it won't reach people over 65 very much. I think the emphasis should be on process not outcomes. Process should represents good faith effort, just like CC, to reach the population that uses the institution and likely to be in involved.

Alex Limkakeng: Agree. Easier to say what it is NOT the goal, than what is NOT the goal. State the goal is not community informed consent. It's not a (reprimand?) on the study. Explicitly state that – it was in document. Be transparent. Not possible to disclose every possible risk and have everyone see it or understand it, given what everyone is paying attention to in the media. It wouldn't be feasible. Can't reach everyone or document that you have reached them.

[LIZ – other thoughts? Goals of PD? - NONE. Additional thought definition of adequacy in relation to risk of the intervention? NONE. Turn over to Rob and Neal….]

> **Probes:**
> - Describe examples of how the PD strategies or methods might differ depending on the PD goal the researcher is aiming to achieve. How feasible are these strategies/methods? How effective are these strategies/methods?
>   > *Probe for recommended methods to achieve specific goals*:
>   - Create transparency
>   - Create awareness
>   - Ensure knowledge, recall or understanding of the trial
> - Does the literature and you past experience support a recommendation that researchers aim for large numbers of respondents like what one can achieve using random-digit dialing or certain types of social media, OR do we emphasize smaller numbers of more human face-to-face interactions directly with investigators?
> - How, if at all, does the adequacy of PD activities depend on the risk of the intervention? What recommendations can you make to help researchers determine whether their PD activities will be adequate in relation to their intervention?

3b. As the next step after researchers design and implement their PD strategies, **what recommendations do you have for demonstrating that they have achieved their goals**?

Probes:
- How do you recommend researchers provide evidence that their PD goals have been achieved?
- In what format should researchers report the output of their PD activities (e.g., in metrics, in qualitative summary, some other demonstration of success)?

Closing Statement

Thinking back to our discussion, does anything else come to mind that you think might be important?

➢ Drs. Silbergleit and Dickert, do you have any follow-up questions you would like to ask or clarifications you'd like to make at this time?

Robert Silbergleit: Neal you go first since I already asked one question.

Neal Dickert: Thanks everyone for being here and for comments on documents and thoughts today. Will mentioned challenge with survey methodology is the different formulations of question, which matters – content and phrasing. Difficult to compare but at same time relative frequency of agreement is often quite uniform within narrow range of studies and across contexts. Wondering what the likely reactions are…are there ways in which repeating this is helping us or is it doing same thing over and checking the box? How are we adding value and how can we be most helpful in thinking about tips for doing this better?

Opeolu Adeoye: Checking box comment. Every time we do it, it's very different. People we are reaching are very different. It just needs to be done again and again. It gets at earlier point about accepting that each study is different. Have to check the box for this study, and have to check the box for the next study, which is different.

Neal Dickert: Interactions with people are different, but seems like survey responses are in a narrow range. I was thinking specifically about the assessment tools and methods.

Alex Limkakeng: Having a broad openly available survey as form of PD allows anyone who can find survey link….democratization of the process. Anyone who accesses the link can comment. Focus groups are invited and perhaps targeted, not open to anybody to provide comment. It's not so much about the process but about the transparency.

Robert Silbergleit: New topic. Goals re: diversity. There is tension we come up against…went to a general community event, make sure it approached the community with diversity that reflects the community we are talking about. If % of racial/ethnic minority, we want the general population group to reflect that as well. Other way to reach diversity have specific events with these specific groups in

isolation….seems like there is a difference between these two. Assume you have a general population group that is balanced, would you still want to go out to do the individual groups?

Tom Aufderheide: I think you do. Can be cultural differences in attitudes toward approach that are import to solicit.

Sara Goldkind: One of the goals of both CC and PD is promotion of transparency. Another is promotion of trust between research institution and research community/catchment area - those potentially part of research, where subjects will be drawn.   Have to ask the question raised by Rob with that in mind. One reason to drill down further into diverse/minority communities is the promotion of trust and the promotion of transparency. These two are potentially linked.

Gail Povar: 100 percent agree with Sara. Add – Liz asked about historical abuses. Making the decision to reach out to communities that don't have a voice typically in our public square, and who are less likely to be the ones to go look at a website about health care issues or fill out survey on a website, is a way to build trust for future by meeting with those communities-- maybe even disproportionately to their overall presence in the community-- is a good way of addressing past oversights. Jeremy Sugarman calls it research justice. How to make up for past behavior? Respectfully make this effort to drill down into communities that have been abused.

Will Feldman: Another advantage to think about with targeting African-American groups or other ethnic minorities, it gives people safe space to think through their opinions, deep ethical questions, what type of trials should we do without consent…[he was] trained in philosophy; it's hard to think through all of the nuances. A lot of people don't have well formed views. Think through in your mind with others that look like you and share some of your values from the same community.

Robert Silbergleit: That is what I was fishing for. There is a tendency to think of this as scientists …. That this is all about info collecting – it's probably only half or less about that.   A lot of it is about demonstrating respect, asking permission, showing people you care enough to sit and talk with them even if they don't give you any new information. The other half is information collecting… Jeremy… telling about what he said…. The information you do collect from people is information about them. They tell you something about them, low likelihood they will tell you something you didn't know about your protocol. Likely they will tell you something about themselves that you didn't know. Rarely learn something that means you will change protocol.   Learn more about how to approach people. A driving method for choosing methods (e.g., surveys vs face to face) could be this idea about demonstrating respect, different level of that in different type activities.

[LIZ – anything else? NO – thank you…].

Understanding Paramedic, Trial Network, and Patient's Family Experiences in Emergency Research Clinical Trials

PROJECT 3: Experience of Family Members of Victims of Cardiac Arrest and Severe Neurotrauma

December 24, 2020

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Executive Summary

Background

Family members' experiences in the emergency department (ED) and intensive care unit (ICU) following a loved one's critical illness or injury and the impact of these experiences on family member and patient outcomes are not well understood. Under the leadership of the Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN), this project aimed to design and implement a robust exploration of existing knowledge and knowledge gaps related to the experiences of family members of victims of cardiac arrest and severe neurotrauma, focusing on the first 48 hours following the patient's hospitalization. Four experts in the field were appointed as "co-chairs" to guide the direction of this project.

Methods

A sequential, qualitative mixed methods approach with data collection occurring in two stages was used to capture information related to the following key research questions:

- What are family members' needs in the first 48 hours after the patient's hospitalization?
- How are these needs addressed by hospital staff and institutions (i.e., EDs and ICUs)?
- How can hospital staff and the institution better address family members' needs?

The first stage was a single-site case study to generate formative research findings from interviews with both family members and health care professionals, and the second stage was a virtual workshop on November 19, 2020 that relied on facilitated discussions among a diverse sample of family members and health care professionals. Information collected from all data sources was analyzed and themes were organized according to an analytic framework based on an ecological model, which grouped family members' needs into five domains – information, communication, emotional, physical, and sociocultural.

Results

In the first stage of the project, seven family members and twelve health care professionals were interviewed. Seventeen family members and 12 health care professionals participated in the virtual workshop. Family members discussed a variety of needs, including information needs (e.g., information about their loved one's care and status, what to expect in the immediate timeframe and post-discharge); communication needs (e.g., consistent and coordinated information from the care team, assistance with processing information); emotional needs (e.g., sensitivity and compassion from care team, support from family and friends); sociocultural needs (e.g., religious support services, equitable treatment); and physical needs (e.g., comfortable spaces while waiting, private meeting rooms for sensitive conversations).

Limitations & Recommendations

The project operated under several constraints that impacted the execution of the research stages, including recruitment challenges and the transition to conducting the workshop virtually due to the COVID-19 pandemic. A key limitation of the study was the small, nonrandom sample of participants. Although an aim of this project was to recruit a demographically diverse sample of family members, there was little representation of marginalized communities who often experience health care inequities. Cross-cutting recommendations are provided based on the knowledge gained from this project, which may be useful to health care professionals and institutions seeking to improve the experiences of family members during the critical time following a loved one's cardiac arrest or neurotrauma.

Introduction

Through experience with patient engagement in planning emergency care research, and empirical ethics research interviewing past emergency trial participants, it has become clear to emergency research networks and trialists how little is known about the experience of family members of patients with critical emergency illness and injury. The impact of that experience on both patient and family member outcomes, and on emergency research participation and retention, is potentially important but remains poorly understood. This project was designed to assess the experiences and needs of family members of victims of cardiac arrest and severe neurotrauma, with particular emphasis on the first 48 hours following the patient's hospitalization.

The purpose of this project, undertaken under the leadership of the Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN), was to design and implement a robust exploration of existing knowledge and knowledge gaps regarding the experiences of family members following a loved one's cardiac arrest or severe neurotrauma as related to the provision of clinical care in emergency departments (EDs) and intensive care units (ICUs). This included the collection of primary data from family members and health care professionals to inform domains for further exploration, and the identification of leading investigators to collaborate on the planning of a workshop to further explore these topics with family members and other stakeholders as a culmination of these efforts.

Research Questions and Study Design

The project followed an exploratory research approach that included several methods of data collection to capture information related to the research questions outlined in Figure 1, below.

Figure 1. Research Questions Guiding Data Collection

- **What are family members' needs?**

- **How are these needs addressed by hospital staff and hospital institutions (i.e., EDs and ICUs)?**

- **How can hospital staff and the hospital institution better address family members' needs?**

Qualitative data collection occurred via two sequential stages (Figure 2). During the initial stage, a single-site case study methodology was employed to generate formative research findings from interviews conducted with family and health care professionals to better understand their experiences after a patient's cardiac arrest or traumatic brain injury (TBI). Concepts generated from the interviews were used to inform discussion topics during the second stage of the project, the virtual workshop.

Figure 2. Overview of Study Design
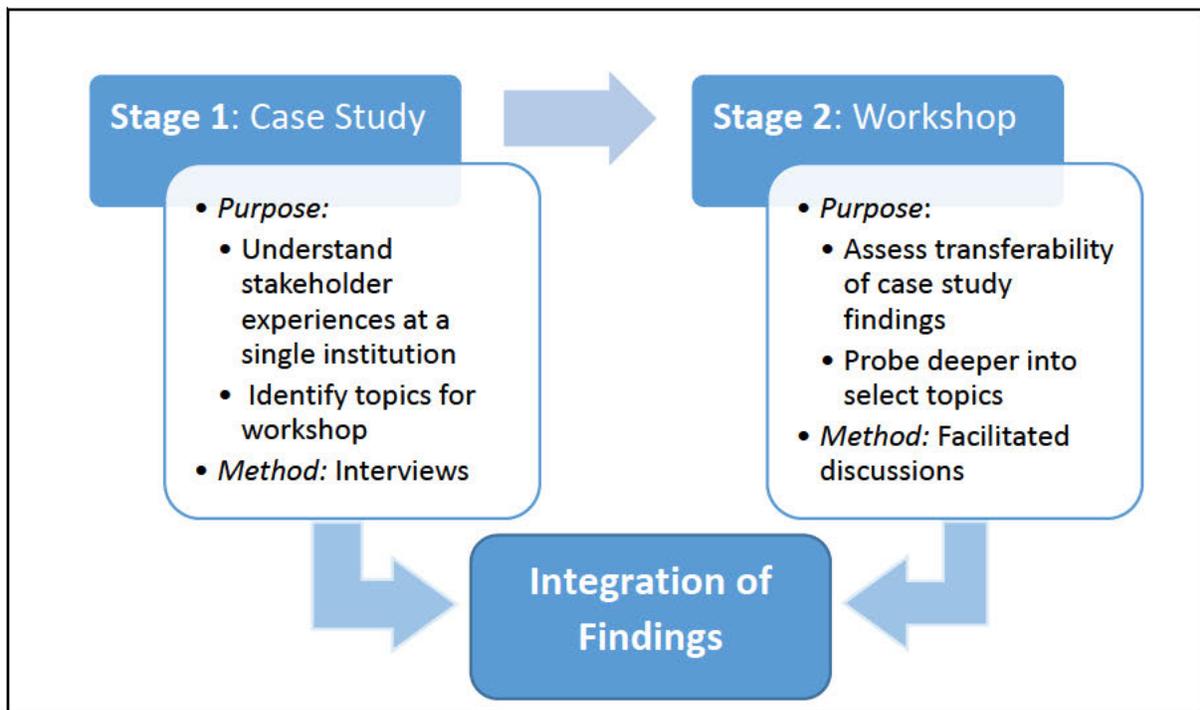
This report presents the methodology for both stages of data collection, a summative assessment of results by domain, limitations that should be considered in understanding the findings from this project, and a set of recommendations for strategies that, if adopted, could address family member needs.

Research Team

Four physician researchers with interest and expertise in this research area were identified and invited by the SIREN project team to serve as co-chairs. Their responsibilities included establishing the direction of pre-workshop data collection, workshop agenda setting and participant recruitment, and executing the workshop. Westat, a research organization headquartered in Rockville, Maryland, provided qualitative research services under subcontract to SIREN. Throughout the project, leadership and guidance was provided by members of the SIREN project team.

Methods

Stage 1: Case Study

The first stage of the project was a single site case study. An academic hospital in a culturally and economically diverse region of the United States was selected for the case site because of its diverse patient population and the large volume of critical care provided to victims of cardiac arrest and severe

neurotrauma. Data were collected via interviews with family member and hospital stakeholders. The qualitative case study methodology is described in more detail below.

Recruitment

Recruitment for interviews occurred via two distinct sequential nonprobability approaches. First, health care professionals affiliated with the case study site, who communicate with family members during the first 48 hours following a loved one's severe neurotrauma or cardiac arrest, were identified and recruited. To obtain a breadth of perspectives, the research team intentionally sought a cohort of health care professionals with diverse roles to reflect the range of care team members who interact with family members. A workshop co-chair whose primary affiliation is with the case study site conducted outreach to the identified health care professionals in July 2020 to request their participation in an interview. Health care professionals who expressed interest in participating received follow-up contact from Westat via email to identify a time for the interview.

To identify family members whose loved ones received care at the case study site following severe neurotrauma or cardiac arrest, the research team engaged participating health care professionals in recruiting family members with whom they had existing relationships in a snowball sampling approach. Health care professionals[1] were asked to contact 2-3 candidate family members to assess their interest in being interviewed. The research team aimed to speak with family members of diverse backgrounds with loved ones having a range of outcomes. [2] If the family member expressed interest in sharing their experiences, they were informed that Westat would be in contact with more details. Westat contacted the referred family members by email in August-September 2020 to provide more information and to schedule the interviews.

Guide Development

The research team used an iterative process to develop the final, semi-structured interview guides for the interviews with family members and health care professionals (Appendix A). The interview guide was based upon four major study constructs that were pre-identified via expert opinion. Questions assessed the types of information needed and received during the first 48 hours, the delivery of information, families' emotional needs, and experiences with emergency research enrollment. Although the domains of the guide were the same for both the family member and health care professional interview guides, questions were tailored to the participant group. Because of the sensitive nature of topics, a distress protocol was developed to minimize risk of participants' emotional distress during the interviews (Appendix B).

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[1] Health care professional participants who interact with patients only briefly or in a non-medical capacity were not asked to provide family member referrals since they often do not keep record of family member interactions.

[2] The coronavirus disease 2019 (COVID-19) pandemic struck the United States in early 2020, and as a result, hospitals across the nation took precautions to reduce the spread of the disease, such as limiting the number of family members in the emergency department and intensive care unit. The experiences of family members whose loved one had a cardiac arrest or traumatic brain injury during the COVID-19 pandemic likely differ from those whose loved one's event took place before COVID-19. Therefore, the research team prioritized speaking to family members whose experiences were before the COVID-19 pandemic, but not more than a few years prior to COVID-19.

Data Collection

Hour-long interviews were conducted with health care professional participants in July-August 2020 and with family member participants in August-October 2020. All interviews were conducted telephonically and were led by a Westat qualitative researcher. A second Westat staff member took notes and served as an observer during each interview.

Data Management and Analysis

Interviews were recorded with participants' consent and were professionally transcribed verbatim. All transcripts were anonymous and any names of individuals or other descriptors that could compromise confidentiality were removed from the transcripts. Once validated, transcripts were posted on a secured drive where members of the research team could access the data for analysis. Transcripts were then formatted and imported into NVivo®11 Pro (NVivo, 2017) for analysis. Sensitive information about referred family members (e.g., contact information) was saved securely in an Excel spreadsheet, only accessible by the research team.

A codebook, based on the interview domains, was developed for coding the interviews (Appendix C). Research team members trained in qualitative data analysis methods utilized NVivo®11 Pro to code the transcripts and retrieve coded segments for analysis. Prior to the start of analysis, all coders met to discuss and agree on specific coding rules to standardize the coding process. An inductive content analysis approach was used to code the transcripts, while also looking for emergent codes. After the team of coders reached consensus on the codebook and coding process, coders continued to meet regularly to discuss the status of coding and resolve any issues.

Analytic Framework

Interview transcripts were analyzed and emergent themes were organized according to an analytic framework that focused on family members' experiences grouped into five domains:

- *Information* – verbal or written information about the loved one's status or care and navigating the hospital and how to ensure the usefulness of this information
- *Communication* – how this information is conveyed to the family member and strategies to present this information
- *Emotional* – range of emotional needs and strategies to address these needs
- *Physical* – how the hospital physical environment can be better suited for family members and how to address these needs
- *Sociocultural* – how cultural, religious and social beliefs affect family members' experiences and support services to address these needs

These domains are affected by various levels of influence, including the individual family member's needs and expectations, the individual hospital staff's ability to address these needs, and the hospital institution's (i.e., ED's and ICU's) organizational processes and systems to accommodate these needs.

This framework was based on an ecological model where there are multiple and bidirectional interactions among the domains and levels of influence (adapted from National Institute on Minority Health and Health Disparities, 2017). Thus, these intersecting domains and levels of influence must be

viewed holistically when considering family members' experiences. The framework addressed the research questions outlined in Figure 1, above.

Stage 2: Workshop

The second stage of the project was a workshop, conducted virtually on November 19, 2020. The goal of the workshop was to assess the transferability of findings from Stage 1, capture any missing themes related to family members' needs, and dive deeper into a subset of topics.

Recruitment

To understand if findings from Stage 1 were transferable, the research team aimed to recruit approximately 30 participants from across the United States[3], including family members with diverse racial-ethnic and socioeconomic backgrounds and health care professionals in a variety of roles that intersect with family members during the first 48 hours. The workshop co-chairs leveraged their networks to identify workshop invitees from across the United States who could bring valuable perspective or expertise to the workshop, including a subset of the case study interview participants. In total, 18 family members and 12 health care professionals were invited to the workshop.[4]

A research team member contacted the family member invitees to provide background on the workshop and assess their experience with online conferencing platforms, access to a video-camera enabled computer, and reliability of their internet connection. The research team was committed to providing assistance to family members who expressed technological need so as not to exclude any interested family member from participation. A "save the date" Outlook meeting invitation was emailed to participants, and was later replaced with an Outlook meeting invitation that provided details for joining the virtual workshop. Family member participants received an honorarium for their participation, arranged by the University of Michigan at the conclusion of the workshop.

Pre-Workshop Survey

A pre-workshop survey of family member participants was conducted as a means of collecting brief biographies about each family member participant for the workshop booklet (described below in *Format and Agenda*), and gathering preliminary information about their experiences to ensure discussion topics at the workshop were relevant and meaningful to participants. The brief survey included eleven questions, six of which captured family members' demographic characteristics. The remaining items asked about their experience, including what they believed was most important for the research team to know (see Appendix D).

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[3] The team aimed to recruit a greater proportion of family members relative to health care professionals as the focus of the workshop was to further explore family members' needs. Similar to the recruitment efforts in Stage 1, the team sought to recruit a sample of family member participants with balanced representation of family members having a loved one who had a cardiac arrest and having a loved one who had severe neurotrauma, with equal proportions of survivors and non-survivors.

[4] Stakeholders from the National Institutes of Health (NIH), American Heart Association (AHA), and the Sudden Cardiac Arrest Foundation, as well as members of the SIREN research team were also invited to attend as workshop observers.

The survey was programmed in *JotForm,* an online survey tool, and administered by email to the 18 family members invited to the workshop. Along with the request for survey completion, the email included a request for a photo of each family member participant (with or without their loved one) to include with their short biography in the workshop booklet. The initial email was sent from SIREN@westat.com on October 28, 2020, and reminder emails were sent thereafter to non-responders. Survey data collection closed on November 13, 2020. Survey data were exported to Excel and securely shared with members of the research team. The team of facilitators met to discuss key themes that emerged from the survey data and used this source of data to refine a list of recommended discussion topics for the workshop.

Email requests for a brief biography and headshot were sent to each of the 12 health care professional participants in advance of the workshop. The biographies and photos collected were used to populate the workshop booklet.

Format and Agenda

The workshop, *Family Experience after Cardiac Arrest and Severe Neurotrauma,* was held on November 19, 2020 from 10:00am – 4:00pm Eastern Time. Out of concern for attendees' health and safety during the COVID-19 pandemic, the workshop was conducted virtually using *Zoom for Government*. *Zoom for Government* is an online conferencing platform that meets federal security standards. Participants were asked to join the workshop from a computer or laptop, and use their device's video camera so all participants could see one another, similar to an in-person gathering. Westat hosted the virtual workshop and provided four trained qualitative researchers to moderate discussion sessions throughout the workshop.

The design of the workshop and selection of discussion topics was guided by the core questions outlined in Figure 3.

Figure 3. Questions Guiding the Workshop Design

- **Are findings from the case study interviews transferable beyond the case study site? (validation)**

- **What needs of family members were not sufficiently captured in the case study interviews? (elaboration)**

Westat supported the workshop co-chairs to develop an agenda for the workshop, taking into consideration the aims for the workshop, findings from the case study interviews, and the pre-workshop family member survey responses. The agenda included a morning session comprised of two presentations led by workshop co-chairs followed by small group discussions to elicit participant reflections on the case study interview findings, and an afternoon session of breakout groups focusing on select topics of interest. Attendees were provided with the workshop agenda and information about the participants in advance of the workshop in a digital booklet (Appendix E). Due to the sensitive nature of discussion topics, a distress protocol to manage and minimize participant distress during the workshop was prepared (Appendix F).

Key segments of the agenda are described in detail, below.

Presentations and Reflection Session. After reviewing the objectives and outlining "ground rules" for participation, two co-chairs delivered presentations. The first presentation provided an overview of the field, and the second presentation focused on findings from the case study interviews. After a brief "question and answers" session, attendees broke into four homogeneous groups (two groups consisted of family members, the other two groups consisted of health care professionals). Each reflection session was led by a trained Westat facilitator with backup support from a workshop co-chair. A few workshop observers joined each group, but did not participate in the discussion.

The purpose of the reflection session was to determine the transferability of findings from the case study interviews. A discussion guide was developed to standardize and guide participant reflections in each group (Appendix G). Discussion questions sought to understand whether or not the case study interview findings resonated with participants and learn about any needs that were not captured in the case study interviews. During the reflection session, Padlet*,* a web-based collaborative discussion board, was used as a tool to collect input from participants.

Breakout Sessions. To probe further into selected interview findings, two rounds of breakout sessions were conducted. The first breakout session included four homogeneous groups, similar to the reflection session (i.e., two groups of family members and two groups of health care professionals), and focused on family member logistical needs in the first 24 hours (for the family member groups) and provider training and care team approach (for the health care professional groups). The second round of breakout groups included four groups of mixed composition, and discussion topics focused on communicating and handling uncertainty in the first 48 hours.

Discussion topics were selected as they emerged during the case study interviews as meaningful gaps that necessitated further elaboration and aligned with key research questions. It is important to note, however, that if a theme was generated during the interviews but not discussed during the workshop, this is not an indication of lower importance to the participants, but due to the limitations in scope to the workshop's agenda.

Similar to the reflection session, each breakout session was facilitated by a Westat researcher with backup support from a workshop co-chair, and observers in attendance refrained from participating in the discussion. Discussion guides were developed for both breakout sessions (Appendix H).

Post-Workshop Communications. Following the workshop, an email was sent from SIREN@westat.com to all workshop attendees to thank them for their participation and follow-up with key items. The email included a link to the slides form the workshop presentations, information about the crisis text line, and an invitation for additional comments or reflections.

Data Management & Analysis

The workshop, including all reflection and breakout sessions, was recorded and professionally transcribed. Once validated, transcripts were posted on a secured drive where members of the research team could access the data for analysis. A rapid turnaround analysis plan was executed, whereby themes from the interview analysis were used to code the workshop transcripts. A team of coders

reviewed transcripts from all workshop discussion groups and the main discussion room, and coded text segments according to the analytic framework. Transcripts were also reviewed for practical recommendations to address gaps in addressing families' needs.

Additional data sources from the workshop included Padlet responses, chat messages, notes and observations from research team members and workshop co-chairs, and additional written comments via email from two workshop participants after the workshop. Secondary data sources were triangulated for validation and to provide a more complete representation of workshop proceedings. All data from secondary sources were saved on a secured drive.

Integration of Findings

Data collected from all sources were integrated to produce a summative assessment of themes related to family members' needs and the strategies used by hospital staff and institutions to address these needs (see Table 1 for complete list of data sources). Analysts assessed the concordance or discordance of workshop participants' experiences relative to the experiences of interview participants. For themes generated in both interviews and workshop discussion, analysts considered the theme transferable beyond the case study. New themes or subthemes that emerged from analysis of the workshop data were added to the overarching analytic framework, indicating an elaboration of a finding that was preliminarily explored in the interviews or a topic uniquely discussed at the workshop.

Table 1. Descriptions of Data Sources

Stage	Source	Form	Detail
Primary sources for analysis			
Stage 1: Case Study	Interview recordings	Transcription	60-minute interviews with family members and health care professionals
Stage 2: Workshop	General session recording	Transcription	Includes discussion following presentations and wrap-up session
	Reflections session recordings	Transcription	Facilitated discussions to validate interview findings with workshop sample
	Break-out session recordings	Transcription	Facilitated discussions to further explore topics/themes generated from interviews
Secondary sources			
Stage 2: Workshop	Padlet (collaboration tool used during reflections session)	Text document	Information from 4 sessions exported to Excel and combined
	Session chats*	Text document	Available chats cleaned and combined into one summary document
	Pre-workshop survey data	Excel data file	Survey data from JotForm, exported as Excel – family members only
	Field notes	Word document, Email	Observational notes from SIREN team member and co-chair
	Post-workshop comments from attendees	Email	Additional comments submitted post-workshop to SIREN@westat.com

Note: *One facilitator received no chat messages from participants.

Results

This section presents the characteristics of the family members and health care professionals who participated in the interview data collection and the workshop, followed by presentation of findings by domain.

Participant Characteristics

Interview Participants

A total of 19 individuals[5] were interviewed, including 12 health care professionals and seven family members. The health care professionals interviewed included four physicians, four non-physician

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[5] Two parental dyads were interviewed. For these interviews, each parental dyad was only counted once in the total number of interviews.

medical providers (i.e., nurse, paramedic), and four non-medical providers (i.e., chaplain, social worker, organ donation coordinator) (Table 2). Half of the health care professional participants interviewed reported 25 or more years in their career.

Table 2. Characteristics of Health Care Professional Interview Participants (Stage 1: Case Study)

	Number of Participants (N=12)
Role	
Medical Provider	8
Physician	4
Non-Physician	4
Non-Medical Provider	4
Gender	
Female	6
Male	6
Years in Profession	
10-24 years	6
25+ years	6

Of the seven family members interviewed, four were parents of a loved one who had a TBI or cardiac arrest and three were spouses of a loved one who had a TBI or cardiac arrest (Table 3). For two of the interviews, both mother and father participated in the interview. There were roughly equal numbers of interviews conducted with family members of loved ones who had a TBI and with family members of loved ones who had a cardiac arrest. Four of the participants' loved ones were survivors and three were non-survivors, creating a range of experiences and outcomes.

Table 3. Characteristics of Family Member Interview Participants (Stage 1: Case Study)

	Number of Participants (N=7)
Relationship	
Parent	4
Spouse	3
Gender	
Female	3
Male	2
Male-Female Dyad	2
Experience	
Traumatic Brain Injury	4
Survivor	2
Non-Survivor	2
Cardiac Arrest	3
Survivor	2
Non-Survivor	1

Workshop Participants

Overall, 29 individuals participated in the virtual workshop.[6] Of these participants, 17 represented the family member perspective and 12 represented the health care professional perspective (Table 4). Unlike the case study interviews, participants' loved ones received care at various hospitals across the United States, and the health care professionals serve diverse regions outside of the case study site. To have a continuous thread with the case study, two health care professionals and one family member interviewed in Stage 1 of the project participated in the workshop. Although there were roughly equal proportions of family members whose loved one had a cardiac arrest and family members whose loved one had a TBI, the vast majority of participants' loved ones were survivors.

All family member workshop participants completed the pre-workshop survey. According to family members' responses to the pre-workshop survey, the large majority of family members (n=15) identify as non-Hispanic white and two identify as black or African American. The sample was highly educated— most family member participants (n=9) reported having more than a four-year college degree, five family members reported having a four-year college degree, and three reported less than a four-year college degree. Moreover, most family member participants (n=9) reported being "extremely" comfortable filling out medical forms alone, seven family members reported being "quite a bit" comfortable, and one family member reported being "somewhat" comfortable.[7] Family member participants reported that their loved ones' cardiac arrest or TBI occurred sometime 2008-2019.

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[6] This number does not include workshop co-chairs, SIREN research team members, Westat facilitators, or observers from the National Institutes of Health, American Heart Association, or Sudden Cardiac Arrest Foundation.

[7] The question assessing comfort with completing medical forms alone was included as a measure of health literacy. See Wallace, L. S., et al. (2006). BRIEF REPORT: Screening Items to Identify Patients with Limited Health Literacy Skills. *J Gen Intern Med*, 21(8):874-877.

Table 4. Characteristics of Workshop Participants (Stage 2: Workshop)

	Number of Participants (N=29)
Family Member	**17[a]**
Relationship	
Parent	8
Spouse	9
Gender	
Female	14
Male	3
Experience	
Traumatic Brain Injury	9
Survivor	7
Non-Survivor	2
Cardiac Arrest	8
Survivor	7
Non-Survivor	1
Race/Ethnicity	
Non-Hispanic White	15
Black or African American	2
Education	
More than 4-year college graduate	9
4-year college graduate	5
Less than 4-year college graduate	3
Comfort Filling out Medical Forms Alone	
Extremely comfortable	9
Quite a bit comfortable	7
Somewhat comfortable	1
Health Care Professional	**12**
Role	
Medical Providers	11
Physicians	8
Non-Physicians	3
Non-Medical Providers	1
Gender	
Female	5
Male	7

[a] 18 family members were invited to the workshop, but one was a "no-show."

Findings: Case Study Interviews and Workshop

The following section represents key themes related to the family member experience that emerged from the interviews and workshop. These themes are categorized by the five domains that are addressed in the analytical framework: information, communication, emotional, sociocultural, and physical. Each table in this section represents themes that relate to these domains. To develop a holistic understanding of this experience, the analytical framework also considers the levels of influence that affect these needs. Thus, in addition to identifying family members' needs, strategies that hospital staff and institutions (i.e., EDs and ICUs) can or do implement to address these needs are also described.

Main themes from interviews and the workshop are presented in the results tables below by level of influence and are in bold text. Subthemes are indicated with bullet points under the main theme. Themes that were endorsed from interviews and/or the workshop are indicated with a checkmark in the designated column in the tables. On occasion, a theme that was discussed during the interview was further discussed in the workshop. Gray highlights indicate additional nuances to these themes which emerged from the workshop.

Illustrative quotes in italics are included in the narrative text that introduces each results table to add context and richness to the findings and are attributed to the participant role (family member [FM] or health care professional [professional]) and data collection activity (interview, workshop discussion [WS], workshop chat [WS – Chat]], workshop Padlet [WS – Padlet], or pre-workshop survey [WS – Survey]).

Given the complex nature of family members' needs during this emotional period, each theme or domain cannot be viewed as mutually exclusive. As often is the case in qualitative research, these concepts may be interrelated. Additionally, as this framework was based on an ecological model, there are multiple and bidirectional interactions among the domains and levels of influence, all of which contribute to family member experiences. For example, there is overlap in the presentation of communication and emotional needs as these concepts are difficult to disentangle and highlights the necessity for viewing family members' experiences in a holistic manner. Thus, in order for hospital staff and institutional strategies to improve the family member experience, they must intervene on multiple domains.

It should also be noted that although the scope of the research questions focused on the first 48 hours after the loved one arrived to the hospital following severe neurotrauma or cardiac arrest, a number of family member participants discussed needs beyond this time period. These participants explained that they are unable to fully describe their experiences within this arbitrary timeframe. This was more apparent in the workshop compared to the interview findings. As a result, several themes and subthemes address the time period beyond the 48-hour period, such as transitioning from the ICU to the hospital ward and transitioning from the hospital to home.

Information Needs

Table 5 presents findings related to families' information needs and strategies implemented by hospital staff or institutions to address family members' information needs. Facilitated discussion during the virtual workshop focused specifically on two areas of information needs: the information needed to navigate the hospital environment and the information communicated when prognoses are uncertain.

In both the interviews and workshop discussion sessions, family members reported needing information about their loved one's disease progression and expected outcomes. This theme was further elaborated upon during the workshop as family members discussed a desire to learn about the possible outcomes for their loved one, especially if the injury or condition may be fatal or seriously impact quality of life.

> *I do remember feeling like frustrated or a little just – like the fear of the unknown. Like first they were talking about like on day one they were talking about like being in a coma, and like nobody ever said to me like your [loved one is] in a coma or – I mean, I could see that she wasn't awake, but I don't know, just to hear those words was hard, and then the next day they're talking about a TBI. … but like nobody ever said to me she has a traumatic brain injury. And I'll tell you, that hit me the hardest.* (family member [FM], interview)

Another salient theme raised in both interviews and workshop discussions was family members' need for information about their loved one's care and status, including receiving results of all tests and updates about care plans. Families discussed wanting to stay updated at all times and expressed frustration when updates were not received in a timely manner. For example, one family member commented,

> *I think things should be forthright and the person like me who is waiting for this stuff, especially if they have a major test like that, a CT scan, MRI, when you have those kind of things, you should be informed on what's going on with them.* (FM, interview)

Not only did families discuss needing information and updates about their loved one's status, they expressed a need to know whom to go to with questions and how to get in contact with the care team if they have questions. Additionally, both interview and workshop participants discussed a need to receive information to help them navigate the hospital (e.g., where to park upon arrival, lodging options), though this was typically viewed as lower priority relative to information about their loved one's care or status. Although both workshop and interview participants agreed that information to help orient them to the hospital and care team were important, there were differences in family members' experiences. As one family member noted, information was provided upfront in a brochure:

> *My recollection is I got a brochure, or a packet, or something. I got something from this spiritual advisor who told me, you know, where the restrooms were, where the cafeteria was. Lots of information. A lot of which I didn't pay attention to because I didn't know what I didn't know, and I didn't know that I even needed that. But later on, you know, a day later or two days later it was very helpful to go back and check that resource. So that printed material was very helpful.* (FM, workshop [WS])

In contrast, another family member reported having to figure out himself how to navigate the hospital environment and receive answers to his questions:

> *I needed help managing logistics: if my wife was going to be hospitalized for a while, where would I sleep? Where can I get food? Where can I get a change of clothes, toothbrush, etc.? What the appropriate/effective ways to get medical updates on my wife? For questions that arose in the middle of the night, what are the best ways to get these answered the next day? I felt like I figured*

this out on my own--I asked a lot of questions. But, a social worker MAIN contact would have been great. (FM, WS – Survey)

To support informed decision-making, families commented on the importance of receiving clear information about options, including therapies and treatments; and discussed the significance of receiving second opinions from trusted medical sources. In both interviews and workshop discussions, family member participants discussed their appreciation of and reliance on family members in the medical field to help them make decisions. Others commented on using the internet to find additional information, though its utility may be limited unless the site is a vetted source of medical information. Searching the internet may be overwhelming for families during this traumatic time. As one family member suggested: "So much scary info online, so need to direct us to trustworthy sites/sources vs. looking up info on our own..." (FM, WS – Padlet).

Despite the project's focus on the first 48 hours of the loved one's hospitalization, comments from family members highlighted information gaps at the point in which families prepare to transition to a different care setting or home. Both interview and workshop participants discussed families' need for hospital staff to share information about what to expect and plan for as the loved one transitions from the ED or ICU. Families of non-survivors spoke about needing information to help them with making decisions about organ donation, arrangements for their loved one, including funeral planning and information about autopsying procedures. Families of survivors discussed needing information on how to apply for disability benefits, information about expected rehabilitation, and information about resources and support options after discharge.

Health care professionals and families discussed a number of strategies used by hospital staff to address the information needs of family members during the first 48 hours. Strategies included honestly and clearly communicating expectations or uncertainty for cardiac arrest/TBI progression, explaining why there is uncertainty, keeping the family member informed of the loved one's care and status, sharing information about different options, and framing end-of-life questions to focus on the patient's wishes. Many strategies discussed during the case study interviews were also raised during the workshop discussion. Strategies uniquely discussed at the workshop included communicating ways family can interact with their loved one and providing ongoing updates to the family—even if nothing has changed.

In particular, workshop participants emphasized the importance of avoiding false hope in communicating with families, and if uncertainty exists, clearly discussing the uncertainty with families. Some families appreciated learning about both best- and worst-case scenarios in these situations. Health care professionals in both interviews and the workshop discussed the responsibility of the physician to communicate uncertainty honestly to families. They noted variation across physicians in communicating uncertainty with patients, and discussed how jumping to conclusions can have deleterious effects on patient outcomes (i.e., a self-fulfilling prophecy) or result in false hope. As one health care professional stated:

> *I don't think everyone does it well, but I can tell you what we try to teach and preach, which is just – In a way embracing uncertainty… So it can be uncomfortable. But I think we do a disservice to our patients when we don't acknowledge uncertainty.* (Professional, WS)

Workshop participants also discussed a role of providers to manage expectations of family members regarding the communications from the health care team. Health care professionals discussed sharing

approximate timelines with family members so they are aware of when they will receive another update about their loved one, or if the next update may be from a different provider.

> *Also, I would add an expectation of how quickly information will change is – you know, sometimes folks are expecting changes hour to hour, and so I try to emphasize, you know, this will probably you'll get chunks of information over 12 hour, 24 hour intervals, not – you know, it's not reasonable to say does he look better at 4:00 compared to 3:00. But tomorrow morning it's reasonable to say, you know, what kind of changes happened.* (Professional, WS)

To support family members' decision-making, health care professionals in both the interviews and the workshop mentioned clearly articulating options for the loved one with the family, providing results of confirmatory tests to the family (e.g., neurologic assessments), and asking family members what the patient would want. Physicians recognized that family members may seek second opinions, including internet searches, and may consult with others outside the care team. One health care professional commented,

> *I encourage people to seek information. I try to be helpful and guide, you know, what information you should seek. So you know, if a person has a particular, you know, issue, I say, you know, you're going to go Google this. Here are the words and terms that you should go read about. Be careful what you read about, but you know, rather than just unstructured looking for cardiac arrest and trying to digest the world's literature for the past 30 years on an internet search, you know, I can help steer that.* (Professional, WS)

Institutional strategies to address family members' information needs in the first 48 hours were discussed in both interviews and workshop discussions, with many themes elaborated upon further or new subthemes identified via the workshop. One institutional strategy raised in both interviews and at the workshop was orienting families upon arrival to the hospital. In general, family members appreciated when they were contacted (even if there were no updates) as they were travelling to the hospital. Families discussed receiving information upfront on where to go when arriving to the hospital and were pleased when they were personally greeted by someone from the care team upon arrival. One family member, however, wished she had received information about the loved one's medical condition prior to arrival:

> *But certain at an institution as large and comprehensive as [name of institution] there should be something in place to be able to at least provide the most basic of medical information to a family on route to connect with their loved one. That was – That made a harrowing nightmare experience even more so. Not knowing.* (FM, WS)

Although not emphasized in the interviews, workshop participants offered many ideas on how the institution could better inform and educate families in those initial few days. Participants discussed the value of the hospital sharing informational materials with families, including "questions to ask your physician," care team information, and fact sheets about cardiac arrest or TBI; and how these materials should be available in multiple formats (e.g., printed, mobile application). Family members' experiences receiving information from the institution to help them navigate the hospital environment varied across participants. Although these logistical needs were not top-of-mind for families as they arrived, the information eventually served them.

Lastly, family members communicated an opportunity for the institution to better equip families for discharge by sharing information that is often needed by families, such as where to find grievance counseling or support. Some family members felt that once their family member was discharged or declared dead, the support from the institution immediately ceased.

The complete list of themes related to family members' information needs is presented in Table 5 below and organized by the level of influence.

Table 5. Family Members' Information Needs by Level of Influence

Information Needs - Levels of Influence[8]		
Family Members' Needs	**Interviews**	**Workshop**
Expectations for Cardiac Arrest/TBI Progression - Understand the injuries, condition, when the LO will awake, what to expect/treatment plans - Honest appraisals, including impact on quality of life and best and worst case scenarios - To be prepared for LO's physical and mental changes - Understand the nature of the trajectory of illness/injury from a holistic perspective, particularly the realities of non-survival and impact on quality of life - Provide range of expectations to the FMs as early as possible so that they are able to prepare for the eventual outcome	✓	✓
LO's Care and Status - Understand symptoms that could occur/signs to watch for and what to do - Understand the "why" regarding clinical events and progression - To hear results of all tests, changes in health status, as soon as possible - Understand procedures and medical devices - Receive debriefing of LO's condition upon arriving to hospital - Include in daily meetings/rounds, in person or virtual	✓	✓
Information to Navigate Hospital and Support Self-Care Needs - Information on where to go/what to expect when arriving to the hospital, parking, food, place to stay	✓	✓
Informed Decision-making - Clear, direct information from providers - Understand options, including life supporting treatments, testing, devices and new or experimental therapies - Information tailored to the LO's lifestyle, condition, age, etc. - Access to information/second opinions/confirmation from outside sources, including trustworthy web links	✓	✓
Trusted Medical Opinions - Access to a medical resource (e.g., family in the medical field, support groups) to help FMs understand health information, questions to ask, and to inform decision-making	✓	✓

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[8] LO = Family member's loved one; FM = Family member

Information Needs - Levels of Influence[8]		
- Personal connection/advocates may be more trusted than health care team		
Continuity of Care – From Admission Through Post Discharge - Information about the types of support that can be expected post discharge - Understand how staff can support transitions (e.g., information on the roles and responsibilities of support staff, such as social workers) - Information to ease FM and LO transition post ED/ICU, including on disability benefits, what to expect when discharged (e.g., personality changes), whom to call with questions, autopsying	✓	✓
Hospital Staff Strategies	**Interviews**	**Workshop**
Expectations for Cardiac Arrest/TBI Progression - Provide direct and upfront (tailored to the degree of certainty) information about the cardiac arrest/TBI progression - Clearly communicate the seriousness of the situation as early as possible, avoiding false hope	✓	✓
LO's Care and Status - Provide ongoing updates, including results of tests, new directions with treatment, or simply to say nothing has changed - Provide information on what to watch for/expect (signs/symptoms) - Give "pointers" for how to interact with LO and explain what the LO is experiencing - Share care plans - Debrief with FMs after rounding with FM - Answer FMs' questions and concerns or work to get FM in touch with right provider to answer questions - Collect information about LO from FM - Ensure that FMs know who is the care team point-of-contact at all times, including during shift transitions	✓	✓
Information about Uncertainty - Be direct and honest about what is known and unknown during the clinical course - Be clear why there is uncertainty, provide examples if applicable - Keep messaging consistent with others on the care team - Provide continuous reassessments and ongoing communications as things evolve - Use statistics carefully when speaking with FMs - Avoid declarative statements when uncertainty exists - Share best-case and worst-case scenarios - Provide a timeline of the process to help FM manage expectations	✓	✓
Informed Decision-making - Clearly explain options - Provide neurologic and other relevant test results to help decision-making - Encourage advocacy	✓	✓

Information Needs - Levels of Influence[8]		
- Identify other individuals for FMs to discuss options if they cannot make decisions - Frame end-of-life questions to avoid bias and relieve FMs of burden and guilt of DNR decisions - Include FM in discussions, even if not legally bound to LO - Include the FM as an essential team member with important clinical and personal information about the LO, including their wishes, values, lifestyle and understand how this information can lead to better outcomes - Understand the context and values of the LO and FM when framing conversations about decisions; align the health care team with these values		
Institution (ED and ICU) Strategies	**Interviews**	**Workshop**
Orientation/Arrival at Hospital - Ease FMs into the event and the unknown - Provide details on where to go in the hospital, what to expect	✓	✓
Generic Education Materials for FMs - Provide FMs with education packets, FAQs, questions to ask physicians, fact sheets to provide basic information - Create an app for FMs to download generic information about their LO's condition or who is in their LO's care team - Ensure multiple formats of information to increase accessibility for all ages/preferences, and for all phases of the LO's treatment	✓	✓
Information to Navigate Hospital/Support FMs' Self-Care - Provide information on place to stay overnight, parking, transportation - Create a checklist of what FMs may need - Identify a specific care team member (e.g., chaplain) to provide logistical support and remind FMs to attend to personal needs	✓	✓
Consistent and Coordinated Source of Information - Institute "point person" (e.g., nurse or attending physician) who attends all meetings with family for coordinated and consistent information, and if possible, as family arrives to the hospital - Ensure the same hospital staff person/role has multiple conversations with FMs to provide consistent information and to build trust	✓	✓
Emphasize FMs as Part of the Clinical Team - Include FMs in rounds to the extent possible - Engage through video chats or calls if unavailable to participate in-person during rounds	✓	✓
Continuity of Care – Post Discharge - Provide information and resources for post discharge, including grievance counseling, rehabilitation	✓	✓

Communication Needs

Throughout interviews and the workshop, participants emphasized the importance of communication between family members and health care professionals. Table 6 presents themes from interviews and the workshop that relate to family members' communication needs; strategies used by health care professionals and the hospital institution to address these needs are also included.

When reflecting on the emotional 48-hour time period when their loved one was admitted to the hospital, family members emphasized the need for health care professionals to be clear, consistent and compassionate in their communication. In particular, family members expressed that they were often overcome with emotion and distracted, and appreciated when health care professionals communicated in ways to assist with information processing. These strategies included repeating information, pausing for family members to ask questions, and avoiding using medical jargon. As one family member explained:

> *They'd answer and explain things in you know, terminology that we could all understand, and never made us feel rushed. We could ask whatever questions we wanted. They gave us their business cards. So I think they were source of comfort and you know, just trying to answer our questions and reassure us about things.* (FM, interview)

Family members in both interviews and the workshop also expressed the importance of being able to communicate with health care professionals to receive updated information about their loved one. Recommendations included receiving contact information from health care professionals so that they can be easily reached. This was particularly important when shift changes among health care team members occurred. This theme was also discussed in the workshop, and family members suggested that they should be made aware of the schedule for rounds so that they can participate and ask questions when needed. Family members also suggested that health care professionals utilize messaging platforms to quickly and easily receive updates.

Family members in both interviews and the workshop explained that often the roles and responsibilities of health care team members were not clearly explained, leaving them unsure of what type of information to request or whom to communicate with for certain questions. Knowing the health care team members' roles and responsibilities would reduce this stressor and allow family members to receive information needed about their loved one. This was echoed by one family member:

> *I took it upon myself to ask the question – what are you going to do for my son and why. And that to me kind of helped simplify this huge structure that I felt like I had to keep track of when I looked at his care team. So I don't know in terms of being proactive if clinicians are comfortable with, hi, I'm Dr. So-and-so, I'm going to do this for your loved one so that, you know, I'm going to do X so we can achieve Y. I don't know if that introduction might be helpful, but it was really helpful for my family. And again, the people that we worked with were more than willing to answer that question and make sure that we were clear with what benefit they were bringing.* (FM, WS)

In interviews, family members stated the importance of being spoken to with compassion. In particular, family members appreciated health care team members delivering unfortunate news about their loved one in an empathetic manner.

During the workshop, family members emphasized the importance of receiving consistent information from health care professionals, particularly when consultants and various team members are involved. These professionals should work as a holistic team, be in close communication with each other, and provide consistent information to family members.

Health care professionals in both interviews and the workshop also spoke of various strategies used to appropriately and compassionately communicate with family. These participants recognized the emotional state of family members during this time and employed various strategies to assist with information processing, such as encouraging questions, and use of appropriate terminology and active listening approaches. As one health care professional explained:

> *I try to do informal feedback after a family meeting to residents in particular about how they talk to families, and sometimes it's simple things and not in a – in a super critical way, but maybe just word choice. Sometimes words are very complicated that residents will use, because it's common language for them, but a family member may not understand that, and so encouraging them to be conscious of the word choices that they're at the level of comprehension for families. And more informal.* (Professional, WS)

The importance of timely outreach to the family was also discussed during the interviews and workshop. Health care professionals should speak with family members early and often, and preferably face-to-face.

Professionals also spoke of the importance of communicating with compassion to family members. These participants explained that they have used various techniques to achieve this, including allowing silent pauses when speaking in order to give family members time to react, and delivering updates in an empathetic manner. Recognizing family members' body language and preferred communication style and responding appropriately were also mentioned as important communication techniques throughout the interviews and workshop. Participants also emphasized the importance of spending time with family members and building their trust.

Participants spoke of various communication strategies implemented on the organizational level. Both interview and workshop participants spoke of the use of specific staff, such as a nurse "mediator" or "point person" to assist with communication between family members and heath care teams. Thus, these dedicated staff are able to communicate with families as needed, allowing physicians to focus on the loved one's care. Health care professionals spoke of how this is extremely helpful, especially during the early, acute stages of care for the loved one:

> *We frequently use chaplains or our charge nurses when we're in the middle of a resuscitation, and they just sit with that family and talk with the family. And so I think that's very useful. And I understand it's hard to do elsewhere, but I think, you know, I hear a lot about care coordinators and navigators, and I think we underutilize those people assuming that only physicians or nurses can talk to families and keep their care coordinated. So one strategy might be to investigate the use of others who are more able to be with families for longer periods of time than very busy clinicians.* (Professional, WS)

Family members spoke of how care team members often vary, given shift changes and consultants. Thus, both family members and health care professionals spoke of the importance of care teams

providing consistent information and functioning as a collective unit, which facilitates communication and builds trust with members of the family. This concept was discussed during interviews as well as the workshop. As one family member expressed:

> *We did not have a social worker greet us. We did not have a single point of contact…never met the neurologist, and I hope I don't offend anybody by saying this, but I felt like they were on two different planets, the cardiologist and the neurologist.* (FM, WS)

One health care professional had a similar view for consistent source of information and emphasized the need for coordinated communication:

> *There may be a traumatic brain injury patient who has multiple injuries, and there are going to be emergency medicine physicians, intensivists, anesthesiologists, neurologists, neuro surgeons, trauma surgeons, and many other consultants that may be involved in the care. And I think it is very important that someone is identified as the point person who is the attending physician, the supervising physician of record to coordinate this.* (Professional, WS)

A health care professional also explained the nature of shift work and implications on the consistency of the care team:

> *One of the principle problems in all of this is that modern medicine is shift work, and so you don't have the same provider from start to finish. And that's true at the nursing level, just as much as that is true at the physician level with very rare exceptions. And that becomes a problem.* (Professional, WS)

In terms of communication training, health care professionals spoke of communication training and observation as a typically informal, one-time event, which is not evaluated. For physicians to strengthen their communication skills, and for hospital institutions to reinforce the importance of this, professionals recommended physicians undergo formal training, such as completing a palliative care rotation. This would provide professionals with the opportunity to learn how to conduct difficult conversations with family members. This topic was further explored during the workshop; professionals also discussed the importance of providing tools and opportunities for professionals to receive feedback on their communication skills with families, including reviewing video recordings of conversations with family members, and identifying models and mentors to emulate.

During the workshop, a number of participants emphasized that an organizational culture that prioritizes communication skills and training is necessary to affect positive changes for the health care team and individual health care professionals. Examples of how the hospital culture can promote improved communication includes supporting continuous learning and quality improvement, setting expectations for communication competency, and holding physicians accountable for their communication errors. A family member expressed her concerns regarding the need for accountability:

> *I think this is a huge topic in medicine, about mistakes, and mistakes come in all different types, and communication errors are huge, and I really feel like that is a huge gap…being able to circle back and have that accountability and personal reconciliation between the people who are involved and – that's a huge cultural thing in medicine…but I think that accountability piece and repair – because it is a very highly – especially in the first 48 hours, it's a highly charged time.*

People are going to misstep all over the place, and building in a way to repair and apologize I think is a very key piece, and being accountable. (FM, WS)

A health care professional spoke about the need for institutions to support communication training in order to incentivize providers to implement best communication practices:

I think relatively speaking we have quite a bit of training here. Again, just to re-emphasize though, it's because individuals are spearheading it and have an interest in it...none of this is supported or reimbursed, and so you have very busy clinicians, providers, paramedics, nurses, whatever, and how do you incentivize them to take time out of their busy days and busy work lives to devote to training. I don't think anyone intentionally wants to do poorly at this, but it's also very difficult to do it well, and it requires a lot of investment, and training, and insight and vulnerability. And so I think there needs to be an approach to it that starts early with education but then provides ongoing education and institutional support for people to take time to go do this kind of work. (Professional, WS)

The complete list of themes related to family members' communication needs is presented in Table 6 below and organized by the level of influence.

Table 6. Family Members' Communication Needs by Level of Influence

Communication Needs - Levels of Influence[9]		
Family Members' Needs	**Interviews**	**Workshop**
Assistance with Processing Information - Need to receive information, repetition - Ability to have several FMs to also listen/process information - Need information to be provided in an easy to understand way - Require opportunities to ask questions - Directness in the face of uncertainty - Receive communication in a calm manner - Be mindful of timing, as well as volume of information, so as not to overwhelm FM	✓	✓
Sensitivity in Delivering Bad News - Appreciate when devastating news or expectations are communicated with empathy	✓	
Connection with Health Care Team - Receive contact information from care team so they can stay connected, particularly if there is a change in care team members - Receive information on when care team members will make rounds, or when consultants visit the LO so that the FM can form a connection with the care team; include FMs in rounds - Consistent access to a trusted care team member - Use social media and networking apps (e.g., Facebook, Caring Bridge) to keep family updated	✓	✓
Consistent Information from Care Team - Receive consistent information from care team members		✓

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[9] LO = Family member's loved one; FM = Family member

Communication Needs - Levels of Influence[9]		
- Care team members are in close communication with each other, should operate as a holistic team		
Care Team Responsibilities - To understand the roles and responsibilities of care team members - A single point-of-contact to avoid confusion and to receive updates, particularly if LO has transferred to another facility - Staff that prioritizes communicating with FMs rather than medical students in teaching hospital environments	✓	✓
Hospital Staff Strategies	**Interviews**	**Workshop**
Assistance with Processing Information - Repeat information to FMs - Encourage questions - Assess FM's understanding of information; listen and observe - Utilize active listening approaches - Use language level that is appropriate for FM's medical literacy - Encourage tools to help process information (e.g., provide keywords to Google) - Prioritize information to FMs (i.e., what is most important for the FM to know and think about right now) - Take time and pause when delivering information - Use language interpretation services when needed - Encourage FMs to take notes or record (with consent) conversations with physicians - Allow FMs to conference other FMs during discussions with physicians so several people will have the same information	✓	✓
Outreach to Family ASAP and Provide Timely Updates - Meet with family ASAP, face-to-face - Ensure all appropriate family receive news/updates - Ensure family that are traveling are kept informed early/often	✓	✓
Communicate with Compassion - Spend time with FMs to build trust, assess communication needs, engage with FMs - Deliver news in a human and empathetic way, with sincerity and authenticity - Be patient, pause, be comfortable with providing silent breaks when speaking with FMs - Recognize that FMs have different styles and communication needs - Pay attention to how FMs respond and how body language and communication style affects people; modify communication style if needed	✓	✓
Institution (ED and ICU) Strategies	**Interviews**	**Workshop**
Specialized Roles - Utilize specific staff to assist with communication between family and medical team, such as a nurse "point person" or "mediator"	✓	✓

Communication Needs - Levels of Influence[9]		
- Dedicated staff are able to spend time needed with FMs, allowing physicians to focus on the LO, particularly during the early, acute, intense stages of care		
Diverse Team Approach - Employ a care team of diverse disciplines (e.g., social workers, nurses, attending physicians) to address communication needs - Utilize a diverse team ensures that FM will find a connection with a team member	✓	
Consistency of Care Team - Create a dedicated, consistent care team to ensure continuity of care and to build trust with FMs - Ensure that care team members are in constant communication with each other and provide consistent information to FMs; consultants and attending physician function as a team - Designate a consistent communication point person	✓	✓
Communication Training and Observation - Require physicians to do training or palliative care rotations to learn how to have proper family discussions, how to address uncertainty - Provide providers with tools and opportunities to improve communication competency (e.g., audio recording and feedback; implementing family meeting debriefs) - Train providers on good communication "models" and strategies - Provide training for religious staff and others to serve as family support facilitators	✓	✓
Organizational Culture that Prioritizes Communication and Communication Training - Support for continuous learning and quality improvement - Setting expectations around communication competency - Buy-in and investment from leadership - Culture should support physicians' accountability for their communication errors; set the expectation for physicians to acknowledge erroneous prognostications - Organizational changes to manage time constraints so that physicians are able to spend time communicating with FMs, include FMs in rounds		✓

Emotional Needs

The emotional needs of family members were also explored during the interviews and over the course of the workshop discussions. Themes and topics are presented in Table 7, by level of influence. Family members experienced a range of feelings, including shock, distress, confusion, and despair, as they attempted to cope with their loved one's critical illness or injury. The unexpected life-threatening event, uncertainty regarding their loved one's condition or outcome, and reliance on the health care team for compassionate updates contributed to the emotional response of members of the family. As one family member expressed:

> *Just the thought of not knowing, and not know if he's dying, is he going to be okay. You know, I didn't know. So I just prayed about it, and I didn't know what else to do.* (FM, interview)

With one exception, similar emotional needs were expressed in both the interviews and the workshop. It was important to family members to receive assurance that members of the health care team genuinely cared for their loved one, expressed by frequent checking in with updates, being respectful and attentive, addressing questions, and being empathetic and compassionate.

> *I never felt like they were giving up on him. I never felt like anyone was giving up hope. I just overall feel like since it was all so sudden (laughs) so unexpected and no one…could tell me because they had no idea. So generally, I never felt like anyone was not going to give him the care he needed. I really, really felt like everyone was doing everything they could to help him…* (FM, WS)

The hospital staff also expressed an understanding of the emotional needs of family members and how they responded with compassion during this stressful period, particularly to assure them that their loved one is receiving the best care and treatment. As expressed by a health care professional at the workshop:

> *So we try to portray that we are [providing] very aggressive care, and you have come to the right place, and anything is possible. Anything is out there that works for your patient – or for your loved ones, it will be available here, and we will make everything possible to do it.* (Professional, WS)

During this critical period, it can be challenging to maintain a sense of control while managing distress and attempting to process information about the loved one's care. Family members struggled to stay "present" in order to be receptive to information coming from different sources and to take care of their personal needs. Family members utilized a range of strategies, such as seeking information from the internet or friends and family in the healthcare field, keeping a daily journal, and seeking solace through prayer. The hospital staff recognize the challenges experienced during this time of intense worry about the loved one's prognosis:

> *And when they are ready, they can realize not only that they are not alone in this experience, because families feel so alone when this has happened to them. They think they are the only person in the world that this has happened to…Blogging, when they're ready for it to read about other people's experiences.* (Professional, WS)

Social support from friends and family, as well as the support services offered at the hospital, also helped family members deal with the emotional overload during this time period. The presence of close friends and other family members was also comforting for some, whereas others preferred to not be distracted by others. As one family member expressed, "I felt very alone when I was there. I mean, [the social worker] helped me to keep a little bit calm, but still, it's a lot to process by yourself without having a family member there with you." (FM, interview)

With regard to support from the hospital, family members appreciated knowing what was available as soon as possible upon arrival to the ED or ICU, though this information may need to be repeated as the family copes with the shock of the event. It was particularly helpful when there was consistency over time in the support person, who understood the family's needs and was accessible to provide guidance.

While some did not recall the details, they expressed awareness of the impact on their experience and their emotional self-regulation, as one family member explained: "I don't even remember what she was called. I think she was there as a spiritual advisor. I didn't need the spiritual advice, but I needed her support, and I got it." (FM, WS)

The value of clear delineation of roles in relation to the balance of providing both clinical care and emotional support was expressed this way by a hospital physician:

> *And I think that it's really important to have roles delineated and have that – have that type of emotional support, really have a plan in place where folks on the team can provide that. Because if every emotional need has to come back to me as an attending physician, I'm probably going to do a poor job in meeting that in addition to all my other responsibilities.* (Professional, WS)

The need to have closure with the care team that treated the loved one was a unique theme expressed by several family members at the workshop. The opportunity to make this connection to express gratitude was described as part of the healing process for family members. As expressed by two workshop participants: "It's vitally important for survivors, family members and the care team to reunite months later. Our hospital facilitated a reunion tour at our request. It was amazing for all... and very healing." (FM, WS – Chat)

> *So that helped me, and it really helped my wife, to go back and actually meet some of those people that – you know, they – especially the nurses, to be honest with you. They had such an impact on our family for a very intense but short period of time, and then they're gone. You leave and you never see them again, and it's like we really do – it makes us feel better when we can be grateful.* (FM, WS)

Several topics related to hospital-level strategies to meet family members' emotional needs emerged through the interview and workshop data collection, including observing family members and responding to their distress, validating their feelings regarding uncertainty and personal guilt, and clearly communicating when they can be at their loved one's bedside. Per a family member at the workshop: "I was so relieved when someone told me I could be with him as long as there wasn't a sterile procedure, etc." (FM, WS – Padlet)

Views on tailoring approaches to helping families manage emotions were explored in the interviews, during which both family members and health care professionals expressed the importance of taking time to assess the particular situation, including the family member's emotional state and capacity to absorb information at that time. Responses and interactions should be appropriately adapted, taking into account observations of family members' reactions and body language under these circumstances. In some instances, participants reported simply being present in silence as the best approach to providing emotional support and comfort.

Other support strategies that bridge the range of emotional and communication needs included keeping the family member apprised on the loved one's condition, expectations for next steps, and when more definitive information may be available. Finding the proper balance in expressing what is known and unknown may depend on the family member's informational processing capacity, prior history and background, and preference for knowing the full range of potential or likely outcomes. The often long and uncertain passage of time can be draining for family members, who in their distress often fail to

consider their own needs, which can contribute to the emotional anguish. Hospital staff provide practical information and suggestions to help occupy the family member and regulate their feelings during this time.

> *Families want something to do, so I often will tell families bring in your favorite music – I mean, this is a little bit past that initial period, but talk to people. Have a conversation. A lot of families in this situation need to do something and something concrete as a way of both distraction and feeling part of the care.* (Professional, WS)

Underlying the emotional reaction of family members is the challenge of managing uncertainty and the need to wait as treatment of the loved one unfolds and the prognosis becomes clearer.   This theme was particularly salient at the workshop as it was the topic of one of the breakout sessions. Family members generally desire information to know what to expect, but may differ in preference for and ability to cope with a poor prognosis. Some expressed that they wished to hear the range of possible outcomes, so that they can prepare for the worst, and several indicated being unaware that death or poor quality of life were possible outcomes for their loved one. Reflecting on their own experience, the observation was made that such information received earlier in the course of treatment may have led them to make different decisions about their loved ones' care, such as allowing more time for family and friends to visit and grieve, or removal from life support to end suffering. A clinician offered this perspective on family member resiliency:

> *…uncertainty is the most powerful human emotion actually. I mean, it's what I say to the families in that moment is that what's amazing about human nature is the capacity to process bad news. And we obviously understand how to process good news in large measure, but we also understand how to process bad news. It is actually more powerfully impactful to receive uncertainty than to receive bad news from a psychological and human nature perspective.* (Professional, WS)

Managing the emotions associated with uncertainty can be challenging for both family members and the health care team. Physicians also discussed the challenge of timing the delivery of information as well as expression of confidence in what was conveyed.

> *But I think I'd be disingenuous if I said we just have absolutely no idea, because that's not really discussing and preparing the family for the situation in which – what you're facing...having done this for a very long time, I'm coming from a place where I've been disappointed at the level of certainty that physicians have had when they're wrong over time. And that's been the biggest concern that I've seen over my 25 year career as a neuro intensivist, is that physicians have overestimated their ability to precisely prognosticate poor outcomes early after injury.* (Professional, WS)

Institutional strategies to address the emotional needs of families emphasized the provision of capable and compassionate staff to help the family members cope, including social workers, counselors, and pastoral care. The workshop participants elaborated on the need for this support to be available as early as possible. Another strategy was to have the capacity for family members to have time with their loved one, to assist with his/her care at the bedside, and to prepare emotionally for end-of-life.

Themes related to family members' emotional needs are presented in Table 7 below and organized by the level of influence.

Table 7. Family Members' Emotional Needs by Level of Influence

Emotional Needs - Levels of Influence[10]		
Family Members' Needs	**Interviews**	**Workshop**
Compassion from Health Care Team (Builds Trust) - Feel the health care team genuinely cares for the LO, doing all they can, part of the "family" - Appreciates empathy, compassion towards family (e.g., checking in, eye contact, asking FMs questions about the LO, listening to FM's concerns and responding to questions)	✓	✓
Sense of Control - Strategies to gain sense of control and make sense of information (e.g., internet searches, discussions with family/friends in the healthcare field) - Self-care strategies to gain sense of control and grounding (e.g., journaling, walking, praying, cleaning) - Empowered to request a new provider if there is not a "good fit"	✓	✓
Family/Friends Support - Ability to have family/friends visit FM	✓	✓
Support Services - A dedicated care team member (e.g., nurse, social worker, peer from support group) to serve as a liaison with the care team and provide emotional support - Should be available and offered early in the course of treatment	✓	✓
Continuity of Care – Post Discharge/Death - Bereavement resources, counseling and other sources of emotional support	✓	✓
Closure with Care Team - Desire to revisit the care team members post-discharge to express gratitude; part of the healing process for the FMs, LO, and care team		✓
Hospital Staff Strategies	**Interviews**	**Workshop**
Compassion from Health Care Team - Waiting for and greeting FM at the door of hospital upon arrival - Providing reassurance to FM - Provide time and space for FM to process information - Encouraging FM to stay in the present - Giving FM simple tasks in the very early period - Helping FM acknowledge and name their emotions - Provide FMs with emotional support, including religious services - Spend time with FMs and ask questions about the FM and LO to build trust - Show empathy; express that devastating news about LO also affects the care team	✓	✓

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[10] LO = Family member's loved one; FM = Family member

Emotional Needs - Levels of Influence[10]		
Addressing Uncertainty	✓	✓
- Recognize that FMs are overwhelmed and emotional		
- Communicate the importance of ongoing critical care, allowing time for the clinical situation to "declare itself"		
- Provide information on what signs to watch for, expect		
- Be honest about not having all the answers immediately, emphasizing the need for more time for clinical signs to emerge		
- Reassure FMs that health care team is working effectively		
- Emphasize that FMs must be patient, comfortable with waiting, continue ongoing care		
- Focus on describing processes (e.g., next steps for testing, observations) and what they mean for LO's course of treatment		
- Find balance of presenting range of what is known and what are possible outcomes while acknowledging level of uncertainty		
- Be careful not to overestimate ability to prognosticate, but provide enough information for the family to prepare for decisions that align with the LO's values		
- Introduce the possibility of uncertainty; losing the person they knew before the event ("ambiguous loss")		
Management of FMs' Emotions and Distress	✓	✓
- Offer support services (e.g., social workers, counselors, pastoral care) early in the process		
- Recognize that FMs are overwhelmed and anxious; attempt to make them as comfortable as possible so that they can accept and process information		
- Reassure/validate FMs' care for LO, alleviating guilt, emphasize patient autonomy (FM cannot control patient's decisions)		
- Encourage FMs to reach out to other FMs, friends (self-care)		
- Suggest ways to "normalize" the situation to handle emotions (e.g., tending to children, crafts, note-taking)		
- Explain when/under what circumstances FM can be with their LO		
Tailored Approaches	✓	
- Consider FM's individual needs, context, tailored approaches, listening, responding (not one size fits all)		
- Meeting FM "where they are;" adapting delivery of bad news based on where the family is emotionally with understanding the life-threatening condition		
- Observing FM reactions and body language to tailor fit of communication		
Encourage Family/Friends Support	✓	✓
- Provide suggestions for communicating with others (e.g., Caring Bridge) so FM on-site not overwhelmed		
Institution (ED and ICU) Strategies	Interviews	Workshop
Provide Support Services	✓	✓
- Provide support services, social workers, counselors, pastoral care		

Emotional Needs - Levels of Influence[10]		
- Offer a dedicated care team staff, such as social workers, early in the course of treatment		
Allow FMs to Spend Time with LOs - Offer FMs to spend quiet time with LOs (e.g., bathing, holding LO), including to prepare for LO's end-of-life		✓

Sociocultural Needs

During the interviews and workshop, family members and health care professionals emphasized the need for equitable treatment and socioculturally appropriate communication to ensure that medical providers and other hospital staff treat everyone with respect, regardless of one's personal characteristics, including gender, age, religion, race or ethnicity, cultural affiliation, geographic location, or family structure. Participants felt that it is "important [for health care professionals] to establish relationship and understand patient values" (Professional, WS – Padlet), because they are vital factors that contribute to effective and positive communication and encourage rapport building between the families and the professional care team.

At the institutional level, interview participants stressed the need for language interpretation services to be offered as a strategy that not only augments the provider-family communication process but also removes the burden of family members having to translate medical terms or details during a stressful, intense time. Family members also described the need for institutionally-sponsored support services, such as subsidizing costs for some of their logistical needs:

> *Something that was really helpful though, I wish that we had known about it sooner, but we had lived an hour and a half away from the hospital, so we needed a place to stay, and we were just booking a hotel, like a different hotel every night or finding (laughs) you know, the best rate in the area, but eventually we found out about the suites, which was a place where family members could stay for, you know, a less expensive rate. It was like a hotel, but it was affiliated with the hospital, and that was really helpful the longer his hospitalization became, the less expensive the rate became for us to stay there. So we needed to stay there for about a month and six days and that was really helpful, because I think by the time, you know, the last couple of weeks it was only like $20 or $30 a night, so that was a huge deal for my family. We like basically had an apartment (laughs) there. You know, that was like a huge logistical need for us. (FM, WS)*

During the interviews, participants described the need for hospital staff to be aware of these needs, but when probed further during the workshop, many participants suggested health care workers go beyond awareness and to actively assess these needs, especially with regard to the family members' grieving process, ability to make end-of-life decisions, and areas of emotional and spiritual support. One health care professional who attended the workshop described the assessment process much like intake procedures used routinely in medicine: "I guess I would say we don't default to an assumption of a specific cultural, religious, whatever, milieu. We have to identify that a priori in each individual case, just like taking a medical history or something." (Professional, WS) In return, family members described their positive experiences when the care team successfully acknowledges and responds to the family's sociocultural needs: "The other thing that was outstanding, and eternally grateful, again, our nurses – I

practice Tibetan Buddhism, and she reached out and found two different monks from two different temples, I suppose, and got them both at the same time to come Tuesday evening and say prayers." (FM, interview)

During the workshop in particular, family members also described negative experiences with regard to their sociocultural needs. For instance, some families felt disregarded, overlooked and even disrespected by some hospital staff:

> *And when I tell you I was treated so nasty, and when I tell you that my son was treated so nasty, (cries) and when I tell you I tried to stay respectful, I didn't say anything out of line to nobody and I just let it pass. And I'm not the one to let nothing pass when somebody's being disrespectful. And you know, I'm glad I'm here to tell my side of the story. I don't know if it's my background, I don't know what it is, but like I said, I have a bunch of professional kids in my family – when we came in there, we were quiet, we kept everything clean. I had to ask for mop buckets for my son's room. I had to ask for – for a sheet, because we had to wash my son up. We had to wipe his butt. We had to suction out his neck and clean his nose out. When I tell you that I was disrespected on every level, I'm honest. I was. But that's okay, though. That's okay. We prevailed. (FM, WS)*

This participant later expressed appreciation for the opportunity to describe this experience, as stated in the workshop chat: "Thank you guys so much, was so glad to share that, never got to share. kind of suppressed it, was glad to let out because I know there's others that will no doubt go thru" (FM, WS – Chat).

Themes related to family members' sociocultural needs are presented in Table 8 below and organized by the level of influence.

Table 8. Family Members' Sociocultural Needs by Level of Influence

Sociocultural Needs - Levels of Influence[11]		
Family Members' Needs	**Interviews**	**Workshop**
Sociocultural Background and Influence - To feel that FMs are not treated differently due to sociocultural background - To be included in conversations, treated with respect, treated as part of the health care team and not belittled or disregarded	✓	✓
Religious Support Services - Ability to receive religious support, such as receiving blessings, last rites, prayers for a variety of religions - Allowing members of one's faith community be present for support	✓	✓
Hospital Staff Strategies	**Interviews**	**Workshop**
Awareness of Sociocultural Background and Influence - Understand how cultural background and beliefs may influence level of trust with providers, communication and how they ask for assistance and support - Understand how cultural and religious beliefs may impact how FMs cope and grieve	✓	✓

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[11] LO = Family member's loved one; FM = Family member

Sociocultural Needs - Levels of Influence[11]		
- Be aware of how racial disparities, systemic racism and historical mistreatment of Black, Indigenous, and People of Color communities in the US health care system affect health decisions, trust in providers - Understand how sociocultural background and social network (e.g., personal relationships with health care providers) affect concepts of quality of life, health care decisions - Understand how social networks (e.g., personal relationships with health care providers) affect health care decisions - Respect FMs' decisions that are based on cultural beliefs that may contradict providers' assessment		
Assessing Sociocultural Preferences and Social Support - Assessing the patient's/FM's cultural and religious preferences - Assessing the patient's/FM's social network and support early in the first 48 hours		✓
Addressing Language Barriers - Use language interpretation services when needed	✓	
Religion and End-of-Life Decisions - Understand FMs' religious beliefs that make end-of-life decisions difficult, provide reassurance that the FM is making the right choice for the LO's quality of life - Provide religious support services to discuss end-of-life decisions - Be aware of FMs' religious beliefs and reliance on faith to heal LO - Clearly communicate LO's condition, treatment and end-of-life options, quality of life - Respect FMs' decisions that are based on religious beliefs that may contradict providers' assessment	✓	
Institution (ED and ICU) Strategies	**Interviews**	**Workshop**
Financial Support Services - Offer discounted parking, affordable housing options, subsidized meals	✓	✓
Religious Support Services - Offer support services for a variety of religions	✓	✓
Addressing Language Barriers - Offer language interpretation services when needed	✓	

Physical Needs

Family members expressed needs during the interviews and workshop that related to physical, tangible or logistical issues they experienced when their loved ones were in the ED and/or ICU. While these needs were not a primary focus of the project, several family members mentioned that they desired a comfortable space in the hospital to have privacy and for updates from the care team, or issues pertaining to meeting their physical needs. During the workshop, physical needs were further discussed and family members and the professionals both described the difficulty family members can have when navigating through the hospital, especially if they have never been, and requiring logistical information, such as how to get to the cafeteria, the hours of the cafeteria, where to park, and how to find lodging.

Sometimes families don't even know – They don't even have the questions to ask. So I do think that people get very lost in hospitals. Can be very confused about where they're going to go, and unfortunately while providers, physicians, nurses are prioritizing the patient's health, families are often literally lost, and don't know what to do... (Professional, WS)

Family members also discussed during the workshop how these physical needs changed over the first 48 hours, especially for those whose loved ones were in a hospital located far from their homes. Family members described being so focused on their loved one's status that many arrived at the hospital without remembering to bring personal belongings and other travel items for their stay of unknown duration.

Some additional physical needs that emerged from workshop discussions included the importance of having a private space for the family member to engage in difficult conversations with the care team, to feel comfortable to express their emotions in private, and to stay away from outside commotion of the hospital. Although interview participants expressed the current challenges of visiting loved ones during the COVID-19 pandemic, family members expressed the need for visitation rules that allowed family members to be with their loved one 24 hours a day and to have access to all members of their loved one's care team. Moreover, family members expressed the importance of allowing other members of the loved one's family and community to visit.

Participants in both the interviews and the workshop described the many ways that individual health care professionals and the institutions they work within work to satisfy the physical needs of family members. Institutions have devoted waiting rooms, conference rooms, and sleeping quarters for family members to use when requiring privacy and long or overnight stays. Participants described some institutions as having procedures in place where family members are escorted to their private room where all of their health care team members know to come find them for updates.

I was met at the door by a clergyman who took me into a little room which kind of scared me, because I knew that that meant things were really bad, but it was a space that I could just be isolated from other places. And he stayed with me the whole time. And then there's a whole compassionate care team at the hospital, and the first thing they did (laughs) was give me this blanket that was knitted by Women In Prayer, which I cherish, and I've taken to the hospital any time [name] had to go back. (FM, WS)

The complete list of themes related to family members' physical needs is presented in Table 9 below and organized by the level of influence.

Table 9. Family Members' Physical Needs by Level of Influence

Physical Needs - Levels of Influence[12]		
Family Members' Needs	**Interviews**	**Workshop**
Adequate Space for FMs - Comfortable space where FMs can stay long periods of time to ensure they are available to communicate and build relationships with care teams	✓	✓

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[12] LO = Family member's loved one; FM = Family member

Physical Needs - Levels of Influence[12]		
Family Members' Needs	**Interviews**	**Workshop**
- Hospital rooms designed so that FMs are able to comfortably spend the night, take notes, research medical topics, provide support to their LO		
Private Conference Rooms - Private conference rooms for sensitive conversations		✓
Visitations Rules - To be able to visit LOs 24 hours/day to provide support, as well as to be available for early morning rounds and visits from care team members - Allowing visitors to grieve and say goodbyes is imperative for FMs		✓
Personal Items when Traveling - Basic items when away from home (e.g., phone charger, toothbrush, change of clothes)		✓
Hospital Staff Strategies	**Interviews**	**Workshop**
Offer Privacy - Offer quiet location for conversations, private conference rooms	✓	✓
Institution (ED and ICU) Strategies	**Interviews**	**Workshop**
Offer Privacy - Ensure an adequate number of waiting rooms (near ED and the ICU) so that FM can have privacy for themselves and also for discussions with providers	✓	
Waiting Areas and Hospital Rooms - Create comfortable areas for FMs, especially when FMs may need to wait many hours or spend the night	✓	

Limitations & Recommendations

Study Constraints and Limitations

The project operated under several constraints that impacted the execution of the research stages and are noted for their potential impact on the transferability of findings. These factors are presented as potential limitations to the study but also as considerations for the conduct of future research on the family member experience.

- **Inclusion of family members in project planning.** Design of the project took place without input or insights from members of the target audience. Family member engagement in all stages of the project would have been beneficial in allowing the team to incorporate their perspectives in the interpretation of interview findings, identification of workshop breakout session topics, and other details regarding the conduct of the workshop that may have facilitated their fuller participation, such as development of the protocol in the event of participant distress. Furthermore, engaging family members in framing the research questions may have illuminated

the challenge of constraining responses to the first 48 hours after the loved one's arrival to the hospital, a relatively arbitrary timeframe given the enormity of their experience.

- **Participant recruitment**.   The case study design, utilized in Stage I, situated the experiences of both families and professionals in a highly regarded Level 1 trauma center, which likely resulted in a higher representation of positive experiences for the case study exploration than would be typical. The intention, therefore, was to validate and elaborate on the findings through the workshop deliberations per the project design. The recruitment strategy employed was successful in identifying health care professionals in diverse roles at the case study site, who then assisted in reaching out to individuals whose loved one received care at the case study site to assess their interest in participating in an interview. Workshop participants' loved ones, in contrast, received care at various hospitals across the United States, and the health care professionals were also from regions outside of the case study site. Recruitment approaches used in both stages yielded highly interested health care professionals, as well as those more engaged in research, which may not be representative of providers in most emergency care settings. Although the institutional perspective is highly relevant, no institutional administrators or representatives were included either in the interview sample or as a workshop participant. With regard to family members, despite the intention to recruit those whose loved one's injury was fairly recent (within the last two years), attendees reported that the traumatic events occurred between 2008 and 2019, potentially introducing a recall bias.
- **Diversity of participants.**   Engaging participants with diverse social and demographic characteristics - both family members and professionals - was challenging to achieve for both stages of the project. The implications of this lack of diversity is the likely underrepresentation of the sociocultural needs of family members, as well as less confidence that the workshop goals – to validate and elaborate on the findings from the case study interviews with more diverse groups – were achieved.   Similarly, whereas the aim was to explore scenarios with different outcomes to represent a fuller range of experience, in most cases the family member's loved one survived the traumatic event.
- **Conduct of the workshop.** Achieving the objectives of the workshop was challenging for several reasons. Original plans to conduct the workshop at a conference facility were deemed infeasible due to the COVID-19 pandemic restrictions. Thus, some of the options and opportunities to more effectively engage family members were not possible in the virtual conference setting. There were also some associated challenges that contributed to delays in finalizing the discussion topics for the breakout groups. Ideally, there would have been more time to crystalize these topics and develop the tailored discussion guides for the breakout sessions, including with family member involvement as mentioned above. Finally, the agenda was designed to be respectful of attendees' time and attention (especially given the virtual format); thus, sessions for small-group reporting back to the larger assembly were excluded. These challenges likely limited the opportunities for bidirectional learning between the family members and the health care professionals.

Recommendations

The findings collected throughout the project have highlighted a variety of ways hospitals and their staff respond to the needs of family members in the ED and ICU following a loved one's critical illness or injury. Many of the families' needs cut across all of the domains, and as reported throughout the project, have corresponding, cross-cutting strategies that are effective at alleviating these needs. Thus, many of the proposed staff and institutional-level strategies have the potential to address family members' needs for information, compassionate communication, and emotional and physical support.

Table 10 below presents three overarching needs expressed by family members and the key recommendations participants agreed would help hospital staff and institutions respond to those needs.

Table 10. Cross-Cutting Recommendations for Hospital Staff and Institutions

Cross-Cutting Recommendations	
Family members need	**Hospital staff can**
Clear, compassionate, and timely information about the patient's status, expectations and care.	- Provide regular updates about the loved one's status, including test results, treatment options, and possible outcomes. - Provide guidance or where to go or whom to approach with questions. - Give assistance to make informed decisions (e.g., use lay terms, guidance with internet searches, explanation for technical details, encourage a second opinion, end-of-life discussions). - Communicate honestly and clearly about expectations or uncertainty. - Be compassionate and deliver difficult news with empathy (e.g., include silent pauses, give time to ask questions).
	Institutions can
	- Provide resources to ensure family members are oriented upon arrival with coordinated communication, and basic information about the hospital and cardiac arrest/traumatic brain injury. - Offer private or separate space for family members to use as a "home base" where providers can meet to conduct sensitive conversations. - Designate a "point person" or a "nurse mediator" to serve as the family's coordinator for the duration of the stay, and clearly delineate the roles of other members of the professional health care team. - Require a palliative care rotation for physicians and provide best practices for the conduct of family meetings. - Establish communication competencies for providers and offer trainings on multiple topics, including empathetic communication, recognizing forms of family distress, and providing comfort.
Family members need	**Hospital staff can**
To feel respected and part of their loved one's care team.	- Spend time with family members to build trust, assess communication needs, and build rapport. - Pay attention to how family members respond when engaging with them and recognize different styles, values, beliefs, and communication needs. - Deliver news in a human and empathetic way, with sincerity and authenticity.

	- Give guidance for how best to interact with their loved one and encourage involvement in their loved one's care and care team discussions. - Encourage additional family and community members to share in the loved one's care or to provide support for the family member.
	Institutions can
	- Promote family and patient-centered care and a culture of continuous learning and accountability for communication missteps. - Implement quality improvement strategies, such as recording family meeting interactions to provide feedback on providers' communication. - Provide training and mentoring for providers to understand how sociocultural background affects trust, communication, health care decisions; how racial inequities affect health; how to bridge gaps in communication and understanding.
Family members need	**Hospital staff can**
Various types of support after their loved one is discharged from the hospital or dies.	- Explain how hospital staff can support transitions (e.g., information on the roles and responsibilities of support staff, such as social workers) and how to access information about resources and support options after discharge. - Provide information to ease the transition post ED/ICU, including accessing disability benefits, what to expect in behavioral or personality changes, whom to call with questions, and what to expect for their loved one's rehabilitation. - Assist families of non-survivors with arrangements, such as funeral planning and autopsying procedures.
	Institutions can
	- Develop a continuity of care procedure for post-discharge support. - Provide family members with basic information about the types of support that can be expected post-discharge. - Assess how staff can support transitions and delineate the roles and responsibilities for staff involved in these transitions. - Consider offering opportunities for families and members of the care team to reunite to express gratitude and share regarding the loved one's outcome

References

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Appendices

Appendix A: Family Member and Professional Interview Guides

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

Family Member Interview Guide Preamble

Thank you for agreeing to participate in this interview. I am [NAME] and will be leading today's call. [NAME] is also on the call. We are part of the team working on this project together with Dr. Jonathan Elmer at the University of Pittsburgh and Dr. Robert Silbergleit at the University of Michigan. This work is paid for by SIREN, an Emergency Care Research Network.

The purpose of this research is to *better understand the experiences of family members and companions after a loved one's severe brain injury or cardiac arrest.* What we learn from you and others will help inform a workshop planned for this fall focusing on improving family member experience and engagement. We are interested in your experiences. Nothing you say will affect the ongoing care your loved one may be receiving.

Before we get started, I'd like to go over a few "housekeeping" guidelines.

- We hope you're comfortable sharing your thoughts and opinions, especially about this difficult experience. There are no right or wrong answers.
- I want to remind you that participation is completely *voluntary.* If you would like to stop at any time, please tell me and we will stop immediately. If there are any questions you do not want to answer, let me know and we can skip them.
- We will be recording today's call. Everything you say will be kept confidential and *not* linked to your name in any report. The recording will be destroyed after we finish the project. If at any time you do not want your comment to be recorded, please let me know and we will turn off the recorder.

Are there any questions before we get started? *Answer any questions.*

Do you agree to participate in this interview, and do I have your permission to record our discussion? *Obtain verbal agreement. Turn on recorder.*

Today is [DATE]. Now that the recorder is on, I will ask you again-- do you agree to participate in this interview today, and do I have your permission to record?

Introduction

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

Thanks again for talking with us today about [your loved one's event]. We understand discussing these experiences may be upsetting and really appreciate your willingness to talk with us.

We want to focus on your experiences early on, specifically in the first 48 hours after [patient's name] arrived to the hospital following [his/her] brain injury/cardiac arrest.

1. **Before we begin, I would like to make sure I understand more about your experience, starting from the beginning.** How did you first find out that something happened to [patient's name]?
    a. Where were you? Were you with anyone else?

Communication Needs

We'll now talk more about the information you received about [loved one] during this time, including conversations you may have had with doctors, nurses, social workers, and other hospital staff.

2. Can you tell me what it was like when you first arrived to the hospital?
    a. Who did you speak to or interact with? What was the nature of the conversation(s)? What did you learn? Where did this take place?
    b. How was this information communicated to you (e.g., written material, verbal communication, meeting, etc.; by doctor, nurse, social worker, etc.)?
    c. What did you think about the information you initially received about [patient's name] and the way it was communicated?
    d. Thinking about what you were told when you first arrived to the hospital, is there any other information that would have been helpful to receive?

3. One thing people in these situations have a hard time with is not knowing what will happen to their loved one. At any point in the first 48 hours, did the health care team tell you that they did not know how [loved one] would recover?
    a. Who shared this information with you? How was this uncertainty communicated to you? When and where? Did anyone else talk with you about the uncertainty of [loved one's] condition?
    b. What did you think about the way [that person] shared this information with you (e.g., communications style, approach)?
    c. During the conversations about the uncertain trajectory of [loved ones'] care or condition, did you feel the [providers] communicated this in a way to you that was easy to understand? Can you say more.

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

      d. When you had questions about the uncertain nature of [loved ones] care, did you know whom to ask? What sources, other than hospital staff, did you draw on for information during this time?

4. In thinking about the first 48 hours, what aspects of the communication were most important to you? Why?

5. Family and companions may be asked to make decisions about their loved one's care. Prior to this event, had you and [patient's name] discussed his/her wishes if something like this were to happen?
   a. Did the team ask for your input about decisions for [patient's name]? [*IF ANSWER IS NO:* Would you have liked to have been more involved in decisions regarding [patient's name] care? *IF YES*: Tell me more.]
   b. Can you say more about how they involved you in decisions for your loved one when there were options? When and where did this decision making take place (e.g., bedside, waiting room, by phone, etc.)? Who (else) was involved in these decisions?
   c. What helped you make decisions for your loved one?
   d. What did you think of the way [that person/team] discussed different options with you (e.g., communications style, approach)? How did you feel about the level of involvement you had in making decisions about [patient's name] care?

Emotional Needs

Now, we'll transition to discussing the emotions you experienced and the social-emotional support you may have received. Again, I would like you to think back from when you first found out something had happened until about 48 hours after [patient name] arrived to the hospital.

6. Can you tell me how/what you were feeling during this time period? How did you feel when you first found out about [patient name]? How did those feelings change over time?

7. How did you cope during this time?
   a. What, if anything, gave you comfort or reassurance during this early period?
   b. What types of emotional support did you receive?
      i. Who provided this emotional support? When, where, and how?
      ii. What did you think about the emotional support provided by the hospital?

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

      c.   Did you feel that your needs for things like food, rest, and privacy were addressed? Can you say more about that? What support, if any, did hospital staff offer to address these things?

      d.   Is there anything else that could have been helpful?

8.   Did you ever feel that medical providers or hospital staff treated you differently because of your personal characteristics, like gender, age, religion, race or ethnicity? How so?

9.   Based on your experience, how do you feel hospital staff and healthcare providers can best support family members during this difficult time?

Participation in Emergency Research/Clinical Trials

10. Now I would like to learn your thoughts about research study participation following a loved one's cardiac arrest/severe brain injury. Did the topic of [patient's name] being in a research study come up?

IF YES:

      a.   How did it come up and how did you feel about it?

      b.   Were you asked to make a decision about [patient's name] being in a study? What information was helpful to you to decide whether [patient's name] should participate in the research study or not?

IF NO:

      a.   One way that emergency research can happen is by asking next of kin for permission to enroll the patient in a research study. I know it might be difficult to imagine now, but how do you think you would have felt if you had been asked about having [patient name] participate in a research study?

11. Can you tell me more about what information would be important to help you decide whether your loved one should participate in a research study or not? When and how should that information be presented to you?

Closing

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

Thank you for participating in this discussion today. Before we close, is there anything else you would like to share?

We appreciate that you have taken the time to share your thoughts and personal experience. Should you have any questions about this project, you may contact Dr. Jonathan Elmer at elmerjp@upmc.edu or 412-647-3078.

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

Professional Interview Guide Preamble

Thank you for agreeing to participate in this interview. I am [NAME] and will be leading today's call. [NAME] is also on the call. We are part of the team working on this project together with Dr. Jonathan Elmer at the University of Pittsburgh and Dr. Robert Silbergleit at the University of Michigan. This work is supported by SIREN, an Emergency Care Research Network.

The purpose of this project is to *better understand the experiences of family members and companions after severe brain injury or cardiac arrest.* What we learn from you and others will help inform an NIH workshop planned for this fall.

Before we get started, I'd like to go over a few "housekeeping" guidelines.

- Your participation in this discussion is *voluntary* and you can end the interview or choose *not* to respond to a question at any time. Everything you say will be kept confidential and *not* linked to your name in any report.
- We will be recording today's call. The recording will be destroyed after we finish the project. If at any time you do not want your comment to be recorded, let me know and we will turn off the recorder.

Are there any questions before we get started? *Answer any questions*

Do you agree to participate in this interview, and do I have your permission to record our discussion? *Obtain verbal agreement. Turn on recorder.*

Today is [DATE]. Now that the recorder is on, I will ask you again-- do you agree to participate in this interview today, and do I have your permission to record?

Introduction

Thinking about family members' experiences in the first 48 hours after severe brain injury or cardiac arrest, our discussion will explore how you and others' address the communication and emotional needs of family members early in the clinical course during their time in the emergency department and the ICU.

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

We understand that you will be discussing these topics from your role as [role here], and will be drawing on your experience with many patients and family members over time. We recognize that some questions may not be relevant to your work, and those we can feel free to skip.

I'd like to start with getting a better understanding of how you interact with family members early on in the clinical course following a patients' cardiac arrest or severe brain injury?

Communication Needs

The next questions focus on your approach to communicating with families during the first 48 hours after the patient's arrival to the hospital.

1. What is your typical approach to communicating with families when you first talk with them?
   a. When and where does this take place?
   b. What influences your approach? How do family members' preferences have an influence?
   c. How can you tell if your approach is effective?
   d. What other approaches do you observe [variations]?

2. What about any other times [during the first 48 hours after the patient's arrival] you speak with the family (e.g., communicating updates about the patient's condition, care, treatment)? How does your approach differ at these times, if at all?
   a. In general, how well do you feel family members' communication or information needs are met during this time?

3. I know that prognosis or the anticipated clinical course early after severe brain injury or cardiac arrest is often uncertain. In your experience interacting with families in the first 48 hours following the patient's hospital arrival, how does talking about the uncertainty of the patient's clinical course come up?
   a. When and where is this brought up? By whom? What is your typical approach for communicating uncertainty about the patient's clinical course with families?
   b. What variations do you see? What seems to work? What doesn't seem to work?
   c. What are the challenges? What helps?

4. How do potential long-term implications [prognosis] for the patient come up?

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

      a.   When and where is this brought up? By whom? What is your typical approach for communicating potential long-term implications?

      b.   What variations do you see? What seems to work? What doesn't seem to work?

      c.   What are the challenges? What helps?

5. Family members seem to fall on a spectrum between wanting to be part of all the decisions and leaving the decision to the doctor. What has been your experience/what have you observed with families wanting to be involved versus leaving decisions with the doctor?

6. Likewise, clinical providers seem to fall on a spectrum between involving the family in most decisions and excluding the family from any decision making by telling them what to do. What is your typical approach/what have you observed with providers involving family members in decisions early in the clinical course?

      a.   When and where does this take place? Who is involved?

      b.   What variations do you see? What seems to work? What doesn't seem to work?

7. [PHYSICIAN ONLY] When there are different treatment options, how do you handle situations when family members express a preference for an option that differs from your own?

      a.   Under what circumstances do you find it most challenging to go along with family preferences, and how do you handle it?

Emotional Needs

Now we are going to focus on the emotional needs of family members during this critical period and how they are addressed.

8. What do you feel are common emotional needs of family members during this time?

9. How are family members' emotional needs typically addressed?

      a.   When, where, by whom?

      a.   In general, how well do you feel family members' emotional needs are met during this time?

      b.   How, if at all, is this influenced by family members' characteristics such as race or ethnicity, age, gender, etc.?

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

    c.   In what way do you feel your own personal identity (e.g., age, gender, cultural affiliation, and minority status) influences your experience with families? Can you share (other) examples where it did?

10. From your perspective, how could the emotional needs of family members during this time period be better identified and addressed?

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Participation in Emergency Research Clinical Trials

</div>

Now we will briefly cover your experience and views on patient participation in **emergency research studies.**

11. Can you tell me briefly about your experience with emergency research enrollment [*INTERVIEWER NOTE*: Can probe on "observations". If No experience, go to Demographics]

    a.   From your experience, what are families' reactions to the enrollment of their family members (the patients) into a clinical trial?

<div style="background-color:#d9cce8">

Demographics

</div>

As we wrap up, I have a few questions about you and your background.

12. How many years have you been in your profession?

13. Which gender do you identify with?

14. Are you of Hispanic or Latino origin or descent?

15. What is your race? [INTERVIEWER NOTE: PROBE AS NEEDED USING LIST BELOW]
    ☐ White
    ☐ Black or African American
    ☐ Asian
    ☐ Native Hawaiian or Other Pacific Islander
    ☐ American Indian or Alaska Native
    ☐ Other

<div style="background-color:#d9cce8">

Closing

</div>

Date:		Time:	
Name:		ID:	
Condition:	Cardiac or Brain Injury [patient-level]	Role:	ALL FAMILY MEMBERS

Thank you for participating. Before we close, do you have any other comments or additional information that you would like to share about *the experiences of family members and companions after severe brain injury or cardiac arrest*?

[INTERVIEWER NOTE: Turn recorder off. Follow-up on family member referrals]

We appreciate that you have taken the time to share your thoughts and personal experience. Should you have any questions about this project, you may contact Dr. Jonathan Elmer at elmerjp@upmc.edu or 412-647-3078.

Appendix B: Interview Distress Protocol

Distress Protocol

SIREN AIM 3: Family Member Experience Interviews

Should the participant become uncomfortable or distressed while discussing their experience, the following actions will be taken:

1. The interviewer will suggest that it is acceptable for the interview to be terminated.
2. If the participant would like the interview to end, the interviewer will thank the participant and terminate the interview. Before ending the call, the interviewer will offer resources to the participant (see possible resources below).
3. If the participant wishes to continue, the interviewer will carry-on with the interview and check-in with the participant, as needed.
4. For any participant whose interview was terminated because of distress, the interviewer will notify the participant that they will call over the next 1-2 business days to ensure that the participant is okay. During the follow-up call, the interviewer will provide contact information for resources/support services once again.

Possible Resources
- UPMC: resolve Crisis Services (24-hour, 365-day crisis service that's free to all Allegheny County residents)
    o 1-888-7-YOU-CAN (1-888-796-8226)

- Crisis Services at UPMC Western Behavioral Health at Safe Harbor
    o 814-456-2014 or 1-800-300-9558

- National Helpline
    o 1-800-662-HELP (4357)
    o Treatment referral and information, 24/7

- UPMC Presby – Speak with a Physician
    o A 24-hour phone number that you may call to speak with a physician after your loved one goes home (for questions/concerns)
    o 412-647-2002

Appendix C: Interview Codebook

Family Member Experience Interviews Codebook – Ecological Model

Parent/Child Code	Description	Notes/Comments
1. Family Member Factors	Factors, concepts that relate to the FMs' experience and perspective	Only code to child codes, if text is related to FM factors but not a child code, use "Other" code
a. Communication needs	Description of discussions from both professionals and FMs around the needs of FMs and whether their real or perceived needs are met or not, communication gaps, preferred communication style. Includes discussion of whether communication needs are met and evidence of this.	Discussion relates more to real or perceived communication needs, less about actual content of communication
b. Decision-making preference	Description of how/when FMs prefer to be involved in the decision-making process; whether they were satisfied with this process	
c. Emotional needs and self-regulation	Discussion of FM's emotional needs; whether they were met, how FMs addressed their emotional needs; emotional state and stress	Any discussion about health care professional approaches to supporting emotional needs should be coded under 2d.
d. Demographics and culture	Examples of how FMs believed that they were treated differently due to their demographics, culture, socio-economic status or situation; examples or stories of how FM background, beliefs, demographics influenced their emotional or communication needs	
e. Other	Other comments that relate to FM experience that are not captured in above child codes.	

Parent/Child Code	Description	Notes/Comments
2. Hospital Staff Factors	Factors, concepts that relate to the professionals' experience and perspective	Only code to child codes, if text is related to HS factors but not a child code, use "Other" code
a. Professional communication approaches	Approaches to communicate with FMs; content of communication, strategies, communication style; where communication takes place; what influences communication approach. Also includes other approaches professionals have observed, and discussion of when and why they may use different communication approaches.	Discussion relates more to content of communication, strategies, typical and tailored approaches
b. Handling uncertainty	Discussions of how professionals communicate or how FMs learn about the uncertainty of the patient's clinical course	
c. Decision-making	Discussions of how/when to include FM in decision-making process, approaches to engage FMs in decision-making; includes how to handle situations when FMs express preferences that differ from their own	
d. Supporting emotional needs	Discussion of professional approaches to address FM emotional needs and how best to address these needs	
e. Family member engagement/ communication training	Discussion of any training (formal or informal), learning from mentors or champions, etc. on how to best engage and communicate with family members and how this affects the professionals' interaction with FMs; include discussion about training needs/gaps	Use this code if professional discusses training in terms of past training outside of UPMC. If training is at UPMC, double code here and under 4a. service culture.
f. Demographic, culture, personal experiences	Descriptions of how professionals' personal identity and experiences influence interactions with FMs	

Parent/Child Code	Description	Notes/Comments
g. Other	Other comments that relate to professionals' experience that are not captured in above child codes.	Use this code for any discussion about the emotional toll placed on health care professionals
3. Physical Environment	Descriptions of how the ED/ICU physical environment could be improved to better support FMs; discussions of how the physical environment supports FMs	
4. Leadership and Policy	Pertains to leadership, culture, policies specific to UPMC	Only code to child codes, if text is related to Leadership and Policy but not a child code, use "Other" code
a. Service culture	Any comments about the general culture of the ED/ICU in terms of respecting FMs, building trust and enhancing communication with FMs, encouraging shared-decision making, including families in bedside rounds. Includes discussion of recruiting hospital staff (e.g., diversity of staff, educators), champions who practice FM engagement, toolkits, lectures, specialized programs or protocols, specialized training for nurses to improve FM experiences, and supporting patient-family advisor roles and counsel for EDs/ICUs (e.g., encouraging patient advisors to serve on safety and quality performance improvement teams).	Use this code for any discussion about pre-COVID visitation policies
b. Visitation policies (COVID)	Comments about visitation policies (during COVID) and how this affected the FM experience	
c. Other	Other comments that relate to ED/ICU leadership and policies that are not captured in above child codes.	

Parent/Child Code	Description	Notes/Comments
5. Participation in Research	Responses about discussion of participating in research studies, conducting research	Only code to child codes, if text is related to research but not a child code, use "Other" code
a. Enrollment experience	Include professionals' discussion of enrolling patients into emergency research studies, and family's reactions to the patient's enrollment	
b. Research discussion - Yes	Comments about whether the FM was asked about enrolling the patient in a study, decisions about participation	
c. Research discussion - No	Discussion of whether the FM would be comfortable enrolling the patient in a research study, how they would make this decision	
d. Consent in research	Thoughts about EFIC studies, how they would have felt if the patient was enrolled	
e. Other	Other comments that relate to emergency medicine research that are not captured in above child codes.	
6. Interesting Quotes	Any interesting, rich quotes that may be helpful for analysis, workshop activities or dissemination	
7. To Discuss	Any quotes that need further deliberation, unsure of where to code	

Appendix D: Pre-Workshop Family Member Survey

Thank you for your willingness to participate in the upcoming NIH-sponsored workshop, Family Experience after Cardiac Arrest and Severe Neurotrauma, to be held virtually on November 19, 2020. We would like to get a better understanding of you and your experiences prior to the workshop. It will take approximately 10 minutes to complete this questionnaire, which we will use to help prepare for the workshop. A couple questions may be distressing to you as you think about your experience. Your participation is voluntary, and you have the right to skip any question for any reason.

With your permission, we will share your name, email address, and the brief introduction you provide— along with those submitted from others—with participants in advance of the workshop. For any reports or publications that may result from the workshop, we will fully de-identify any information you provide. If you have any questions about this questionnaire or the upcoming workshop, you may contact SIREN@westat.com.

Checking the box below indicates that you:

- Have read the above information
- Are 18 years of age or older
- Voluntarily agree to participate

*

☐ Yes

1. When was your loved one's brain injury or cardiac arrest? (MM/YYYY)

For this workshop, we will be compiling a list of participants with photos and brief introductions about each participant. The purpose is to set the stage and help you and others know a little bit about the other participants. If you prefer that we do not share your introduction with other workshop attendees, you may

select "No" in question 2c.

2a. Your Name

First Name   Last Name

2b. Please provide 2-3 sentences that will serve as a brief introduction about yourself, focusing on your experience that brought you to this workshop. (See example, below.)

Example: My spouse was in a car accident in June 2019 and suffered a TBI. He was flown to UPMC Presby where he had an emergency surgery. The doctors and nurses were great and kept us very informed, but he unfortunately died because of his severe brain injury. Since he was registered as an organ donor, his organs were given to others in need.

0/500

2c. Do we have your permission to share your introduction (provided above) with other workshop attendees?

☐ Yes

☐ No

2d. Do we have your permission to share the email address where we sent this survey with other workshop attendees?

☐ Yes

☐ No

☐ A different email address can be shared

Please enter the email address that can be shared.

3. What do you feel is most important for us to know about your experience with your loved one's cardiac arrest or traumatic brain injury (TBI)?

0/500

4. A focus of this project is learning how to improve the experiences of family members in the first couple of days after a loved one's cardiac arrest or brain injury. From your perspective, how can hospital staff and the health care team best support family members during these difficult first days?

0/500

About You

The next set of questions ask about you.

5. With which gender do you most identify?

☐ Female
☐ Male
☐ Other

6. What is the highest grade or level of school that you have completed?

☐ Less than high school
☐ High school graduate or GED
☐ Some college or 2-year degree
☐ 4-year college graduate
☐ More than a 4-year college graduate

7. Are you of Hispanic or Latinx (Latina/Latino) origin or descent?

☐ Yes
☐ No

8. Which of the following best describes you?

☐ Asian or Pacific Islander
☐ Black or African American
☐ Native American or Alaskan Native
☐ White or Caucasian
☐ Multiracial or Biracial
☐ A race not listed here

9. What is your age?

☐ 18 to 24
☐ 25 to 34
☐ 35 to 44
☐ 45 to 54
☐ 55 to 64
☐ 65 to 74
☐ 75 or older

10. How confident are you filling out medical forms by yourself?

☐ Extremely
☐ Quite a bit
☐ Somewhat
☐ A little bit
☐ Not at all

11. You may use the space below for anything else you would like to share with us about your loved one or your experience following your loved one's brain injury or cardiac arrest.

0/500

Submit

Appendix E: Workshop Informational Booklet

Family Experience after Cardiac Arrest and Severe Neurotrauma: Virtual Workshop

November 19, 2020

10:00 AM – 4:00 PM ET

Informational Booklet

Zoom Link:
https://westat.zoomgov.com/j/1609576539?pwd=MEF5dEl2L2R3ejFXdHpBNVBtV0YxZz09
Meeting password: Nov2020

Table of Contents

Agenda

I. **Welcome & Objectives (10:00 – 10:15 am ET)**

II. **Housekeeping & Introductions (10:15 – 10:30 am ET)**

III. **Overview of the Field & Findings from Qualitative Interviews (10:30 – 12:05 pm ET)**
   a. **Presentation 1**: Family Involvement in the Early Phase of Cardiac Arrest and Traumatic Brain Injury (TBI)
   b. **Presentation 2:** Preliminary Interviews: A Single Hospital's Experience
   c. **Q&A**
   d. **Reflection Session:** Participant reflections on interview findings

IV. **Breakout Session #1 (12:05 – 1:05 pm ET)**
   Topics: Family needs in the first 48 hours; provider training and care team approach

V. **Break (1:05 – 1:40 pm ET)**

VI. **Breakout Session #2 (1:40 – 2:45 pm ET)**
   Topics: Uncertainty and information processing

VII. **Break (2:45 – 3:00 pm ET)**

VIII. **Takeaways & Closing (3:00 – 4:00 pm ET)**
   a. **Synthesis/Key Themes**
   b. **Prioritization Activity**
   c. **Next Steps**

NOTE: This workshop will be recorded for notetaking purposes. Only members of the study team will have access to the recording.

Attendee	Biography
Family Member Participants	
██████████	██████████
██████████	██████████

| Health Care Professional Participants	
Dr. Benjamin Abella	Dr. Abella is Professor and Vice Chair for Research in the Department of Emergency Medicine at the University of Pennsylvania. He has studied cardiac arrest and post-arrest care for over 15 years, and has received research funding for these topics from the National Institutes of Health, Patient-Centered Outcomes Research Institute and the American Heart Association. He has authored over 200 works pertaining to these topics, and currently serves as the Co-Chair of the global Resuscitation Science Symposium of the American Heart Association. He has worked with cardiac arrest survivors to advocate for CPR training and improved post arrest care in a program he founded known as the Philadelphia Mobile CPR Project, www.themobilecprproject.com
Dr. Sachin Agarwal	Sachin Agarwal is an assistant professor of neurology and neurocritical care at Columbia University Medical Center (CUMC) and the Director of NeuroCardiac Comprehensive Care Clinic (N4C), the first of its kind in the United States. It is a "One-Stop-Shop" that offers comprehensive, multi-disciplinary, well-coordinated care for survivors of cardiac arrest and their families. Dr. Agarwal's research interests lie in characterizing the psychological and health behavioral dimensions of cardiac arrest survivorship including sleep and physical activity, and their association with future cardiovascular disease risk, and quality of life.
Michelle Biros	I am an emergency care researcher with extensive experience in the conduct of multicenter trials in the ED, the prehospital ,and the outpatient setting , where enrolled subjects patients have no previous relationship with the investigative team. My personal research focus on the use of exception from informed consent (EFIC) for emergency research, including issues of consent, community consultation, and public disclosure for emergency care research. I participated in the panel that developed federal regulation 21 CFR 50.24, which lays out the federal regulations for EFIC research. Working with the IRBs of the NETT research network, I was able to develop and publish the first unified EFIC plan allowing local community consultation and public disclosure in a way acceptable to multiple IRBs in the network, a model that has been emulated by other research networks to improve efficiency and reduce the time required to complete EFIC activities and start multicenter enrollment.

Dr. Clifton Callaway	Dr. Callaway is a professor of emergency medicine at the University of Pittsburgh, whose clinical practice includes management of patients hospitalized after cardiac arrest. He has served as an investigator enrolling patients in clinical trials and studies after cardiac arrest, traumatic brain injury, and other emergency conditions. He has worked with paramedics and other emergency providers on trials conducted in the prehospital setting
Gail Delfin	Gail Delfin MSN RN. With 35 years of experience in cardiac critical care, I served as a bedside nurse and Clinical Nurse Specialist at the Hospital of the University of Pennsylvania. In addition, I was a nurse researcher in the Center for Resuscitation Science at Penn. My expertise includes post-cardiac arrest care, with an emphasis on Targeted Temperature Management (TTM); with Dr. Benjamin Abella as my mentor, I have co-authored publications, and presented at both American Heart Association conferences and at Penn Medicine post-cardiac arrest teaching seminars.
Dr. Claude Hemphill	Dr. Claude Hemphill is Professor of Neurology at the University of California, San Francisco and Chief of Neurology at Zuckerberg San Francisco General Hospital. His research focuses on advanced neuromonitoring, clinical treatment trials, and prognostication for acute neurological emergencies such as traumatic brain injury and stroke. He is the current co-chair of the Neurocritical Care Research Network and the *Curing Coma Campaign* of the Neurocritical Care Society.
Dr. Karen Hirsch	Karen Hirsch is an Associate Professor of Neurology and Neurosurgery at Stanford University. She specializes in neurocritical care, caring for patients in the intensive care unit with critical brain, spine, and nervous systems injuries and illnesses. Dr. Hirsch's research focuses on neuroimaging, prognostication, and critical care management of patients with traumatic brain injury and brain injury after cardiac arrest.

Paula Kovanic Spiro	Paula Kovanic Spiro, LMSW, MPH is the program coordinator for the BRAVE (Buffalo Rising Against Violence at Erie County Medical Center) which is a federally funded hospital based violence injury program. Prior to this, she worked as the unit social worker in both the neuro trauma and surgical care unit at the University of Pittsburgh Medical Center.
Dr. Christos Lazaridis	Dr. Christos Lazaridis is a neurointensivist at the University of Chicago. His interests include neurotrauma critical care, multimodality neuromonitoring, shared decision making and ethics in acute brain injury.
Dea Mahanes	Dea Mahanes has been a neuroscience nurse for over 25 years. She is currently a Clinical Nurse Specialist in the intensive and intermediate care units at the University of Virginia Health System. In this role, Dea works directly with patients and families and is also a resource for nurses and other members of the healthcare team.
Nick Nudell	As a scholar practitioner, Nick has been a paramedic, paramedic executive, and health system consultant for over 20 years in rural, suburban, and urban settings. He has participated in over 150 cardiac arrest resuscitations in both hospital and out-of-hospital settings as a team leader and a provider.

	Dr. David Okonkwo is Professor of Neurological Surgery and Director of the Neurotrauma Clinical Trials Center (NCTC) in the School of Medicine at the University of Pittsburgh. He serves as Director of Neurotrauma and of the Scoliosis and Spinal Deformity Program at UPMC. Dr. Okonkwo is also a member of the Medical Staff for the Pittsburgh Steelers
Dr. David Okonkwo	

Workshop Co-Chairs/Presenters

	Jonathan Elmer is a physician who works in both the emergency department and intensive care unit. The focus of his clinical work and research is improving care of patients with severe brain injury such as that which occurs after cardiac arrest or trauma.
Dr. Jonathan Elmer	
	Dr. Adrianne Haggins is an emergency medicine physician and medical educator. Her primary research interests are related to examining health disparities in access to care, and designing socio-cultural educational curriculum to improve care to vulnerable populations.
Dr. Adrianne Haggins	

Dr. Susanne Muehlschlegel	Dr. Muehlschlegel is an Associate Professor of Neurology, Anesthesiology and Surgery at the University of Massachusetts Medical School in Worcester, MA. She is Director of Neurocritical Care Research at UMASS with a research program in <u>Shared Decision Making</u> and <u>neuroprognostication</u> in severe acute brain injury, in particular traumatic brain injury and stroke. Her clinical research lab focuses on designing and testing shared decision making interventions in critically ill neurologic patients as well as understanding and improving the way doctors communicate with and prognosticate to families. She is the co-chair of a large international guideline on "Neuroprognostication", a joint guideline between the *Neurocritical Care Society*, and the *German Society for Neuro-Intensive Care Medicine (Deutsche Gesellschaft für Neurointensivmedizin).* She leads the NIH "Curing Coma" Common Data Elements working subgroup "Goals of Care Decisions / Family Data" with national and international group members. www.umassmed.edu/nccresearch
Dr. Sarah Perman	Dr. Perman, MD MSCE, is an Associate Professor of Emergency Medicine at the University of Colorado School of Medicine. She obtained her medical degree from Temple University in 2007, general emergency medicine residency at the University of Pennsylvania in 2011 and a Resuscitation Research fellowship at the University of Pennsylvania Center for Resuscitation Science in 2013. Dr. Perman's clinical interests are focused on post-cardiac arrest therapies and acute critical care in the emergency department. Her research is focused on post-cardiac arrest neuro-prognostication and decision-making, in addition to sex/gender differences in cardiac arrest outcomes. Dr. Perman is an active member of the American Heart Association and a member of the Emergency Cardiovascular Care Science Subcommittee.
Dr. Robert Silbergleit	Robert Silbergleit MD is a Professor of Emergency Medicine at University of Michigan. His research focuses on clinical trials of acute interventions for neurological emergencies including status epilepticus, cardiac arrest, stroke, and traumatic brain injury. He is a key investigator in the leadership of the NIH funded NETT and SIREN clinical trial networks. Dr. Silbergleit is dedicated to improving the structure, efficiency, and accountability of the clinical trial enterprise. He has been a co-investigator on a regulatory science grant from the NIH and FDA to investigate adaptive clinical trial methods in confirmatory phase trials, and is Principal Investigator on an NIH funded empirical ethics research project to study local context review by individual and centralized Institutional Review Boards. He has published and presented on issues relating to emergency research, consent, and exception from informed consent at meetings of PRM&R, and the Society for Clinical Trials.

Other Attendees and Workshop Organizers

- National Institutes of Health (NIH)
  - Jeremy Brown
  - Mary Groesch
  - Amy Patterson
  - Nina Schor
  - Nivedita Sengupta
  - George Sopko
- University of Michigan
  - Erin Bengelink
  - Michael Fetters
  - Deniel Harney
  - Renee Kasperek-Wynn
  - Valerie Stevenson
- Medical University of South Carolina
  - Sharon Yeatts
- Emory University
  - Neal Dickert
- American Heart Association
  - Leslie Hearn
  - Comilla Sasson
- Sudden Cardiac Arrest Foundation
  - Mary Newman
- Westat
  - Jennifer Huang
  - Liz Jansky
  - Jess Kirchner
  - Paula Darby Lipman
  - Natalie Teixeira

Appendix F: Workshop Distress Protocol

Distress Protocol

11/19/20 SIREN AIM 3 Virtual Workshop

Discussion during the November 19, 2020 workshop, *Family Experience after Cardiac Arrest and Severe Neurotrauma,* may cause emotional distress for participants as they reflect on their experiences. The following actions will be taken to protect participants:

1. *Before the workshop*
   a. Participants will be emailed the workshop agenda and alerted to the sensitive and potentially distressing nature of topics
   b. Participants will be emailed a crisis support resource (e.g., https://www.crisistextline.org/).

2. *During the workshop*
   a. During the opening segment, participants will be informed that it is acceptable for them to step away for a moment or turn their camera off if the participant needs a break. Participants will be asked to inform **Renee Kasperek-Wynn by email, phone, or Zoom chat** if they will be stepping away for more than 20 minutes at any point during the workshop. Breakout room facilitators and Renee will be observing participation throughout the entire workshop. Breakout room facilitators will let Renee know if a participant unexpectedly leaves the workshop for more than 20 minutes. If a participant has unexpectedly left the workshop for more than 20 minutes or does not return within 30 minutes of when they said they would, Renee will call the participant to check in on them.

   b. Should a workshop participant become noticeably distressed during the workshop, the PI **(Robert Silbergleit)** will send a private chat message to the participant to check on him/her.[13]

   Breakout room facilitators and Renee Kasperek-Wynn will be monitoring participants' distress and alert Robert by email or Zoom chat if someone is very distressed.

   c. Should a workshop participant express homicidal or suicidal thoughts, **Renee Kasperek-Wynn** will call the participant's local police and inform them of the participant's contact information so they may visit the participant to check in on them.

   Breakout room facilitators will be monitoring participants and alert Renee by emnail or Zoom chat if any participant expresses homicidal or suicidal thoughts.

3. *After the workshop*
   a. Participants will be provided with the crisis support resource once again via email.

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[13] Family member participants will be informed that workshop organizers may check-in with them by phone or Zoom chat if they appear very emotional or have unexpectedly left the workshop.

Appendix G: Reflection Session Discussion Guides

SIREN Subproject #3

Reflection Sessions Guide – <u>Care Team Groups</u>

Total time: 1 hour

11/19/2020

Hi everyone and welcome to the Reflection Session of our workshop.   As Jonathan previously mentioned, we're in this breakout room to discuss our reflections on the interview findings. I am [facilitator name], and I will be starting today's discussion. [Co-chair] may also ask a few follow-up questions or provide additional insight during the session. But most of the conversation will come from you all, as we'd like to learn more about your thoughts about the interview findings.

All of you participating in this discussion are members of a care team that see patients with cardiac arrest or traumatic brain injury in the ED or ICU. There are several others in the breakout room who are either members of the SIREN team or from NIH. They are only observing and will not participate in the discussion.

Jonathan mentioned that one of the limitations of the findings is that the interviews were conducted with care team members that service one hospital in Pittsburgh, PA. These providers then referred family members that had a loved one admitted to this hospital. We'd like to take the time during this session to understand if our findings also resonate with those that are not affiliated with this hospital, or if we are missing any information.

It's important to express yourself openly during our discussion today. There are no right or wrong answers. We simply want to know what you think. I would like everyone to be a part of this conversation. You do not need to wait for me to call on you to talk, but only one person should speak at a time. Also, we ask you keep what we discuss today within this group and not share what we discussed with others who did not participate in the workshop. This is to make everyone feel comfortable sharing their honest opinions with the group.

As we stated earlier, we are recording the workshop, including this reflection session. What you say will not be linked to your name in any of our reports, and the recording will be destroyed after we have analyzed the discussions.

Lastly, before we begin, I want to note that if you anticipate leaving the session for more than 20 minutes, please send a chat to [backup.] We just want to make sure that we haven't lost or overlooked anyone during the session.

Do you have any questions about what I've said so far? [*Answer any questions.]*

Practice Padlet – 5 min

For this session, we will use Padlet, which is a website that allows several people to collaborate and share ideas in real time. We'll post some initial ideas of our feedback on the interview findings and then discuss further. First, let's walk through a practice Padlet so that we can understand how to use it.

I'm adding a link to Padlet in the breakout room chat. Please click on that link, which will take you to the Padlet website.

Once you are in Padlet, you'll see that there is a question on the top of the page. *[Read the practice Padlet question]* Click on the plus sign to add in your response. Everything is reported anonymously. You can also vote if you agree or disagree on someone's response, and comment on it as well. *[Allow a few minutes to play around with the features, demonstrate some features, and respond to any questions.]*

Great. Now that we have the hang of Padlet, let's review the findings that Jonathan presented and then hear your thoughts about these findings. We'll group the findings by information, communication, emotional, and sociocultural needs and go through them one by one.

Information Needs – 10 min

First, let's review the information needs and strategies to address these needs that were discussed during the interviews.

[Present slide by sharing screen and review bullets]

- Both family members and care team participants expressed the need for clear expectations for the progression of illness/injury.
- Family members emphasized the need for procedural information to navigate the hospital environment.
- **From your perspective, what other information is important to provide to family members in the first 48 hours after their loved one has been admitted to the hospital?**

I'm now adding a link to another Padlet in the chat. Please click on that link, which will take you to the Padlet website. Here, you can add your response for additional information under the "Information Needs" column. Click on the plus sign under that column to add in your responses. We're just focusing on information needs at this time.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Communication Needs – 10 min

Now, let's review the communication needs and strategies to address these needs that were discussed during the interviews.

[Present slide by sharing screen and review bullets]

- Both family members and care team participants expressed the need for effective communication strategies when conveying health information about the loved one.
- Family members emphasized the need for the care team to assist with information processing:
    o Give direct, understandable information
    o Use repetition to assist with understanding
    o Provide opportunities to ask questions
    o Receive contact information for care team
- The care team spoke about specific strategies used to assist with information processing:
    o Suggest taking notes
    o Recommend key terms to search in Google
    o Offer translation services
    o Provide time for questions
- **From your perspective, what communication strategies are missing from this list?**

Please click on the link to Padlet again, where you can add your response under the "communication needs" column.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Emotional Needs – 10 min

Families and care team members also discussed emotional needs and strategies to address these needs throughout the interviews.

[Present slide by sharing screen and review bullets]

- Both family members and care team participants expressed the importance of:
    o Displaying compassion in all interactions
    o Encouraging support from other family and friends
    o Utilizing social/religious support services
    o Engaging in self-care activities (e.g., sleep, eating, walking, etc.)
    o Being with the loved one as much as possible
- Family members expressed the need to:
    o Personally help their loved one (e.g., internet searches, journaling, praying)
    o Receive continued support (after ICU transfer, after death or hospital discharge)
- The care team emphasized the need to address uncertainty in clinical course and outcomes:

- How to convey; how much to convey
- Balancing communication of uncertainty with clarity
- Emotional toll on overwhelmed families
- Need for time to observe course of illness
- Effect on shared decision-making
- Consistency of messaging across teams
- Perils of using statistics
- **From your perspective, what additional strategies are used to address emotional needs?**

Please click on the link to Padlet again, where you can add your response under the "emotional needs" column.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Sociocultural Needs – 10 min

[Present Slide by sharing screen and review bullets]

Now we'll talk about sociocultural needs, or the needs family members may have based on their background including but not limited to their culture, race and ethnicity, religious beliefs, geographic location, and family structure.

- Both family members and care team participants emphasized the need for equitable treatment and socioculturally appropriate communication
- **From your perspective, what strategies are used to address the needs families may have based on their background?**

If participants don't respond to the above questions, ask: What does equitable treatment and socioculturally appropriate communication mean to you?

Please click on the link to Padlet again, where you can add your response under the "Sociocultural Needs" column.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Other Needs – 5 min

[Present Slide by sharing screen and review bullets]

- Thinking about the first 48 hours, are there any other family needs or strategies that we haven't addressed in the interview findings or in this reflections session?

Appendix H: SIREN Subproject 3 – FAMILY MEMBER EXPERIENCE   91
Reflection Session Discussion Guides

Please click on the link to Padlet again, where you can add your response under the "Other Needs" column.

Discuss common responses, clarify differing responses, and generate discussion

Closing – 5 min

Thanks so much for all of your feedback! Your comments are extremely helpful for us to understand FMs' needs in various types of settings. Do you have any last minute comments to add?

If you have time, summarize main points and reflect back to the group for confirmation.

Now, we'll go back to the main meeting room in a few moments. When you see the prompt that we'll return to the main room in a few seconds, please don't click on it yet, as it will take you immediately to the room.

SIREN Subproject #3

Reflection Sessions Guide – <u>FM Groups</u>

Total time: 1 hour

11/19/2020

Hi everyone and welcome to the Reflection Session of our workshop.   As Jonathan previously mentioned, we're in this breakout room to discuss our reflections on the interview findings. I am [facilitator name], and I will be starting today's discussion. [Co-chair] may also ask a few follow-up questions or provide additional insight during the session. But most of the conversation will come from you all, as we'd like to learn more about your thoughts about the interview findings.

All of you participating in this discussion are family members of a loved one who suffered from a cardiac arrest or traumatic brain injury. There are several others in the breakout room who are either members of the SIREN team or from NIH. They are only observing and will not participate in the discussion.

Jonathan mentioned that one of the limitations of the findings is that the interviews were conducted with care team members that service one hospital in Pittsburgh, PA. These providers then referred family members that had a loved one admitted to this hospital. We'd like to take the time during this session to understand if our findings also resonate with those that are not affiliated with this hospital, or if we are missing any information.

It's important to express yourself openly during our discussion today. There are no right or wrong answers. We simply want to know what you think. I would like everyone to be a part of this conversation. You do not need to wait for me to call on you to talk, but only one person should speak at a time. Also, we ask you to keep what we discuss today within this group and not share what we discussed with others who did not participate in the workshop. This is to make everyone feel comfortable sharing their honest opinions with the group.

As we stated earlier, we are recording the workshop, including this reflection session. What you say will not be linked to your name in any of our reports, and the recording will be destroyed after we have analyzed the discussions.

Lastly, before we begin, I want to note that if you anticipate leaving the session for more than 20 minutes, please send a chat to [backup.] We just want to make sure that we haven't lost or overlooked anyone during the session.

Do you have any questions about what I've said so far? [*Answer any questions.]*

Practice Padlet – 5 min

For this session, we will use Padlet, which is a website that allows several people to collaborate and share ideas in real time. We'll post some initial ideas of our feedback on the interview findings and then discuss further. First, let's walk through a practice Padlet so that we can understand how to use it.

I'm adding a link to Padlet in the breakout room chat. Please click on that link, which will take you to the Padlet website.

Once you are in Padlet, you'll see that there is a question on the top of the page. *[Read the practice Padlet question]* Click on the plus sign to add in your response. Everything is reported anonymously. You can also vote if you agree or disagree on someone's response, and comment on it as well. *[Allow a few minutes to play around with the features, demonstrate some features, and respond to any questions.]*

Great. Now that we have the hang of Padlet, let's review the findings that Jonathan presented and then hear your thoughts about these findings. We'll group the findings by information, communication, emotional, and sociocultural needs and go through them one by one.

Information Needs – 10 min

First, let's review the information needs that family members discussed during the interviews.

[Present slide by sharing screen and review bullets]

- Both family members and care team participants expressed the need for clear expectations for the progression of illness/injury.
- Family members emphasized the need for procedural information to navigate the hospital environment.
- **From your perspective, what other information would have been helpful to receive during the first 48 hours after your loved one was admitted to the hospital?**

I'm now adding a link to another Padlet in the chat. Please click on that link, which will take you to the Padlet website. Here, you can add your response for additional information under the "Information Needs" column. Click on the plus sign under that column to add in your responses. We're just focusing on information needs at this time.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Communication Needs – 10 min

Now, let's review the communication needs that family members discussed during the interviews.

[Present slide by sharing screen and review bullets]

- Both family members and care team participants expressed the need for effective communication strategies when conveying health information about the loved one.
- Family members emphasized the need for the care team to assist with information processing:
    - Give direct, understandable information
    - Use repetition to assist with understanding
    - Provide opportunities to ask questions
    - Receive contact information for care team
- **From your perspective, what communication needs are missing from this list?**

Please click on the link to Padlet again, where you can add your response under the "communication needs" column.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Emotional Needs – 10 min

Family members also discussed several emotional needs throughout the interviews.

[Present slide by sharing screen and review bullets]

- Both family members and care team participants expressed the importance of:
    - Displaying compassion in all interactions
    - Encouraging support from other family and friends
    - Utilizing social/religious support services
    - Engaging in self-care activities (e.g., sleep, eating, walking, etc.)
    - Being with the loved one as much as possible
- Family members expressed the need to:
    - Personally help their loved one (e.g., internet searches, journaling, praying)
    - Receive continued support (after ICU transfer, after death or hospital discharge)
- **From your perspective, what emotional needs are missing from this list?**

Please click on the link to Padlet again, where you can add your response under the "emotional needs" column.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Sociocultural Needs – 10 min

[Present Slide by sharing screen and review bullets]

Now we'll talk about sociocultural needs, or the needs you may have based on you and your family's background including but not limited to your culture, race and ethnicity, religious beliefs, geographic location, and family structure.

- Both family members and care team participants emphasized the need for equitable treatment and socioculturally appropriate communication
- **From your perspective, what other needs based on you and your family's background, are missing?**

If participants don't respond to the above questions, ask: What does equitable treatment and socioculturally appropriate communication mean to you?

Please click on the link to Padlet again, where you can add your response under the "Sociocultural Needs" column.

Discuss common responses, clarify differing responses, ask if the findings resonated, and generate discussion

Other Needs – 5 min

[Present Slide by sharing screen and review bullets]

- Thinking about the first 48 hours after your loved one arrived to the hospital, are there any other needs that we haven't already addressed in the interview findings or in this reflection session?

Please click on the link to Padlet again, where you can add your response under the "Other Needs" column.

Discuss common responses, clarify differing responses, and generate discussion

Closing – 5 min

Thanks so much for all of your feedback! Your comments are extremely helpful for us to understand FMs' needs in various types of settings. Do you have any last minute comments to add?

If you have time, summarize main points and reflect back to the group for confirmation.

Now, we'll go back to the main meeting room in a few moments. When you see the prompt that we'll return to the main room in a few seconds, please don't click on it yet, as it will take you immediately to the room.

Appendix H: Breakout Sessions 1 & 2 Discussion Guides

SIREN Subproject #3

Breakout Session #1 – <u>Care Team Groups</u>

Total Time: 50 minutes

11/19/2020

Breakout Session Preamble – 5 min

Hi everyone and welcome to the first Breakout session of our workshop.   As Sarah mentioned, we're in this breakout session to have a more in-depth discussion about the needs identified in the qualitative interviews.

I am [facilitator name] and just as in the Reflections Session, I'll facilitate and start the discussion, but most of the conversation will come from you all. Also, just as in the last session, all of you participating in this discussion are members of a care team that see patients with cardiac arrest or traumatic brain injury in the ED or ICU. There are several others in the breakout room who are either members of the SIREN team or from NIH. They are only observing and will not participate in the discussion.

The same ground rules for the Reflections Session also apply here. It's important to express yourself openly; there are no right or wrong answers. You do not need to wait for me to call on you to talk, but only one person should speak at a time. Also, we ask you to keep what we discuss today within this group and not share what we discussed with others who did not participate in the workshop. We will also record this breakout session.

Lastly, before we begin, I want to note that if you anticipate leaving the session for more than 20 minutes, please send a chat to [backup.] We just want to make sure that we haven't lost or overlooked anyone during the session.

For this Breakout Session, we'd like to hear more about **provider communication training and care team approaches**. Throughout our project, care team members brought up these topics, and we'd like to hear more about this from your perspective.

Understanding Provider Communication Trainings and Gaps– 20 min

During the interviews, we heard family members and care team members speak about the importance of being able to convey information about patients in a compassionate, clear and appropriate way to family members. We'd like to hear more about the communication skills that providers need in order to effectively and compassionately communicate with family members.

1.   What types of communication training does your institution provide?
     o   *Probe*: What do you think about the trainings that are offered?
     o   *Probe*: If not offered, how would a training benefit you and your health care team? What types of team members should be included in the training?

2. In lieu of formal training, how can providers improve their family-centered communication/emotional intelligence?
    o   *Probe:* Have you been able to use these strategies (e.g., continuing education, finding mentors, modeling after others)? How have they affected your communication style?
    o   *Probe:* Are these strategies widely used by your colleagues?
3. What tools or strategies have been helpful to you or your organization in communicating with families?
    o   *Probe*: Use of specific care team members, technology
4. What are some of the challenges with training providers in family-centered communication/empathic communication?
    o   *Probe*: What are potential solutions to address these challenges?

Care Team Approach– 20 min

We also heard several family members and providers speak about the care team, including variations in the composition of care teams and specific roles and responsibilities of each member (e.g., physicians, nurses, social worker, hospital chaplains.) We learned that family members found certain care team approaches helpful to address their communication and emotional needs.

5. What care team configurations and approaches do you think are best for meeting family members' needs during the first 48 hours after a loved one's cardiac arrest or TBI? Why?
    o   *Probe*: Are there specific roles and responsibilities that are important to include in the care team (e.g., mediator, liaison between providers and families)?
6. What challenges does your organization have in its care team approach?
    o   *Probe*: What are potential solutions to address these challenges?

Closing – 5 min

Thanks so much for all of your feedback! Your comments are extremely helpful for us to further understand how the care team can best address FMs' needs, especially during this challenging time. Do you have any last minute comments to add?

If you have time, summarize main points and reflect back to the group for confirmation.

Now, we'll have a break for 35 minutes. Please come back to the Workshop at [time]. We'll then reconvene and hear reports from each of the Breakout Sessions. Thank you!

SIREN Subproject #3

Breakout Session #1 – <u>FM Groups</u>

Total Time: 50 minutes

11/19/2020

Breakout Session Preamble – 5 min

Hi everyone and welcome to the first Breakout session of our workshop. As Sarah mentioned, we're in this breakout session to have a more in-depth discussion about the needs identified in the qualitative interviews.

I am [facilitator name] and just as in the Reflections Session, I'll facilitate and start the discussion, but most of the conversation will come from you all. Also, just as in the last session, all of you participating in this discussion are family members of a loved one who suffered from a cardiac arrest or traumatic brain injury. There are several others in the breakout room who are either members of the SIREN team or from NIH. They are only observing and will not participate in the discussion.

The same ground rules for the Reflections Session also apply here. It's important to express yourself openly; there are no right or wrong answers. You do not need to wait for me to call on you to talk, but only one person should speak at a time. Also, we ask you to keep what we discuss today within this group and not share what we discussed with others who did not participate in the workshop. We will also record this breakout session.

Lastly, before we begin, I want to note that if you anticipate leaving the session for more than 20 minutes, please send a chat to [backup.] We just want to make sure that we haven't lost or overlooked anyone during the session.

For this Breakout Session, we'd like to hear more about the **logistical needs for FMs for the first 48 hrs after their loved one has been admitted to the hospital**. Throughout our project, FMs brought up this topic, and we'd like to hear more about this from your perspective.

Navigating the Hospital and Logistical Support – 15 min

During the interviews, we heard many family members speak about having to navigate through the hospital and the importance of receiving logistical information, especially when they arrived at the hospital. This can include things like how to get to the cafeteria, the hours of the cafeteria, where to park, and options for lodging. Please think back to when you first arrived at the hospital when your loved one was admitted.

1. When you first spoke to someone from the hospital or arrived at the hospital, what information related to navigating the hospital and logistical information did you expect to receive?
   - *Probe*: What would have been helpful for you to receive?

2. What information related to navigating the hospital should be communicated to families during the first contact?
3. How did your needs related to navigating the hospital and logistics change over the first 48 hours?
    o *Probe*: Were you able to find the information or resources that you needed? If you can recall, who provided you with this information/resource? For example, if your loved one moved to another department, did you require new or different information?
4. Did you need help from someone to manage your logistical needs during the first 48 hours? What are some examples?

Interactions with the Care Team – 15 min

We also heard several family members speak about their loved one's care team and how they communicated with the team, particularly within the first 48 hrs after hospital admission.

5. Were the roles and responsibilities of your loved one's health care team clear to you?
    o *Probe:* If the roles and responsibilities were not clear, what specifically was not clear? Were you able to get clarification about this?
6. What was your experience with connecting to your loved one's health care team when you had questions or concerns?
    o *Probe*: What would have helped you to get in touch with the health care team?

Support Services – 15 min

The interviewees also spoke about several types of support services they received from the hospital during the first 48 hrs after their loved one was admitted to the hospital.

7. What types of support services (e.g., discussions with a social worker, meeting with the hospital chaplain) did you find helpful during this time?
8. What other support or services should be offered to families during this time?
    o *Probe*: In hindsight, what do you now wish you had in the first 48h that you did not have then?
9. What recommendations do you have for hospital staff communicating available support services with families during such a hectic and emotional time?

Closing – 5 min

Thanks so much for all of your feedback! Your comments are extremely helpful for us to further understand FMs' needs, especially during this difficult time. Do you have any last minute comments to add?

If you have time, summarize main points and reflect back to the group for confirmation.

Now, we'll have a break for 35 minutes. Please come back to the Workshop at [time]. We'll then reconvene and hear reports from each of the Breakout Sessions. Thank you!

SIREN Subproject #3
Breakout Session #2 – <u>Mixed FM and Care Team Groups</u>
Total Time: 50 minutes
11/19/2020

Breakout Session Preamble – 5 min

Hi everyone and welcome to the last Breakout Session of our workshop.   Just as before, we want to have an in-depth discussion about the needs identified in the qualitative interviews. This time, those of you participating in the discussion are either family members of a loved one who suffered from a cardiac arrest or traumatic brain injury, or are members of a care team who see patients with cardiac arrest or traumatic brain injury in the ED or ICU. Again, there are others in the breakout session who are either members of the SIREN team or from NIH; these individuals are only observing and will not participate in the discussion.

Similar to the previous Reflection and Breakout Sessions, the same ground rules apply about speaking one at a time and not sharing what we discuss with others who did not participate in the workshop. We will also record this session. As before, if you anticipate leaving the session for more than 20 minutes, please send a chat to [backup.]

For this Breakout Session, we'd like to hear more about **how family members experience and manage their feelings after they are notified that their loved one's prognosis is uncertain**. We'd also like to hear **how providers help manage family members' discomfort with uncertainty, including how they help family members process technical information during this highly emotional time.**

Uncertainty and Emotional Needs – 20 min

For family members, please think back to the first 48 hrs when your loved one was admitted to the hospital and if there were any discussions of uncertain prognosis, or if there were any unknowns or areas of uncertainty about your loved one. For providers, please think of a time when you've had to convey information to families about uncertain prognosis and how you responded to their questions or concerns.

1. If you are a family member who had discussions of an uncertain prognosis with your loved one's provider (that is, the care team was not sure how your loved one's illness or injury would progress or what the outcomes might be), how did you react to this information?
   o *Probe*: Emotional responses, need for information, need for support

2. For those whose loved one's prognosis was known, did you experience any feelings of uncertainty in other areas (e.g., treatment, procedures, discharge)?
   o *Probe*: If yes, in what areas? How did you react to this information?

3. Were there any activities or tasks that you did to manage your feelings and emotions about the uncertain prognosis or other areas of uncertainty?
   o *Probe*: Gather information, seek emotional or spiritual support

4. For providers, what are some ways that you have responded to family members' emotional needs when they are experiencing uncertainty?
   o *Probe*: From your experience, how was this received by family members?

5. For both family members and providers, are there additional suggestions about how to manage family members' emotional needs during this time of uncertainty?
   o *Probe*: Strategies for both FMs and providers to help manage their needs

Uncertainty and Information Processing– 20 min

6. For family members, thinking about your experience, what information did you receive from your provider to help you understand the uncertain prognosis (e.g., percentages, statistics, data tailored for loved one) or other areas of uncertainty?
   o *Probe*: Is there any type of information that you didn't receive that would have been helpful for you to better understand the situation?

7. For providers, what types of information are you comfortable sharing with families when there is uncertainty for their loved one? (e.g., percentages, statistics, data tailored for loved one)?
   o *Probe*: What makes this information appropriate to share with families? How are these types of information helpful to family members? Or not helpful?

8. For providers, how do you help families understand this information?
   o *Probe*: From your experience, how are these strategies viewed by family members? How have they been helpful? Or not helpful?

9. For both family members and providers, are there any additional thoughts about the types of information that families need to understand uncertain prognoses or other areas of uncertainty?
   o *Probe*: Strategies for how providers can help family members better understand information related to uncertain prognosis?

Closing – 5 min

Thanks so much for all of your feedback! Your comments from this breakout session as well as the earlier sessions have been extremely helpful. Do you have any last minute comments to add?

If you have time, summarize main points and reflect back to the group for confirmation.

We'll now take a 15 minute break. Please come back to the Workshop at [time.] We'll then hear some main takeaways from the day. Thank you!

[End of Report]