Patient and Surrogate Views of Community Consultation for Emergency Research

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ABSTRACT

Objective: Pretrial community consultation (CC) is required for emergency research conducted under an exception from informed consent (EFIC) in the United States. CC remains controversial and challenging, and minimal data exist regarding the views of individuals enrolled in EFIC trials on this process. It is important to know whether participants perceive CC to be meaningful and, if so, whom they believe should be consulted.

Methods: We conducted a secondary analysis of data from two studies interviewing patients and surrogates of two recent EFIC trials (PEER-RAMPART and PEER-ProTECT). These interviews included similar open- and closed-ended questions regarding participants' views of the importance of CC, the rationale for their responses, and their views regarding which populations should be included in consultation efforts. A template analytic strategy was used for qualitative analysis of textual data, and descriptive statistics were tabulated to characterize demographic data and instances of major themes.

Results: Ninety percent of participants perceived CC to be valuable. Participants' reasons for finding CC valuable clustered in two categories: 1) as a method of informing the public about the trial to be conducted and 2) as a way of obtaining input and feedback from the community. Participants cited the medical community (43%) and individuals with a connection to the study condition (41%) as the most important groups to involve in consultation efforts; only 5% suggested consulting the general public in the area where the research will be conducted.

Conclusion: Participants in EFIC trials and their decision makers generally valued CC as a method of informing and seeking input from the community. Participants felt that the most appropriate groups to consult were the medical community and individuals with connections to the condition under study. Consultation efforts focused on these two groups, rather than the general public, may be more efficient and more meaningful to individuals involved in EFIC trials. These findings also reinforce the importance of the distinction between public disclosure and CC.

To facilitate research for emergent conditions, FDA and DHHS regulations allow an exception from informed consent (EFIC).[1] This is essential for studies in which interventions must be delivered quickly, patients are not fully capacitated, and surrogates are unavailable. The EFIC regulations have several

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distinctive requirements, including the conduct of community consultation (CC) prior to study approval and initiation.[2]

The role of CC and best methods for doing it remain controversial. It is widely perceived as a barrier, particularly because CC can be time- and labor-intensive.[3,4] Additionally, CC can be performed with different methods and participants. Ambiguities about which methods (e.g., surveys or group meetings) or participant groups should be used have bred heterogeneous approaches and uncertainty about the value of the process.[5]

One of the goals of CC is to show respect for enrolled subjects.[1] However, limited data exist regarding the perspectives of those enrolled in EFIC trials on the CC process. Prior reports suggest that patients and surrogates are generally in favor of CC, but have not examined how they find it meaningful or valuable.[6,7] Knowing the ways in which actual EFIC trial participants perceive CC to be meaningful and whom they believe should be consulted may help CC practices to be more efficient and effective in expressing respect.

METHODS

We conducted a retrospective, secondary analysis of data from two previously published interview studies with patients and surrogates (for patients without capacity to be interviewed) enrolled in EFIC research.[6,7]

1. The Patients' Experiences in Emergency Research (PEER) study was an interview study of 61 EFIC-enrolled patients (n = 24) and surrogates (n = 37) from 5 sites in the Rapid Anticonvulsant Medication Prior to Arrival Trial (RAMPART), a double-blind, randomized, controlled trial comparing intravenous lorazepam with intramuscular midazolam in prehospital treatment of status epilepticus.[6,8]
2. The PEER-ProTECT study was an interview study with similar design and included 74 EFIC-enrolled patients (n = 28) and surrogates (n = 46) from 12 sites in the Progesterone for the Treatment of Traumatic Brain Injury (ProTECT III) study, a phase III, randomized, placebo-controlled trial of progesterone in treatment of moderate and severe traumatic brain injury.[7,9]

Interviews were conducted over the phone by trained interviewers. Interview guides were cognitively pretested. They were interactive and combined closed-ended, Likert-scale questions as well as open-ended questions to obtain quantitatively meaningful estimates of participants' views and in-depth information regarding the reasons for these views. The interview guides contained additional follow-up questions to assess participant understanding and provide opportunities for participants to ask clarifying questions. Primary domains focused on participants' experiences and views of EFIC research and their attitudes toward enrollment in the parent trial.

Participants were also asked specifically whether they believed CC is important and, in an open-ended format, the reasons for their view and whom they thought should be consulted. Phrasing of these questions in each study were similar (Data Supplement S1, available as supporting information in the online version of this paper, which is available at https://doi.org/onlinelibrary.wiley.com/doi/10.1111/acem.13265/full). Prior reports focused on participants' attitudes toward EFIC and inclusion in the respective trials. This report combines the two data sets in a focused analysis of responses to questions related to CC alone (Data Supplement S1).

Informed consent was obtained from all participants. Both studies were approved by institutional review boards at Emory University and participating sites.

Data Management and Analysis

All interviews were transcribed verbatim. Qualitative descriptive analysis was conducted using the MAXQDA software package and a template analytic method. Prior to textual analysis, a priori codes were developed based on expected response categories from the literature. Additional inductive codes were created during analysis. Once it was determined that no new themes were emerging (saturation), the codebook was reviewed and approved by all authors as final and then used to code all interviews. Coded instances of major themes were reviewed by all authors to ensure they reflected the same concept. Discrepancies were resolved by consensus among all authors. Descriptive statistics were tabulated for demographic data and instances of major themes. Bivariate analysis (chi-square tests for proportions) were conducted to explore relationships between demographic data and major themes.

During analysis, participants were identified who demonstrated an explicit and fundamental misunderstanding of the meaning and process of CC. These

responses were reviewed by all authors. Those for whom there was consensus regarding such misunderstanding were excluded from further analysis.

RESULTS

Seventy-four PEER-ProTECT interviews and 61 PEER-RAMPART interviews were analyzed. Of 135 total respondents, five terminated the interview prior to CC questions, and 21 were excluded due to clear misunderstanding of CC. The most prevalent misunderstanding was a misperception that CC involved asking community members to make real-time decisions regarding trial enrollment for a particular individual.

Of 109 participants with analyzable responses, the mean age was 47 years (range = 20–86 years), 66 (61%) were female, 59 (56%) were white, and 58 (53%) had at least some college education. Among these participants, 98 (90%) considered CC to be important, seven (6%) considered it unimportant, and four (4%) were undecided.

Positive Responses to CC

Of the 98 participants who considered CC to be important, 79 provided one or more reasons for this response. These reasons focused on two distinct, though not mutually exclusive, functions (Table 1):

CC as a method of informing the public: 30 participants. These participants felt CC would fulfill investigators' obligation of transparency, facilitate trust, and respect the public's "right to know" what is happening in their community (Table 1). Some also mentioned that it may help prepare community members emotionally and practically in the event they were enrolled in the trial. Others suggested CC may help public relations by helping bolster or maintain a positive perception of the hospitals or researchers in the community.

CC as a method of obtaining feedback and input from the community: 54 participants. Some participants felt community input could be used by researchers to improve the study. This view was particularly common among individuals who advocated consulting local health professionals and the individuals with connections to the study condition (Table 1). Others focused more on allowing the community to have an opportunity to exercise oversight by assessing whether a study is in the community's best interest and influencing whether the study is approved.

Table 1
Supporting Quotes

Positive View of CC: 98 participants (90%)
1. CC as a method of informing the public
"I believe when they put studies together, people should have access to the information that it is being done, but I don't know if you have to go around the community asking if it is alright to do it."—3–005
2. CC as a method of obtaining feedback and input from the community
"As the director explained to me, they reached out to several medical organization and community leadership groups that relate directly to seizure patients. I believe this is a good move because those organizations are more in touch with the demographics of the patients in the area. It gives them a good chance to get a cross section view of how such a study might affect that local populous."—4–009
Negative View of CC: 7 participants (6%)
"I don't really know what the community members would have to say about it . . . It doesn't bother me that they do, I just think it's an unnecessary step."—C256
Whom to Consult
Medical Community
"So when you say they ask community members . . . Maybe it seems like they should ask more like people at a hospital . . . Um, well I think that if somebody's a community member doesn't mean they would know a lot about, you know, health. So I think it would, I think instead of a community member maybe it should be like the hospital staff or something."—C204
Condition-related Community
"Because it's not really, 99 percent of the people out there, it would never be pertinent to them, you know. Unless you've been there, I don't think you can, either in patient or the medical field, I don't really see how you form a, make an informed decision about it."—C230

CC = community consultation.

Negative Responses to CC

Among the seven (6%) participants who did not believe that CC is important, reasons included the belief that community members are unqualified or do not understand research sufficiently to provide meaningful input on the study (Table 1). Some participants were specifically concerned that uninformed individuals might object and prevent a needed trial from taking place.

Whom to Consult

Participants most frequently suggested that CC efforts should involve healthcare professionals (44 [43%]) and individuals such as patients or family members who have personal experience with the study condition (42 [41%]). Interestingly, 64% of African American participants suggested involvement of individuals with connections to the study condition, compared to

only 24% of white participants (p = 0.001). Other groups less frequently mentioned included religious communities (7 [7%]) and specific demographic groups (i.e., the elderly, minorities; 22 [22%]). Twenty-five respondents (25%) said they did not know whom to consult. Only five participants (5%) suggested consulting the general public.

DISCUSSION

This study provides novel insights regarding enrolled patients' and surrogates' views of CC.[6,7] Two key findings have practical importance and implications for researchers.

First, participants identified two populations as most meaningful to consult: those with connections to the study condition and health care professionals. While the general public is often included in CC due to prevalent interpretations of the regulatory requirement to involve the "community in which the research will be conducted" as the geographic community, participants did not prioritize this group. Some even expressed concern that uninformed members of the general public may derail meaningful research.

It is important to recognize that FDA guidance does not require the involvement of the general public or consider the geographic and condition-related communities to be necessarily distinct.[10] Moreover, the guidance document explicitly states that health care professionals at research sites may be considered part of the geographic community.[2] Thus, CC efforts focusing on local health professionals and individuals with connections to the condition under study may satisfy regulatory requirements and align with the preferences of enrolled patients. CC focused on these two groups may also be more time- and cost-efficient than methods designed to represent the general public.[10]

Second, many participants attributed CC's value to its ability to inform the public about the study. Pre- and posttrial public disclosure (PD), however, is a distinct regulatory requirement.[1] Although some CC activities serve dual purposes, ideal methods for increasing awareness about a trial are likely different from ideal methods for soliciting high-quality input from relevant stakeholders. While FDA guidance, to some extent, may blur the distinction between PD and CC by including community notification as a goal of CC, disaggregating these functions may help to promote efficiency and optimize both PD and CC.[10]

This study had two principal limitations. First, the process of CC and the regulations of EFIC research are difficult to understand, as evidenced by frequent misunderstandings and the need to exclude responses from 21 participants. Second, not everyone included in the parent EFIC trials was represented in these interview studies. It is possible those who declined participation in these interview studies[6,7] may have different views of CC and EFIC. However, as reported previously, PEER populations were similar demographically to their parent trials.[6,7]

CONCLUSION

Patients and surrogates enrolled in two exception from informed consent trials valued community consultation as a way to inform and obtain feedback from the community. These findings underscore the importance of appreciating the distinction between community consultation and public disclosure and of designing consultation efforts to maximize meaningful feedback. Participants prioritized involvement of health care professionals and individuals with a connection to the condition under study. Community consultation activities targeting these two groups, rather than the general public, appear most consistent with the preferences of trial participants and may improve consultation efficiency while satisfying regulatory requirements.

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Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1111/acem.13265/full

Data Supplement S1. Interview questions.