The People Speak: Community Consultation in Emergency Research

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Since 1996, specific federal regulations (21 CRF 50.24) have permitted the performance of emergency research when critically ill or injured patients and their surrogates are unable to provide meaningful prospective informed consent. The regulatory requirements for emergency research using exception from informed consent are aimed at providing additional safeguards for vulnerable patient-subjects. Included among these requirements is pre-study consultation between investigators and the community. Community consultation is not the same as community consent or dissent; concerns from the community are considered by institutional review boards as they decide whether a proposed research trial is ethically and scientifically suitable for the local environment.

Community consultation has proven to be a particular challenge when exception from informed consent studies are performed. The best methods of performing community consultation, the definition of the appropriate community, and appropriate metrics to determine the success of different methods of community consultation are not yet known. Often, there seems to be a gap between what communities want to know (such as more information about the medical condition under study) and what they need to know (for example, that the study will be performed without prospective consent). Little guidance has been provided about how much community penetration is necessary to meet the letter and the spirit of the regulations. No systematic assessment has been done to determine how community consultation has influenced institutional review board decisionmaking. Since the inception and availability of 21 CFR 50.24, few studies of the community consultation process itself have been conducted, and few detailed descriptions of the community consultation methods used for specific clinical trials have been published. Indeed, it is not known whether community consultation has actually provided the additional patient-subject safeguard it was meant to provide. Answers to these questions are crucial if we are to perform exception from informed consent trials in a timely and cost-effective manner, reduce the regulatory burden that surrounds exception from informed consent, and use the exception from informed consent regulations to achieve their stated aim.

In this issue of Annals, Kasner et al report the results of a carefully crafted qualitative study to assess community attitudes about clinical research trials conducted with exception from informed consent. By identifying themes, opinions, knowledge gaps, and misperceptions that arose during focus groups, the investigators provide us with useful information that may guide the content and method of conducting community consultation for future exception from informed consent trials. For the neurologic studies proposed here, the focus groups included healthy young men, who are presumably at increased risk of injury because of their activities and lifestyle choices, and survivors of neurologic injuries. To avoid bias or perceived undue influence, focus groups were facilitated by a moderator not involved with the proposed studies. Under the concept of thematic saturation, data collection was considered complete once nothing new emerged from additional discussions. This occurred after 5 focus groups, with 40 total participants. In focus group methodology, a minimum number of participants required for thematic saturation is usually described as 15 to 20; with more than 60, the size of the group interferes with the ability of all members to actively contribute. Transcriptions of the group discussion and notes taken by observers were subjected to a coding scheme that allowed emerging concepts to be categorized.

Many medical researchers are unfamiliar and uncomfortable with qualitative research methodology. Yet, when the subjective viewpoint of a participant is the desired data, other research methodologies fall short. Focus groups are a unique method of collecting such data. When participants are allowed to interact with one another, unique insights may arise. In addition, because focus groups are driven by participant response, the facilitator does not control the discussion once key concepts have been presented. Unlike written surveys, focus groups do not discriminate according to literacy; unlike individual interviews, the anonymity of a focus group encourages participation of those intimidated by or reluctant to speak in one-on-one situations. A challenge for those of us who perform exception from informed consent trials is the determination of what potential study subjects already know and what they need to know to engage in meaningful community consultation.
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consultation. Because focus group methodology relies on opinions, impressions, and implications, rather than numbers, they answer this question.

Although the study by Kasner et al\(^8\) is limited to a single site and only 2 specific proposed research trials, many of the themes that emerged among the focus groups have been reported by others using different methods of community consultation. For example, general support of exception from informed consent, especially within the context of a described trial, has also been described in community consultation using individual interview techniques.\(^7\) Difficulty differentiating between research and treatment and limited understanding of key research concepts such as placebo and randomization have also been reported among survivors of cardiac arrest.\(^8\) The makeup of the focus groups in the study by Kasner et al\(^8\) was somewhat homogeneous; although this may be a limitation in quantitative research, homogeneity in focus groups may actually be an advantage by bringing together people with shared experiences to discuss common concerns.\(^6\) Because the present results appear to reflect attitudes determined by other methods of community consultation, concerns about the generalizability of these results are lessened. Community attitudes about research may transcend the method by which they are uncovered; focus groups may provide a streamlined method of identifying key concepts that need to be explicitly addressed, regardless of the method of community consultation.

Although never specifically stated by participants or broached by the investigators, the concept of trust or mistrust in the medical and research endeavor resounds throughout the discussions of the focus groups. When participants thought that the use of placebos could deprive patients of potentially beneficial treatment, an obvious lack of knowledge is identified that can be addressed in the next iteration of the focus group and in other methods of community consultation. Although this illustrates therapeutic misconception, it also may suggest a mistrust of researchers’ intentions. Participants could not understand or accept the concept of randomization and asked to rely on medical professionals for treatment group assignment. Again, a knowledge gap emerges: here, blind trust is the participants’ solution to an overwhelming concept. Although it may seem contradictory that trust and mistrust occurs simultaneously, it is not unexpected. It is a further illustration of how confusing it may be to patients when a clinician is also a researcher and may be perceived to have ulterior motives. It is unlikely that these concerns would be detected in quantitative research.

Qualitative research relies on words. We as clinicians are accustomed to listening to and interpreting the words of our patients. Listening to our community express their concerns, doubts, and beliefs is revealing and humbling. Although the aims of community consultation and the exception from informed consent regulations in general are to provide added safeguards for patient-subjects, perhaps a better outcome is to hear what our communities know and need to know for community engagement in emergency medical research. This knowledge can inform the next steps in effective community consultation related to a specific clinical trial. Respecting the words of our communities will also go a long way in reestablishing and reconfirming trust in the research enterprise.

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