Does Community Consultation Matter?

Since 1996, emergency clinician researchers have conducted a relatively small number of clinical trials using the exception from informed consent (EFIC) regulations for emergency research (21 CFR 50.24).1–3 Because of the sensitive nature of research that involves patients rendered vulnerable by their critical emergent conditions, the EFIC regulations include safeguards that were never before mandated for clinical trials, including the need for community consultation (CC). An exception was CC required for a trial of hypothermia for head injury conducted in the early 1990s, before the EFIC regulations. This was not FDA regulated; it was conducted with a secretarial override that allowed a waiver of, and not an exception from, informed consent.4

Community consultation is not community consent or veto. It is a two-way communication, in which the concerns of the local community regarding a proposed EFIC research study are heard and considered before the trial can begin locally. The effectiveness, community penetration, and additional safety provided by CC is under constant (and skeptical) debate by EFIC investigators.5 Given that CC adds cost and time to the pre-study phase of a clinical trial, a measure of its value and effectiveness is important so that it is not just considered a necessary exercise or burden. If CC is to be meaningful, its purpose and its effects must be clear and convincing to the communities and investigators alike.

When the EFIC regulations were developed, the intent of the added safeguard of CC was to prevent unanticipated harm to patient-subjects by soliciting from the community concerns that may not have occurred to the investigators. Subsequent questions by investigators and guidance by the FDA2,6 seemed to concentrate more on the logistics of CC activities rather than their purpose. The definition of community and who could represent the community has been investigated.7 The pros and cons of various methods of CC are under continuous discussion.2,8 The added cost of (and time for) pre-study CC has been described.9 However, there have been no formal reports describing the effects of CC on institutional review board (IRB) decision-making or how CC concerns are dealt with by investigators and IRBs. No metrics have been established to measure the effect of CC, and in fact, since the purpose is vague, metrics of success cannot really be defined. Given this lack of data, and the lack of an obvious means to systematically collect it, the real question is: does CC even matter?

In this issue of Academic Emergency Medicine, Govindarajan et al.10 describe the responses given by participants of CC activities when they were asked what they thought about the CC process. They were also asked what they learned about EFIC and a proposed EFIC study, RAMPART.11 The vast majority of the respondents indicated that they were satisfied with CC and their CC participation; they liked the education they received and they liked to be asked their opinions. Although not designed to measure in detail, the study did reveal a few specific areas of community concern, such as the concept of randomization, the fact that EMS providers would be directed by the research protocol and not clinical judgment, and that the study drugs were not approved for the pathology under study. And, of course, that the subjects would not provide prospective informed consent.

Similar concerns have been described in other studies of community opinions about EFIC trials.12,13 In fact, Kasner et al.14 showed that thematic saturation is eventually reached during CC; at some point, no additional concerns emerge, and further CC likely does not offer any more direction or information to the investigators. What is remarkable in all of these studies is that community concerns are not about safety or harm, but rather about key research concepts, the willingness to learn about them, and the community’s desire to be heard.

There is no doubt from this study that the community studied by Govindarjan et al. appreciated the engagement in the local research process. However, even this community had questions about the goal of CC. Although they felt listened to, and they trusted the investigators, the majority believed that their concerns would have no influence on the ultimate execution of the research project. Since they were not convinced that what they said made a difference, why were they satisfied with the process?

In the late 1990s, I was involved with CC activities for a proposed EFIC trial that altered the decision by our IRB regarding the study. The trial involved a blood substitute product for use in trauma patients15; our CC reminded us of the large number of Jehovah’s

A related article appears on page 98.
Witnesses seeking care at our hospital, and the concern that the proposed intervention might be inconsistent with their religious beliefs. In this circumstance, CC altered the local research plan: the study was not done in our community. Community concerns were not related to physical safety or harm at all, but rather to respect of a belief system. We believed that if we performed the study locally, the perception of our lack of respect would cause great harm to subsequent local research endeavors and perhaps the subsequent delivery of medical care. This was an isolated event, and the study proceeded at other clinical sites. Since then, many EFIC trials have been conducted within our same community (including RAMPART), and all have been enthusiastically supported during CC. In fact, CC has become a community (including RAMPART), and all have been enthusiastically supported during CC. In fact, CC has become one of the most educational and enjoyable aspects of my research efforts. I believe that our response to CC was indeed meaningful to this community; we listened to them, and they subsequently have listened to and supported us.

Like my community, the communities surveyed by Govindarajan et al. were very engaged in the CC process and eager to learn about the research. This suggests that CC was indeed meaningful to this community, despite their opinion that the investigators would not change the study to address their concerns. CC provides a concrete means of community engagement, is an easy method of providing education about research concepts, and is a show of respect for the individuals who may someday be our research subjects.

During the development of the EFIC regulations, I was skeptical about CC and its ability to produce useful information related to unanticipated harm. Harm, of course, has several meanings, and perhaps its definition needs flexibility when we apply the EFIC regulations as a safeguard. I am not a skeptic anymore; I have a more realistic view of CC and what it provides. Mutual respect among investigators and their potential subjects, and community engagement in the research process, can enhance any research endeavor. Especially in EFIC studies, community consultation matters.

Michelle H. Biros, MD, MS
(Michelle.biros@gmail.com)
Department of Emergency Medicine
Hennepin County Medical Center and
University of Minnesota
Minneapolis, MN

Supervising Editor: David C. Cone, MD.

References