

STATE OF THE ART AND SCIENCE

Defining “Community” and “Consultation” for Emergency Research that Requires an Exception from Informed Consent

Samuel A. Tisherman, MD

Abstract

Trauma care requires rapid interventions to optimize the chances for survival. Many patients are either in shock or unconscious and are, therefore, unable to provide informed consent even for standard procedures. Research-related interventions must similarly be initiated rapidly with no opportunity to obtain consent from the patient or the patient’s legally authorized representative. Federal regulations allow for an exception from informed consent in these circumstances once the investigators complete a process of community consultation and public disclosure. The challenges for investigators include how to define the at-risk community for enrollment in the trial and then how to adequately reach out to that community. Many approaches have been used, with varying success. What constitutes true engagement with the community needs to be further explored.

Exception from Informed Consent for Emergency Research

The management of severely injured patients is time sensitive, focusing on the “golden hour” to maximize likelihood of preventing death. Novel interventions need to be initiated rapidly. Conducting clinical trials during this brief window of opportunity presents significant ethical challenges.

In 1991, the US Department of Health and Human Services developed the [Common Rule](#), designed to protect human subjects from harm and to promote uniformity and compliance across all federal agencies [1]. Informed consent of the individual subject or legally authorized representative (LAR) is standard for most clinical trials [1]. In emergency situations, the decision to initiate many interventions must be made within minutes, but patients are often in shock or unconscious and therefore unable to give consent, even for standard procedures. The LAR is often not available or in a state of emotional distress [2]. Standard practice for emergency treatment is to proceed without consent. But what about research?

Community Consultation and Public Disclosure

Prior to 1991, without guidance from federal agencies, researchers studying novel therapies in emergency situations (e.g., cardiac arrest or major trauma) developed the concept of “deferred consent.” They enrolled subjects and later approached a LAR for consent [3]. After the Common Rule was adopted, however, all resuscitation research was halted unless prospective consent could be obtained. In 1996, the Final Rule allowed research to be performed without informed consent in emergency circumstances [4]. To proceed, investigators need to demonstrate that: (1) the subject has an acutely life-threatening condition, (2) currently available treatments are untested or unsatisfactory, (3) the potential subject cannot consent because of the acute condition, (4) there must not be time within the proposed therapeutic window to contact the LAR to obtain prospective consent, and (5) the subject might directly benefit from participation.

The federal regulations also mandate [community consultation](#) and public disclosure, overseen by a local institutional review board (IRB), as protective measures before researchers are permitted to enroll subjects [5]. Community consultation is a two-way process often conducted through a variety of mechanisms to gather information regarding community members’ attitudes and beliefs related to the appropriateness and acceptability of the design, risks, and benefits of the planned research. The investigators reach out to community members who attend town hall or civic group meetings or who respond to surveys distributed by the researchers. Feedback from community consultation is reported to the local IRB, an independent Data Safety and Monitoring Board (DSMB), the Food and Drug Administration (FDA), and funding agencies for review. There is no standard for how much community support for a study is needed, but study protocols and the community consultation process itself may be revised based upon the feedback. Nonetheless, community consultation does not constitute community consent. By contrast, public disclosure is a one-way process whereby the investigators inform the community about the study.

The goal of public disclosure *prior to initiation of the study* is to provide sufficient information to allow a reasonable assumption that the broader community is aware of the plans for the investigation, its risks and expected benefits ... and the fact that the study will be conducted without obtaining informed consent from most study subjects [6].

The IRB determines the adequacy of the researchers’ community consultation and public disclosure plans and has the prerogative to ask for revisions.

Subjects are enrolled without prospective informed consent into clinical trials with severely injured patients based upon the inclusion and exclusion criteria for the study. Once a subject is enrolled in the study, either the subject or the LAR must be informed of the research and approached for consent for further participation with an opportunity to

withdraw [5]. If the subject or LAR decides to withdraw, the subject remains enrolled and data collected up to the time of withdrawal is retained [5]. Any public information about the subject, such as vital statistics, can also be used by the researchers [5].

Ethicists proposed that community consultation would help mitigate the risks and enhance the benefits of research and contribute to its legitimacy via community members' shared responsibility with investigators [7]. Implementation of the regulations regarding community consultation and public disclosure, however, remains open to interpretation by researchers and IRBs, leading to significant variability.

Experiences with the Community Consultation and Public Disclosure Process

In 2008, the Resuscitation Outcomes Consortium (ROC), which was developed to study early interventions for cardiac arrest and trauma, reported on regulatory challenges, including community consultation and public disclosure [8]. (The author of the present paper was a co-investigator for ROC and the chair of its regulatory committee.) Approaches to community consultation varied significantly among sites. Many sites sponsored town hall events with members of the community and IRB representatives, but these events tended to be poorly attended and yielded little useful feedback regarding the attendees' attitudes towards the study and little information about attendees. Investigators were better able to engage with community members and leaders when they presented the study to a group that was already meeting for a different purpose, such as government groups or community organizations (e.g., Rotary clubs or church groups). Focus groups, composed of persons who had survived conditions similar to those in the proposed study, were very engaged and provided excellent feedback. Several ROC sites reached out directly to members of the community in the geographic catchment area using a random-digit-dialing, structured telephone survey conducted by an independent professional group [9]. Telephone surveys have several potential advantages over other approaches including large numbers of respondents, better representation of the community, known demographics, impartiality, and speed [9]. The downsides are the expense, fewer people using landlines (making the geographic location based on phone number impossible to determine), and the lack of dialogue between the community and the investigators [9]. The techniques used for public disclosure by ROC sites typically include press releases with newspaper, radio, and television interviews; creation of websites with information about the study and opportunities to complete surveys; and paid advertisements [8]. One ROC site has more recently used social media to supplement the process [10].

Nevertheless, current approaches to community consultation and public disclosure might reach only a small segment of the population. Surveys of convenience samples of potentially eligible subjects in three separate studies demonstrated that only 5-10 percent of members of the public were aware of the study [11-13]. Given this low level of public awareness, it's probable that very few subjects enrolled in emergency research

studies are aware of the study beforehand, although there is no data to support this hypothesis.

High-Risk Emergency Research Studies

For patients who suffer a cardiac arrest from traumatic hemorrhage, the chances for survival are 5-10 percent [14, 15]. Surgeons can't operate fast enough to stop the bleeding before irreparable vital organ damage occurs. Emergency preservation and resuscitation (EPR), which uses rapid cooling of the patient to decrease oxygen requirements of vital organs, has been developed to buy time for surgical hemostasis. This experimental procedure involves infusing a large amount of cold saline directly into the aorta to cool the body to 10-15 degrees Celsius [16]. After bleeding is controlled, delayed resuscitation requires cardiopulmonary bypass because of the body's cold temperature.

The EPR for Cardiac Arrest from Trauma (EPR-CAT) study is a safety and feasibility study led by the author that is currently enrolling subjects at the Shock Trauma Center in Baltimore, Maryland [16]. UPMC Presbyterian in Pittsburgh, Pennsylvania, was involved in 2014 but is currently on hold. Given that operative management of victims of penetrating trauma (e.g., a gunshot or stab wound) can be more straightforward and that victims don't often have head injuries, which would confound functional outcome determinations, the study is limited to patients with penetrating trauma.

Challenges for community consultation and public disclosure faced by the EPR-CAT trial include explaining a complex, high-risk procedure quickly in lay terms at community events and reaching out to the at-risk population for penetrating trauma. Unlike blunt trauma, which can readily affect people of any gender, age, or socioeconomic status, penetrating trauma predominantly affects young black males, a population that is difficult to reach via standard community events or media.

The approach to community consultation differed in the two cities. Community consultation in Pittsburgh initially included town hall events and meetings with the Pittsburgh Commission on Human Relations and the University of Pittsburgh Center for Minority Health Community Research Advisory Board [16]. These groups recognized the potential benefit of the study but raised concerns about how to reach the community at risk [16]. Consequently, the process was revised to include a random-digit-dialing survey in the at-risk community based upon trauma registry data [16]. Surveys were also placed in the trauma clinic, where patients represent the population at risk. The surveys were developed to explain the study in lay terminology, and the verbiage was approved by the IRB. The majority of respondents (approximately 70 percent) reported being willing to participate themselves or to have a family member participate in the study [16]. The community consultation process in Baltimore focused on reaching out in person to the communities at risk [16]. The principal investigator (the author) and a

research coordinator attended events in East and West Baltimore, where community members could discuss the study and then complete a survey [16]. Surveys were also available in the trauma clinic and online. The responses to conducting this study were overwhelmingly positive [16].

Public disclosure in both Pittsburgh and Baltimore involved press releases with local and national media attention. Both sites developed websites [17, 18]. Advertisements were run in the *New Pittsburgh Courier* and the *Baltimore City Paper*, which focus on the African-American community. The feedback from both communities was positive and was acceptable to the local IRBs, the DSMB, the FDA, and the US Army Human Research Protections Office.

How Should We Define and Engage with the Community?

As explained above, for emergency research, federal regulations require consultation with “representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn” [19]. How the at-risk community is defined is dependent upon the institution conducting the research, the particular disease entity being studied, the availability of an appropriate specialized center (e.g., a trauma center), and modes of transportation. For example, in ROC studies that involved paramedics administering a fluid to trauma patients, the community included the population served by participating emergency medical services. Because EPR needs to be initiated by specialists at the trauma center shortly after injury, however, the at-risk community was limited to the local area near the trauma center.

Patients may define community differently than researchers. In one study, almost all patients in an urban emergency department identified with a community based upon geography or religion, not race or ethnicity [20]. They welcomed consultation with their communities and felt that community leaders would be appropriate consultants to provide robust feedback to researchers, who should therefore consider revising community consultation approaches based upon a differently defined community.

When reaching out to a community, researchers need to consider community members’ potential mistrust of the medical system. In general, subjects in trauma studies, such as ROC, meet the typical demographics found in trauma registries [21]. In contrast, a study of penetrating trauma victims, like the EPR-CAT trial, is complicated by race, socioeconomic status, and gender. Blacks’ skepticism toward [medical experimentation](#) is the result of a long history of medical exploitation and mistreatment [22]. Conversely, variables that might contribute to trust of medical experimentation include a perception of the need for help and prior knowledge of the procedure, conditions which can be met by diligent researchers. One could hypothesize that the community in Baltimore is supportive of the EPR-CAT study because it recognizes both the need to save trauma

victims and that the Shock Trauma Center is there to help, and the investigator personally engaged with community members.

Future Directions

Community consultation remains an ill-defined concept for both investigators and IRBs. For the process to achieve its goal of meaningful dialogue between the researchers and the community, both need to agree on what constitutes the community (i.e., the at-risk population). The experience of the EPR-CAT study demonstrates how community consultation helped refine the definition of community and make the community consultation process more meaningful.

No single strategy works across all studies and communities. Incorporating a variety of activities can broaden community involvement and maximize the interactions between the investigators and the community. As community consultation continues to evolve, more ongoing, in-depth engagement with members of the community would be extremely helpful for identifying and examining points of concern related to acceptability of medical research in general and resuscitation research in particular.

Future research should try to demonstrate that improving community consultation and public disclosure strategies leads to a better understanding of the research project—its goals, risks, and benefits—and to a true partnership between the investigators and the community. Ultimately, research subjects and patients will reap the benefits.

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Samuel A. Tisherman, MD, is a professor in the Department of Surgery and the Program in Trauma at the University of Maryland School of Medicine in Baltimore. He also serves as director of the Surgical Intensive Care Unit and the Center for Critical Care and Trauma Education at the R Adams Cowley Shock Trauma Center, part of the University of Maryland Medical Center. His research focuses on resuscitation from trauma and hemorrhagic shock, with a particular focus on therapeutic hypothermia.

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