In 1947, the Nuremberg Doctors’ Trial produced the Nuremberg Code on the ethics of human research, which identified voluntary consent as essential for performing any experimentation or clinical study involving human subjects. In 1964, the World Medical Association adopted the Declaration of Helsinki, which mandates post-trial access of study subjects to appropriate care and emphasizes the importance of both ethical and scientific review prior to initiating a study. It states that medical research can be combined with medical care only when the research can be justified by its potential prophylactic, diagnostic, or therapeutic value.

In the past 4 decades, the ethical basis of human experimentation has been expanded, strengthened, refined, and, in fact, institutionalized in the form of institutional review boards to ensure that informed voluntary consent is obtained and that the proposed studies are scientifically sound and safe.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the Belmont Report, which cites three basic ethical principles: respect for persons, beneficence, and justice. Respect for persons was defined as requiring acknowledgment of autonomy and protection of all research subjects. If there is a documented societal need for experimentation on a class of patients with diminished autonomy, special measures must be taken to protect those patients.

Historically, such patients were excluded from a study, entered into a study by obtaining permission from the legal next of kin, or entered into a trial for which informed consent requirements had been waived by a local oversight board. In the latter case, Food and Drug Administration Regulation 21 CFR 50.24 of 1996 exempts emergency research from informed consent requirements when patients are in a life-threatening situation, when obtaining informed consent is not feasible, and when the research could not otherwise be carried out. Additional required protections include consultation with community representatives, public disclosure to the communities in which the study will occur, and public disclosure of the study results upon completion of the investigation.

Current studies of stroma-free hemoglobin solutions have evoked concerns about the use of community consultation as a means of informing the community, facilitating the conduct of emergency research, and adequately identifying individuals who do not wish to participate in an emergency trial for which the informed consent requirement has been waived. Fluid resuscitation of trauma patients with hemorrhagic shock has moved from inadequacy, indexed by acute renal failure, to excess, indexed by compartment syndrome. Experimentation on severely injured patients to refine resuscitation and ideally define optimum fluid therapy is needed and can be justified by its ability to produce results that otherwise cannot be obtained and to benefit other trauma patients and society as a whole.

To conduct community consultation in the resuscitation fluid trial cited above, the trauma service of one of the participating hospitals scheduled 14 community meetings. The number of attendees at all of those meetings totaled 103 and ranged from 1 person, at four meetings, to a high of 22. All attendees were asked to complete a survey, but only 83 of the total 103 did so, of which 75 indicated willingness to participate in the study and 8 declined.

That same hospital conducted 17 community meetings to obtain community consultation for emergency research on the use of a pharmacologic agent in trauma patients. The results of those meetings were similar; a total of 188 individuals attended, 156 completed the survey instrument, and only 5 declined to participate. The catchment area of that hospital includes more than 2 million people, and it is reasonable to assume that more individuals in that hospital’s community would decline to participate in those studies than the few who indicated such at those meetings.

The data from these community consultation programs suggest that the process can be characterized as a series of information sessions in which the investigator-attendee ratio often approaches the Socratic ideal and fails to identify the true fraction of the population that would decline participation in emergency research. Neither “community consultation” nor “community representative” is defined in the National Institutes of Health or FDA regulations. Similarly, the regulations do not specify the format of the consultation or the informational content. Nowhere do the regulations address what should be done with the results obtained at the consultation nor do they identify a level of opposition that would necessitate canceling a study.

To increase the effectiveness and relevance of community consultations, the process will have to be definitively described and standardized. Even with such reforms, other measures will be needed to enhance the visibility of emergency research and public awareness. The number of prospective study patients reached could be expanded by periodic announcements on television and radio and quarterly or semiannual meetings to update the community on the status of emergency research projects.

Television announcements mobilized the Jehovah’s Witness community to request exclusion bracelets for the two emergency research studies cited above. The process could be augmented further by establishing a readily accessible FDA-maintained Web site that lists each approved emergency research study, the study sites, and information about how to decline participation. That Web site could be cross-referenced and linked to the Web sites of the American College of Surgeons’ Committee on Trauma, the American Association for the Surgery of Trauma, and similar organizations.

Some experts have suggested creating a national board to oversee such research but without indicating how the composition, authority, or specific function of such a board would improve upon what is available already at the FDA and the NIH. Although the history of human experimentation approved by a “National Board” in Germany during World War II evokes disquieting memories, a broad-based, representative board consisting of experts from professional organizations and government agencies, as well as lay members, could allay those concerns. By adhering to the Belmont Report’s basic ethical principles, the board could serve to verify societal needs, enhance patient safety, and ensure a proper balance of risks and benefits.

Along with the suggested standardization and amplification of the current informational program, the board could enhance the efficiency and effectiveness of community consultation and provide the potential participants in emergency research with the information necessary to make their preinjury acquaintances to entering a study closer to the ideal of voluntary informed consent.

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