Ethical Considerations of Research in Disaster-Stricken Populations

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Abbreviations:
EFIC = exception from informed consent
FDA = [US] Food and Drug Administration
IRB = Institutional Review Board

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Abstract

Recently, emphasis has been placed on improving and expanding research in disaster response and the treatment of disaster-stricken populations. However, research in these settings presents unique ethical challenges with which the scientific and biomedical ethics communities continue to struggle. At the core of the controversy is the question of how best to balance the critical need for research with the equally important obligation to respect and protect the interests of research participants within the unique stress of a disaster. This concern stems from the potential of increased vulnerability of individuals stricken by disaster over and above their usual vulnerability to risk and exploitation as research subjects. Ethical principles that must be considered in these situations are the same as those that are important when conducting any human research: respect for persons, non-maleficence, beneficence, and justice. This paper explores the ethical challenges that accompany inadequate resources and personnel, the potential vulnerability of research participants, the dual role of physician-researcher, and the importance of the public's perception and trust are explored. It then proposes a number of potential avenues through which to conduct ethically justifiable research that could answer many of the pressing questions in disaster medicine and response.

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Introduction

Recently, emphasis has been placed on improving and expanding research on disaster response and the treatment of disaster-stricken populations (Table 1).[1–5] However, research in these settings, presents unique ethical challenges with which the scientific and biomedical ethics communities continue to struggle. At the core of the controversy is the question of how best to balance the critical need for research with the equally important obligation to respect and protect the interests of research participants within the unique stress of a disaster. This concern stems from the potential vulnerability of a population affected by a disaster over and above their usual vulnerability to risk and exploitation as research subjects. Ethical principles that must be considered in these situations are the same as those that are important when conducting any human research—respect for persons, non-maleficence, beneficence, and justice (Table 2). This paper will attempt to enumerate the dilemmas posed by disaster research and suggest ethical considerations important to resolving those challenges.

Setting the Scene

Disaster, *catastrophe*, and *complex emergency* all are terms used to describe unusual situations resulting in substantial damage, illness, and injury to large numbers of individuals.[6] Frequently, the medical needs of disaster victims far outweigh the available resources of the affected community.[7] A disaster may result from a great variety of events, some from natural and others from man-made hazards. Some have been publicized widely, such as the 2004 tsunami in

General Topic	Potential Research Questions
Mass Casualty Management	- What is the most efficacious method of triage in a given type of disaster? - What is the most effective means of mass decontamination in a chemical, biological, or radiation exposure?
New Technology	- Are new, rapid diagnostic tests for chemical and biological exposures useful in the immediate aftermath of a disaster? - Is ultrasonography an effective adjunct to field triage?Are portable laboratory diagnostic tools for measuring anemia, electrolytes, etc. an effective use of resources in disaster settings?
Infectious Disease	- What methods of water purification and distribution are most effective during a disaster? - Which medication regimens are most efficacious in the setting of widespread respiratory or waterborne illness during a disaster? - How effective are rapid mass-vaccination programs during a disaster, and how can they best be implemented?
Mental Health	- How can culturally appropriate and effective mental health support be delivered during a disaster? - What are the best methods for rapidly assessing the mental health needs of a disaster-stricken population? - What early interventions are most effective at preserving the mental health of both responders and victims following a disaster?
Resource Management	- What complement of medical, logistics, and other responders is most appropriate for a given type of disaster? - What balance of medical, food, shelter, and other supplies is most appropriate for a given type of disaster?
Education and Assessment	- What methods of didactic education, training, and simulation are most effective at preparing individuals for disaster response? - How can data and outcomes from a disaster best be used to improve upon future responses to similar environments?

Table 1—Proposed research topics in disaster medicine

Principle	Summary
Respect for Persons	Individuals should be treated as autonomous agents, and those with diminished autonomy are entitled to protection.
Beneficence	There is a obligation to maximize possible benefits and minimize potential harms.
Non-maleficence	Often considered a subsection of beneficence, this principle requires the avoidance of harm.
Justice	Equals ought to be treated equally and those who are not equals treated unequally.

Table 2—Basic ethical principles: The guiding principles that form the basis for federal research regulations from the Belmont Report[10,15]

the Indian Ocean, the release of sarin gas in Tokyo, the avian influenza and severe acute respiratory syndrome (SARS) outbreaks, the attacks on the World Trade Center, and the Rwandan genocide. Many others, however, were not covered by the media as extensively, which may lead one to believe that disasters occur only sporadically. In fact, on average, the world experiences a disaster each day.[8]

The taxonomy of disaster scenarios is relevant to preparing treatment teams for common injury patterns and medical needs, but it is beyond the scope of this paper. What is more important to researchers is to assess how disaster events may increase the vulnerability of victims, including their decision-making capacity. In a study of 60,000 disaster victims, Norris *et al* describe that various disasters have in common their potential to "engender an array of stressors, including threat to one's own life and physical integrity, exposure to the dead and dying, bereavement, profound loss, social and community disruption, and ongoing hardship".[8] To the extent that these stressors affect potential research participants, investigators may find it more difficult to involve them in an ethically justifiable research study.

The mental, physical, and environmental consequences of disasters are well documented. In a review of approximately 250 articles, chapters, and books between 1981 and 2001, from research that involved 29 separate countries and 160 distinct samples of disaster victims comprising >60,000 individuals, several psychosocial health outcomes were identified. Specific psychological problems were noted in

77% of samples of disaster victims, including post-traumatic stress disorder, major depressive disorder, and generalized anxiety disorder; health problems and concerns were observed in 23% of the samples, including increased self-reported somatic complaints, poor sleep, and increased use of alcohol and drugs. Chronic day-to-day problems were reported in 10%, and psychosocial resource loss in 9%.[8] The physically traumatic nature of hurricanes, earthquakes, violent displacement, and genocide is even more clear. The existence and magnitude of these harms demonstrate a need for research on affected populations during and after a disaster. The World Health Organization (WHO) outlined the following seven categories of necessary research in complex emergencies: (1) nutrition; (2) reproductive health; (3) communicable diseases; (4) health service management; (5) information management; (6) mental health; and (7) ethics.[5] Additionally, emphasis has been placed on maximizing the value of available resources by basing policies and practice on the best available evidence from disaster research.[2]

However, the ethics of disaster research has been a matter of recent debate and discussion. Much already has been published on the ethics of research with potentially vulnerable populations both domestically and internationally. *The Belmont Report, Declaration of Helsinki*, the Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects, and the Code of Federal Regulations on the Protection of Human Subjects* all are documents indirectly relevant to disaster research. However, there is not a set of guidelines that relate the core principles of biomedical ethics specifically to research conducted during or in the immediate aftermath of a disaster. Moreover, there are unique characteristics of disasters that make ethically justifiable research particularly difficult and that are worth considering.

Ethical Considerations

Resources Overwhelmed

During a disaster, it is impossible to devote the full extent of resources to every individual. Disaster responses require some form of triage, or system that categorizes patients by their medical needs and likelihood of benefit. There are many proposed approaches to triage, but common among them all is the utilitarian notion of doing the most good for the most people; in the context of disaster response, this ethic satisfies the formal principle of justice—to "treat similar cases similarly and equals equally."[9] However, it would be a mistake to assume that utilitarian principles used to triage victims of a disaster also apply to research. Individual rights and the basic principles of respect for persons, beneficence, non-maleficence, and justice may not be ethically subjugated for the "collective good" gained from research. If they were, immoral acts could be justified and even considered morally obligatory to achieve maximal societal utility.[10] The Tuskegee Syphilis Trials, during which black research participants were denied access to penicillin (an effective treatment for syphilis) in order to complete the research study, as well as atrocities disguised as research conducted by Nazi physicians during World War II, are two blatant examples of the abuse of individual research participants for the advancement of knowledge and science.[11] These examples are cited frequently, and arguably are obsolete within the context of current research regulations and oversight. A review by Henry Beecher, however, listed 22 unethical or questionably ethical studies in a single year from "leading medical schools, university hospitals, private hospitals, governmental institutions, governmental military departments, Veteran's Administration hospitals, and industry."[12] Furthermore, concerns regarding the ethics of certain studies led to suspensions of federally supported research in response to the 1999 death 18-year-old Jesse Gelsinger in a gene transfer trial at the University of Pennsylvania, and to the 2001 death of Ellen Roche, who was enrolled in an asthma study at Johns Hopkins.[13] Beecher noted that many instances of unethical research resulted from thoughtlessness and carelessness, "rather than from a willful disregard of patients' rights."[12] The unpredictability and uncontrolled nature of a disaster would exacerbate the potential for similar unintentional research participant mistreatment. Moreover, while medical personnel may expect injured disaster victims to accept available medical treatment and may presume consent for life-saving treatment of incapacitated victims, it is not as clear that such expectation or presumed consent is applicable to research without violating the victims' rights and the principle of respect for persons.

In addition, the rapid response that would be required of disaster research teams would preclude a formal review of any research study unless the proposal was submitted prior to and in anticipation of the event. Aside from identifying potential participants as "disaster victims," a principal investigator would have little information to include in the research proposal submitted to an Institutional Review Board (IRB). The precise research location, knowledge of barriers to participant access, and other logistical difficulties all would be unknown variables that may impact the research budget, required personnel, and even overall project feasibility. The difficulty involved in submitting a proposal without this information is by no means a justification to bypass the IRB. The US Office of Human Research Protections (OHRP) requires that any federally conducted or supported research be subject to formal IRB approval.[14] Now, it is widely understood and accepted that research involving human participants must undergo an independent scientific and ethics review to ensure the validity of the research question and methods as well as to ensure the existence of adequate protections against research participant mistreatment.

Vulnerability

The concept of vulnerability in research involving human participants provides a description of a population more susceptible to abuse, and imposes a responsibility to provide them added protections against such mistreatment. The Belmont Report states that certain vulnerable groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized should not be used for administrative convenience or ease of manipulation due to their ready availability and their "frequently compromised capacity for free consent."[15] The US federal regulations, which are based upon the Belmont Report, identify children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons as "particularly

vulnerable populations."[14] Both documents call for the inclusion of additional safeguards for vulnerable research participants in order to protect their rights and welfare.

During or immediately after a disaster-producing event, victims may be in acute need of the basic requirements of life—namely, the provision of food, water, shelter, sanitation, and medical treatment. Their personal safety may have been, and may continue to be, compromised. Their dependence on the assistance of others may be extensive or nearly absolute. Due to these circumstances, potential participants may feel indebted to their rescuers or perceive an implicit expectation of research participation. For example, in a study designed to assess the ethical considerations of research participation among acutely injured trauma survivors, 19% of the 117 research participants felt they could not decline participation.[16] Furthermore, the cultural background of the affected population may add its own expectations and perceived obligations toward relief workers and researchers. Without previous knowledge of the affected population and geographic area, it would be impossible to predict how cultural beliefs and practices would affect individual decisions to participate in a research study.

Due to the unfortunate circumstances in which they find themselves, the decision-making capacity of disaster victims may be impaired. Of course, this is a principal concern, as it pertains directly to the basic principle of respect for persons. Disaster victims are predisposed to psychological and emotional distress, including acute anxiety, post-traumatic stress, depression, and the stresses that accompany social and financial disruption and resource loss. In the majority of cases, the effects of such events tend to lessen over time.[17] As a result, research conducted during or immediately after a disaster would seem to maximize the potential vulnerability of disaster victims.

The concept of vulnerability, however, has been criticized because it "stereotypes whole categories of individuals, without distinguishing between those in the group who might have special characteristics that must be taken into account and those who do not."[18] For example, there is little compelling data that all or even most individuals who experience severe trauma are unable to make autonomous choices. Rather than stigmatize all disaster survivors as unable to make decisions for themselves, in the majority of cases, researchers may presume the decision-making capacity of survivors while providing additional safeguards to those individuals assessed and found to have actual impaired capacity.[19] More generally, classifying a population as vulnerable does not preclude strong arguments for their participation in research—"a protectionist stance implies a need for institutional and public scrutiny, not an *a priori* exclusion."[20] While it is reasonable to consider the circumstances and the potential that people may be prone to exploitation during and after a disaster, automatic exclusion of such persons from research is not reasonable. Consequently, ethics review committees, or IRBs, ought to seek a favorable risk:benefit ratio and assess vulnerability on a case-by-case basis.[21]

The Physician-Researcher

During disasters, scarce resources and insufficient numbers of healthcare providers may make it impossible to separate the roles of provider from investigator. Traditional biomedical ethics has discouraged this dual role, because of the Kantian notion that a physician ought to treat patients as ends in and of themselves and cannot do so if simultaneously using patients as means to answer a research question. This situation may lead to confusion among physician-researchers regarding the nature of their task, and how they view themselves and their patients-participants.[22] As physicians, their task is to treat the ailments of the patient, and as researchers, their goal is to seek out answers to research questions for the benefit of future patients. There also may be confusion in the minds of disaster victims, who may assume their rescuers only have the victim's best interests in mind. Within the acute stress of a disaster, victims may mistake research participation with definitive treatment, falling into what is called the "therapeutic misconception". If voluntary, informed consent is to be obtained, physician-researchers must emphasize the right to refuse participation and explain the concept of "clinical equipoise"—a state of genuine uncertainty of whether it is better to be a research participant within the experimental group or the control group.[23]

There is more complexity to these arguments, but what is immediately obvious is that these efforts take a significant amount of time. They should not, however, impede the progress of disaster relief. To do so would violate the basic principle of non-maleficence, to do no harm. If a potential research participant is unconscious or the urgency of the situation is too great, it may be impossible to elicit true voluntary, informed consent. Even if there were ample time to educate potential research participants, there is something unreasonable about attempting to discuss the intimate details of a research protocol in the middle of or immediately after a disaster.

Public Perception of Disaster Research and Trust

Engendering and maintaining public trust is critical to the cooperation of disaster victims and, consequently, to the success of disaster research and disaster response efforts. In an exercise called "Dark Winter", designed to examine the challenges senior-level policy-makers would face when confronted by a simulated smallpox attack in the US, participants were concerned that without public cooperation, it would be impossible to impose vaccination and travel restriction programs on large groups of the population in response to a bioterrorist event.[24] Public trust and cooperation are equally important to disaster research, and are difficult to recover once lost. The lack of trust among the African-American population, who easily recall racial discrimination during research in the early 1930s, directly impacts their response to public health crises today.[25,26] Regardless of the necessity for rapid response or the benevolent intentions of the research and disaster relief communities, public cooperation will not be forthcoming without trust.

A modern example of the importance of attending to the need for public trust in research can be found in the PolyHeme trial. This study, a trial designed to test an oxygen-carrying blood substitute against the current standard of care in hemodynamically unstable trauma patients en route to the hospital and into their hospital stay, received

harsh criticism from the *Wall Street Journal*, *The American Journal of Bioethics*, ABC News, and a US Senator.[27] This outcry stemmed from the absence of an opportunity for research participants to express a choice of whether to participate and from inadequate community notification. A separate study of attitudes and awareness of an on-going trial with a similar waiver of informed consent for emergency research found low overall awareness and low acceptance of such practices even after community consultation and notification.[28] Severe public resistance to research conducted without informed consent, even when consent is impossible to obtain due to an emergent condition, suggests that extending a waiver of informed consent to include disaster research would face similar opposition.

The impact of an erosion of public trust on the effectiveness of research and public health establishments must not be understated or ignored. The ability of researchers to continue medical progress and further advance capacity to mitigate disease and improve human life is dependent on individuals who volunteer for research trials and on public funds that support research.[29]

Future Directions and Potential Solutions

There are a number of potential avenues through which to ethically pursue answers to the myriad research questions in disaster medicine and response. Many of these questions can be answered without actually conducting research on disaster-stricken populations. Instead, many research priorities—for instance, determining how best to implement a mass-vaccination campaign immediately following a disaster—initially could be studied using probalistic modeling and simulations. Other questions, such as how to predict the number of medical patients presenting after a given type of event, can be answered by deriving estimates from previous events. Yet another potential approach to disaster research is to prepare study designs including informed consent protocols well in advance of any disaster. This "research-in-a-box" approach would allow for early scrutiny and revision by IRBs and ethics committees, and would avoid some of the pitfalls inherent to crafting a study design on the fly. There are inherent challenges to this approach, as the study design would need to provide flexibility to adapt to the unique circumstances of each disaster. However, this approach would encourage advance planning and consideration of how best to protect potential research participants.

Additionally, existing guidelines for traditional research could be adapted to the disaster environment. The US Food and Drug Administration (FDA) already grants IRBs the power to provide waivers from consent in research that presents "no more than minimal risk," and that involves no procedures that would require patient consent outside the research context. An individual is exposed to minimal risk when a research study involves no greater probability or magnitude of harms than he/she would encounter in daily life or by routine examinations or tests.[30] Valuable disaster research could be conducted under the minimal-risk waiver. For example, knowing that disaster scenarios likely will require triage, research of which system of triage is most appropriate (Triage Sieve, Simple Triage, and Rapid Treatment, CareFlight Triage, etc.) during particular types of disasters is a relevant and important research question.[31] In addition, determining methods of recording clinical data, identifying critical resources, and investigating how to optimize the distribution of these resources, all are equally appropriate and necessary research questions that would benefit future disaster responses. In the great majority of cases, these examples pose little risk to disaster victims, may impart direct benefit to research participants, and would not be feasible if voluntary informed consent was required. While the minimal-risk waiver is not without some controversy, it is an established practice that would allow for ethically justifiable disaster research when combined with already existing research participant protections.

The more difficult question concerns how to conduct disaster research that exposes research participants to more than minimal risk. Within the small subset of research conducted during emergencies, the FDA has codified an exception from informed consent (EFIC) under its Final Rule guidelines.[32] Accordingly, the protocol must meet a number of stringent conditions: (1) the participants must be in a life-threatening situation with no proven or satisfactory therapy; (2) obtaining informed consent must not be feasible; (3) participation may be therapeutic; (4) the research could not be carried out without a waiver of consent; (5) the investigator makes an attempt to obtain consent from the participant or a legally authorized representative; (6) the IRB has approved a consent document to be used where and when consent is possible; and (7) additional protections of the rights and welfare of participants are provided. Contrary to the common assumption that such waivers are used infrequently, 51% of 98 IRBs surveyed at academic medical institutions around the country have reviewed and approved EFIC requests.[33] Given the similarities between emergency research and the broader category of disaster research, the EFIC waiver may provide an avenue for researchers to gain IRB approval for research during disasters. However, great caution and vigorous scrutiny must be exercised when employing this approach for disaster research. As demonstrated by the PolyHeme trial, using the EFIC waiver to perform research without consent can cause significant damage to public trust and therefore, has the potential to impede disaster research and general disaster response. Consequently, it would be prudent to abstain from research that involves more than minimal risk when meaningful voluntary informed consent is not possible. Further public deliberation should be encouraged and actively nurtured by the scientific and healthcare communities until a greater consensus can be reached on how best to conduct much needed "more-than-minimal risk" research in the setting of a disaster. While an unmistakable need for disaster research exists, the approach to determining if and when to grant an EFIC waiver remains unclear.[27]

Conclusions

There is a clear need for research during disasters in order to improve existing methods of disaster response and management. However, there are equally compelling ethical issues concerning how best to conduct such research while also respecting the individual rights and interests of poten-

tial research participants. This paper proposes a number of potential avenues through which to conduct ethically justifiable research that could answer many of the pressing questions in disaster medicine and responses. These include focusing on research questions that pose minimal risk to participants, avoiding more than minimal risk when full voluntary informed consent cannot be obtained, and crafting flexible study designs that can be implemented in a wide variety of disasters and that could be scrutinized thoroughly prior to implementation.

This paper has explored how the unique situational stress of a disaster affects the challenges that accompany inadequate resources and personnel, along with the potential vulnerability of research participants, the dual role of the physician-researcher, and the importance of the public's perception and trust. Other ethical considerations concerning disaster research surely exist. However, this paper has attempted to delineate the most immediate concerns that must be addressed as the research community attempts to broaden its efforts within this unique environment.

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