Ethics of Research on Survivors of Trauma

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Essential elements of all research include balance of risks and benefits, unbiased selection of research samples, and assurance of the rights of individual participants. This paper highlights some key ethical issues and summarizes recent evidence relating to participation in, and conduct of, trauma-focused studies with special reference to vulnerable populations (eg, women and children, refugees, survivors of human rights violations, and survivors of trauma in the developing world). A concise ethical framework, rather than rigid guidelines (that may not be applicable to all trauma studies), may be a more useful point of reference for investigators and ethics committees or institutional review boards. Despite the increased empiric data available to inform ethical dilemmas regarding trauma research, more cost-burden analysis research in varying trauma populations and careful investigation of factors that contribute to risk and benefit is required.

Introduction

Research that involves individuals who have been exposed to life-threatening events (*eg,* childhood physical and sexual abuse, adult rape, and natural and technologic disasters) and who may have a heightened vulnerability for adverse outcomes raises a range of ethical issues. As with other areas of research, there are concerns of confidentiality, disclosure, informed consent, and risk of harm to participants. The basic principles of research, as outlined in the International Guidelines for the Ethical Review of Epidemiological Studies [1], include the following: 1) respect for the individual (encompassing respect for autonomy and protection of vulnerable participants); 2) non-maleficence (minimizing harm to research participants); 3) beneficence (maximizing benefits to research participants); and 4) justice (balancing the risks with the benefits). In trauma-focused research, there is some debate about whether one or more of these ethical principles should take precedence. Certainly, in all phases of trauma-focused research it is important to be vigilant of the risks to safety and confidentiality for all subjects while at the same time promoting well-being, dignity, and autonomy. In addition, the principle of distributive justice implies that research risks and burdens should not be carried disproportionately by vulnerable groups [2•]. The trend in most Western countries is to emphasize autonomy over beneficence; however, in developing countries, concern for distributive justice often enjoys a higher priority [3], and the risk that the research poses to the community is usually afforded higher priority than the risk to the individual.

Evidence for Benefits and Risks in Trauma-Focused Studies

There are several broad ethical considerations that are especially relevant to trauma populations [4•]. In research settings, trauma assessments typically comprise the use of structured or semistructured interviews and rating scales (researcher-administered or self-reported). This includes investigation of traumatic life experiences, mental health symptoms (*eg,* acute stress, post-traumatic stress, or depression), physical health status, health-related quality of life, and some aspects of role functioning (*eg,* occupational and social functioning). The question is raised as to whether, for survivors of trauma, inquiry into trauma is associated with any risks.

Recent observations that many trauma survivors are grateful for the opportunity to share their experiences with a researcher who is unlikely to judge or condemn them suggests that this population may be less fragile than we think, even in the acute aftermath of a traumatic event [5••]. Empiric data on participant reactions to different assessment procedures in trauma samples (*eg,* domestic violence, rape, and physical assault) demonstrate that the majority do not find the experience distressing, but rather view it as valuable and relieving [5••]. For many survivors, sharing stories of trauma provides an opportunity to give testimony about the past and is perceived as therapeutic.

Conversely, it can be argued that research interviews have the potential to make participants relive visual or auditory reminders of unpleasant events, and in so doing, feelings of fear, shame, anger, and other painful emotions may

be evoked. "The memory of a trauma suffered or inflicted is itself traumatic because recalling it is painful or at least disturbing" [6]; the process of investigation may itself be traumatogenic, eliciting disabling memories of painful experiences to which participants may have already adapted. However, the notion that participants are "re-traumatized" through research participation may be inaccurate, because perceptions of uncontrollability that characterize actual trauma cannot be equated with the experience of reliving an event in the controlled research setting.

Essentially three types of participant reactions have been identified in trauma-focused studies—participants who are positive about the experience, those who feel that participation is effortful or time-consuming, and those who are negative and find it intrusive or cumbersome [7,8]. Some trauma survivors may have difficulty reintegrating their experiences at the end of the research interview, and any unanticipated upset that is incurred can persist for some time. Some distress or discomfort is arguably inevitable in trauma-focused studies and should be allowed. However, what constitutes acceptable discomfort or risk needs to be balanced with the actual value of conducting the study.

In a large-sample, two-stage study, the problems of combining survey and clinical methodologies and ethical standards were examined as part of a survey of stressful life experiences and related psychopathology (n=1755) [9]. Although some mild, short-term distress was observed in participants, on assessment, the interviews did more good than harm. Respondents expressed relief for having talked and actually enjoyed the opportunity to talk. In the first stage, interviews were conducted by lay interviewers who rated 2.6% of respondents as being distressed by the experience. A slightly higher rate of respondent distress (7.1%) was reported in the second stage, in which interviews were conducted by mental health professionals (psychologists and social workers). In a similar vein, the adequacy of informed consent and the frequency of adverse reactions resulting from participation were investigated in a trauma-focused health survey of female members of a health maintenance organization (n=1174) [10••]. The vast majority of respondents who chose to participate reported personal benefits and no regrets, with the cost-benefit ratio remaining stable over time for most participants. For example, 74% of women reported benefits after being given 48 hours to consider the process that they had been through. Women reported that they did not feel coerced, harmed, or tricked into participation. Overall, participation was well-tolerated and informed consent procedures were adequate, regardless of sexual maltreatment status and post-traumatic stress disorder (PTSD) symtomatology. Women with higher levels of PTSD symptoms endorsed greater subjective distress while completing the questionnaire, but also reported less regret than those with fewer symptoms. Further, it has been suggested that individual personality and health characteristics may play a role in differentiating participation experiences of subgroups of individuals in trauma studies [11]. For example, in a postal survey of former burn patients (n=78), maladaptive personality traits and PTSD symptoms were found to be markers of negative reactions to participation. This suggests that in some trauma survivors negative reactions may be associated with underlying psychologic vulnerabilities. However, more work is needed to understand the individual characteristics (*eg,* trauma, personality, illness, and so forth) that identify persons who are most at risk from trauma-related research.

Special Trauma Populations

Ethics of research on acute trauma survivors

In recent years, increased attention has been given to early assessment and treatment of acutely injured trauma survivors who may be at a high risk for later psychiatric morbidity, in particular PTSD and depression [12]. Few studies, however, have investigated ethical concerns surrounding participation, particularly the perceived loss of autonomy and well-being that may occur in emergency settings [13•]. Acutely injured trauma patients who are hospitalized often lose the capacity to make decisions related to the emergency care they receive and frequently undergo treatment procedures of which they have little awareness or understanding [13•]. Research interviews that elicit traumatic memories and exacerbate symptoms of acute stress may potentially worsen psychologic distress [13•].

In the first empiric investigation of this nature in 117 physically injured motor vehicle accident and assault patients who were hospitalized, 95% reported that the benefits of protocol participation outweighed the costs and 94% reported no regrets. The majority reported that they experienced control over initiation and discontinuation of the protocol and that in retrospect they would again agree to participate. A minority of participants endorsed unwanted thoughts as a result of participation (30%), unanticipated emotional upset (12%), and felt that they could not refuse participation (19%). Although the study assessed the immediate responses of survivors and did not assess for the emergence of negative responses after discharge from hospital, these findings suggest a role for acute evaluation and early treatment intervention in this setting [13•].

Ethics of research on survivors of human rights violations and refugees

Research into the mental health effects of human rights violations is inherently risky, particularly because a breach of confidentiality may lead to severe harm or death. Furthermore, research in countries with poor human rights records may be associated with the following: 1) possible retribution to participants for associating with researchers; 2) dangerous conditions for research staff; and 3) difficulties in obtaining valid data [2•].

In South Africa, massive human rights abuses were perpetrated under apartheid [14]. Survivors of state-perpetrated violence were not free to disclose their injuries or distress to health professionals for fear of persecution or

harm. Data indicate that in this setting in which human rights violations were chronic, high rates of PTSD, depression, and other anxiety disorders existed [15]. However, few sought treatment because of concerns of confidentiality, mistrust, and fears that talking about the experience might re-awaken painful memories [15]. This suggests that there is perhaps an ethical imperative on researchers in countries that have been dogged by human rights abuses to proactively screen for histories of trauma and document rights violations (with a few carefully phrased questions) in medical and psychiatric settings.

In order to expose and document the abuses that were perpetrated, the South African Truth and Reconciliation Commission (TRC) was established in the late 1990s [14]. Participants were individuals who had been personally violated or whose family members had been violated. Although some who testified before the TRC found the experience to be psychologically healing, there were others who were disillusioned. The findings of one study indicate that regardless of whether participants chose to give public testimony, closed testimony, or no testimony, this had no bearing whatsoever on psychiatric status (*ie,* rates of PTSD, depression, and other anxiety disorders were similar) [16]. This contrasts with the findings of aforementioned trauma studies. Because giving testimony before the TRC was a process coupled with an apparent lack of justice (no punishment for perpetrators), it may be argued that this could have been counter-therapeutic for some participants [16,17].

Refugees are vulnerable subjects in trauma-focused research because they are essentially displaced individuals who possess few political rights in their host country. In addition, they may continue to experience oppression, reprisal, and humiliation even after fleeing [18]. Applying principles of informed consent, confidentiality, "do not harm," and beneficence in refugee populations may be especially challenging against the backdrop of language, cultural, and social norm differences. Focusing on the traumatic experiences of refugees through research may further jeopardize safety and increase the risk of retribution. It also may be hard to justify how a study in a mobile, displaced sample could realistically confer benefits to individual participants [18].

Ethics of research on domestic violence survivors

The few studies that have addressed the question of whether it is harmful to include survivors of domestic violence in trauma research show that most women report positive gain and that women with higher levels of psychopathology (depression and PTSD) and poorer coping mechanisms are more likely to experience regret and distress [19].

Debate exists on the format that informed consent procedures should take and there is little consensus on what constitutes adequate consent and how much and what type of information participants of domestic violence research need to be given. Whereas some argue that participants should be informed at the outset that the study will include questions on violence and trauma, others feel that this may introduce a source of bias and discourage participation [10••]. At the very least, it is recommended that participants be reminded just before being asked violence-specific questions that this is about to occur. Permission should again be obtained to proceed with the interview [4•,20]. With respect to the research team, stereotypes and biases about domestic violence among researchers should be adequately addressed because this may deter the interview process and the data collection [4•].

Women living with violence may be at a risk of physical harm should a partner discover that the abuse has been divulged to a third party [4•]. To ensure confidentiality, interviews with women should ideally be conducted in complete privacy, away from other members of the household [21]. In addition, the World Health Organization recommends interviewing only one woman per household to ensure participant safety and to prevent others from learning of the study [21]. They recommend not doing any research on violence in men in the same community as women who have been interviewed, and not informing the community at large that the survey includes questions on violence [4•].

Ethics of research on traumatized children

Little is known about the effects of participation in research studies on children and adolescents and their families. Children and parents who have been directly interviewed about psychopathology and psychosocial stressors and asked about their experiences of research participation have reported satisfaction overall [22]. None of the parents reported that they would discontinue participation of their children despite the sensitive nature of inquiry.

The first systematic study of children's, adolescent's, and parents' reactions to participation in trauma research examined responses to participation in a study of acute stress disorder symptoms in children hospitalized for a traumatic injury [23]. Children were assessed 2 to 4 days postinjury in the first study and at 1 month postinjury in the second. The Reactions to Research Participation Questionnaire for Children and for Parents (which included items such as "being in this study made me feel upset or sad" and "the things that I said will stay private") were used to assess child and parent views. Although positive and negative reactions were endorsed, children and adults were willing to answer honestly even about their negative experiences. This occurred regardless of whether questionnaires were completed verbally with an interviewer or whether they were completed independently in writing, suggesting that the format of the interview that was used was not critical in facilitating self-disclosure.

Informed consent in children and adolescents usually entails providing the parents of potential participants with information about the study, procedures to be used, the right not to take part, and answers to any questions that they may have [24]. Developmental factors impact on a child or adolescent's capacity to participate in informed assent and consent procedures, and on the capacity to weigh up relative risks and benefits of participation [25]. Developmental

changes also may underlie some of the differences between children and parents in understanding of concepts of consent, risk, and benefit.

It is unclear at what age children and adolescents are truly able to make an informed choice. One study that examined children's assent to a clinical trial found that the quality of assent in children younger than 9 years was very poor (children under this age could not consent or assent to clinical research in any meaningful way), and recommended that the current age of 7 years for initiating assent (in addition to parental consent) is probably not appropriate [26]. The issue of consent versus assent in children and adolescents is contentious, more so in situations in which a child or adolescent appears to have been pressurized by the parents. A naturalistic study that examined children's consent to treatment at an outpatient clinic found that one third were attending the clinic against their will [27]. In another study of Bosnian refugee families' experience of research [28], it was found that parents often neglected to consult with or inform their children about study participation; however, the majority of children said that they would have preferred to have been asked separately about their willingness to participate in the study. In addition, four of 14 children reported that it was useful to talk to someone outside the family.

Careful negotiation with the child and parent may be critical in trauma research, especially when a child's wish to please the parents or a fear of stigmatization may impede his or her ability to make a truly informed and objective decision. Confidentiality of information may be tricky in this setting. Although researchers have clearly defined legal obligations (*eg,* with respect to disclosure of sexual and physical abuse of children and adolescents), their ethical obligations are not as clear (*eg,* whether to inform a parent of risky sexual behavior in a child) [29].

Recommendations for Research in Trauma Survivors

Ensuring human rights and justice

In any trauma-based study, the integrity and dignity of trauma survivors should be weighed against the pursuit of scientific inquiry [9]. Study participants should be selected on the basis of scientific principles and every effort should be made to avoid selection bias on the basis of accessibility and cost [18]. Ultimately, the guiding principle should be one of beneficence. Studies should only proceed when it can be demonstrated that the importance of obtaining potentially sensitive and painful information justifies the emotional discomfort that it may generate, and that the trauma research question cannot be studied in another way. In addition, trauma-related content should not be asked when negative after-effects are a possibility *and* there are no adequate mechanisms in place to handle these or to monitor harmful outcomes. For research involving refugees or survivors of human rights violations in which the actual benefits may be less evident, participants should be made to understand in the informed consent process that they are agreeing to enter into a study that has some risks and that may not give them any benefits [18].

Informed consent

In many instances, ensuring that consent is voluntary and informed may be more a question of detecting and eliminating the lack of consent [30]. More research is needed on informed consent procedures for studies on trauma and violence, specifically with regard to the quantity and nature of information that should be given. Because of the sensitive nature of the inquiry in trauma research, participants should be informed that they may refuse to answer any questions should they choose and that they may terminate participation at any time. As participants may not realistically be able to anticipate the degree of "traumatization" or distress that such inquiry may cause, it is important to outline in the consent document that distress may increase for a minority of participants after the interview.

The decision ultimately rests with the researcher on whether a participant is competent to make an informed decision. To ensure that ethical standards are met, participants should be adequately informed of the aims, objectives, methods, anticipated benefits, potential risks and discomforts of the study and should be able to understand and rationally evaluate the contents of the consent form. This gives potential participants an opportunity to decide for themselves whether the benefits of participating for them outweigh any risks that they may be unwilling to take.

Disclosure

Under certain circumstances, for example, when there is ongoing childhood sexual violence or violence by an intimate partner, it is important to maximize disclosure of trauma/violence in participants, especially when there is ongoing childhood sexual violence or violence by an intimate partner. Under-reporting may yield inaccurate data about the extent and severity of trauma and also may skew the relationship with mental and physical health outcomes [4•]. Because full disclosure of trauma may be essential to ensuring participant safety and data quality, the nature and wording of questions and the skill and sensitivity of the interviewers are paramount. A mix of open-ended questions and direct questions about trauma exposure may be useful, while at the same time allowing respondents to skip evocative questions if they so choose. To minimize participant distress, interviewers should 1) be trained to identify and respond appropriately to symptoms of distress, 2) know when to terminate the interview (*ie,* when a participant becomes too distressed), and 3) how to terminate the interview (*ie,* without reflecting disappointment or discouragement or undermining self-esteem) [4•].

Methodologic considerations

It is important that the study design imposes the absolute minimum additional risk. Combining different modes of data collection (*eg,* postal survey, in-person survey, or face-to-

face interviews), rather than focusing on one main method, may be useful, because there are some data to suggest differences in perceived benefits between filling in a questionnaire and being interviewed [10••]. Research assessments and treatments in trauma research (*eg,* refugee samples) should be culturally sensitive and take cognizance of the cultural variations in symptom expression and diagnosis.

The use of lay researchers to conduct diagnostic interviews in nonpatient populations is controversial. Those who are opposed to the practice contend that lay interviewers lack sufficient training to assess the presence and severity of clinical symptoms and this compromises the ability to obtain good data [31]. In support, studies that have compared the consistency in psychiatric diagnoses between professional clinicians and lay interviewers have found a low overall level of diagnostic agreement [32–34]. Data indicate that respondents may be more open and may report more symptoms to psychiatric interviewers than to lay interviewers, even with the status of the interviewer not revealed [35]. Arguably, the discomfort that lay interviewers may experience with gathering symptomatic material may be contributory.

Given that the cost in employing mental health professionals over lay interviewers for trauma research can be prohibitive, an alternative would be to ensure that lay interviewers are adequately trained to gather traumatic or symptomatic material and to distinguish normative from pathologic responses to trauma.

Referral of participants

The question of what to do when subjects are assessed as distressed and in need of treatment during the course of research remains unresolved. As a minimum standard, it has been suggested that researchers are ethically obliged to refer those requesting assistance to available sources of care and support [21]. If there are few existing resources, it may be necessary for the research team to arrange its own short-term support for participants [21].

Researcher support

Researchers involved in trauma-focused work should be carefully selected and receive sufficient training and ongoing supervision and support [21]. The most common risk to researchers is the emotional toll of listening to trauma stories. For researchers who have had personal experiences of trauma/violence, this can elicit emotional distress. Training of researchers should include the opportunity to discuss personal experiences, ventilate, and if necessary receive supportive therapy [4•].

Conclusions

When conducting studies on trauma populations, it is important that precautions be taken at every step of the way to maximize the possible benefits and minimize the potential risks. Additionally, the local social, cultural, and economic context in which the research is being conducted must be carefully considered such that the risks and benefits of research can be optimally understood, measured, and addressed.

Although most participants in traumatic stress studies demonstrate favorable attitudes toward participation, a minority do experience negative reactions. To make the best risk-benefit assessment, direct empiric assessment of participant appraisal ("what was it like to be in the study?") in more research protocols may be useful. This could take the format of a brief assessment or questionnaire. Quantifying upset, regret, and benefit will provide a more accurate estimate of distress and satisfaction, which then could be used to inform the decision-making of researchers and ethics committees or institutional review boards [10••].

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