Ethical Issues in Post-Disaster Clinical Interventions and Research:
A Developing World Perspective.
Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007

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Abstract

Disasters, natural or man-made, can occur virtually anytime and anywhere in the world. They bring mass destruction and loss of human lives. The effects of a disaster can be amplified many times in resource poor settings, especially in developing countries.

In a post-disaster period, many clinical interventions and a lot of research takes place which focuses on the disaster-affected populations.
While many of these interventions and research are conducted in the hour of need, some, unfortunately, are opportunistic. While many of these activities happen in accordance with internationally accepted ethical and other regulations, many of them violate ethical norms, and disaster-affected populations end up being exploited. Also, many ethical regulations are culturally inappropriate for the setting where research is taking place.

In the aftermath of the 2004 tsunami, a group of Sri Lankan and international academics and researchers observed these irregularities and formed a group to counter the exploitation of vulnerable populations, especially in developing countries. The Working Group on Disaster Research and Ethics (WGDRE) was formed in 2007 and has produced a set of ethical guidelines applicable to post-disaster research focusing on the developing world perspective.

Introduction

On 26 December 2004, an earthquake with a magnitude of 9.3 occurred resulting in the catastrophic tsunami which affected 12 countries. The human impact of the tsunami was enormous in terms of families affected, displaced or dead. Indonesia, Sri Lanka, India and Thailand were the most affected countries.

Several authors of this paper, as members of Institute for Research and Development (IRD), were involved in relief and psychosocial work in the immediate aftermath of the tsunami. They had firsthand experiences of a post-disaster provision of care to a vulnerable population, and of how provision of care and clinical interventions are affected in a developing country setting. In the long-term post-disaster period, they experienced the influx of foreign academics and researchers intent on conducting various researches on these tsunami-affected populations, and saw how beneficial and detrimental these research activities can be on the said populations. Many of these researchers were from the developed world and their research agendas and interventions were based on a western perspective which acted negatively on the local vulnerable populations. All these experiences led them to recognise the need for a sound ethical framework for post-disaster clinical interventions and research with a developing world perspective. This recognition in turn led to the formation of the Working Group on Disaster Research Ethics (WGDRE) in 2007 with the collaboration of academics and researchers from South Asian and Southeast Asian developing countries.
Background and Significance

Disasters

According to EM-DAT Emergency Disasters Data Base (WHO), there were 16,000 major disasters and over 500,000 deaths over the last hundred years. In 2006, 44% of disasters happened in Asia. Large scale disasters such as the 2004 tsunami in the Indian Ocean, 2005 earthquake in Pakistan, floods in India, 2008 landslide in the Philippines, 2008 earthquake in China and typhoon in Myanmar, the 9/11 terrorist attacks and Hurricane Katrina in the US, and the 07/07 tube bombing in London, have brought about many novel challenges related to human rights, ethical issues and social policies. During disasters, government policies (or their absence) and the influx and activities of a wide variety of non-governmental organisations affect mobilisation of response to and provision of care to those affected.

Disasters in the Context of Existing Global Divide

The global divide and disparities already existing within societies become wider during disasters, especially in the developing countries, as well as in under-developed regions of developed countries. Furthermore, disasters by their very nature may result in vulnerability of individuals and of social groups; especially children, women, impoverished communities and individuals (some with long-term disability), whether they live in the developed or developing world. Human right abuses, conflict and emergencies have been shown to be associated with poor mental health outcomes, physical and social conditions; all of these three can occur post-disaster.

Human Subject Research Following Disasters

Disasters cause destruction, death, disease/disorders, displacement, disappearance, and disarray, all of which have implications for mental health, public health, ethical/human rights and social policies. There is a growing collection of empirical evidence about best practices in responding to post-disaster health needs; however this needs to be buttressed through more field research. Hence, research pertaining to human subjects is crucial in the disaster context. Such research can range from clinical trials involving medical interventions to social science research involving focus group discussions.

Existing Global Divide in the Context of Research Ethics

Less than 10% of the world’s research resources are earmarked for 90% of the health problems while 93% of the world’s burden of preventable mortality
occurs in developing countries. Only 6% of psychiatric and 7% of medical articles in leading international journals originated from 90% of the global population. Little empirical research is available on the ethics of research in middle and lower income countries, and the extent and nature of ethical problems on human subject protection in research.

**Existing Evidence Base and Gaps**

The divide in global research and publications highlighted above is the same if not worse in relation to disaster research. Gaps in existing knowledge are highly likely, as research related to disasters and the ethical issues has not been systematically mapped.

The evidence base of mental health interventions for people exposed to conflict and disasters is weak, especially for psychological interventions conducted in the midst of emergencies.

**Potential Ethical Dilemmas**

Given the sudden nature of the disasters and the general breakdown of services and systems, research may be carried out without proper scientific rigour or ethical considerations. Several examples can be shown to support this. A case study was published by IRD on how a Japanese research team tried to take biological samples out of Sri Lanka in a study to test stress biomarkers without any ethical approval. In another example, a research testing cognitive ability was conducted on tsunami survivors also without any ethical approval. The list of such incidences are long and it is important to point out that on the other end, numerous important research projects were and are still being carried out with proper ethical approval and standards. This proves the double side of the coin where research and interventions can be carried out ethically and unethically.

If post-disaster research is important and can be done ethically, why would unethical research take place? This may be unintentional due to a lack of awareness of ethical issues, or intentional due to conflict of interests, deliberate exploitation of vulnerable survivors or a lack of respect for survivors.

Disaster response should be integrated, appropriate and evidence-based. Research needs to be contextual, and culturally and regionally appropriate. However, exploitation and abuse of vulnerable survivors should be prevented. It may be unethical not to conduct research in such situations, since ethical research that takes into account the needs and priorities of affected communities can contribute to mitigating the effects of future disasters.
Therefore, in addition to the accepted national and international guidelines for conduct of research, particular attention should be paid to enhanced ethical standards when conducting research in disaster-affected situations. These include the potential for harm resulting from the research process, and potential for exploitation of research participants and the affected community."However they offer little technical guidance."

More stringent policies and guidelines have to be followed to prevent unethical data collection and exploitation of the disaster survivors,\textsuperscript{15} giving due attention to issues such as: (i) what types of research; (ii) how soon; (iii) if based on local needs and priorities; and (iv) complexities when combined with aid and clinical care.

During the post-tsunami period, as stated in the introductory part of this paper, a need arose for a concentrated campaign to counter the detrimental effects of interventions and research conducted on the vulnerable tsunami affected populations.

A campaign titled “Prevent Re-traumatisation of the Traumatised” was launched with local, regional and international works, along with an invited editorial in \textit{The Lancet} on tsunami research and ethics.\textsuperscript{16} This initiative was developed in collaboration with regional and international professionals with similar interests (Appendix 1).

\textbf{Why This Initiative and Another Set of Guidelines}

Important but limited work has been done in this area. \textit{Journal of Traumatic Stress} published a special section in 2004 on the ethics of disaster research, based on a meeting organised by The New York Academy of Medicine and the US National Institute of Mental Health.\textsuperscript{17} It identified four areas of critical importance for the development, evaluation, and conduct of research protocols after a disaster: (a) decision-making capacity of potential participants; (b) vulnerability; (c) risks and benefits of participation; and (d) informed consent.\textsuperscript{18} The attendees were professionals from diverse backgrounds and family members from victims of the Oklahoma and World Trade Center attacks. They agreed that research after a disaster is important and can be done ethically, and highlighted that the survivors are not necessarily vulnerable. This notion of disaster survivors not being always vulnerable is not always shared by ethicists from the developing world.

In complex disasters such as the 2004 tsunami and earthquake in Pakistan, all existing infrastructure collapsed unlike in circumscribed disasters such as the Oklahoma bombings and World Trade Center attacks. Survivors in the Asian disasters willingly participated in multiple needs assessments and research possibly in the hope of benefitting from participation.\textsuperscript{19}
Approval from an ethical review committee (ERC)\textsuperscript{20} and ensuring informed consent from the participants are the cornerstones of ethical research.\textsuperscript{21} Issues and concerns regarding ethical reviews in collaborative research have not been explored in detail.\textsuperscript{22} The potential for further deviations from the accepted norms of informed consent and ethical review processes is likely to be even greater in research conducted in disaster situations. This may be due to the critical nature of the situation, the lack of functioning authority and regulatory mechanisms in the post-disaster backdrop, and sheer negligence and ignorance of the researchers. As priority may be given to providing essential care to disaster victims, other activities such as ethical committee meetings and issuing ethical approval may be considered as of secondary importance which may lead researchers to exploit the situation, or simply go ahead with their research, putting the ethical concerns aside.

There are some very specific issues regarding the ethical practice of research in the context of disaster and complex emergencies:

1) Health in low income countries is under researched. After natural disasters, with the attention of the world’s media focused briefly on the setting, local and international research teams often appear in large numbers. This leads to the possibility of over-research, and exploitation.

2) Complex emergencies are defined by the breakdown of established infrastructure, including any capacity that may have existed to regulate, monitor and ensure appropriate governance for research.

3) Research efforts are usually uncoordinated and poorly integrated with humanitarian relief operations, leading to the real danger that research efforts can interfere with urgent priorities of the moment.

4) Given their desperate circumstances, survivors are especially vulnerable to exploitation through undue inducement and compensation, and through an understandable confusion regarding the researchers’ objectives.

While general ethical issues on research are still very much applicable, the following issues become more crucial given the specific characteristics of populations affected by disasters and complex emergencies:

(i) **Scientific rigor and professional competence** of the research team for their specific tasks; the highest standards of scientific research and peer review should apply.

(ii) **Quality and adequacy of ethical review process** especially in relation to the expedition of ethical review, obtaining ethical permission from the host country, the potential for collusion by local ethics committees due to conflict of interests, and the lack of governance to deal with these issues.
(iii) **Undue inducement or compensation for participation**, and **therapeutic misconception**.

(iv) **Unequal burden** *(The Belmont Report)* — the choice of the research is based more on the accessibility of the population than the relevance to the situation.

(v) **Public interest and distributive justice** — the research undertaken may not provide direct or indirect benefits to the researched group, the disaster-affected community or future disaster-affected populations. In fact, the research may be a gross additional burden on people, who are already traumatised.

(vi) **Risks** acceptable under ordinary circumstances may not necessarily be acceptable in disaster situations.

(v) **Dissemination of results** — much disaster research is published in international journals not easily accessible within the country where the research was conducted.

### Process of the Drafting and Consensus Generation on a Position Statement

Faced with the aftermath of the Asian tsunami, earthquakes, volcanic eruptions, recurrent floods, cyclones, droughts, conflicts, and other disasters that devastate communities in the South and Southeast Asian regions, we have come together as a multidisciplinary working group of persons involved in research ethics to draft this statement on the ethical management of disasters and research related to disasters.

The Working Group for Disaster Research and Ethics *(WGDRE)* met in Colombo on 15 and 16 January 2007 to draft a consensus statement as agreed among the participants. The draft guidelines have since been widely circulated to gain international feedback *(Appendix 2)*.

### Conclusion

Disasters result in damage, displacement, and death of large numbers of people with significant disruption on society. They can happen at any time, affect anyone from any community and any state, be sporadic or regular in nature, and occur as a natural phenomenon or as a result of human design. Disasters create an imbalance between the capacity and resources of a society and the needs of its survivors and affecters.

The global divide and disparities that already exists within societies become even more exaggerated in disasters, especially in developing countries. During
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such calamities, government policies (or their absence) and those of a wide variety of governmental and non-governmental organisations impact on mobilisation of response to the disaster and provision of care of those affected. Disaster response needs to be integrated, appropriate and evidence-based. It also needs to flow along coordinated and well-managed governance systems. Rules to prevent the exploitation and physical, sexual and psychological abuse of vulnerable survivors and their families need to be strictly enforced.

Therefore, there is a need to systematically map existing and relevant evidence pertaining to disasters, their management and their impact on communities. There may be gaps in the existing knowledge, in the implementation of research recommendations, and in the development of evidence-based guidelines for proper management during the disasters and its immediate and long-term aftermath. Research is needed in such areas as disaster response and relief, healthcare, management and public health issues, and even the ethics of disaster management. Disaster anticipation and early warning systems, mitigation and preparedness are preferable to disaster response and need research. Therefore, further evidence needs to be gathered through culturally appropriate research for more effective and compressive responses from all sectors of society in dealing with those affected populations. This research needs to be contextual, as well as culturally and regionally appropriate, in order to facilitate the shaping of policies by the local management teams and the governments. It should also examine what stages of the recovery process are appropriate for conducting research and what type of research should be done at such stages. In fact, it may be unethical not to conduct research in such situations since ethical research that takes into account the needs and priorities of affected communities must be encouraged and promoted.

Disasters, by their very nature, result in vulnerability in individuals and in societal groups, particularly in disadvantaged communities. Any process of research involving human participants requires a robust and ongoing ethical review. Existing guidelines and norms pertaining to research on human participants may not be sufficient to address all situations that arise during disasters. Greater vigilance is necessary in disaster-related research to ensure that the general ethical principles are adhered to and participants are protected.

Research involving disaster-affected populations must adhere to universal humanitarian imperatives of alleviating human suffering, preserving human dignity as well as protecting and respecting human rights regardless of race, culture, creed, nationality or political beliefs. More specifically, work with such populations needs to place special emphasis on the unique needs and special concerns of survivors, thereby ensuring that the services and opportunities for rehabilitation are appropriate and acceptable to these individuals.
Appendix 1

Formation of the group

The first author took the initiative to convene the group. His interest in research ethics had been grounded through the experience of conducting research in Sri Lanka since 1997 and tsunami-related work in his capacity as the head of the psychosocial work at the Centre for National Operations (CNO) for tsunamis. The tsunami resulted in a huge influx of foreign organisations and individuals offering humanitarian aid, including counselling to Sri Lankan survivors. Doctoral students from developed countries acquired data to finish their theses, harassed survivors with multiple needs assessments and even collected blood for neurobiological markers of stress. In a rush to provide assistance, a lack of familiarity with local customs raised cultural concerns. As disaster survivors are vulnerable, any research involving human participants requires a robust and ongoing ethical review. Particularly when research is combined with humanitarian aid or clinical care (therapeutic misconception), there can be undue inducement for participation and survivors may not realise that they are participating in research. Issues get more complicated because researchers might rush to collect data without adequate planning.

Parallel bioethics initiatives took place in Sri Lanka, India, Pakistan, and the Philippines over the past few years. Capacity building in biomedical ethics through workshops, seminars, certificate courses and higher degree programmes existed in all these countries to varying extents. Similarly, research on ethical issues also took place in these countries although to a lesser extent. Networking among those who were interested in ethics within these countries existed but on a limited scale. Faced with the aftermath of the Asian tsunami, earthquakes, volcanic eruptions, recurrent floods, cyclones, droughts, conflicts, and other disasters that devastated communities in the South and Southeast Asian regions, we came together as a multidisciplinary group to form the Working Group on Disaster Research and Ethics (WGDRE) in 2007, through a Wellcome Trust conference Grant.
Box 1
The group

Several members of our group have a track record of designing and conducting high quality biomedical research (quantitative and qualitative), including South-South and North-South collaborations. They may not necessarily have equivalent expertise in bioethics. Others have formal professional training and expertise in bioethics, and a modest but growing track record of international publications on research into ethical issues. All of us, to varying degrees, have demonstrated a sustained interest in disaster-affected populations, whether through direct involvement in disaster management, advice to policymakers, or advocacy. Castro chaired the Committee of the Philippine Health Research Ethics Board (PHREB) that formulated the “National Ethical Guidelines for the Conduct of Research on Populations Traumatized in Emergencies and Disasters”. As co-Chair, he is partly responsible for ensuring that the Guidelines are observed. Jafarey provided humanitarian medical assistance after the Kashmir earthquake. Ahmad reviews research for the Medicines Sans Frontiers Ethics Review Board. Bhan works closely with networks of civil society organisations, which have been involved in disaster responses, is also part of the UN Disasters Management Solution Exchange Community in India, and is a member of the University of Pune’s ethics review committee. Kumar assisted ICMR in developing research agendas and ethical guidelines for disasters. Jafarey has a Masters in Bioethics from Harvard. Ahmad, Bhan and Kumar have Masters in Bioethics from the University of Toronto. Ahmad has received funding from NIH (2002, 2007), the Wellcome Trust (2005), USAID and the Government of Pakistan (2004–6) to develop a Masters in Bioethics, run Research Ethics Certificate Courses and workshops, and supervise research training fellowships. Jafarey has received two training grants from the Wellcome Trust (2001, 2005). Kumar has received two bioethics training grants from FIC/NIH for India-wide certified courses in bioethics, and to train five Masters students annually for three years. Sumathipala has received two WT grants to deliver basic and advanced courses in bioethics and has a growing track record in bioethics research (grants and publications). Macer and Castro are widely recognised as leading experts in Bioethics with links to UNESCO, WHO, US NIH (Fogarty International Center), and the European Union. Macer is the UNESCO Regional Advisor on Social and Human Sciences in Asia and the Pacific. UNESCO is working closely on disaster management and reduction among member countries, and he will thus link to governments in the region.
Appendix 2

The Draft Statement/Guidelines for Disaster Research

In addition to the accepted national and international ethical guidelines for the conduct of research, we urge researchers to pay particular attention to the following ethical principles when conducting research in disaster-affected situations. These guidelines are meant to supplement the relevant existing national and international documents and not to replace them. The areas which these guidelines address include the potential for harm resulting from the research process and its socio-political implications, and the potential for the exploitation of the research participants as well as the affected community. They also look at conflicts of the researchers’ interests with that of the community being studied, and the process of recruitment of survivors as participants with a particular emphasis on obtaining valid and truly informed consent. These guidelines also emphasise gender and cultural sensitivity, and the need for research to contribute to the healing and empowerment of the disaster-affected community.

1. **Relevance to disaster situations**
   a. Research planned to be conducted after a disaster should be essential and is not possible in non-disaster situations.
   b. The objectives of all potential research in disasters should be weighed very carefully for their potential contribution to the survivors, and for their value in future disaster situations.
   c. All phases of the research must be culturally sensitive and should involve those familiar with the community’s situation and their cultural beliefs and practices.

2. **Informed consent and voluntariness**
   a. Any research is only to be carried out with the prior, free and informed consent of the person concerned based on adequate information.
b. The research team must identify factors that serve as a barrier to the freedom of individual members of the participant population to give consent, and provide effective mechanisms to address them.
c. Survivors of disaster situations are particularly vulnerable and should not be subjected to inducement.
d. Research should not be disguised as treatment, relief or humanitarian aid. Every effort must be made in the informed consent process to make research participants aware of the difference between participating in a study and receiving humanitarian aid. The different roles of the researchers, caregivers, and volunteer workers must always be clarified, and the potential conflicts of interest declared.
e. In cases of collection and storage of human biological materials during a disaster, the purposes of such collection and storage should be explicitly stated in the informed consent process and also that these materials gathered would not be used for any other purpose.
f. The requirement for research on children affected by disasters cannot be ruled out. However, due to their greater vulnerability, the researcher will have to justify the need to use children as research participants. The informed consent process will have to incorporate mechanisms of proxy consent by their parents or guardians and include provision from permission by the child whenever applicable. The reviewers will look very carefully at the process of consent involving children who have lost one or both parents in the disaster.

3. Community consultation and participation
   a. Community participation before and during the research is essential in disaster-affected communities.
   b. The researchers and review process need to identify the communities that may be affected by the research and consult with them. The research team must describe a preliminary community mapping/scoping exercise to ensure familiarity with the community as well as identify local resources who will support ethical execution of the research.
   c. A community representative or advocate must be identified by a process which is acceptable to the study population.
   d. Community representatives or advocates should be involved in conceptualisation, review, research and dissemination of research involving disaster-affected populations.
   e. In no case should a collective community agreement or the consent of the community leader or other authority or advocate substitute for an individual’s informed consent.
4. **Non-exploitation**
   a. The selection of research participants must be made on scientific reasons and not based on accessibility, cost, gender or malleability.
   b. The research should not impose additional burdens on people who are already traumatised, and on the local infrastructure.

5. **Dignity, privacy and confidentiality**
   a. Given the circumstances that survivors of a disaster face, extra care must be taken to protect the privacy and confidentiality of individuals and communities.
   b. In the collection of data and human biological material, human dignity must be respected for both survivors and the deceased.
   c. Similarly, stringent standards must be maintained for the storage and possible sharing of human biological material and data.
   d. Utmost attention must be paid to prevent stigmatisation, ostracisation, and other harm to individuals and communities at all stages in the research process.

6. **Risk minimisation**
   a. Since disaster-affected populations are particularly vulnerable, it must be ensured that the conduct of research imposes the absolutely minimal risk.
   b. Risks that are acceptable under ordinary circumstances may not necessarily be acceptable in disaster situations.
   c. The research team must demonstrate the ability to anticipate adverse reactions and facilitate appropriate interventions.

7. **Institutional arrangements**
   a. Institutions that sponsor and conduct research should recognise that a stronger ethical obligation is required in disaster-related research.
   b. Research in disasters should be coordinated with other disaster relief activities.
   c. Research should not disrupt or further burden the existing infrastructure.

8. **Professional Competence**
   a. Ensure professional competence of all members of the research team for their specific tasks.
   b. The highest standards of scientific research and peer review should be maintained through the entire process.
9. **Public interest and distributive justice**
   a. The research undertaken should provide direct or indirect benefits to the researched group, the disaster-affected community or future disaster-affected populations.
   b. Prior agreement should be reached, whenever possible, between the community and the researcher on what benefits could arise from the research, and how they would be shared.
   c. The actual benefits arising from research should be shared with society as a whole and with the international community with due consideration to the potential negative effects upon the participants and the communities involved, in consultation with the community.

10. **Dissemination of results**
    a. Transparency in the dissemination of results should be a prior condition for the conduct of research in disasters.
    b. Research published in open access journals will ensure the widest dissemination of findings.
    c. Efforts should be made to use the results of research to influence the formulation and modification of policy.
    d. The presentation of the results of research to the community who participated in the research, and to the public, should be after a process of peer review has validated the conclusion reached.
    e. The relevant results need to be presented in understandable language to research participants and the participating community.

11. **Ethics review**
    a. Independent, multidisciplinary and pluralist ethics committees should assess all the relevant ethical, cultural, legal, scientific and social issues related to research projects. These should include representation or advocates from the disaster-affected community.
    b. All research should be subject to local ethics review that includes regular feedback from the researchers and community representatives.
    c. In addition, there should be a centralised mechanism (such as a national ethics review committee) for review and coordination of all research in the disaster-affected area to ensure a wide perspective on all the research and to prevent unjustified repetitive work.
    d. A central/national “clearing house” on an open website would be more effective in preventing duplication, as well as letting everyone know what topics have been covered, are currently being researched, and which ones are being planned.
    e. Prior ethics review and approval may be taken before initiating research in an expected disaster situation of periodic or recurrent nature.
However, the research may commence only after consultation with the actual disaster-affected community.

d. Expedited review may be necessary in exceptional situations, but should be conducted with extreme caution. This expeditious review must follow the standard procedure considering the guidelines mentioned above, with a quorum agreed beforehand.

g. In the case of research projects that commenced before a disaster, the investigators must go back to the ethics review board to consider — in consultation with the community, wherever or whenever possible — whether the research may continue or stop.

h. Where applicable, the protocol should include provisions for aftercare, including appropriate mechanisms for continuation of essential services that were associated with the research protocol, and a proper referral mechanism to deal with the needs of participants and members of the research team.

12. International collaborative research

a. All research in the disaster-affected area needs to be done with a local partner(s).

b. Such collaborations should be based on mutual respect and partnership. Collaboration needs to be undertaken between national researchers, policymaker and the community, to share responsibility for determining the importance of the problem, assessing the value of the research, planning, conducting, and monitoring the research, and integrating that research into the social system.

c. Contribute to developing the capacity for researchers, policy makers, and the community to become full and equal partners in the international research enterprise.

d. Permission taken from local authorities does not exclude the requirement for ethics review at local and national levels.

e. Special consideration should be given to the transfer of biological material, ownership of data and intellectual property rights issues. The export of biological materials from a disaster-affected area should be strictly regulated through a central mechanism.

f. Benefits of the research, if any, financial or non-financial, should be shared fairly with the community and decided a priori.

Notes


**References**


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