

Introducing MADRES (Mapping Disaster Research Ethical Scenarios)

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Introductory Remarks

- Aim of the presentation:
 - To provide an overview on what MADRES is **supposed** to be
 - To describe how things stand **recently** with MADRES
 - To point the **audience's** attention towards collecting cases

Proposed Outcome of the Project

 EUROPEAN COMMISSION / European Research Area / Science in society

European Textbook
on Ethics in Research

The International Center for Health, Law and Ethics

Faculty of Law, University of Haifa, Israel

The UNESCO Chair in Bioethics

Informed Consent



Israel National Commission for UNESCO

List of Articles

1. Schopper et al. (2009): Research Ethics Review in Humanitarian Contexts: The Experience of the Independent Ethics Review Board of Médecins Sans Frontières
<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000115>
2. Brown et al. (2008): Research in Complex Humanitarian Emergencies: The Médecins Sans Frontières/Epicentre Experience
<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050089>
3. Black (2003): Ethical Codes in Humanitarian Emergencies: From Practice to Research?
<http://onlinelibrary.wiley.com/doi/10.1111/1467-7717.00222/abstract.jsessionid=956A50A8888F236275C6323393845A08.f02t04>
4. Pittaway et al. (2010): 'Stop setaling our stories': The ethics of research with vulnerable groups. <http://jhrip.oxfordjournals.org/content/2/2/229.short>
5. Barzilay et al. (2013): Cholera surveillance during Haiti epidemic.
<http://www.nejm.org/doi/full/10.1056/nejmoa1204927>
6. Sumathipala et al. (2010): 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 researchand Ethics (WGDRE)
<http://muse.jhu.edu/journals/asb/summary/v002/2.2.sumathipala.html>
7. Collogan et al. (2004): Ethical issues pertaining to research in the aftermath of disaster.
<http://link.springer.com/article/10.1023%2FB%3AJOTS.0000048949.43570.6a>
8. Ford et al. (2009): Ethics of conducting research in conflict settings.
<http://conflictandhealth.biomedcentral.com/articles/10.1186/1752-1505-3-7>
9. Calain (2009): Research Ethics and International Epidemic Response: The Case of Ebola and Marburg Hemorrhagic Fevers
<http://phe.oxfordjournals.org/content/2/1/7.fulltext>
10. O'Mathúna (2010): Conducting research in the aftermath of disasters: ethical considerations
<http://onlinelibrary.wiley.com/doi/10.1111/j.1756-5391.2010.01076.x/full>
11. O'Mathúna (2015): Research ethics in the context of humanitarian emergencies
<http://onlinelibrary.wiley.com/doi/10.1111/jebm.12136/full>

About the Cases:

- „In practice, despite the potential obstacles to research highlighted earlier, one of the remarkable things about the emergency in Liberia is the extent of knowledge and information that is available, from a wide range of sources, albeit often not in published form (and sometimes not strictly definable as ‘research’).” (Black)

„People who are recruited by health workers during a disaster may confuse research with treatment and fall prey to the therapeutic misconception” (Macklin)

„Survivors in the Asia disasters willingly participated in multiple needs assessments and research possible in the hope of benefitting from participation” (Sumathipala et al.)

„In humanitarian crises, researchers are also often the providers of assistance, and particular care must be taken to ensure that consent or refusal to participate is in no way interpreted as being linked to the provision of assistance” (Ford et al.)

„People caught in a disaster are too emotionally unstable to provide valid informed consent to be a research subject; victims in the midst of a disaster are rendered too vulnerable by the situation to permit their inclusion in research” (Macklin)

- „There are data to support the notion that some potential research participants postdisaster will have impaired decision- making capacity as a result of their traumatic experience



It would, however, be inaccurate and potentially stigmatizing to assume that all persons who have experienced terror or other disasters are decisionally impaired and unable to make choices for themselves.” (Collogan at al.)

- „For example, provisions for informed concern are essential considerations. In the context of investigations regarding an FHF outbreak, however, several difficulties coexist. Patients are kept in isolation (voluntary or forcible), and their condition is generally critical. Clinicians and field researchers are not in favorable conditions either: they typically have different cultural or linguistic backgrounds, and wear protective barriers under which nonverbal communication is considerably limited. (...) Venipuncture obviously does not fit among ‘minimal risk’ procedures considered under commentaries to Guideline 4 of CIOMS (2008) with regard to conditions for waiving consent.” (Calain)

Cultural Differences

„In refugee and IDP contexts, complex and contested issues of community representation are also often encountered. Community leaders and those familiar with the language, social systems, and culture in these settings may exert tight control through their ability to offer patronage to some researchers” (Pittaway et al.)

“While community leaders may be prepared to take risks disclosing information, community members might not share this view. Often this divide is gendered, with male leaders speaking on behalf of the entire community” (Pittaway et al.)

Exploitation, reciprocity

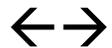
- “Research on experimental drugs during and after disasters presents particularly challenging ethical issues. One such controversial study occurred in 1996 in Kano, Nigeria during an epidemic of meningitis” (Collogan et al.)
- “Blood and genetic samples are believed to have been smuggled out of the devastated regions for research on neurobiological stress markers” (Sumathipala et al.)
- “Some researchers allegedly harassed survivors (of the South Asian tsunami) with questionnaires and pressurized people to participate in research projects” (Sumathipala et al.)

Greater exposure to risk

- “Past studies have revealed several characteristics of participants and types of studies in which disaster research has increased the subjects’ potential for experiencing harms. ‘These characteristics include pre-existing distress or mental illness, age (both young and old), history of multiple trauma exposures, social vulnerability, and physical injury. Furthermore, evidence suggests that repetitive research involving the same participants carries a potential for risk’ (Collogan et al.)
- “In other situations, concerns have been raised that disaster survivors can be further stressed by multiple requests to participate in redundant studies” (O’Mathúna)
- „One investigation was included as part of three telephone surveys conducted in New York City in the aftermath of the 11 September attacks that had proven this traumatizing effect” (Collogan et al.)

Greater Exposure to Risk

“Some fear that research interviews could ‘retraumatize’ disaster victims, although adverse effects appear to occur infrequently and evidence points to a number of beneficial effects from participation (...)



However, the patients were told they could refuse to complete the survey and that they could talk to clinic staff about any concerns they had about the study. Approximately 1% of the patients refused to participate, and an informal survey of participants found that the patients appreciated the fact that people were trying to understand how the hurricane had affected them personally” (O’Mathúna)

„Research participation may upset subjects but it does not traumatize them as a disastrous event would. Being upset or re-traumatization could have beneficial effects.(...) the majority of subjects who experience strong emotional reactions do not regret or negatively appraise research participation, suggesting that distress may be understood as an indicator of emotional involvement in the research project rather than as an indicator of harm.” (Collogan et al.)

Greater Exposure to Risk

- „In one site in Bangladesh, refugees who talked to researchers had very serious threats made against them by criminal elements operating in the camp, necessitating high-level intervention from those in authority” (Pittaway et al.)
- “In another instance, following a visit by the authors, over 100 families at risk were resettled from a particular refugee camp in an African nation to countries in the West.” (Pittaway et al.)
- „At the same time, there are a number of intellectual ownership issues that emerge in relation to data collection and research in Liberia during the war that have wider resonance. As noted above, much of the work that did go on was consultancy led and owned by powerful external agencies. Whatever the rhetoric of individual agencies, it was ultimately controlled by them and not independent. In some cases, this led to evaluations not being published. Meanwhile, even where material did come into the public domain, it has often remained hidden or dispersed, making comparative analysis of humanitarian activity highly problematic. Once again, the ODI work on Liberia stands as an exception to this criticism.” (Ford et al.)

REC approval

- „Among the 34 definite research interventions, individual consent was sought in 15 cases and consultation with an REC was mentioned in three cases. In these three cases, consulted institutions were described as based in countries of foreign investigators, but approval by local health authorities was granted as well.” (Ford et al.)
- „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.” (Sumathipala et al.)
- “In another example, a research testing cognitive ability was conducted on tsunami survivors also without any ethical approval.” (Sumathipala et al.)

Types of research

„Most studies reviewed in 2006–2008 were designed to either test a new intervention (diagnostic test or clinical procedure) or to assess the effectiveness of an intervention through a prospective descriptive study (49/70 protocols reviewed). Only five clinical trials, comparing the effectiveness of two or more treatment schemes, were submitted. On the other side of the research spectrum, a posteriori analysis of routinely collected data represented almost a quarter of the requested reviews.” (Schopper et al.)

Risks to researchers

- „W. Courtland Robinson of Johns Hopkins University recalled a situation in which ethnic Karen public health workers crossed the Thai border in Burma accompanied by armed insurgents as security guards in order to conduct public health surveys. Can one ethically make use of the data they collected? (...) An example is given by the imprisonment in 2005 of a representative of a humanitarian organisation for the publication of data exposing the extent of sexual violence in Darfur” (Pittaway et. al)
- “In work on Sudanese refugees in Uganda, Neefjes (1999) reports how a wide-ranging participatory review was carried out, but that this was quickly overtaken by further violence and evacuation of staff.” (Ford et al.)
- “Meanwhile, researchers are no more immune to the theft and looting of equipment and resources than humanitarian actors, and a number have been killed or injured in the process of carrying out research” (Ford et al.)

Thank you for your
kind attention!