Research ethics governance in disaster situations

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What type of disasters are we thinking about?
« Disasters » during which research may be carried out

- Natural catastrophe: hurricane Katharina, tsunami South-East Asia, earthquake Haiti
- Man-made catastrophe: Tchernobyl, Fukushima, Seveso
- Acute epidemics: SARS, avian influenza, Ebola/Marburg
- War: Iraq, Afghanistan, Somalia ....
- Terror attacks: Oklahoma, 9/11

*Disaster – Emergency – Post-disaster: acute and massive disruption of people’s lives and communities*
Ethical scrutiny of disaster/emergency research in real life: some examples

- Filovirus haemorrhagic fever outbreaks (Ebola/Marburg)
  - Review of published research 1999-2007
  - Among 34 research interventions, ethical review (international and local) mentioned in 3 cases

- War trauma research US military – Irak, Afghanistan
  - Charges by journalists that researchers rushed experimental treatments onto the battlefield without proper ethical review or sufficient safety testing
  - Stringent review mechanism: pre-screening for feasibility and other ethical issues → submitted to independent US army IRB
  - Independent ethics assessment: extra scrutiny justified


Bohannon J. War as a Laboratory For Trauma Research. Science 2011;331:1261-63
Research ethics in disaster situations: baseline assumptions

✓ Research needs to be initiated quickly to be meaningful, in particular for the study community

✓ Research in emergency or post-emergency situations must be submitted to ethical scrutiny

✓ The same ethical principles apply as in any research involving human subjects

✓ Ethics review procedure must be timely and flexible

✓ ...but also more stringent due to potentially greater vulnerability of study communities
Research ethics governance in emergency/disaster situations: fundamental issues

• How is research defined
  ? Generalizability of research results
  ? Hypothesis testing
  ? Testing of new or little documented intervention
  ? Publication of results
  ? Research “intention”

• Who decides that ethics review is necessary?

• Public health practice Public health research: 
  – Can hinder rapid implementation of life-saving public health measures
  – May allow collection of sensitive health data in possible violation of privacy
Does the type of research influence the review procedure?
What is special (1)?

- Normal oversight mechanisms may be unavailable in the country/region struck by disaster.
- Communities and people may be more vulnerable than under “normal” circumstances.
- The duty to provide emergency care may conflict with research priorities.
What is special (2)?

- Local research infrastructure may be seriously depleted or unavailable.
- Research may involve (several) institutions from different parts of the world.
- The duty to provide emergency care may conflict with research priorities.
Important criteria to judge the ethics of disaster research

• Relevance of research to the population affected by disaster ⇒ potential direct impact?

• Expected additional harm or suffering due to research

• Freedom of participation possible?
  • Political pressure
  • « Humanitarian » misconception

• Feasibility in disaster setting
How can/must research ethics review be adapted under these circumstances?

⟹ No international regulation

⟹ Several approaches have been recently proposed

- CIOMS guidelines 2009
- Working Group on Disaster Research and Ethics 2007: *Statement on ethical issues in disaster-related research – a developing world perspective*
- Tansey et al. CMAJ 2010: *A framework for ethics review during public emergencies*
CIOMS guidelines for epidemiological studies (2009)

- Only short note on research in emergency situations

- Establish basic research design before emergency
  \[\Rightarrow\] prior ethical review (guideline 2)

- Proviso if person with acute condition is incapable of giving informed consent (guideline 6)
Tri-Council Policy Statement: Research ethics review during **publicly declared emergencies**

- Plan for research ethics review should be established beforehand
- Exceptions to “normal” review procedures and infringement on ethics principles must be justified
- Anticipate what research, if any, needs to be done

⇒ *Puts the onus on (academic) institutions; mainly geared towards “national” emergencies*
Statement on ethical issues in disaster-related research – a developing world perspective *(WGDRE, 2007)*

**Recommendations on ethics governance**

- **Stronger ethical obligation required in disaster-related research**
- Independent, multidisciplinary and pluralist ethics committees with representation from disaster-affected community
- Local ethics review mandatory
- Centralized mechanism for review and coordination of all research in the disaster-affected area to [...] prevent unjustified repetitive work
- Prior ethics review and approval possible, but research start only after consultation with the actual disaster-affected community
- Expedited review in exceptional situations *(not defined?)*, with extreme caution and with quorum agreed beforehand.
A framework for ethics review during public emergencies: 3 key elements combined

• Proportionality ⇒ most intense scrutiny for most ethically challenging research

• Special scrutiny ⇒ increased diligence of ERB
  – Frequent/sequential reviews
  – Increased monitoring/oversight of informed consent process
  – Additional expertise to assess scientific validity and risk-benefit ratio

• Expedited review?? Only if minimal risk

Tansey CM, Herridge MS, Heslegrave RJ, Lavery JV. CMAJ 2010;182(14):1533-37
Tool to help ERBs and institutions to plan emergency procedures...

- **Increased diligence (special scrutiny)**
  - Complex/high risk protocols
  - Special expertise, also non-members
  - Focus on specific aspects

- **Enhanced procedural flexibility (expedited review)**
  - Depending on risk/complexity/urgency
    - Only chair
    - Chair + triage committee
    - Tele/videoconferences

- **Proportionality**
  - Depth
  - Speed

Proportionate to perceived risks and specific circumstances
The Ethics Review Board instituted by Médecins Sans Frontières

• Why does a humanitarian organisation need an ERB?
  – MSF has concerns distinct from academic institutions
  – Not all countries in which MSF works have (functional) ethics committees
  – Sometimes local or national government is not a guarantor for the wellbeing of the population

• Few « disaster/emergency » research, but…
  – Highly vulnerable populations
  – Strong power imbalance
  – High risk of therapeutic misconception
How does the ERB function

• Members are co-opted according to CIOMS and other guidelines
  – Understanding of humanitarian and NGO realities,
  – Geographic variety (Africa, Asia, Europe, North America)
  – Professional variety (medicine, public health, law, anthropology, bioethics)
  – To ensure independence and avoid conflict of interest ⇒ no working relationship with MSF or member of board

• Working procedures defined in Terms of Reference
  – Protocols transmitted to chair by medical director
  – Reviews coordinated by chair
  – Comments provided electronically, discussions on divergent views mainly through e-mail exchange
  – Most frequent situation: 1st review – reply – 2nd review – reply - approval
  – Final decision of the ERB transmitted to medical director responsible
  – His/her responsibility to ensure approved implementation of the research
Proportionality of ERB review

Full review = participation of all ERB members
- procedure or therapy of unknown effectiveness or efficacy tested on human subjects
- research involves collecting body/tissue samples with hypothesis testing (e.g. all clinical trials and some operational research projects)

Expedited review = 2-3 ERB members
- research carries only minimal risks to human subjects
- descriptive studies involving monitoring and evaluation as a means to test a new approach
- social science research in health and health systems
- prevalence and incidence studies

Review exemption
- Routine programme implementation
- Needs assessment
- A posteriori analysis of routinely collected data (with proviso)
A framework with benchmarks

- Derived from ethical theory and international guidelines
- Tailored for developing world context
- Employs principles and specific, practical benchmarks
- Does not add ethical requirements but makes them explicit and systematic
- Consistent framework and format for reviewers - consistent format delivered to the field
- Field knows what review board is evaluating
- Narrows scope of disagreement

Emanuel EJ et al. What makes clinical research in developing countries ethical? JID 2004;189:930-937
Dealing with emergency research ethics review in MSF

- Researchers /institutions know what they want to test in the next emergency ⇒ prepare and submit a “generic” research protocol for ERB pre-approval
- Rapid approval for local context in case of emergency
- Obligation to submit to local ethics committee/authorities
- Expedited review decided by chair, but can be challenged
- A posteriori ethics review not accepted, but advice can be provided
Particular vigilance of ethics committees required on certain issues

• Vulnerability
• Informed consent
• Benefit and burden
• Dual use of tissue samples
• Community engagement
• Humanitarian misconception

Dealt with in other presentations
Special issue: dual use of tissue samples collected during an emergency response

• Individual informed consent: CIOMS guidelines 4 and 24
  – Under which conditions is waiver of consent ethically acceptable?

• Community engagement

• Potential commercial use (e.g. vaccine development, patent claims over nucleic acid sequences)
Involving the community: main issues in disaster/emergency situations

• Frequently research carried out in resource-constrained countries by institutions from « rich » countries

• Community may be disrupted: who represents which community?

• How to establish local partnerships?

• How will results be reported back to community and research participants? **WGDRE:** “The relevant results need to be presented in understandable language to research participants and the participating community.”
Humanitarian/therapeutic misconception

• Research participants may be unaware of the difference between participating in a study and receiving intervention as part of humanitarian aid

• Likely to misconceive research (interventions) as aid – postdisaster research often not explicitly therapeutic
  ⇒ informed consent procedure very important

• Example of FHF: more scientists on the spot than experts to provide patient care
Recommendations (1)

- Clearer guidance on boundaries between research and public health/medical intervention
- Design of basic research protocols prior to emergencies and submission for provisional approval
- Involve potentially or previously affected communities ahead of time in research development
- Define a standard of care below which patient care has **absolute** priority over research activities
Recommendations (2)

- Engagement with/strengthening of local/national ethics review committees, if possible ahead of time

- Rapid and flexible procedure for (final) approval, e.g.
  - Electronic consultation among ERB members
  - Expedited review decided by chair, but can be challenged

- In case of major disaster and many potential research activities and institutions: oversight mechanism to prevent redundant research and oversampling of affected population
Thank you!