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

Calain P et al. Research ethics and international epidemic response: the case of Ebola and Marburg hemorrhagic fevers. Pub Health Ethics 2009; 2(1):7-29

Bohannon J. War as a Laboratory For Trauma Research. Science 2011;331:1261-63

Research ethics in disaster situations: baseline assumptions

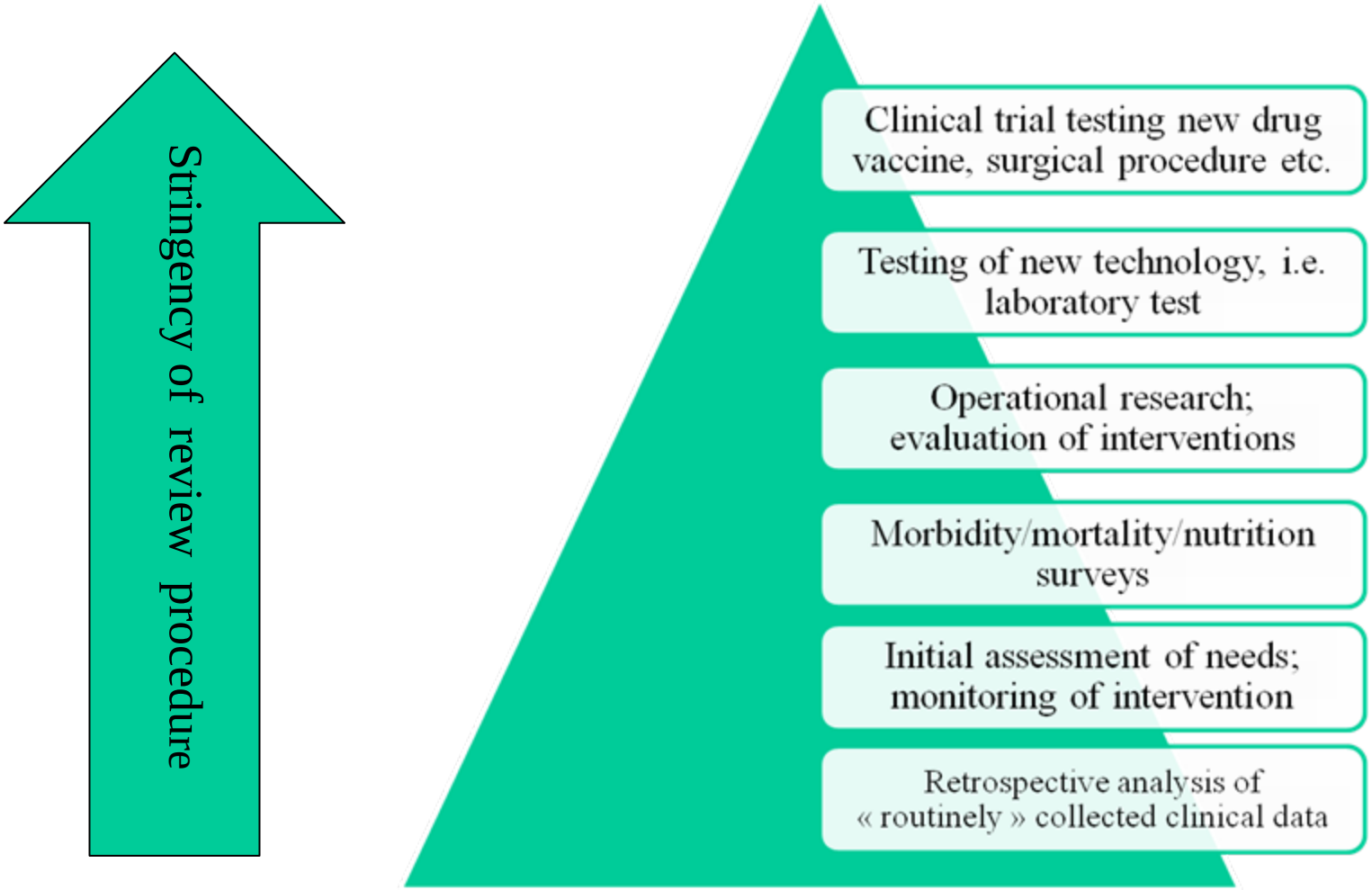
- ✓ Research needs to be initiated quickly to be meaningful, in particular for the study community
- ✓ Research in emergency or post-emergency situations must be submitted to ethical scrutiny
- ✓ The same ethical principles apply as in any research involving human subjects
- ✓ Ethics review procedure 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 $\Rightarrow$ 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
- Tri-Council Policy Statement 2010 (Canada) : *Ethical Conduct for Research Involving Humans. Research Ethics Review during Publicly Declared Emergencies*
- 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*
- Schopper et al. PLoS Med 2010: *Research Ethics Review in Humanitarian Contexts: the Experience of the Independent Ethics Review Board of Médecins Sans Frontières*

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

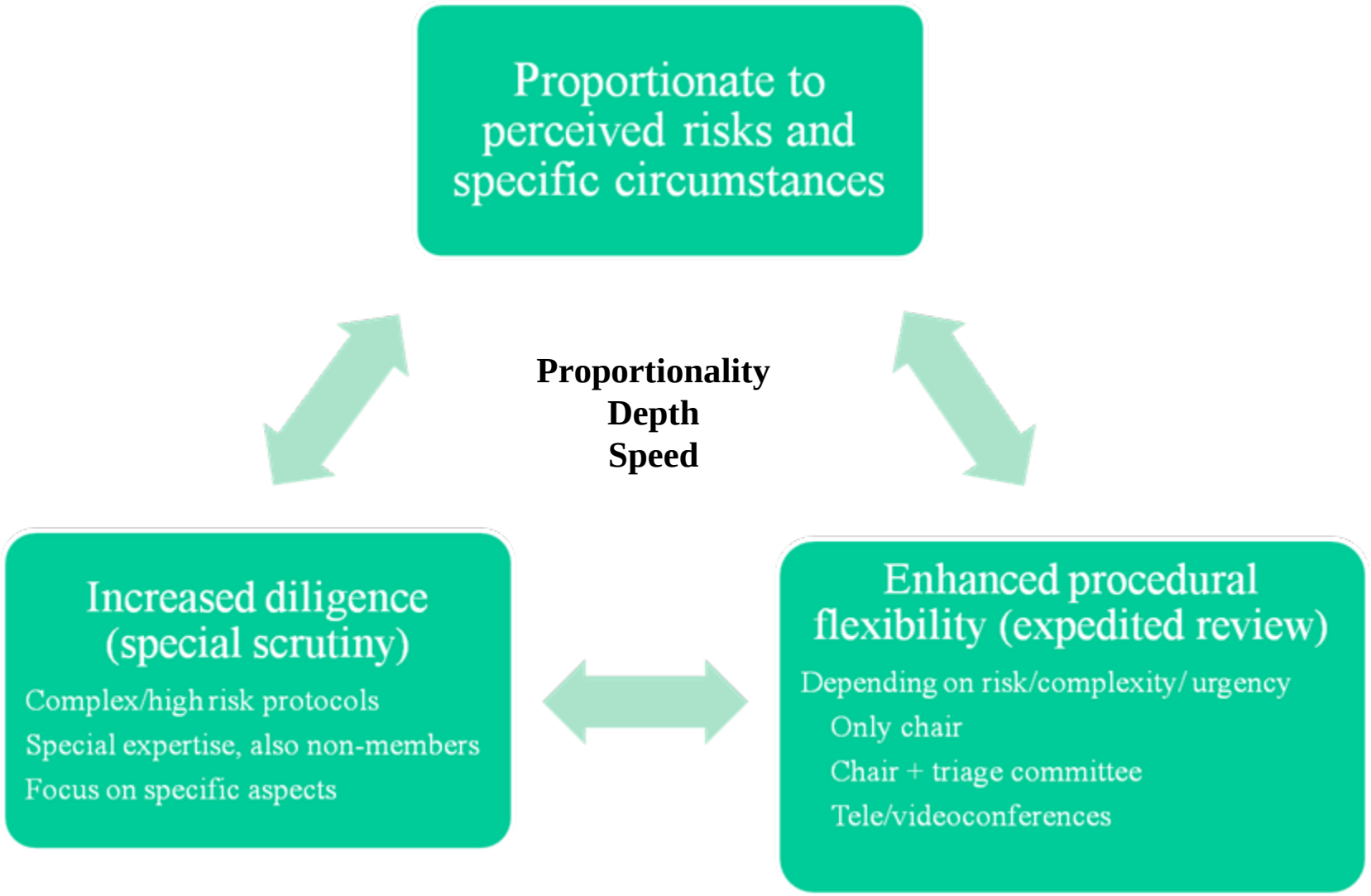
- **Stronger ethical obligation required in disaster-related research**
- Independent, multidisciplinary and pluralist ethics committees with representation from disaster-affected community
- Local ethics review mandatory
- Centralized mechanism for review and coordination of all research in the disaster-affected 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...



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

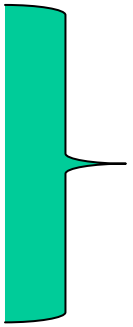
Ford N et al. Ethics of conducting research in conflict settings. BioMed Central 2009;3:7

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!