Ethics of Research in Emergencies

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Context
The Research for Health in Humanitarian Crises (R2HC) programme is an initiative of the Wellcome Trust. The overall aim of the Research for Health in Humanitarian Crises (R2HC) programme is to improve health outcomes by strengthening the evidence base for public health interventions in humanitarian crises.

The specific outcome of the programme will be to directly increase the level and quality of collaborative research on recognised public health challenges in humanitarian crisis contexts, leading to improved health outcomes and cost-effective improvements in humanitarian interventions.
Project Domain: *Humanitarian Public Health*

“Humanitarian public health is defined for the purposes of this programme as: *Interventions that contribute collectively, in combination or singularly to saving lives, building resilience and promoting better health outcomes in humanitarian emergencies.* In this approach public health interventions should be considered in their broadest scope including all relevant practice areas including water, sanitation, nutrition and mental health.”

TOR, June 2013
Health Interventions in Humanitarian Crises

- Communicable Diseases
  - Immunization
  - Preventive Behaviors
  - Therapeutic Services/Strategies

- NCDs
  - Therapeutic Services/Strategies

- Health Maintenance
  - Nutrition
  - Water
  - SRH
  - Mental/Psychosocial Health
  - ... (omitted)

- Trauma
  - Injury (conflict/disaster)
  - Violence (GBV+)
  - Mental/Psychosocial Trauma
  - Rehabilitation
  - ... (omitted)

- Security
  - Protection
  - Shelter
  - Infrastructure
  - ... (omitted)
Recent Literature: Example #1 [No ethical reviews]

Publication: Bulletin of the World Health Organization; Type: Lessons from the field
Article ID: BLT.12.117044

Jeanette J Rainey et al.

Emergency vaccination campaigns in Haiti

This online first version has been peer-reviewed, accepted and edited, but not formatted and finalized with corrections from authors and proofreaders.

Rapid monitoring in vaccination campaigns during emergencies: the post-earthquake campaign in Haiti

Jeanette J Rainey, a David Sugerman, a Muireann Brennan, b Jean Ronald Cadet, c Jackson Ernsly, d François Lacapère, e M Carolina Danovaro-Holliday, f Jean-Claude Mubalama d & Robin Nandy g

Abstract

Problem The earthquake that struck Haiti in January 2010 caused 1.5 million people to be displaced to temporary camps. The Haitian Ministry of Public Health and Population and global immunization partners developed a plan to deliver vaccines to those residing in these camps. A strategy was needed to determine whether the immunization targets set for the campaign were achieved.

Approach Following the vaccination campaign, staff from the Ministry of Public Health and Population interviewed convenience samples of households – in specific predetermined locations in each of the camps – regarding receipt of the emergency vaccinations. A camp was targeted for “mop-up vaccination” – i.e. repeat mass vaccination – if more than 25% of the children aged 9 months to 7 years in the sample were found not to have received the emergency vaccinations.

Local setting Rapid monitoring was implemented in camps located in the Port-au-Prince metropolitan area. Camps that housed more than 5000 people were monitored first.

Relevant changes By the end of March 2010, 72 (23.2%) of the 310 vaccinated camps had been monitored. Although 32 (44%) of the monitored camps were targeted for mop-up vaccination, only six of them had received such repeat mass vaccination when checked several weeks after monitoring.

Lessons learnt Rapid monitoring was only marginally beneficial in achieving immunization targets in the temporary camps in Port-au-Prince. More research is needed to evaluate the utility of traditional rapid monitoring, as well as other strategies, during post-disaster vaccination campaigns that involve mobile populations, particularly when there is little capacity to conduct repeat mass vaccination.
Recent Literature: Example #2 [Very limited ethical review]

PLoS Medicine
(Accessed 9 November 2013)
http://www.plosmedicine.org/

Measles Outbreak Response Immunization Is Context-Specific: Insight from the Recent Experience of Médecins Sans Frontières
Andrea Minetti, Cameron Bopp, Florence Fermon, Gwenola François, Rebecca F. Grais, Lise Grout, Northan Hurtado, Francisco J. Luquero, Klaudia Porten, Laurent Sury, Meguerditch Terzian
http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001544

Summary Points
:: During the recent resurgence of measles in sub-Saharan Africa, the majority of cases were reported from the Democratic Republic of the Congo and Malawi, two countries with vastly different measles epidemiology.
:: Non-selective mass vaccination campaigns targeting children aged 6 months to <15 years old are the commonly implemented strategy for responding to measles outbreaks in humanitarian emergencies.
:: Differences in measles epidemiology and country-specific control goals necessitate more than a one-size-fits-all strategy.
:: Measles outbreak responses should be tailored to local measles epidemiology following early assessment: the age distribution of early cases should guide the decision on which age groups to vaccinate.
:: In settings where the main objective is mortality reduction, the youngest children—who account for the most deaths and complications—should be prioritized by the outbreak response.
Ethical considerations for vaccination programmes in acute humanitarian emergencies

Keymanthri Moodley, Kate Hardie, Michael J Selgelid, Ronald J Waldman, Peter Strebel, Helen Rees & David N Durrheim

Abstract Humanitarian emergencies result in a breakdown of critical health-care services and often make vulnerable communities dependent on external agencies for care. In resource-constrained settings, this may occur against a backdrop of extreme poverty, malnutrition, insecurity, low literacy and poor infrastructure. Under these circumstances, providing food, water and shelter and limiting communicable disease outbreaks become primary concerns. Where effective and safe vaccines are available to mitigate the risk of disease outbreaks, their potential deployment is a key consideration in meeting emergency health needs. Ethical considerations are crucial when deciding on vaccine deployment. Allocation of vaccines in short supply, target groups, delivery strategies, surveillance and research during acute humanitarian emergencies all involve ethical considerations that often arise from the tension between individual and common good. The authors lay out the ethical issues that policy-makers need to bear in mind when considering the deployment of mass vaccination during humanitarian emergencies, including beneficence (duty of care and the rule of rescue), non-maleficence, autonomy and consent, and distributive and procedural justice.
Ethical Framework in Emergencies

 Framework should be “enabling”…with due diligence for protection of vulnerable populations and adherence to international standards and norms
Ethical Framework

But also a responsible, ethical framework should be designed to move the aid forward.
- Ethical Framework Overview
- Guidelines and Principles
Guidelines and codes of best practice

1. Nuremberg Code
2. Declaration of Helsinki
5. UNAIDS/WHO, Ethical Considerations in Biomedical HIV Prevention Trials (2007)
Statutes and regulations

1. The Universal Declaration of Human Rights
5. Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 2005
What Makes Clinical Research Ethical?

Ezekiel J. Emanuel, MD, PhD
David Wendler, PhD
Christine Grady, PhD

What makes research involving human subjects ethical? Informed consent is the answer most US researchers, bioethicists, and institutional review board (IRB) members would probably offer. This response reflects the preponderance of existing guidance on the ethical conduct of research and the near obsession with autonomy in US bioethics. While informed consent is necessary in most but not all cases, in no case is it sufficient for ethical clinical research. Indeed, some of the most contentious contemporary ethical controversies in clinical research, such as clinical research in developing countries, the use of placebos, phase 1 research, protection for communities, and involvement of children, raise questions not of informed consent but of how it is implemented.

Many believe that informed consent makes clinical research ethical. However, informed consent is neither necessary nor sufficient for ethical clinical research. Drawing on the basic philosophies underlying major codes, declarations, and other documents relevant to research with human subjects, we propose 7 requirements that systematically elucidate a coherent framework for evaluating the ethics of clinical research studies: (1) value—enhancements of health or knowledge must be derived from the research; (2) scientific validity—the research must be methodologically rigorous; (3) fair subject selection—scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individual subjects; (4) favorable risk-benefit ratio—within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review—unaffiliated individuals must review the research and approve, amend, or terminate it; (6) informed consent—individuals should be informed about the research and provide their voluntary consent; and (7) respect for enrolled subjects—subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored. Fulfilling all 7 requirements is necessary and sufficient to make clinical research ethical. These requirements are universal, although they must be adapted to the health, economic, cultural, and technological conditions in which clinical research is conducted.

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What parameters should an ethical framework include?

A  Protocol design: validity, feasibility
    Placebo/study design
B  Team strength: competency
C  Subject Recruitment/ Equitable access
D  Vulnerable subjects?
E  Risks/benefits
F  Consent
    Ability to drop out
G  COI
H  Compensation for injury
I  End points/DSMBs
J  Return findings to subjects
Conflict and Health

Review

Ethics of conducting research in conflict settings
Nathan Ford*1,2, Edward J Mills3, Rony Zachariah4 and Ross Upshur5

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Abstract

Humanitarian agencies are increasingly engaged in research in conflict and post-conflict settings. This is justified by the need to improve the quality of assistance provided in these settings and to collect evidence of the highest standard to inform advocacy and policy change. The instability of conflict-affected areas, and the heightened vulnerability of populations caught in conflict, calls for careful consideration of the research methods employed, the levels of evidence sought, and ethical requirements. Special attention needs to be placed on the feasibility and necessity of doing research in conflict-settings, and the harm-benefit ratio for potential research participants.
What parameters should an ‘emergency’ ethical framework include?

A. - Scientific Requirement to Conduct Protocol in Emergency Setting
   - Clear Articulation of Benefits/Risks/Harms
B. - Protocol Design: Scientific Validity/Feasibility
   - Research Focus: Relative Priority
C. - Team Strength: Competence/Collaborative Structure/
   - Declared Interests
D. - Quality of Community Engagement
   - Respect for Cultural Context/Norms/Values
E. - Community and Individual Benefit
   - Confidentiality/Data Security
F. - Informed Consent
Reviewing proposed studies

**R2HC Ethical Framework – Parameter Clusters**

- A: Scientific Requirement to Conduct Protocol in Emergency Setting
  - Articulation of Benefits/Risks/Harms

- B: Protocol Design: Scientific Validity/Feasibility
  - Research Focus: Relative Priority
  - Team Strength: Competence/Collaboration

- C: Independent Ethical Review & Oversight
  - Strategies for Safeguards, Security, Exits

- D: Quality of Community Engagement
  - Respect for Cultural Context/Norms/Values

- E: Community and Individual Benefit
  - Confidentiality/Data Security

- F: Informed Consent

**R2HC Research Protocols – Pool for Funding Consideration**
- If, Consent is tenuous
- then, IRB review must be vigorous
Consultation on Applied Health Research Priorities in Complex Emergencies

28-29 October 1997

4.7.2. Template of ethical guidelines. Recommended was that WHO (EHA and SCRIHS) and UNHCR set up an ethical expert group to prepare a template of ethical guidelines reflecting the overarching need to protect the rights, dignity and autonomy of research subjects in emergencies. Building on work done elsewhere, such template would serve as guidance for the peer reviewers of the Ethical Review Committee mentioned above.
Health in Action

Research Ethics Review in Humanitarian Contexts: The Experience of the Independent Ethics Review Board of Médecins Sans Frontières

Doris Schopper¹, Ross Upshur², Francine Matthys³, Jerome Amir Singh⁴, Sunita Sheel Bandewar⁵, Aasim Ahmad⁶,⁷, Els van Dongen⁸†

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Summary Points

- In 2001, the international humanitarian aid organisation Médecins Sans Frontières decided to institute an independent ethics review board to ensure that the increasing amount of operational and clinical research it undertakes is scientifically valid and ethical.
- This article describes the functioning of this ethics review board and the challenging ethical issues that it has discussed since its inception.
From Executive Summary. P.1

- The ultimate goal for public policy should be to ensure that most, if not all, emergency public health activities are subject to some form of ethical oversight, whether or not those activities are formally characterized as research. The specific nature of the oversight should be commensurate with the activity’s objectives, methods, risks and benefits, as well as the extent to which the activity involves vulnerable groups.

- To achieve this goal, it is crucial to streamline the ethics review process and to establish appropriate, flexible mechanisms and procedures for ethical oversight not limited to traditional REC systems.

- While some crucial emergency health research should still undergo full REC review because of significant risks to individuals or populations under study, a “fast-track” review approach should also be adopted. However, review should not be expedient to the point of dropping or narrowing ethical principles.
What parameters should an IRB / REC Meet?

A. Speed
   a. On call
   b. ‘assemble’ fast
   c. Move quickly
B. Experience
C. Pluralistic
D. Centralized
E. Insight to vulnerable communities
F. Expertise in Humanitarian crises
G. Calibrate risk to fit emergency
H. Transparent
I. Industry, NGO, Govt, Pt adv
J. Required follow-up/debrief