Research Ethics in Epidemics and Public Health Emergencies

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Research Ethics in Epidemics and Public Health Emergencies

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Scope

- Processes of ethics review for research in public health emergencies
- Changed procedures of ethics review in emergency situations

Scope


Research?
No
Public health surveillance
Yes
Health Emergency?
No
Standard normative instruments
Yes
Framework for adapted ethical review

Outline

1. Research Ethics in Epidemic Disasters
   - Introduction into Research Ethics
   - Standard procedures for ethics review
   - Different types of research
   - Areas covered by standard ethics reviews
   - **Challenges raised by the review of public health emergencies research**
2. Case Study and discussion – 3 Case Studies
3. Closing

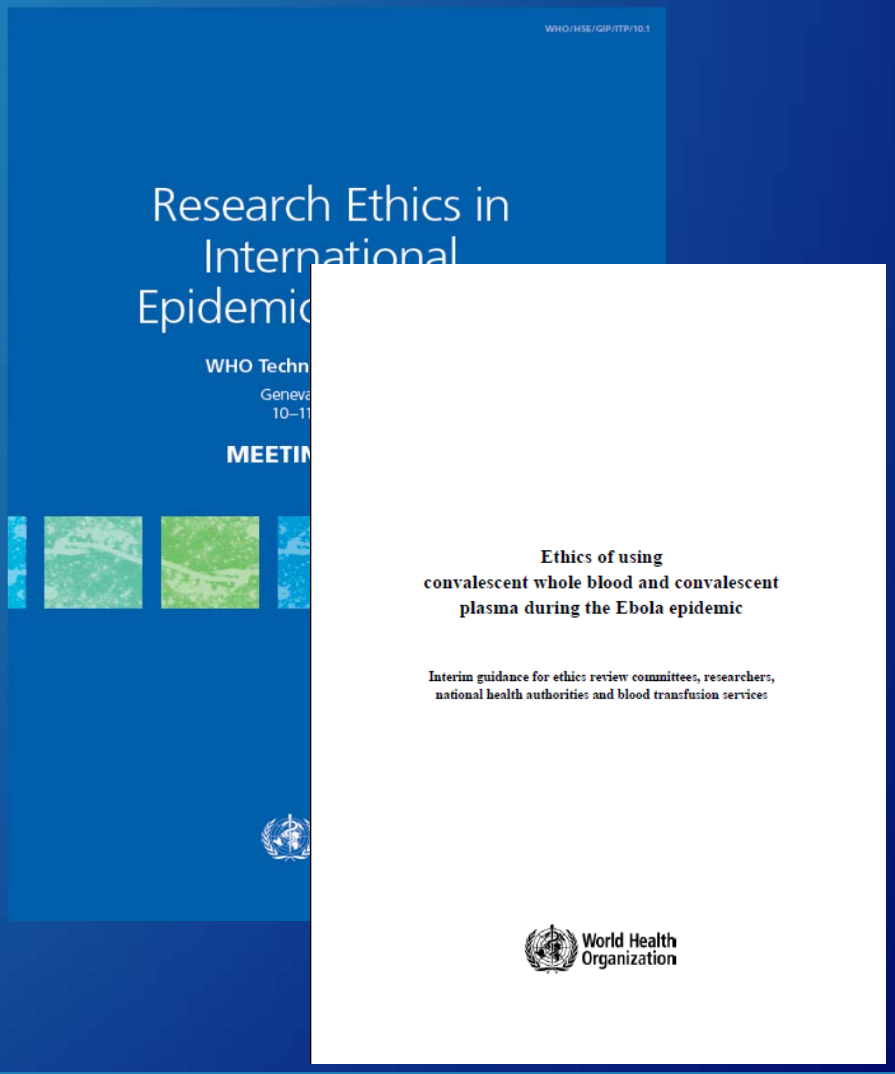
Suggested time	**0-35** ***(35 min)***	**35-50** ***(15 min)***	**50-90** ***(40 min)***
Activity	Class	Group activity	Group presentations

Workshop objectives

- Obtain understanding of the ethical principles and requirements addressed in current normative instruments
- Identify the shortcomings of current normative instruments for use in disaster situations, and evaluate alternatives
- Present an ethical evaluation of your case studies (Training sessions)

Background Papers

- Training Manual “Ethics in research, surveillance and patient care in epidemics, emergencies and disasters”, (World Health Organization/Global Health Ethics 2015)
- Ethics in research, surveillance and patient care in epidemics, emergencies and disasters, (World Health Organization 2014)



Research versus Practice

“The distinction between research and practice is blurred partly because both often occur together [...]

(1) The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.

(2) By contrast, the term "research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.”

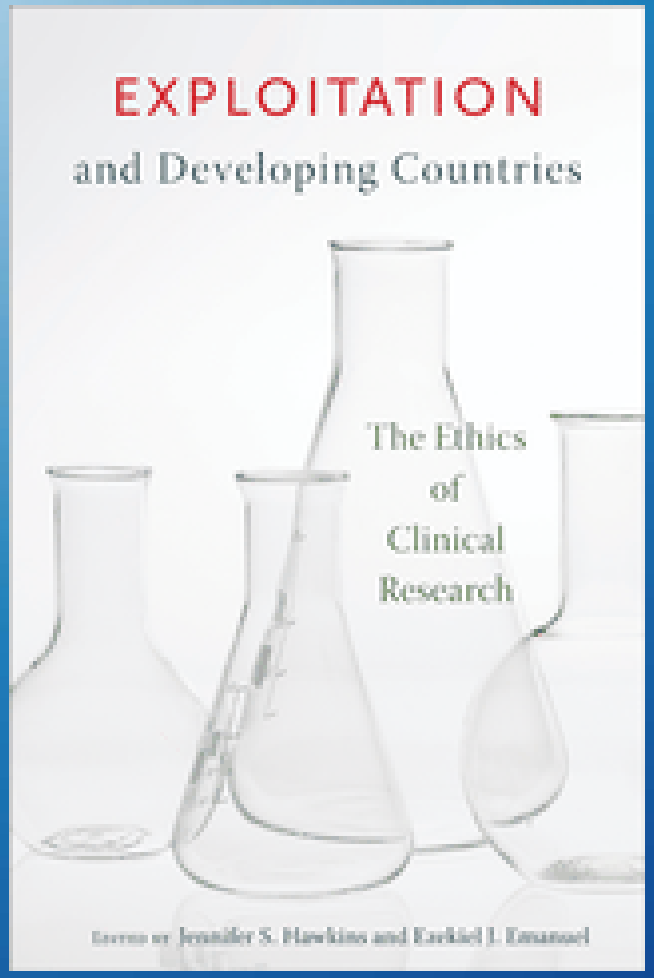
(National Commission 1979, The Belmont Report)

Research versus Public Health Surveillance

Distinction on the basis of intent and purpose of the activity (CDC 2010)

- The purpose of research is to generate or contribute to generalizable knowledge
- The purpose of surveillance (non-research) comprehends non-research activities to prevent or control disease or injury and to improve health

Research versus Practice



Research versus Practice

Requirements for the conduct of research

- Research is generally subject to independent ethics review
- Documents and guidelines regulating the ethical conduct of research
  - The Nuremberg trials and the Nuremberg Code (1947)
  - World Medical Association Declaration of Helsinki (1964)
  - The Belmont Report (1979)
  - Council for International Organizations of Medical Science (CIOMS) guidelines (2002) etc.

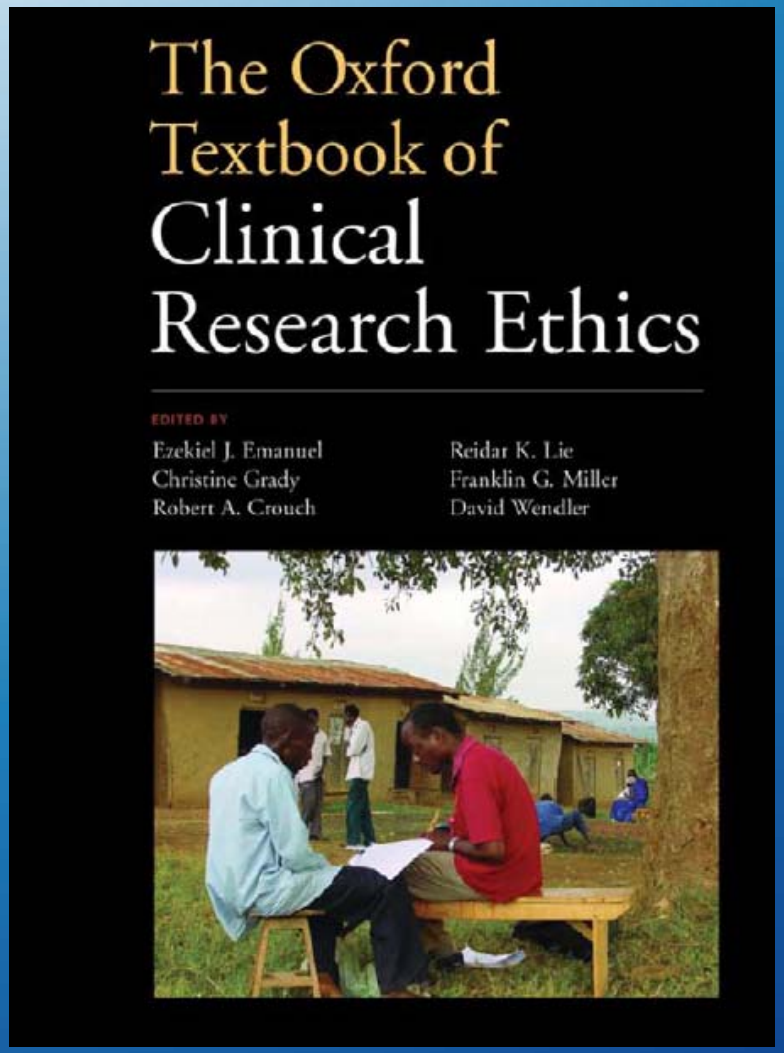
Core ethical principals and issues covered by guidelines

- Respect for people's autonomy
- Informed consent
- Beneficence
- Non-maleficence

Core ethical principals and issues covered by guidelines

- Justice
- Vulnerability
- Privacy
- Confidentiality
- Research ethics review

Emanuel et al. 2008
(NIH Department for research ethics)



Emanuel et al. 2008

(1) value-enhancements of health or knowledge

(2) scientific validity

(3) fair subject selection

(4) favourable risk-benefit ratio

(5) independent review

(6) informed consent

(7) respect for enrolled subjects

RECs/IRBs

- Research ethics committee (REC) or institutional review boards (IRB) (in the USA)
- Research projects involving human subjects must be submitted to the REC and provide a detailed description of the research project
- ‘Research protocol’ provides an account of how ethical issues will be addressed through the project

RECs/IRBs (WHO)

Research protocol
(http://www.who.int/rpc/research_ethics/format_rp/en/)

- Project summary
- General information
- Rationale & background information
- Study objectives
- Study Design
- Methodology
- Safety considerations
- Follow up
- Data Management and Statistical Analysis
- Expected outcome
- ...
- Ethics
- Informed consent

Areas covered by Ethics Reviews (Sumathipala et al. 2010)

- Relevance of research to disaster situations
- Role of community consultation and participation
- Dignity, privacy and confidentiality
- Dissemination of results

Areas covered by ethics reviews (Sumathipala et al. 2010)

- Risk-benefit analysis
- Informed consent process
  - Sufficiency of information
  - Voluntariness
  - Mechanism to ensure individual's capacity to understand
- Protection of vulnerable populations
- Equitable distribution of benefits and burdens of participation

Important types of research (I)

- Basic science research
  - Research that is laboratory-based, such as testing of human biological materials
- Clinical research
  - Research in which participants (individuals or groups) are prospectively assigned to a health intervention, from drugs and biological products to devices and preventive programmes
- Health services and health systems research
  - Research addressing the administrative and social aspects of health and health care, including financial aspects

Training

Most normative instruments governing research were developed specifically with a clinical/biomedical model in mind.

Discuss in groups of 2-3 persons: are those standards applicable to public health/epidemiological research?

Challenges reviewing public health emergency research

https://www.youtube.com/watch?v=Hj-2HGFp9C8

Training

1. Identify altered research parameters and ethical considerations in a public health emergency
2. Come up either with arguments in favor or against of the following question:
   - “Is it ever permissible to alter the review standards of research ethics committees?”

Considerations in public health emergencies

- Altered research designs – new ethical and logistical challenges
- Limited expertise of REC members in public health emergencies
- Community representation – challenge of limited time
- Altered standards – e.g. standard of care, waiving consent

Ethical issues in public health emergencies

- Beneficence and non-maleficence
  - Risks to research subjects is acceptable if expected benefits outweigh those risks
  - Level of ethical review determined by foreseeable risks

- Perception of risk may differ in a public health emergency
  - Individuals may accept higher levels of risk than they would have accepted in non-emergency circumstances
  - Changed perception of risk may influence policies
  - Example: testing vaccination is based on sub-optimal evidence

Standard variations (I)

- **Expedited review**
  - Studies with minimal risk and no novel or worrisome ethical issues (Tansey et al., 2010; World Health Organization, 2010).
  - Should not be misinterpreted as relaxing the usual procedures for a full review by a research ethics board.
  - Conducted with extreme caution (Sumathipala et al., 2010; Tansey et al., 2010).

- **Generic protocols**
  - Developed in advance of public health emergencies
  - Should be adapted to specific settings.
  - This approach might facilitate prompt implementation of research and time-sensitive review once a disaster strikes.

Standard variations (II)

- **Pre-approved protocols**
  - Final ethics review and approval before initiation of research for public health emergencies of a periodic or recurrent nature.
  - The research should be started only after consultation with the affected community (Sumathipala et al., 2010; Mathúna, 2012).

Review waiving

- For routine programme implementation
- No foreseeable risk of harm or discomfort to participants beyond “risk of daily activities”

Example for alternative guidelines for public health emergencies

- Pandemic influenza preparedness and response (WHO)
  - Distinguishing crucial tasks from non-crucial ones during public health emergencies (expedited review)
  - Proportional review (risk analysis)
  - Fast-track reviews
  - Establishment of a platform to store “best practices” in emergency research design

Concerns on variation

- Could lead to neglect of issues of exploitation
- Emergencies create and exacerbate vulnerabilities, and may deepen already existing disparities
- Increased risk of “therapeutic misconception”, “positive transference”
  - May be lack of clarity as to whether endeavour is routine care or part of research

Case Studies

(1) Vaccine (Edwards 2013)

(2) Convalescent blood (based on a case reviewed by the REC at WHO)

(3) Bioterrorism (composite case, Missouri Department of Health 2009)

Thank you!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