3.4 Ethics in research

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Learning objectives

To understand key concepts in research ethics as they apply to health emergency disaster risk management:

- Role and importance of ethical considerations throughout the different phases of a research project.
- Limitations of normative ethical guidelines when operationalized in emergency and disaster contexts.
- Importance of reciprocal community engagement in ensuring valid and valuable results.
- Role of project managers, research funders, national governments and research ethics committees.

Introduction (1)

Health EDRM shifts risk management to an **all-encompassing**, **multi-hazard**, **community-focused, proactive** approach that reduces vulnerability by:

- Prevention
- Mitigation
- Preparedness
- Response
- Recovery

Decisions and priorities in Health EDRM programmes and research require **ethical considerations** that minimize short and long-term harm.

Ethical guidelines are tools to promote more **equal partnerships** between researcher/participant and **uphold integrity** throughout the life-course of a project in such a way that respects the community's welfare.

Introduction (2)

Ethical guidelines take into consideration:

- The value of undertaking the project itself
- Assessing its contribution to social good
- Potential to save lives and reduce suffering
- The significance of knowledge outcomes

The consequences of failing to ensure ethical considerations are addressed can lead to problems of moral significance, such as:

- Loss of public trust
- Disruption of livelihoods
- Confusion about roles and responsibilities
- Low morale of both researchers and participants

Limitations of normative ethical guidance (1)

There is an ethical imperative to collect good data in all research. In Health EDRM, these data are essential to provide high quality evidence to:

- Assess the impact of a crisis
- Identify necessary risk management measure
- Plan for future interventions

Appropriate research findings are often lacking in Health EDRM because many interventions are not evaluated in rigorous trials that produce evidence of adequate depth and quality.

Emergencies create unique challenges in logistics, security resources and time-management, meaning that processes and procedures for non-emergency circumstances are likely to not be sufficiently flexible to adapt to the uncertainty that is characteristic of disaster circumstances.

Changes to process and/or methodology can be perceived as undermining ethical rigour.

Limitations of normative ethical guidance (2)

Lower income countries are disproportionately impacted by disasters. Technical capacity, governance and resources may be limited and poorly coordinated, putting further strain on research implementation. Other areas that face pressures that are not well addressed in normative guidance are:

- Determining a fair approach to research participation;
- Duties and roles at the interface between research, treatment and public health;
- Management of expectations on the front line; and
- Protection of participants from stigmatization, discrimination and exclusion

In spite of these challenges, stakeholders must **prioritise the interests of the communities involved**, many of whom are vulnerable during and after emergencies and disasters.

Pressures in time and situation should be assessed in the overall context and not be excuses for bypassing ethical values that ensure research is rigorous and fit for purpose.

Case study: *Deviation from normative procedure: use of unregistered interventions for Ebola in West Africa (1)*

During the 2014 West Africa Ebola outbreak, the rapidly rising case fatality rate under a fragile health system prompted calls to accelerate the development of interventions that had not yet been evaluated for safety and efficacy in humans.

WHO concluded that although this was a departure from well-established systems of regulation, it was acceptable on ethical and evidential grounds to **offer the experimental interventions in the absence of any existing effective interventions** due to the unprecedented and exceptional circumstances.

Case study: *Deviation from normative procedure: use of unregistered interventions for Ebola in West Africa (2)*


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Ethical considerations for use of unregistered interventions for Ebola virus disease (EVD)

West Africa is experiencing the largest, most severe and most complex outbreak of Ebola virus disease in history. Ebola outbreaks can be contained using available interventions like early detection and isolation, contact tracing and monitoring, and adherence to rigorous procedures of infection control. However, a specific treatment or vaccine would be a potent asset to counter the virus.

Over the past decade, research efforts have been invested into developing drugs and vaccines for Ebola virus disease. Some of these have shown promising results in the laboratory, but they have not yet been evaluated for safety and efficacy in human beings. The large number of people affected by the 2014 west Africa outbreak, and the high case-fatality rate, have prompted calls to use investigational medical interventions to try to save the lives of patients and to curb the epidemic.

Therefore, on 11 August 2014, WHO convened a consultation to consider and assess the ethical implications for clinical decision-making of the potential use of unregistered interventions.

In the particular circumstances of this outbreak, and provided certain conditions are met, the panel reached consensus that it is ethical to offer unproven interventions with as yet unknown efficacy and adverse effects, as potential treatment or prevention.

Ethical criteria must guide the provision of such interventions. These include transparency about all aspects of care, informed consent, freedom of choice, confidentiality, respect for the person,

Relevant ethical considerations included:

- The need to **prioritise** essential public health measures and resources
- **Transparency** to participants about the status of medical products and their uncertainty
- Transparency on potential harms and benefits
- **Informed consent** and freedom of choice, emphasizing the preservation of dignity
- **Fair distribution** of products in the event of scarcity
- **Community** involvement
- Research team capacity to **monitor and manage** side-effects

Case study: *Deviation from normative procedure: use of unregistered interventions for Ebola in West Africa (3)*

The panel also stressed the moral obligation of researchers to **rapidly** and **transparently** share all relevant data with the scientific community.

Researchers have a moral duty to continue the evaluation of these interventions in clinical trials in order to establish the safety and efficacy of the interventions for both **current** and **future** benefit.

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Sharing research data to better understand and tackle Ebola

TDR news item
13 July 2020

June 2020 saw the first applications to access data stored on a new Ebola Data Platform managed by the Infectious Diseases Data Observatory (IDDO), following a partnership with the governments of Guinea, Liberia and Sierra Leone. Significantly, three of the successful applications were from principle investigators based in these disease-affected countries, where these data were originally collected.

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Ensuring Ethical Data Access: The Sierra Leone Ebola Database (SLED) Model

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Abstract

Background—Organizations responding to the 2014-2016 Ebola epidemic in Sierra Leone collected information from multiple sources and kept it in separate databases, including distinct data systems for Ebola hot line calls, patient information collected by field surveillance officers, laboratory testing results, clinical information from Ebola treatment and isolation facilities, and burial team records.

Methods—Following the conclusion of the epidemic, the Sierra Leone Ministry of Health and Sanitation (MoHS) and United States Centers for Disease Control and Prevention (CDC) partnered

Value, feasibility and validity

Decisions about research must take into consideration value, feasibility and validity:

Value: Identifying the necessity and added value of the proposed research to justifying the financial, human and time resources. Research design must consider needs of the target community.

Feasibility: Research should be compatible with the existing healthcare response and needs. Consider when research should be done; its duration; and the method and duration of data collection.

Validity: Unreliable or unsustainable findings can interfere with good practice and use up necessary resources, and risk undermining the process to establish baselines, standards or trends.

Researchers must consider the benefit of a project along with the cost of a missed opportunity, including. the risk of not undertaking research, or of prioritizing one project over another.

Participant selection and exclusion

Research participation must be determined **fairly**, **equitably** and **in line with objectives** - and not be due to privilege, access, perceived vulnerability or other subjective factors.

Exclusions should be based on valid scientific justification.

Some populations are particularly at risk of exclusion, including marginalised people, older people, women, etc.

Informed consent

Informed consent: process by which potential research participants decide whether they wish to join a proposed study, having clearly understood the purpose and process of the research, including potential harms and other implications.

It is the researcher's responsibility to ensure:

- all information has been communicated transparently, considering the health literacy of participants and any other barriers, and
- decisions made by participants are well-informed, voluntary and anonymous.

Challenges in Health EDRM:

- An individual's' desire to survive may alter their perception of the potential harms of research participation.

Harm-benefit

Health EDRM projects operate in unstable contexts. In justifying the necessity of the research, potential harms must be considered, and there is an ethical responsibility to minimize risks and protect both researcher and participant. Risks can extend from simple inconveineces to psychological or physical harm.

Potential harm can be mitigated through

- **Training** in cultural awareness and practical protection measures
- **Community representatives** providing advice.
- **Delaying** research until potential harms are minimized.

Participant protection

Participants should always be protected from intrusive research, particularly in vulnerable settings. **Welfare, privacy, confidentiality, protection from stigma and respect** must always be acknowledged and of priority. Breach in trust or reinforcing stigma can result in harm to participants and the wider community, compromising the research and public health outcomes

To protect participants and their information, research should:

- Avoid exposing participants to further harm
- Respect the freedom to withdraw from research
- Assist participants in understanding rights and risks
- Collect only necessary information
- Be explicit about the intended use of the data
- Securely store information limit access
- Fully consider the impact of publishing

Case study: *Research participant engagement during the 2006 Israeli-Hezbollah war in Lebanon (1)*

Military conflict between Israel and Hezbollah resulted in 1200 deaths and 1 million displaced people.

Research by the American University of Beirut **assessed the psychosocial status and needs of the internally displaced people** to inform psychosocial interventions.

Case study: *Research participant engagement during the 2006 Israeli-Hezbollah war in Lebanon (2)*

The experience of the researchers illustrated how conducting surveys in wartime intensifies certain ethical considerations, including:

- **Different expected outcomes between researchers and participants**, especially if participants have needs outside of the scope of research. Reserachers have a duty to **clarify expectations**.
- The **scope for harm** in asking participants to reflect on a traumatic experience. Researchers have a duty to be sensitive to individuals' reaction to research.
- Potential **feelings of humilitation** by participants, many of whom have lost their home and livelihood.
- Ensuring vulnerable participants have **freedom from participation**, with no sanctions for refusal.

Community engagement (1)

Emergencies most affect the vulnerable and marginalised.

Ethical integrity in research is rooted in **mutually respectful partnerships** between researcher and participants, developing **mutual trust** and ensuring results are valuable to the community.

This includes understanding the local health system, staffing, infrastructure, community relationships and culturally sensitive topics.

Time pressure during emergencies should not limit the researcher's ability to **engage with participants**.

Community engagement (2)

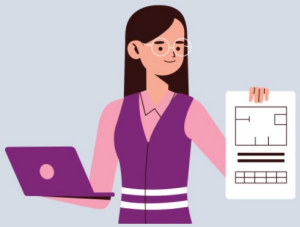
Community engagement is a **two-way, reciprocal** process:

- Leaders are identified, religious, military, women's groups, social influencers, etc.
- Needed information is gathered through surveys, interviews, focus groups, etc.
- Do not promise what cannot be delivered
- Researchers must make their role very clear (e.g., distinct from aid workers)

Stakeholder roles and responsibilities (1)

There are other important stakeholders in the research process, beyond the researchers. These stakeholders ensuring a project is planned, designed and implemented appropriately.

Research manager



- Ensure collaboration is needs-based
- Accountable for staff safety
- Responsible for staff training, including local staff

Research funder

- Be informed of resource and access constraints when defining priorities
- Promote collaboration
- Have a holistic overview and avoid duplicative funding

Stakeholder roles and responsibilities (2)

National Governments

- Strengthen emergency preparedness
- Push a scientific agency for coordinated research
- Protect community from research fatigue

Research ethics committees

- Promote high ethical standards
- Be flexible in the context of Health EDRM
- Ensure reviewers have technical capacity to review related research

Case study: *Delivering on the promise of research: Collaborating with the New York City Fire Department following the 9/11 terrorist attacks*

People are more willing to participate in research if it is seen to benefit the health system, recovery efforts, or clinical services, rather than be purely experimental.

New York firefighters agreed to participate in research about cancer in 9/11 survivors, if outcomes were beneficial to them.

With community buy-in, and partnership with credible organisations such as the American Cancer Society and the US Centers for Disease Control and Prevention (CDC) the New York City Fire Department published early assessments of cancer in 9/11 survivors, which resulted in federal healthcare policy adding cancer to 9/11 insurance coverage.

Conclusions

- For Health EDRM in particular, balancing the pursuit of knowledge with ensuring the safety and wellbeing of participants can be challenging.
- Successful outcomes are dependent on ethical practices throughout the entire life-course of a project, that ensure validity, accountability and sustainability.
- Experience-sharing will promote robust ethical practices that prioritize participant protection within the complexities of Health EDRM research.
- Learnings must be fed back into the community for their use so that they may build evidence-based resilience against future emergencies.

Key messages

- There are ethical considerations throughout the design, review, implementation and publication phases of research, beyond ethical approval, helping the researchers maintain transparency and mitigate against potential harm to stakeholders.
- Decisions about the design, implementation or use of research should consider the value, feasibility and validity of the research question, to justify the financial, time and human resources invested.
- Normative ethical guidelines for research may have to be adapted when operationalized in emergency and disaster contexts due to the unique challenges faced across different areas including security, logistics, time-constraints, or availability of adequate human resources.
- Reciprocal and continued engagement with the affected community is key to understanding practical and contextual elements, facilitating data collection, the quality of evidence and is essential for developing a respectful partnership with vulnerable communities in the Health EDRM context.

Further readings

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