Retrospectively exploring research ethics during the Ebola epidemic

All research trials are subject to ethical standards, but in public health emergencies such as Ebola outbreaks, it is unclear to what extent these are upheld. The study 'Perceptions and moral experiences of research conducted during the 2014-16 West Africa Ebola outbreak' was led by McMaster University, Canada, between 2016 and 2018. Prioritising learning from people with lived experience, it gathered and analysed first-hand accounts of navigating clinical research ethics, including for vaccines and treatments.

Evidence indicates that the study has deepened the understanding of researchers and research ethics boards in West Africa on the complexities and feasibility of conducting research ethically in a public health emergency. It has reinforced the need for researchers to maintain strong internal ethical review processes and has influenced research practice, including for other outbreaks such as COVID-19. Direct involvement of Ebola survivors in the study has helped to facilitate increased community involvement in ethics committees in Guinea and Sierra Leone. The study has informed new projects on tools and resources for ethical research.

Title: Perceptions and Moral Experiences of Research Conducted During the 2014-16 West Africa Ebola Outbreak

Location: Guinea, Sierra Leone and Liberia

Study type: Literature review and key informant interviews

IMPACTS

- Provided Ebola survivors' groups with evidence used in advocacy
- A shift towards increased community involvement on research ethics boards
- Findings helped secure funds for development of Participants Research Ethics Toolbox

RESEARCH IMPACT LEARNING

- The value of conducting research post-epidemic
- The importance of including local stakeholders and those with lived experience in research

BACKGROUND

Three practices are core to ethical research in public health emergencies: gaining meaningful consent from participants; clear communication with participants to prevent harm occurring; and building collaborative, equitable partnerships with all people and organisations involved in the research. When the Ebola outbreak hit West Africa in 2014, no vaccines or treatment had yet been shown to be effective against the disease. As the epidemic grew and spread, research trials assessing potential agents were rolled out. All research trials are subject to ethical standards, but there was little evidence to show how these standards could be upheld in such a challenging context.

Guinea, Sierra Leone and Liberia are the three West African countries that were most affected by the Ebola outbreak of 2014–2016. They were the location of many research trials during the outbreak, presenting an ideal scenario for retrospectively examining the ethics of such trials.

THE STUDY

A literature review was first conducted to comprehensively identify all the ethical challenges faced by research teams across Guinea, Sierra Leone and Liberia when planning and implementing research during the Ebola outbreak.

This study also examined the perspectives of a wide range of people who had been directly involved in Ebola research during the outbreak (between 2014 and 2016). It was retrospective, qualitative and conducted 1–3 years after the epidemic. It sought to better understand the social and moral experiences of those involved in the trials, and how their experiences align with the best practice ethical standards available. Data was collected via in-depth and semi-structured interviews with 108 Ebola research stakeholders, including research participants, Ebola survivors, proxy decision-makers for research participants (eg, relatives), researchers, research ethics board members and policymakers.

The aim of both the literature review and the interviews was to inform context-sensitive guidance and preparedness around ethical research and deliver practical resources to diverse research stakeholders. The research aimed to create space for study participants in affected countries to clarify when and how gaining informed consent was challenging in the context of the emergency.

FINDINGS

This study found that building and maintaining trust with all research stakeholders was essential for upholding best practices essential to ethical research, but this can be difficult given the global and national political and historical contexts within which research is conducted.

It found that a range of motivations led people to take part in research, including that many people believed that yet-unproven treatments would be more effective than the current standard of care. However, illness and stress in the Ebola treatment centres contributed to imperfect consent processes. Some participants took part due to perceived lack of choice, feeling they would enter a trial or die.

Some participants were unsure of what, if any, experimental treatments they received. Lack of communication at the end of the studies about the research processes and findings left some participants feeling confused, concerned or betrayed. The study identified a need for lay persons' improved preparedness for navigating invitations to research.

Ebola research was found to have strengthened health research infrastructure and upskilled local personnel, but the rapid influx of international researchers worsened power imbalances and undermined existing capacity. The study found that few opportunities arose for ownership of research by local and national stakeholders.

COMMUNICATIONS AND ENGAGEMENT

Crucially, this study facilitated community engagement with research. It was the first study to significantly engage with communities of people affected by Ebola about the ethical conduct of research, and it offered a space for people to share stories and ask questions. This approach made some progress towards closing the gap between researchers and study participants and strengthened researcher accountability. The community supported the study team to develop appropriate communication tools and offered continued reflection for improved research outcomes.

Strong pre-existing relationships between partner organisations and the Humanitarian Health Ethics research group were important to leverage opportunities to disseminate study findings. Workshops were held to engage research participants, and a report to clearly communicate study findings to research participants was produced. Outputs were presented at national and international conferences and symposia. The study team, with members of Ebola survivor groups, also participated in a regional workshop in Senegal in 2019 organised by the Nuffield Council on Bioethics, an independent body working on ethical issues in biology and medicine with whom the study team engaged. The literature review on the ethical challenges of conducting research during the epidemic was published online in 2019. A research report was also published on the Humanitarian Health Ethics website that year. Important partnerships were also formed between the study team and the national research ethics committees in Guinea and Sierra Leone.

UPTAKE AND IMPACT

The study findings have added to the humanitarian evidence base, and research more generally, on conducting research ethically in public health emergency settings. They have influenced stakeholders' views on how research ethics should be performed, crucially the need for community engagement with research and research governance.

The findings helped Ebola survivors' communities communicate their needs to health and social service delivery providers. For example, the Sierra Leone Association of Ebola Survivors (SLAES) used evidence provided by the study, such as explanations of treatment side effects to engage with healthcare providers, who then used this as evidence for improvements to service delivery.

"We were involved, and such actions make our community stronger...They (the research team) strengthened our capacity through trainings and involvement in the research and we also improved their research by guiding them about how best to approach and engage with people like us. As Ebola survivors we now no longer get that stigma and pain which comes from participating in research about our experience." – Yusuf Kabba, President of SLAES

SLAES also used the findings to advocate to the Ministry of Social Welfare for better support for orphans and older Ebola survivors. In part influenced by SLAES, the Sierra Leone government launched the $13.5 million Post-Ebola Recovery Social Investment Fund Project (PERSIF) for their social welfare. SLAES also advocated for participant engagement in research at the 2019 Annual International Bioethics Forum, attended by key humanitarian policy and decision-makers, practitioners and researchers.

"Research Ethics Committees have changed the way they work...I am now a member of the Research Ethics Panel for Paediatric Mental Health but also trained and certified in research participant protection." – Yusuf Kabba, President of SLAES

Increased community involvement on research ethics boards was also seen in Guinea and Sierra Leone. In Guinea, the National Ethics Committee for Health Research experienced increased knowledge and capacity, which led to it including representatives from the community in its membership.

"There has been a lot of engagement with us, trainings and several publications which we are using to improve the way research is conducted within our country and other Southern countries. The research was really useful and the partnership was very fruitful." – Professor Oumou Younoussa Bah-Sow, President of the National Ethics Committee for Health Research, Guinea

UPTAKE AND IMPACT

Finally, findings influenced wider dialogue on research ethics. The Nuffield Council on Bioethics integrated the study recommendations into its guidance on how research activities should be conducted in global health emergencies. The findings informed development of the Participants Research Ethics Toolbox (PRET)' with additional funding from the International Development Research Centre and Canadian Institutes of Health Research. The idea was initially proposed by Ebola survivors during the study. PRET was developed with and for adults with limited literacy in sub-Saharan Africa. It facilitates reflection and understanding of clinical research processes and the rights of research participants. PRET was endorsed by the Chairman of the Guinea Ebola Research Commission.

Ebola public health mural outside Université de Sonfonia, Guinea. Credit: Elysee Nouvet

RESEARCH IMPACT LEARNING

LISTENING TO SURVIVORS’ VIEWS

The findings demonstrated the feasibility and value of such a study after an epidemic has ended. Reflecting on lessons learned and asking for the views of groups of people typically excluded, such as Ebola survivors, can inform research practices in subsequent health emergencies so that mistakes are not repeated.

WORKING WITH NATIONAL AND COMMUNITY-LEVEL STAKEHOLDERS

The study has reinforced the importance of international researchers working closely with stakeholders, such as affected country research ethics committees, and the value of empowering community representatives with lived experience in the active use of evidence for change. In this case, SLAES’ engagement in the research has led to sustained instrumental impacts. The study team reflected their learning about meaningful partnerships in a brief.

PARTNERS

McMaster University; Western University; Comité partnership National d’Éthique pour la Recherche on Santé (CNERS); the Humanitarian Health Ethics Research Group; University of Conakry

ABOUT ELRHA

Elrha is a global organisation that finds solutions to complex humanitarian problems through research and innovation. This study was funded by Elrha’s Research for Health in Humanitarian Crises (R2HC) Programme which aims to improve health outcomes by strengthening the evidence base for public health interventions in humanitarian crises.

R2HC is funded by the UK Foreign Commonwealth and Development Office (FCDO), Wellcome, and the Department of Health and Social Care (DHSC) through the National Institute of Health Research (NIHR).

R2HC captures detailed case studies through a process that triangulates and validates evidence on uptake and impact. The case study methodology and full version of this summary case study including references are available on request.

Research for health
in humanitarian crises

www.elrha.org

https://twitter.com/Elrha

www.linkedin.com/company/elrha/