Research ethics during infectious disease outbreaks: A survey of African research stakeholders using the Ebola virus disease outbreak as a case

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Abstract. Conducting research during disease outbreaks can be ethically challenging as evidenced in the 2014-2016 Ebola outbreak in West Africa and COVID-19 pandemic. Yet, there has been little empirical research conducted for understanding the views and perspectives of different stakeholders regarding ethical issues in conducting research during disease outbreaks. This preliminary study was conducted to empirically explore African public health research stakeholders' views about research ethics issues during infectious disease outbreaks in Africa. We conducted an online survey of 330 participants attending the International Conference on Re-emerging and Emerging Infectious Disease (ICREID) meeting that took place from 13-15 March 2019 in Addis Ababa, Ethiopia to elicit their views on various research ethics complexities experienced in the 2014 Ebola outbreak. Study results revealed some divergent views on several ethical themes including: *ethics of using unregistered interventions in outbreaks; acceptable study design; ethics review processes; risks-benefit assessment*; *exclusion of pregnant women and children*; and *biological sample and data sharing*. Majority (76.3%) of respondents felt that in the absence of available standard treatments or prevention modalities, the use of investigational interventions can be ethically justifiable if there is a strong scientific rationale and favorable risk-benefit ratio. Regarding conventional placebo-controlled trials during outbreaks with high case fatality rates, respondents that considered this unethical were more than three times those that felt such design were ethically justifiable. We were somewhat surprised that a majority (almost 60%) of respondents were satisfied with the exclusion of pregnant women and children in clinical trials during outbreaks. All respondents concurred with the prioritization of informed consent for research during an outbreak. Based on our findings, research ethics guidance is needed to equip research stakeholders in dealing with ethical complexities arising in the conduct of research during emerging disease outbreaks-especially regarding using experimental interventions; placebo trial design; inclusion or justified exclusion of pregnant women and children; and biological sample/data sharing. The findings will be used in ongoing efforts of developing a consultative and coherent African-centric framework to support ethical conduct of research for future emerging infectious disease outbreaks in Africa.

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Introduction

Emerging infectious disease outbreaks continue to be a major concern for global health and security (1). There is increasing recognition of the moral imperative to conduct ethically and scientifically rigorous research during outbreaks (2,3), and the need to ensure that such research does not supersede the rights, safety and dignity of research participants, even in the midst of public health emergencies. However, research during epidemic emergencies may present unique ethical complexities and challenges to research ethics oversight (4-6). Existing ethics review systems may have limitations in addressing the practical ethical issues when conducting research in outbreaks (7). Researchers often encounter challenges in identifying the most ethical approach for conducting research in outbreaks emergencies (8). For example, during the 2014-2016 Ebola outbreak in West Africa important research was delayed and disparately organised due to disagreements around the ethics of randomizing patients to placebo in the midst of a deadly epidemic (3). Research ethics governance systems during disease outbreaks need to be timely, flexible and have technically relevant capacity to assess and monitor research in the dynamic circumstances that comes with infectious disease outbreaks.

Notwithstanding the emergency nature of disease outbreaks, there is still need to ensure that research is

conducted ethically. Well-resourced research stakeholders, including research ethics committees (RECs), have a key role in ensuring adequate ethics oversight and governance in health research during epidemics (9-11). Ensuring adequate oversight of research in outbreaks and other public health emergencies can raise challenges for RECs, partly because of the urgency and need for rapid reviews of proposed research (12). There is need for robust ethical frameworks to better guide researchers and ethics committees when reviewing research projects during epidemics and other public health emergencies. As such, some commentators have suggested model frameworks for research ethics review during public emergencies (13).

While after the 2014-16 Ebola outbreak, some international organisations including the World Health Organization (WHO) and Nuffield Council on Bioethics, have published guidance on ethics of research during epidemics and public health emergencies (14,15), there is currently no African-centric and continent-wide, coherent guidance which promotes African values, written by Africans for hosting clinical research during epidemics in Africa. However, empirical studies exploring research stakeholders' views and perspectives on the ethical issues during outbreaks are surprisingly scarce, despite the potential utility of such data for example in informing training for researchers and REC members on how to deal with these issues in epidemic research. Therefore, this descriptive study aimed to survey research stakeholders' views on ethical issues during infectious disease outbreak across Africa.

Methods

Ethical considerations. This study received ethics approval from the University College London Research Ethics Review Committee (ethics approval number STSEth156), and all participants gave their implied informed consent. All data were de-identified to ensure data confidentiality and privacy.

Design. This is a descriptive study on research ethics during infectious disease outbreaks across Africa. The design of our survey instrument was informed by a literature review of relevant scholarly publications on current ethical controversies over clinical research in epidemics and public health emergencies. An online survey was conducted using the web-based software SurveyMonkey. The survey consisted of Likert-scale questions as well as some open-ended questions (Appendix 1). The questionnaire was tested during a pilot interview and subsequently refined for clarity and comprehensiveness.

Participant sampling. For convenience, three hundred and thirty participants who registered for the second International Conference on Re-emerging and Emerging Infectious Disease that took place from 13-15 March 2019 in Addis Ababa, Ethiopia were invited to participate in the survey as advertised to take place in real-time during the last day of the conference event. This high-profile conference brought together public health research stakeholders across Africa to share important clinical developments and updates on ongoing and new trials in the field of re-emerging and emerging infectious diseases. Participants included health-related researchers, research sponsors, healthcare practitioners and policy makers. All conference delegates were eligible to attend the survey session and opt into the study.

Data analysis. Respondents were asked questions related to the following topics: *ethics of using unregistered interventions in outbreaks; risks-benefit assessment; acceptable study design; ethics review processes; exclusion of pregnant women and children; role of community engagement; sample and data sharing*. Descriptive statistics such as frequency distributions, proportions and percentages were used to analyse the responses. Some of the responses were presented in figures and tables. The statistical package DescTools was used for detailed data analysis. For confidence intervals (CIs), the responses 'agree/strongly agree' and 'disagree/strongly disagree' were merged into single response categories to provide more clarity about what the overall preference is for a given question. CIs were then calculated using the multinomial approach over the new set of merged response categories (16) From this analysis, overall 20 of 36 questions had statistically significant answers, i.e. where the majority response had non-overlapping 95% CIs with other responses (Table II).

Results

Response rate. There were a total of 330 participants from 51 countries who had registered for the International Conference on Re-emerging and Emerging Infectious Diseases (ICREID) in Addis Ababa, Ethiopia, 13-15 March 2019. However, only 78 (23.6%) respondents completed the survey in real-time on the day and constituted the sample size for this study. Of the 78 participants considered in this study, 48 (63.2%) were health researchers, 15 (19.7%) were healthcare professionals, and 7 (9.2%) were policymakers.

Key findings. Table I below summarizes the main results of the survey, by highlighting the exemplar questions asked and the frequency of responses. In what follows below, we further highlight some of the key findings from the present study.

Ethics of using unregistered interventions in outbreaks. The majority of respondents felt that, in the absence of available standard treatments, the use of unregistered interventions for which there is some scientific rationale might benefit patients during an epidemic.

Risk-benefit assessment. Concerning risks and expected benefits, 50% of respondents felt that clinical research during infectious outbreak should be permitted only when prior animal studies have shown promising safety data. However, about one-third of participants disagreed with the statement.

Acceptable study design. Regarding the use of conventional placebo-controlled trials during infectious disease outbreaks with high fatalities, 61% of respondents felt that such trial designs were unethical whereas only 19% considered them to be ethically justifiable.

Community engagement. When asked about community engagement, more than 90% of respondents underscored the

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Table I. Summary of key findings.

Item	Question	Statistically significant findings aggregated (95% CI: agree + strongly agree)
4	In the absence of available standard treatments, patients with confirmed infection during epidemics will benefit from unregistered interventions for which there is some scientific rationale.	76.32%-Majority agree (95% CI: 68.42, 86.22%)
5	Despite the urgency and pressure of response during infectious disease outbreak, it is important for Government, researchers, and the affected populations to concentrate efforts on only a few research priorities to complete within the same outbreak.	68%-Majority agree (95% CI: 58.67, 79.04%)
6	Maintaining clear distinctions between the activities of 'research', 'health care'and 'public health interventions' in an infectious disease outbreak is ethically required.	78.67%-Majority Yes (95% CI: 70.67, 88.05%)
7	It possible to speed up the ethics and regulatory review processes enough to respond to the time pressure inherent in an infectious disease outbreak?	86.67%-Majority Yes (95% CI: 80.00, 93.46%)
8	Regulatory approval of certain projects designed during previous outbreaks should be possible prior to a new outbreak.	82.43%-Majority agree (95% CI: 75.68, 91.33%)
9	Ethics approval of certain projects designed during previous outbreaks should definitely be possible prior to a new outbreak within the same country?	82.43%-Majority agree (95% CI: 75.68, 91.21%)
10	Is it possible to 'harmonize' ethics and regulatory review processes during an infectious disease outbreak across different countries in Africa?	81.08%-Majority Yes (95% CI: 74.32, 90.40%)
12	Should decisions about what risks and expected benefits it is acceptable to expose patients to for scientific purposes be affected by the conditions of an infectious disease outbreak?	59.15%-Majority Yes (95% CI: 47.89, 70.46%)
16	Should decisions about study design be affected by the fact that the research will be taking place in a setting of infectious disease outbreak?	78.87%-Majority Yes (95% CI: 70.42, 88.02%)
18	Conventional placebo-controlled trials are ethically justifiable during outbreaks with high case fatality rates.	61.43%-Majority No (95% CI: 51.43, 73.77%)
20	Community engagement is important to ensure local compliance to standardised protocols designed by scientists during outbreaks.	82.86%-Majority Agree (95% CI: 75.71, 91.83%)
22	Are field anthropologists the best people to engage with communities over research in the context of infectious disease outbreak?	51.43%-Majority Yes (95% CI: 40.00, 63.94%)
24	Researchers and other research stakeholders should have a legal obligation to work collaboratively in the context of infectious disease outbreak?	85.71%-Majority Yes (95% CI: 78.57, 92.94%)
29	Patient consent for an investigational treatment could be ethically sought in ways suited specifically for the conditions of an outbreak?	85.48%-Majority Yes (95% CI: 79.03, 94.60%)
30	Is patient consent always necessary to use personal data for research?	78.69%-Majority Yes
31	Is patient consent always necessary to use surplus tissue for research?	66.67%-Majority Yes (95% CI: 56.67, 79.62%)
32	Should all clinical research undertaken during an outbreak conform to the principles of Good Clinical Practice (GCP)?	86.44%-Majority Yes (95% CI: 79.66, 94.95%)
33	Should regulators of human medicines use data from veterinary science as well as laboratory studies on nonhuman animals?	78.95%-Majority Yes (95% CI: 70.18, 89.44%)
34	Should ethics approval from an animal research ethics board be sought before any research is done on animals that are involved in disease outbreaks either as source of infection, reservoir, or victim?	76.92%-Majority Yes (95% CI: 67.31, 88.23%)
35	Where wild animals are involved in research on containing an outbreak, should researchers consider how the wider ecosystem would be affected when the focus is on improving human welfare and health?	90.38%-Majority Yes (95% CI: 84.62, 98.29%)

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importance of community engagement for research during infectious disease outbreaks. However, while recognizing the importance of local voices in the design of health-related research during infectious disease outbreaks, 41.4% of

respondents maintained that this should not allow the study to become less scientifically efficient.

Human biological sample and data sharing. Majority (53.4%) of respondents agreed that it is a good ethical practice to share data and biological samples obtained during an infectious disease outbreak with other researchers in order to maximise scientific knowledge. However, views were divided on whether data and samples collected during an infectious disease outbreak should remain in Africa or not, with 43.3% respondents each for and against the query. Concerning whether it is ethical to export personal data collected during an infectious disease outbreak outside of Africa, 47.7% of respondent felt it was ethically correct to export tissue samples collected during an infectious disease outbreak outside Africa, but 38.5% disapproved of this practice.

Consent. All respondents concurred with the need for patient consent for research into experimental drugs during an outbreak. Furthermore, majority (78.7%) of respondents stated that patient consent is always necessary before personal data can be used for research during infectious disease outbreak. Similarly, most respondents believed that informed consent is always necessary for collecting, storing and future research using surplus biological samples collected during outbreaks.

Discussion

This article is the first to report empirical data on the views of a sample of African public health research stakeholders regarding research ethics issues in infectious disease outbreaks, with particular reference to controversies which arose during the 2014-2016 Ebola outbreak. The findings are also relevant to other epidemic contexts such as the current ongoing COVID-19 pandemic. While all respondents concurred with the need to ensure that research in outbreaks (just like in non-emergency settings) should be ethically and scientifically rigorous, we found divergent views on some of the ethical themes. As highlighted in the results, some respondents expressed concern on the ethics of using unregistered experimental interventions never tested for safety and efficacy in humans. Nearly 50% of the respondents strongly felt that clinical research during an outbreak should be permitted only when prior safety testing in humans has been completed. It remains unclear how African REC members deal with such ethical dilemmas during outbreaks where effective treatment or preventative vaccines are non-existent.

Indeed, the 2014-2016 Ebola outbreak highlighted challenges on the ethics of using experimental interventions (17,18) and post-trial access of an intervention that proves safe and effective (19). While the World Health Organization (WHO) endorsed, for ethical reasons, the use of unregistered experimental treatments in the Ebola outbreak using a framework called monitored emergency use of unregistered interventions (MEURI) (20), little is known about what national ethical guidelines and regulatory frameworks for research across Africa say regarding the use of experimental drugs in emergency disease outbreaks. There is an urgent need for a robust ethics-regulatory framework and guidance to provide more explicit direction on experimental drugs during deadly epidemics with no approved treatments and to better delineate the boundaries between the using experimental drugs via compassionate access (MEURI) vs. clinical research.

Furthermore, respondents felt that while the use unproven experimental interventions (never tested in humans) in epidemic emergencies is somewhat acceptable, this has to be based on a favourable risk-benefit assessment. Risk/benefit assessment of research protocols by RECs is an important ethical requirement underpinned by the fundamental principles of beneficence and non-maleficence. There is need to ensure that proposed research protocols have favourable risk/benefit ratio to ensure protection of research participants from excessive risks (7,10). Thus more support may be needed for ethics reviewers, more so in research during outbreaks, to ensure favourable balance of potential risks and benefits. Encouragingly, a recent review (21) assessing to what extent the Ebola trials adhered to ethical guidelines, found that most of the studies demonstrated a favourable risk-benefit ratio considering the high fatality rate of Ebola.

Our study further highlighted divergent views on the ethical acceptability of randomization and control groups. Study design was a key consideration of the WHO Ethics Working Group during the Ebola outbreak in 2014 (22). The report of the Group's discussion provides a valuable summary of the issues to be considered by investigators, ethics committee members, and other stakeholders in developing ethically acceptable and scientifically sound studies during the Ebola outbreak. The main debate relates to the question of whether 'gold standard' placebo-controlled trials are ethically justifiable during outbreaks with high case fatality rates. The arguments (23) against RCTs are primarily based on an assumption that it is unethical and unacceptable to deprive patients of an intervention that could potentially prevent or treat a potentially fatal infectious disease with no known available treatment options. The concept of equipoise (24) (genuine uncertainty over whether a treatment will be beneficial) is the ethical basis for assigning only some participants to receive an experimental treatment. Future studies could perhaps explore local communities' attitudes towards placebo controlled trials during outbreaks. Community engagement is increasingly recognized as an important ethical principle whose goals include enhanced protection of research participants, enhanced benefits, legitimacy, and shared responsibility.

We were somewhat surprised that a majority (almost 60%) of respondents were satisfied with exclusion of pregnant women and children in clinical trials during outbreaks. This is despite reports suggesting that outbreaks such as Ebola significantly affect the health of pregnant women and their offspring (8,25,26) Pregnant women are often excluded as participants from research-sometimes without clear ethical and scientific justification. The default mode of excluding pregnant participants in research is often due to the understandable intention to minimize fetal harm. Encouragingly, there is growing international guidance calling for ethical, socially just and respectful inclusion of pregnant women in clinical research during emerging infectious diseases (27,28). However, more ethics guidance is still needed to equip ethics reviewers to be able to optimally address ethical and regulatory issues related to research with pregnant women during outbreaks. There is need for future empirical studies about how research ethics

committees or institutional review board (IRB) view and make decisions on research with pregnant women.

Lastly, our study also found that-while acknowledging the importance of sample and data sharing during infectious disease outbreaks (29)-most respondents, raised concerns about exportation of samples outside Africa. There have been long standing concerns by some African researchers and commentators about unethical exportation of samples and data to developed countries without fair benefit sharing and adequate ethics governance to protect sample donors (30,31).

Conclusions

Similar to non-emergency research, it is ethically imperative that the rights, dignity, safety and welfare of individuals are protected during research on epidemic outbreaks. It goes without saying that high ethical standards e.g. informed consent is a necessary and key ethical requirement for research. However, it is acknowledged that the context of an infectious disease outbreak might inevitably render the processes involved in obtaining individual consent deviate from those typically used in non-emergency research and still be ethically appropriate. Of particular importance is the need to ensure that individuals understand the distinction between consenting to participate in research vs. routine public health response activities. However, the fear, uncertainty and desperation associated with deadly outbreaks could impact research participants' understanding of the difference between research and public health practice. This can raise ethical challenges for human research during disease outbreaks. This study represents the first attempt to provide empirical data on the views of African stakeholders regarding research ethics in epidemics. The findings will be used in ongoing work attempting to develop an African-centric framework to support ethical conduct of research during epidemics in Africa.

Limitations of the study

There are potential limitations to the present study. First, there was a rather low response rate (23.6%) despite efforts to get responses in real time from all those who registered for the conference. However, as the survey was held on the last day, it is unclear what proportion of delegates were still available and chose not to participate. Hence, the findings reported here might not reflect the views of all research stakeholders. Future studies could perhaps survey a larger sample. Furthermore, the proportion of REC members in the survey was relatively small-an important stakeholder group that is responsible for providing ethics reviews of research proposals. However, we are currently undertaking a series of consultative meetings with ethics committees across Africa to better understand their views on research ethics in epidemics with a view of developing an African framework to support ethical research during epidemics in Africa. Furthermore, the present survey referenced controversies which arose during the 2014-2016 Ebola outbreak. While the findings might be relevant to any epidemic, further comparative studies could explore stakeholders' views in a different epidemic setting such as the current COVID-19. Though our study has limitations, it offers important insights and makes scholarly contribution to better understanding what African public health research stakeholders think about ethical issues in research during epidemics.

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Authors' contributions

RT was responsible for data collection, analysis, and preparation of the first draft. BS contributed to data analysis and writeup of the paper. AY developed the survey and analyzed the data including statistical analysis. SE designed the survey questions for piloting and contributed in various ways to the work reported in this article, including supervision, writing and approval of final version. All authors read and approved final version.

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Potential conflict of interests

None declared.

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