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Considerations for community engagement when conducting clinical trials during infectious disease emergencies in West Africa

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Abstract

Community engagement in research, including public health related research, is acknowledged as an ethical imperative. While medical care and public health action take priority over research during infectious disease outbreaks, research is still required in order to learn from epidemic responses. The World Health Organisation developed a guide for community engagement during infectious disease epidemics called the Good Participatory Practice for Trials of Emerging (and Re-emerging) Pathogens that are Likely to Cause Severe Outbreaks in the Near Future and for which Few or No Medical Counter-Measures Exist (GPP-EP). This paper identified priorities for community engagement for research conducted during infectious disease outbreaks drawing on discussions held with a purposive sample of bioethicists, social scientists, researchers, policy makers and laypersons who work with ethics committees in West Africa. These perspectives were considered in the light of the GPP-EP, which adds further depth and dimension to discussions on community engagement frameworks. It concludes that there is no presumptive justification for the exclusion of communities in the design, implementation and monitoring of clinical trials conducted during an infectious disease outbreak. Engagement that facilitates collaboration rather than partnership between researchers and the community during epidemics is acceptable.

1 Introduction

Miller et al¹ argued that community engagement in research, including public health related research, is an ethical imperative because both the conduct and the outcomes of research can have significant impacts on communities. Research and research outcomes should not be imposed on people without providing the opportunity for communities to collaborate and determine the goals, structures and processes of proposed research. Such engagement helps to address the complex inter-relationships between the biological dimension and consequences of the diseases and their social, cultural and political dimensions² in ways that can promote health and well-being.

During infectious disease outbreaks, medical care and public health action generally take priority over research. However, this prioritisation does not imply research is unimportant during epidemics. Research is critical for generating information that may enable current or future outbreaks to be better controlled and thus reduce human suffering. One of the lessons from

human rights-based public health is that research should not displace measures that directly address care needs and curtailment of ongoing transmission for both humanitarian and pragmatic reasons, because it instrumentalises people when they are at their most vulnerable, and because the cooperation of communities in epidemic control depends on their interests being recognised and respected.³

In the outbreak context, research has often been packaged with both medical care and public health action. In some documented instances⁴ research conducted during epidemics has not adhered to foundational requirements such as informed consent and ethical review, let alone more demanding standards such as community engagement.⁵ The development by the World Health Organisation (WHO) of a document that outlines the responsibility to include community engagement in research conducted during an infectious disease outbreak is thus an important step. The WHO document, which has the descriptive title ‘Good Participatory Practice for Trials of Emerging (and Re-emerging) Pathogens that are Likely to Cause Severe Outbreaks in the Near Future and for which Few or No Medical Counter-Measures Exist’, or GPP-EP for short, cements the centrality of community engagement even when there are many potentially conflicting priorities.⁶

This paper will consider priorities for community engagement for research conducted during an infectious disease outbreak drawing on discussions held with a purposive sample of bioethicists, social scientists, researchers, policy makers, and laypersons. These include persons that work in the field in West Africa, those who work with ethics committees in West Africa, and experts who work on cross-cutting bioethics and community engagement issues in and outside West Africa and at a global level. We have focused on West Africa for a number of reasons. First, the sub-region has very low capacity for research conduct. The implication is that, for the near future, most critical health crisis research responses will be initiated by partners from the North. Second, the community in West Africa is largely communitarian in practice. This has significant implications for research conduct as highlighted by Folayan and Haire.⁷ The perspectives shared will be considered in the light of the GPP-EP, which will add further depth and dimension to discussions on community engagement frameworks.

2 Background

One of the lessons learned from the conduct of HIV research is that community engagement enhances the quality of research and promotes a sense of joint ownership by both researchers and community members.⁸ This in turn promotes community support for the research process that can translate to timely recruitment of study participants, improved informed consent and enhanced uptake and use of research outcomes (knowledge and skills) irrespective of what the results of the research may be.⁹ Generally, the belief is that communities are thereby left better off at the end of the research, and research capacity is strengthened by the efficiencies created in collaborative processes.

Predating GPP-EP, a set of guidelines known as the “Good Participatory Practice (GPP) guidelines for [stakeholder engagement in] biomedical HIV prevention trials” were developed by UNAIDS and AVAC. GPP stipulate some minimum requirements for community engagement in biomedical HIV prevention research¹⁰ many of which are applicable beyond the HIV prevention

research field. The GPP counsel that researchers engaged in HIV prevention research can improve the outcomes and uptake of their work through the conduct of—among other things—formative research. Formative research will help the study identify and understand nuances about the community and relevant stakeholders that should inform the development of stakeholder engagement plans, stakeholder advisory mechanisms, communication plans, stakeholder education plans, and unforeseen or unexpected issues management plans.

While the GPP is a useful guide in planning and conducting many HIV prevention clinical trials,¹¹ the applicability of these principles during the conduct of a public health emergency of the nature witnessed during the 2013 to 2015 West Africa Ebola epidemic is unknown. The West Africa Ebola epidemic resulted in an underestimated 28,616 suspected cases and 11,310 (39.5%) deaths in Guinea, Liberia, Nigeria and Sierra Leone.¹² The outbreak spread to Mali, Senegal, United Kingdom and Italy. There were secondary infection of medical workers in the United States and Spain.¹³ This was the 25th outbreak of Ebola since its discovery in 1976.¹⁴

In the absence of a preventive or curative therapy for Ebola; and in view of the biosecurity threat that Ebola posed, a few treatment and vaccine trials were initiated in the countries worst affected by the epidemic.¹⁵ In such a situation, the urgent need for action may be considered a higher priority than a (potentially time consuming) collaborative community engagement processes. Nevertheless, even in an emergency context, cooperation between local citizens, public health authorities, providers of medical services and researchers is required to minimise friction and conflict between these actors.

Emergency infectious disease outbreaks usually require swift action to address morbidity and mortality and limit ongoing infection. Where an epidemic has the potential to run its course, there is usually a need to fast-track essential research data collection processes. Despite the urgency involved in an emergency outbreak response, it is expected that the ethical principles that have been pivotal in the conduct of ethical biomedicine research – autonomy, beneficence, non-maleficence, justice¹⁶ – will apply. Of note, however, there may be tensions between the frameworks that govern research ethics, which emphasises the individual, and those that govern public health, which include concepts of health maximisation, transparency and proportionality.¹⁷ Considerations for humanitarian ethics that promotes humanity, neutrality, impartiality and independence, also introduces additional conflicts and complexities in decision-making.¹⁸ Where urgent decisions need to be taken, ethical trade-offs may be required some of which may imply that actions are taken that preclude transparency, neutrality and inclusiveness.¹⁹ There is little clarity however, about how to negotiate the ethical terrain when principles come into conflict during such an emergency.

There is a substantial body of work discussing perspectives, propositions and case studies on models for community engagement during clinical trials that are conducted in non-outbreak conditions. Until a new version of the GPP adapted specifically for use in emergency infectious diseases outbreaks (the GPP-EP) was developed by the WHO,²⁰ there was scant literature on how to balance conflicting demands regarding community engagement during an infectious disease outbreak. The GPP-ED proposes that effort be made to foster respect between the research team, the community and its representatives, ensure parties negotiate and achieve clear

understanding of diverse roles and responsibilities, establish community engagement mechanisms that are independent of the research systems and structures, and hold open and honest communication in a clear, comprehensible and timely fashion.

While the GPP-EP was published after the West African Ebola outbreak, the principles articulated within it are not novel – the innovation lies in the consideration of how these apply under emergency conditions. The GPP-EP also provides a tool with which to analyse the clinical research that was conducted during the West African Ebola outbreak, not to measure compliance (as the GPP-EP was not published), but to test the extent to which norms articulated in the GPP-EP were normative practices during the outbreak. The question that arises is whether the GPP-EP provides a sufficient framework for community engagement practices in research during emergencies, or whether further articulation and refinement is likely to be necessary.

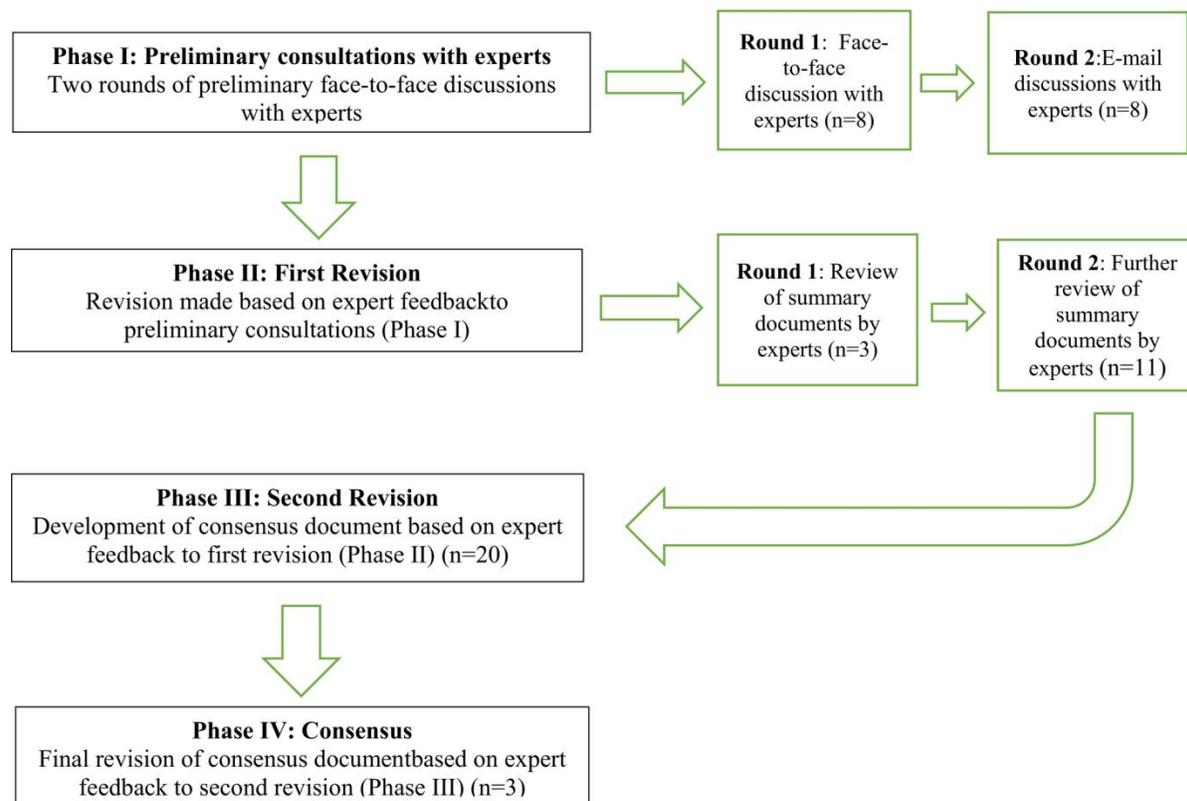
Given the magnitude and scale of recent infectious disease outbreaks and the need to conduct clinical trials to develop therapies and vaccines for infectious diseases with a propensity to cause Ebola-like epidemics, we identified a need to distil further recommendations about community engagement programmes in outbreak research. A starting point is to develop a model for community engagement in research that can be applied during an emergency infectious disease outbreak.²¹ We aim to present elements of a community engagement framework that may be applicable for the West African region. We shall also be focusing on community engagement during clinical trials rather than during social and behavioural science research as clinical trials may be more disruptive to the routine norms and social values of communitarian societies found in West Africa that protects collectivism²² than individualism otherwise promoted during clinical trials. Critical considerations for community engagement during clinical trials is therefore needed.

3 Methodology

In order to develop this model, we considered the following four research questions: 1) what should the objectives of community engagement during infectious disease epidemics be; 2) how should community engagement be conducted during an infectious disease epidemic of the nature like Ebola; 3) how should the histories, politics and the socio-cultural context of communities inform the design and implementation of such research; and 4) when is the omission of community engagement acceptable for clinical trials conducted in an emergency situation?

The Delphi process was adapted for the process of answering these questions, drawing on the views of stakeholders with experience in research ethics, clinical trials and the West African Ebola outbreak. Multiple iterations of views were considered until consensus was achieved.²³ Figure 1 below is a diagrammatic representation of the iteration process. Data were generated through four study phases involving consultative meetings with various groups of experts for the purpose of validating results generated prior consultations.

Figure 1: Flow diagram of the consensus reaching process for the consultations using Delphi method



Phase I:

This phase was made of two rounds of consultation with experts

Round 1:

Following an online survey that collected initial perspectives from the participants, we conducted a two day face-to-face discussion with experts in the fields of ethics and community engagement on 14th-15th December 2016 in Abuja, Nigeria. They all had experience in both disciplines. The meeting brought eight experts together: four from Nigeria, two from Liberia and one person from Canada and Australia respectively. The meeting sought to answer the four research questions over a series of six meeting sessions. These began with a discussion of the online survey, followed by iterative process of eliminating areas of contention until consensus was reached.

At the end of each day's meeting, a daily assessment was conducted to enable participants share other perspectives and opinions on the topics discussed. This was an additional avenue to harness further thoughts and ideas not shared during the consultative meeting. These ideas and concepts were pooled into the report of the meeting outcomes.

Round 2:

Nine months later, between 12th and 19th of August 2017, the summary document based on the outcome of the discussions in round 1 was shared with eight experts engaged in face to face meeting in round 1. In addition, three new experts from Nigeria (bioethicist), Sierra Leone (clinical trialist involved with Ebola trial) and Kenya (expert on community engagement issues) were invited to share comments on the document. Comments were shared via email and a summary document was produced. Areas of disagreement and agreement were identified. After further exploration of views, issues on which there was disagreement were dropped.

Phase II:

Between the 24th of August and 4th of September 2017. The Phase II process conducted in two rounds.

Round 1:

The consensus document developed from Phase I was shared with three new experts via email: a bioethicist, a clinical trialist involved with Ebola epidemic in West Africa, and a seasoned researcher on community engagement issues. This new group reviewed the consensus document and provided comments. A consensus document was developed from this round of discussions.

Round 2:

The consensus document developed from the Phase II round I was shared with the eight of the 11 experts (three made no contributions to the discussion despite several promptings. The three experts were from Nigeria) engaged in Phase I and the three experts engaged in the Phase II. They were required to review the document, make comments, inputs and issue clarifications. The final document developed from the Phase II round 2 process only contained consensus statements reached by this panel.

Phase III:

From the 25th to 27th of September, 2017, 20 persons – bioethicists, social scientists, researchers, policy makers and laypersons – who work with ethics committee in West Africa and met in Senegal and discussed the consensus statements reached by the panel of experts through group works. This phase included two of the eight experts involved in the round 1. The aim of this review process was to validate the consensus statements. The review of this document was expected to be grounded in the lived experiences of this group of reviewers. The reviewers studied the consensus document, and discussed the statements initially during group work and then during a plenary session. The output of the validation process was a consensus document statement containing only statements agreed to by participants.

Phase IV:

The final phase of the process was the review of the consensus document by three new experts in the field of bioethics and community engagement in clinical trials and research. These experts had worked in the field for several years, and had been involved with the development of

international guidelines on bioethics and community engagement in research. These experts reviewed the validated consensus document. They focused on establishing ethical justifications for the consensus statements. Statements that could not be substantiated with an ethical rationale were dropped from the consensus statements.

Ethical considerations:

Ethics approval for the study was obtained from the Institute of Public Health, Obafemi Awolowo University, Ile-Ife, Nigeria (IPHOAU/12/700).

4 Outcomes of Deliberations

What should the objective of community engagement during clinical trials conducted during infectious disease emergencies be?

1. Relationship building for the purpose of facilitating the successful implementation of the research by enhancing public health education, promoting collaboration and dispelling unfounded fear and rumours is a key objective.
2. Research should be locally responsive – research aims and processes should serve the interests of people locally and not be merely ‘acceptable’.
3. Community engagement should build in-depth understanding of how research processes are likely to work out in practice in a given setting, maximize benefits and minimize costs/burdens to participants and communities.
4. Community engagement should strengthen scientific outcomes by making sure that research tools are appropriate; and the implementation process will likely result in collection of valid information.
5. Priorities of researchers and community advocates might differ: for advocates, the critical role is protecting the rights and integrity of the citizenry, including ensuring the research addresses its needs. For researchers, critical goals are to ensure success and minimize challenges, misconceptions and the fueling of rumours able to jeopardize research.

Ideally, the goal of community engagement should be threefold: to increase the validity of research; improve research measures, interpretations, and knowledge translation and dissemination; and provide a platform for vulnerable and excluded communities to be included in decision-making about the research.²⁴ Doing so can facilitate joint researcher and community ownership of the research; and stimulates community members’ interest as they are empowered by their own home-grown efforts/contributions to address the peculiar health related challenges affecting their community. This also can help to promote sustainability of the community response, improve the research outcome, and minimize rivalry for leadership positions within the research enterprise by community members. The ultimate goal of community engagement is to ensure that the research is responsive to the needs of the community, and the research methods and processes are acceptable to them.

During the consultative meetings, participants argued that these benefits of community engagement were laudable but some goals may be considered utopian and aspirational for off-shored clinical trials conducted during infectious disease emergencies in communities where

research literacy is low. Even when ideal goals of community engagement are not achievable, at the least, researcher should implement a structured community engagement plan that can be monitored for its impact. Researchers should also acknowledge community members as essential, strategic, and uniquely knowledgeable and skilled actor²⁵ in the research enterprise. This requires that space be created for the two parties – researchers and communities - to collaborate and exchange ideas with the intention that the outcomes of these deliberations can improve the outputs of science.

Participants in the consultative meetings recognized that models developed for community engagement aimed at democratising science and liberalising its paternalistic tendencies. Models that focused on advancing social equity, inclusion and well-being may struggle to be implemented in an epidemic of an emergency nature like that seen during the West Africa Ebola epidemic; and in societies where respects for rights of persons are not institutionalized as is the case with many countries in West Africa. Participants recognized also that while rights of communities are limited by the laws that govern public health response, there are no laws that limit the scope of a community engagement plan conducted for any research. Efforts supportive of research implementation – inclusive of the community engagement process - should nevertheless, not distract from the public health response instituted to contain an emergency epidemic outbreak, nor from associated medical care and public safety.

How should community engagement be conducted during an infectious disease epidemic in West Africa?

1. Community engagement should occur through a collaborative model that actively involves community stakeholders in discussions and deliberations on the implementation of the research in ways that ensures transparency and accountability.
2. Community engagement process should be guided by a context-specific community engagement plan developed in consultation with political leaders and community members.
3. The key value that should underpin community engagement processes during research implementation is respect: respect for community values and the competency all parties bring to the deliberations.
4. The implementation of the community engagement plans should be fast-tracked. Community emergencies identified in the course of the implementation of the plan should be resolved through notification of appropriate agencies in charge of managing the emergency.

Model of engagement should be collaborative: Participants at the consultative meetings felt that a useful model for community engagement for clinical trials to be conducted in an infectious disease epidemic outbreak context, is one that facilitates collaboration between researchers and the community rather than one that promotes partnership. The distinction may be small, yet important. Partnership requires that the research activities are responsive to the needs of the host community allowing for communities to have a say in the design and implementation of the research²⁶ whereas collaboration provides a mechanism for consultation and dialogue between researchers and community members that contributes to protecting communities and fostering meaningful research.²⁷

Values that should underpin the engagement process: Respect was a key value identified as critical to a community engagement process. Ethics committee members reviewing research protocols can help ensure protocols reflect this value. Engagement of researchers with trusted community members/ political, security, religious and cultural gatekeepers is a demonstration of respect. Respect is also demonstrated by adopting existing community communication structures to facilitate open bi-directional dialogues. Participants at the consultative meetings recognized that equity during dialogues may be challenging. It can however be achieved through acknowledgement of each party's (researchers and community members) competency and equality; and recognising the contribution each can make for successful research outcomes.

Recognition of competencies: Both researchers and community members have important skills and competencies. Researchers will be science literate and highly competent in thinking through how generated data can be translated to useful information that can improve the course and change the negative trajectory of an infectious disease epidemic. On the other hand, community members are community literate and can provide information that will facilitate the generation of data about disease transmission and its dynamics, in a timely manner. Together, researchers and community members can identify the issues; collect, analyze and interpret the data; and decide how to use the results to inform policy, change practice and improve conditions in the community.²⁸

Develop a community engagement plan: It is reasonable to develop context-specific 'best practices' on community engagement for specific research goals as opposed to the proposal by Pedit et al²⁹ for a set of global standards for meaningful community engagement. Context-specific community engagement programmes (outlined in a developed community engagement plan) should be grounded in the social practices and norms of the community thereby allowing for prompt identification and response to community specific issues that may otherwise impede or delay the engagement process. It also helps to foreground the interplay between community dynamics, local understanding of the disease and cultural practices around care seeking, and dealing with illness and death.³⁰ Conducting formative research prior to research implementation will help identify the social norms, practices and values that can influence the research process and how to address them effectively. The plan should include activities on advocacy, media engagement, external communications and community mobilization related issues.

Knowledgeable community members and survivors of diseases being investigated should be sought and engaged as community representatives. It will not always be easy to identify community members who have a) the requisite technical experience to give advice on research; b) the close understandings and connections with community to reflect the views and values of the wider community; and, c) the integrity and reputation to be able to serve as community a representative. Given this challenge, community accountability—how the wider community can come to know who is taking on the role of community representatives, and how they are fulfilling it—is an issue to be resolved.

Fast-track context-specific community engagement process: This will also help shorten the time for implementing the community engagement process. In effect, though the GPP-EP

should be adapted to the local context, the breadth and depth of the community engagement programme should not compromise on the breadth and depth of the requirement of the GPP-EP. This implies that rather than engage community with pre-protocol development activities, the community may be engaged to critique and amend the protocol. However, when protocols are developed ahead of an outbreak (generic/pre-review protocols), the community engagement process should follow the requirements of the GPP – community members should be involved with research conceptualisation and design.

Engage political leaders: National and local community leaders should be engaged first prior to engagement of community members. The process might include meeting with national and local leadership, religious and traditional leaders, community health practitioners, community based organizations as well as community advocacy groups. This can help to create the needed political will and promote a conducive environment for the research. Engagement with political leadership should not however subsume the goal of engaging local community members. Also, the political expediency to conduct research during outbreaks, and political support for any research should not result in omission of engagement with community members.

Consultation participants also acknowledged that political leaders can exercise power in perverse ways that researchers may not want to support. It is therefore important to identify multiple channels through which to engage with community members rather than relying solely on a political leader as portal of entry to the community.

Resolve emergency community needs that may impact research negatively: Where there are emerging community needs identified through a community consultative process that may affect disease control, researchers would appear to have a moral obligation to help the community resolve the emergency needs. These needs do not have to be addressed through direct funding from the research. Researchers can link the community to appropriate institutions in the position to address those needs. Consultation participants recognized that these needs are often complex and deep-seated; and are related to cultural and socio-political structures like gendered power or economic inequities that realistically researchers will not be able to resolve. Some of the needs may be ameliorated by facilitating referrals or providing technical support for effecting change.

What are the considerations for research design and implementation during an infectious disease epidemic?

Formative research should be implemented. This should inform the design and implementation of the main study and the development of the community engagement plan.

Formative research can be conducted prior to the design of the research implementation plan, using a participatory approach to identify considerations for research design and implementation during an infectious disease epidemic. Formative research can highlight historical, social and political concerns that can influence community participation in research. It can also generate information about the concerns of vulnerable community members and how their needs could be addressed while implementing the research. Vulnerability is a contextual

concept and should be qualified by an understanding of what the person is vulnerable to and why.³¹ In many low resource settings in West Africa, almost everyone in a remote rural setting will be vulnerable to poor health care access. Formative research helps define the situation on the ground and generate evidences to support decision-making about research design and implementation.³²

How should the history, political and socio-cultural context of communities inform the design and implementation of clinical trials conducted during infectious disease emergencies in West Africa?

The history, political and socio-cultural context of communities helps researchers to understand the context of actions, perspectives and expectations from research. This should influence the design of the clinical trials.

When research is situated in contexts where inequities are reflected through facets like political distrust, low research literacy and poverty, community members are at increased risk of a range of harmful events such as exploitation, coercion and undue inducement. Formative research conducted prior to study design and implementation can be used to create historical and socio-cultural maps of communities. The local nuances – culture, norms, values, religion and practices – should be respected. Consultation participants identified the importance of local knowledge and local rationality. History helps one understand the rationale for what communities consider important. History can provide grounds for understanding the context of actions, perspectives and expectations from research. Experiences with disease control — proximity to disease, proximity to death, history of unethical trials, socio-economic contexts of individuals and communities — all influence the understanding of the rationality and context for research in emergency situations, and attitudes towards community engagement.

When is community omission (an active conscious action of exclusion) permissible in clinical trials conducted during infectious disease epidemics in West Africa?

There is no absolute justification for community omission of in clinical trials conducted during infectious disease epidemics in West Africa.

It was not a task of the consultation or of this paper to provide a scan of the multitude of ways and forms of community engagement processes. Neither did the consultative process plan to map the different forms of community engagement processes during the Ebola outbreak in West Africa. Yet it is evident that engagement is fluid and can be expected to differ in how it is enacted per the context of any given emergency epidemic relative to pathogen, geography, culture, time, need, and a range of logistical barriers associated with community engagement processes. ‘Acuteness of emergency’ is an important concept here and a lower intensity of community engagement may be justified in research in which the risk involved is not more than that faced in the day to day realities of the emergency epidemic in question. In clinical trials however, there may be a higher requirement to include community concerns and considerations in the component risk/benefit analysis before making a decision on the merit of the research.

The scope of a community engagement plan may be limited when there are safety concerns. In a context where the disease is highly contagious, safety concerns may preclude face-to-face community engagement processes. Safety concerns should however not preclude all forms of community engagement. Rather, community engagement related activities should use appropriate strategies that address the safety concerns.

Consultation participants found no absolute justification for community omission during an epidemic emergency. There are multiple reasons why community exclusion might happen in practice, however. Some of these are researcher-driven such as lack of knowledge of engagement and engagement skills, inadequate funding to engage, and researchers who do not believe in the benefit or the moral imperative to engage. While on a case by case basis these reasons are arguably justifiable, they are not a priori justifications for community exclusion. While it can be argued that in an emergency epidemic, civil and other liberties may be suspended for the greater good, we argue that presumptive community omission for the benefit of the greater good can foster resistance and contempt for science processes; and it is a prelude for research failure.

5 Discussion

This study provides a timely account of how a range of community-connected experts prioritised issues relating to community engagement in research during an infectious disease emergency. Consultation participants recognized that the objectives of community engagement during outbreaks may differ between researchers and communities. This may be as simple as researchers seeking the cooperation of community members to ensure smooth clinical trial implementation while community members want to ensure that communities are left better off at the end of the research. The use of a collaborative community engagement approach can enable both parties to mutually achieve their goals. The onus however rests on the researchers to develop a community engagement plan that is informed by the outcomes of a formative research that identifies ways and means by which the histories, politics and the socio-cultural contexts of communities can and may influence the design and implementation of the research. In the context of an emergency epidemic, the implementation of a community engagement plan, developed in collaboration with the community (through its representatives) should be fast-tracked, and where possible, without compromise of the breadth and depth of the engagement process. Participants concurred that the omission of community engagement would not be acceptable for the conduct of clinical trials during an outbreak, though safety concerns may limit face-to-face community engagement activities.

One of the strengths of this research is the extensive consultation with people with a wide range of expertise, including ethics committee personnel, researchers, and people in the region who were involved with the Ebola response. The iterative consultative process with experts helped to validate the findings of this research. Thus, within the limits of current realities about how infectious disease epidemics may emerge in a region, we feel strongly that the community engagement model discussed may be of use to clinical researchers planning to conduct clinical trials during an infectious disease epidemic in West Africa.

Our study also had limitations. As previously identified by Folayan et al,³³ while the use of the Delphi method was appropriate for reaching consensus on a complex issue with no history

of conclusive decisions, it suffers from the possibility of some of the points of dissent and contention getting lost. Also, the consensus reached are based on the constructed reality of the experts. Our study also relied on the perspectives of expert laypersons who were members of ethics review committees in countries affected by Ebola and did not include the perspectives of general community members who were not engaged with research ethics processes. We felt having trained laypersons was appropriate as laypersons on ethics committee represent the interests of the community.³⁴ In this capacity, they have had to handle protocols for research to be conducted during the epidemic, monitor such research and thus, are able to present informed opinions on the research questions.

Our study had considerable agreement with the ethical framework articulated in the GPP-EP, in that participants identified inclusivity, transparency, accountability, openness to diverse perspectives and paying attention to diverse vulnerability as critical underpinning values.³⁵ Further, participants' identified the need to develop a community engagement plan based on evidence derived from the formative research, which recognises how the nuances of histories, economies and the socio-cultural contexts of the community may inform research participation.³⁶ This validates the proposition by the WHO on the need to conduct formative research prior to commencement of any research during infectious disease outbreaks.

In the interests of pragmatism, our consultation identified that while the ideal goal for any community engagement process is partnership and joint ownership of the research,³⁷ a merely collaborative model would be acceptable during an emergency outbreak. This recognises that at present and in the foreseeable future, most of the clinical trials which will be conducted during infectious disease emergencies will be off-shored research due to limited clinical trial capacity in the region. Building a full partnership model of community engagement that promotes equitable, collaborative decision-making power between communities and researchers takes time and this may not be feasible during outbreaks.

Partnership would require that the community engagement process focuses on building competency and trust between trial staff and community members, and promoting equity through active involvement of community representatives in the design and implementation of the research. It is a process that recognises the differing allegiances, power dynamics, vulnerabilities of diverse group of stakeholders that will be impacted by the outcome of the research; and engaging these diverse voices in the designs and implementation of a research through an inclusive deliberation process. This is a time consuming process.

On the other hand, a collaborative process focuses on active engagement of the different stakeholders that will be impacted by the outcome of the research primarily to ensure the implementation of the research is conducted in an accountable and transparent process. Unlike in partnership where stakeholders are expected to be involved in the study design, with collaboration, active community engagement focused on research implementation. This proposal differs from the model proposed by Folayan et al.³⁸ Like Folayan et al³⁹ however, consultation participants in this study also identified other stakeholders in addition to survivors – political leaders, community leaders and community members - that should be engaged in the consultative process. This research finding answers the question that begged to be answered in the manuscript by Folayan et al⁴⁰ - how should community engagement be implemented during infectious

disease epidemics? While Folayan et al⁴¹ acknowledged the need for local investigators to lead off-shored research because of their ability to negotiate the potential barriers and challenges that may otherwise delay research implementation, consultation participants did not raise this as a consideration for community engagement in research during an emergency. Future studies may want to specifically explore this consideration.

Our study acknowledges the limited ability to promote the goal of partnership for research conducted in West Africa knowing that most clinical trials are funded externally. The current context and climate of clinical trial practice in West Africa also makes the goal of partnership aspirational. We also acknowledge that as useful, equitable and value added community engagement is posited and found to be,⁴² emergency contexts are chaotic, often occur within social structures that are far from ideal, making even efforts at collaboration challenging. Researchers however, need to seek ways to overcome these challenges and conduct a collaborative engagement at the minimum.

Community engagement in research also needs to take place alongside other critical elements in infectious disease epidemic control: early case detection and diagnosis, comprehensive contact tracing, prompt patient isolation, supportive clinical care, and rigorous infection control.⁴³ However, a community engagement plan that enhances these other infection control practices is feasible and important during infectious disease epidemic. Such plans should enhance mutual adaptation of local cultural and public health practices.⁴⁴

The consensus reached with stakeholders during these consultative processes was that while the public health response to the epidemic will require urgent and expedited process, the priority should be to use available resources at the disposal of the community, nations, regions and international actors for public health responses to contain the spread of the infection, and improve survival rates.

6 Conclusion

This study further corroborated Miller et al's⁴⁵ stance that community engagement is an ethical imperative for clinical trials. It is an ethical imperative for clinical trials conducted during infectious disease epidemic outbreaks like the recent Ebola epidemic in West Africa. Clinical trial research in such a context should aim to facilitate a collaborative process that both enhances the conduct of the clinical trial, and leaves the community better off. The community engagement plan developed in collaboration with community representatives should be informed by evidence generated from formative research that maps how the histories, politics and socio-cultural and economic contexts of the community will inform the community engagement process. Finally, despite priorities that compete in the response to an infectious disease outbreak, there is no presumptive justification for the exclusion of communities in the design, implementation and monitoring of clinical trials in West Africa.

Conflict of Interest Statement

No conflicts declared.

Footnotes

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