Original Article

Stakeholders Engagement and Advocates' Role in Biomedical HIV Prevention Clinical Trials – Perspectives of Advocates Working in Africa

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ABSTRACT

Objective: The aim of the study was to identify the perspectives of community advocates working in Africa about meaningful and ethical stakeholder engagement with biomedical HIV prevention trials; and their role in facilitating this engagement.

Materials and Methods: An open-ended questionnaire was administered through an online survey made accessible through listservs and community liaison officers devoted to biomedical HIV prevention research advocacy. The survey included five questions that explored respondents' perspectives about meaningful and ethical stakeholder engagement in clinical trials, and the roles of advocates in facilitating this engagement. Analysis of the 32 transcripts consisted of structural coding of transcripts, summary of responses, identification, description of emerging themes and quotes reflecting the themes corresponding to interview questions.

Results: Meaningful and ethical community engagement was majorly conceptualised as the involvement of stakeholders throughout the research life-cycle: Planning, design and implementation of clinical trials; and providing community-wide information about trial progress and results. Identified advocates roles include advocacy for ethical standards of practice, facilitating community research literacy and community inputs into research protocols, empowering community members to engage with researchers, and monitoring research practices.

Conclusion: Advocates self-identified their perspectives on and roles in meaningful and ethical engagement with research conducted in Africa. Some of these roles have not been articulated in community engagement guidance documents like the UNAIDS/AVAC Good Participatory Practice guidelines.

Key words: Advocacy, Africa, community engagement, ethics, stakeholder engagement

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INTRODUCTION

Stakeholder engagement in biomedical HIV prevention clinical trials requires individuals or groups with an interest in HIV interventions to make inputs that have both biomedical and behavioral outcomes in the design or conduct of the trials.[1] It is a collaborative approach to research that *values the unique perspectives and strengths of nontraditional research partners*. Stakeholder engagement approaches blend the lived experiences and expertise of interested laypersons to the research enterprise, the power of policymakers, and rigorous science.[2] Discussions about stakeholder engagement with biomedical HIV prevention research have largely focused on ethical considerations because it is considered an ethical requirement for good research conduct by global, country specific and research networks and organisations.[3-10]

Ethical concerns about the importance of community representation in the design and implementation of biomedical HIV prevention trials was amplified by the disruption of the early pre-exposure prophylaxis trials.[11-14] This led to the development of the Good Participatory Practice (GPP) guidelines to facilitate researcher-stakeholder interactions in

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the conceptualisation, design and implementation of biomedical HIV prevention clinical trials.[15] This document has since been adapted by several other fields.[16-18] Other guidance documents on stakeholder engagement have also been developed since the first version of the GPP. [19-22] Stakeholder engagement in other medical research fields is now occurring, in recognition of its effectiveness in creating more effective (and acceptable?) medical interventions and accelerating the translation of research into practice.[23-27]

Despite the recognition of the importance of stakeholders' engagement with biomedical HIV prevention research, evaluation of these research protocols for stakeholder engagement is limited by lack of consensus on what the ethical measures should be.[28] Day *et al*.[1] evaluated 108 HIV prevention research publications using the benchmarks proposed by the GPP and identified that fewer biomedical HIV prevention clinical trials conducted in low and middle-income countries conducted stakeholders' engagement than trials in high-income countries. Yet the need for stakeholders' engagement is essential in these regions where the issues are more complex.

There are multiple documents on how stakeholders' engagement should be conducted.[3-10] There are, however, very few publications on what community actors expect as outcomes from engaging with research stakeholders, and their perception of their role in these processes. There are multiple community actors, one of which is the community advocate. Community advocates are community members who have stakes in the overall vitality of the community, and take actions to ensure its vitality.[29] Their actions are best informed by their perception of what their understanding of and expectations from engagements with researchers. Many acts as individual agents, while others work as members of an organisation that play watchdog roles.

This research aims to identify how African community advocates conceptualise meaningful and ethical stakeholder engagement with biomedical HIV prevention clinical trials; and what they perceive as their role in facilitating meaningful and ethical stakeholder engagement in such trials. The focus was on Africa based on the outcome of Day *et al*.'s[1] study that highlighted limited engagement of stakeholders with biomedical HIV prevention clinical trials on this continent. The information will provide insight into the priorities of community advocates, and thus contribute to strengthening stakeholders' engagement process with biomedical HIV prevention clinical trials in Africa.

MATERIALS AND METHODS

An eight-question open-ended questionnaire was developed to generate information on respondents' perspectives on their consideration of how to facilitate community engagement with biomedical HIV prevention clinic trialists in an ethical manner. The questionnaire was developed through a face-to-face consultative meeting with the nine core team members of the Africa Free of New HIV Infection (AfNHi), a network of biomedical HIV prevention research advocates, who were interested in exploring the issues to enable it to formulate a research ethics advocacy agenda. Five of the eight open-ended survey questions were directly relevant to this study. The questions were: (1) what does it mean to have meaningful and ethical stakeholder engagement in HIV prevention clinical trials; (2) give examples of good stakeholder engagement in any known HIV prevention clinical trials; (3) give examples of poor stakeholder engagement in any known HIV prevention clinical trials; (4) list the stakeholders that can facilitate meaningful and ethical community engagement in HIV prevention clinical trials and (5) identify the role of HIV prevention research advocates in facilitating meaningful and ethical community engagement in clinical trials. The questionnaire was shared with three long-term advocates working in the field of HIV prevention clinical trials, for content validity before finalisation of the questionnaire.

An open-ended questionnaire was administered online using Survey Monkey® from 11 December 2018 to 20 January, 2019. The inclusion criteria for survey participation were individuals with a history of working directly with the community at HIV prevention research sites in Africa, or those who were advocates for HIV prevention research and worked with HIV prevention research sites in Africa. Furthermore, individuals who worked directly with communities included community liaison officers working with research networks, and community advisory board members, were eligible to participate in the survey. Survey participants needed to be 18 years of age and needed to consent to study participation before they could proceed to respond to the survey. Interested participants in the survey needed to self-exclude themselves from research participation based on the listed criteria.

The survey included a consent sheet that presented background information, study objectives, the estimated time required to fill out the survey, eligibility criteria and the consent requirement to participate in the online survey. Participants were also informed of the inability of the research team to identify and delete any information from the survey once the survey was concluded. Participants were not able to go ahead with the online survey without checking the box that identified they consented to study participation.

Invitations to fill out the survey were sent out through listservs that were accessible by large numbers of HIV prevention research advocates. These included the International Rectal Microbicide Advocacy, the New HIV Vaccine and Microbicide Advocacy Society and the AfNHi listservs. Members of the listserv were encouraged to disseminate the survey further to their networks. In addition, the survey was sent to the community liaisons of two National Institute of Health-funded research networks conducting HIV prevention clinical trials in Africa. The community liaisons were encouraged to share the survey link with community liaison officers and community advisory board members working at their Network's research sites in Africa. These research networks were targeted for the

survey tool dissemination since the community stakeholders working in these networks are likely to have experiential information to share.

Data analysis was conducted by having three persons-two persons who developed the study questionnaire, and an independent researcher who initially worked independently to pull out the responses from the transcripts. The independent researcher was a public health expert with no affiliation with AfNHi (the organisation who initiated the study), and with no engagement in any prior discussions about the study. The three researchers initially worked independently, exchanged discussions by E-mails and then held two teleconferences to discuss, reach consensus and finalise the findings to ensure accurate representation of participants' responses.

The three researchers read through the transcripts multiple times, analysing for recurring phrases and issues that represented answers to the questions, and drawing conclusions on the responses. First, a data reduction table was created containing all the information from the transcripts for each of the five questions explored. The three analysts then made comments on areas of commonalities and differences in the response of participants for each question identified. Next, some texts of the transcripts were eliminated to enable the analysis to focus on only the data that were used to answer the research questions. Themes for each of the questions were identified and a streamlined list of quotes was developed.[30] Quotes that reflected the themes identified during the analysis were identified during the team discussions. Furthermore, quotes that were in contrast to the other responses were also identified.

Ethical approval for the study was obtained from the Institute of Public Health, Obafemi Awolowo University, Ile-Ife, Nigeria Health Research Ethics Committee (IPH/OAU/12/1309). Responses were collected anonymously. Since the field of HIV prevention research advocacy was small, information on the organisational affiliation, age and sex of the respondents were not collected to enhance anonymity. Only responses on the country of the respondents were collected. No incentive was given for study participation.

RESULTS

The invitation was sent out to the 960 members of the International Rectal Microbicide Advocacy listserv, 9273 members of the New HIV Vaccine and Microbicide Advocacy Society listserv and 81 members of the AfNHi listserv. Furthermore, the project reached out directly to four liaison officers of two National Institute of Health-funded research networks conducting HIV prevention clinical trials in Africa.

Responses were received from 32 participants: 7 (21.9%) from Nigeria, 5 (15.6%) from Liberia and 4 (12.5%) from South Africa and the United States of America, respectively. Other were 3 (9.4%) from Kenya and Malawi, respectively, 2 (6.3%) from Zimbabwe and 1 (3.1%) from Tanzania and Uganda, respectively. Two respondents did not indicate their country (3.1%). Below is a summary of their responses.

What is meaningful and ethical stakeholder engagement in clinical trials?

One of the themes participants identified as meaningful and ethical engagement of stakeholders in HIV prevention clinical trials was their involvement throughout the lifecycle of the HIV prevention clinical trials– conceptualising, designing, planning, implementing and dissemination of trial results.

> "It is the engagement of the stakeholders during the trial, design and implementation (in the research process and research conduct) which is beyond the engagement of trial participants only" -Respondent 1, Malawi

> "Active involvement of the community at all levels from research design, implementation, results dissemination to roll out" -Respondent 2, Uganda

> "Meaningful engagement of stakeholders from before the study and locations are chosen for funding; from the beginning of the writing of the protocol through the end of data collection; on into post trial studies and marketing" -Respondent 6, USA

> "Meaning Community engagement is a process of identifying community health and development priorities through input from the research community from the initial beginning to the exit phase of a research" -Respondent 16, Nigeria

A second major theme was the need to ensure community-wide information about the trial, research progress and the results of the clinical trial. Information about the trial should not be only provided to research participants. Furthermore, research recruitment process should also include all populations.

> "This entails informing people about the trial, enlisting some of the community members in the CAB. Creating opportunities for the community members to air their views on how the trials are being run and ensuring that there is no harm done to the community members by ensuring that all ethical standards are being followed." -Respondent 20 Malawi

> "It involves full disclosure to communities on the purpose of the trial and the procedures of the trial and consent from communities and sharing all relevant information." -Respondent 24 Kenya

> "It ensures that stakeholders are well informed with ongoing access to study information and that stakeholders outside of the clinical trial fraternity can easily comprehend." -Respondent 31 South Africa

> "My understanding is involving everyone and not leaving others behind. Most of these trials happen to the heterosexual community leaving key populations behind. If we include everyone we will have a better understanding." -Respondent 21 Zimbabwe

One other theme that emerged was that community engagement requires discussions be held with the community so that consensus can be reached on the standard of care, and treatment before protocol finalisation.

> "It is about engaging participants and communities in the design, planning as well as the implementation of the clinical trial. It is about giving the communities a chance to contribute towards decisions on how such trials should be conducted, including defining the standard of care that should be provided to trial participants. It is also about providing the communities with adequate information so that they are able to make an informed decision about their participation in the clinical trial. It is also about keeping the communities informed about the progress as well as the results about the trial" Respondent 18, Malawi

What are your considerations for meaningful and ethical stakeholder engagement?

Many respondents felt that the constitution and support for the operations of a community advisory board was a means of facilitating ethical stakeholder engagement.

> "Consultative meetings at all stages, having a CAB, update meetings at every stage." -Respondent 2 Uganda

> "Establishment of community forums like Community Advisory Boards, periodical events that inform and hear from communities' voices, views and understanding for consideration on matters that affect them" -Respondent 13, South Africa

> "Stakeholders consultations prior to the design of a clinical trial, broad representation of relevant stakeholders in the Community Advisory Board" -Respondent 18, Malawi

Others opined that holding community consultative meetings to develop strategies and policies for the research, to provide feedbacks and to disseminate information about the research were ways to ensure meaningful and ethical stakeholder engagement.

Consulting stakeholders, providing feedback, disseminating information -Respondent 8 USA

Ensuring that you fully and wholly engage the community, such as involving them in developing policies, strategies, and provision of friendly services– Respondent 16, Kenya

Stakeholders' consultations before the design of a clinical trial, broad representation of relevant stakeholders in the Community Advisory Board -Respondent 18 Malawi

Engagement in the planning implementation and evaluation of the research process -Respondent 22, Zimbabwe

Furthermore, participants identified the need for stakeholder engagement processes to facilitate research literacy and ensure the cultural sensitivity of the research process.

> "Increasing scientific literacy, building capacity for local understanding with attention to language and culture." -Respondent 4, USA

> "Advocacy, mobilization, taking into serious consideration social and cultural practices that are accustom to a community" -Respondent 10 Liberia

A number of respondents identified that adherence to the Good Participatory Guidance document was a way to ensure meaningful and ethical stakeholder engagement process.

> "The processes are outlined in the GPP documents which allow sufficiently for customization, adaptation, and implementation with and by those on the ground and at the front lines." -Respondent 6 USA

> "Community engagement ought to occur across the entire life of a clinical HIV trial not only community engagement which is patchy, and selective (Following of the GPP guidelines)" -Respondent 1 Malawi

Examples of good stakeholder engagement during clinical trials

Twenty-one (65.6%) of the 32 respondents cited a number of specific examples of good stakeholder engagement during clinical trials. These practices include holding discussions with different stakeholders, enabling community members to make inputs into the research protocol, ensuring broader community HIV research literacy beyond the immediate research site, establishing community advisory boards and research sites developing and implementing a stakeholder engagement plan.

> "Meeting with community leaders from the lowest level of society as they are the ones that are mainly recruited during clinical trials. Using the local vernacular and community social networks such as market associations, churches, and mosques to serve as advocates." -Respondent 10 Liberia

> "In the process of conducting meaningful engagement with the target community, the SMC ensured the principles of GPP were adhered to. In that engagement, the title of the research was changed to a name that the target community preferred. This consideration by the study protocol team was highly significant." -Respondent 9 Liberia

> "The metric for successful engagement is not recruitment but understanding of choice regarding trial participation-…… create videos, podcasts, edutainment events to increase understanding" -Respondent 4, USA

Examples of poor stakeholder engagement during clinical trials

Ten (31.3%) of the 32 respondents gave examples of poor community engagement citing reasons for this. These include non-meaningful community engagement, failure to consider the cultural context in research design and poor information dissemination.

> "Community consultations of a study was done in the [name of the province]. When we as the CAB learnt of this

study at the CAB meeting where they were presenting it, the researchers were already having a date for implementation in our community. So, the study was stopped by the CAB before it even started in our community. Another reason we did not agree for this study to be rolled out was for engaging us at implementation stage…" -Respondent 23 South Africa

Poor advocacy and ownership including imposing will on community -Respondent 26, Nigeria

"Failure to understand and consider cultural practices and religious beliefs." -Respondent 8 USA

"Absence of fully informing and involving the community members in the process would mean bad community engagement or using the participants and not being able to share with them the results in the end." -Respondent 19 Tanzania

"The [name of study]-we only heard that trials were made but we don't know who took part where and what was the [study] outcome." -Respondent 21 Zimbabwe

Stakeholders to facilitate meaningful and ethical community engagement in clinical trials

The list of stakeholders who could facilitate meaningful and ethical community engagement in clinical trials was extensive. These include advocates, research ethics boards, the Ministries of Health, community leaders, religious leaders, government agencies, non-governmental organisations, journalists, health-care professionals, project funders/sponsors and the project implementers. Those who may be impact by the research conduct and its findings may be the criteria for selection of targeted stakeholders for engagement. Respondents noted:

"At community level no one should be excluded-even where people are in opposition, the door should always be open for anyone to participate and be able to ask questions, and receive information inasmuch as it does not directly or indirectly harm trial participants" Respondent 31, South Africa

"Nearly everyone-the funders, the sponsors, the implementers, those in the community participating, those in the recruitment pool, those who have relationships with these people, the community, governmental, and cultural institutions who may be impacted by both the research itself and any possible findings." Respondent 6, USA

Role of HIV prevention research advocates

Twenty-eight (87.5%) respondents identified roles that HIV prevention research advocates can play in strengthening meaningful and ethical stakeholder engagement with HIV prevention clinical trials. These include identifying community priority research [1 participant], advocacy for ethical community engagement standards and post-trial access [6 participants], capacity building to empower community members to engage with researchers [5 participants] and community research literacy [10 participants]. Other roles include facilitating the active involvement of communities in the research protocol development [7 participants] and monitoring the community engagement process [4 participants].

"Their role is to help research communities identify priorities and develop skills in advocacy,…. and lastly help to create an environment where communities can interphase with implementers of research programs"– Respondent 15, Nigeria

"To mobilise community and educate and promote the current prevention toolbox as well as advocating for access should it be found to work or get licensed. Advocate for vulnerable groups as well as all community members who may benefit from it. Engage with all population groups to understand their issues and how HIV prevention can address their issues"– Respondent 7 RSA

"Empowering communities on their rights and advocacy on policy formulation for ethical practices and monitoring to ensure enforcement of policy." -Respondent 24 Kenya

"Community sensitization on key meaningful community engagement ethics. Basic norms and acceptable practices"– Respondent 29, Nigeria

"HIV prevention research advocates should be given opportunities to provide feedback on community engagement strategies within different countries-throughout planning, implementation and evaluation of community engagement strategies"– Respondent 31, RSA

"To partner with researchers and be part of various community formations and or consultations by researchers and strongly monitor the importance of community involvement and participation that is not tokenistic, but meaningful." -Respondent 13 South Africa

"Holding researchers to account to good participatory practices"– Respondent 18, Malawi

Participants also identified roles that advocacy organisations working in Africa can play. These include building the capacity of youths as advocates, coordinating researcher-community partnerships, capacity building of stakeholders to enable them to engage meaningfully with researchers, facilitating communications, advocacy for various purposes, including increasing funding for community engagement processes and monitoring stakeholder engagement processes.

Strengthening advocacy skills amongst Africans, especially young people and building platforms where researchers and advocates interact to get to a common understanding and common goals to improve ethical community engagement like the HIV cure research academy a good example (these are really important locally and regionally)." Respondent 19 Tanzania

"Coordinate the regional and country level efforts to strengthen the relationship of the researchers and

> Advocates (to deal with the "Them and us" syndrome)." Respondent 1 Malawi
>
> Providing a platform for different advocates to come together and share and exchange best practices as well as challenges from our different contexts. A site through which to push for specific practices as a regional collective– Respondent 31, RSA
>
> "Information sharing, Lobbying with regional Bodies or researchers on the need for meaningful community engagement in the clinical trials, advocating for increase resource allocation for research with an allocation for community engagement, this is usually not prioritized by researchers." -Respondent 18 Malawi

DISCUSSION

Our findings suggest that respondents conceptualised meaningful and ethical engagement of stakeholders in biomedical HIV prevention clinical trials as the engagement of a wide range of stakeholders during the lifecycle of the trial. They emphasised that engagement should commence before the submission of protocols to ethics committees. Participants framed the purpose of the stakeholder engagement as ensuring that community views and perspectives are taken into consideration in the planning and implementation of the trial. They also suggested that advocates can play an active role as research implementation partners by facilitating engagement with stakeholders working with other populations not directly targeted by the research. Participants also discussed the monitoring of the research, facilitating community research literacy and translation of research findings into policies and programs, and the need for this work to be planned and funded.

These results confirm that community engagement processes before, during and after a trial are needed, according to the reports of key stakeholders in eight African countries, together with US-based respondents. This finding is particularly important in light of the review by Day *et al*.[1] which showed that these processes were less likely to occur in low- and middle-income countries.

The perspectives reported by participants in this study aligned with the guidance provided by the Council for International Organizations of Medical Sciences (CIOMS). The CIOMs international ethical guidelines for health-related research involving human subjects, states that: *"Researchers, sponsors, health authorities and relevant institutions should engage potential participants and communities in a meaningful participatory process that involves them in an early and sustained manner in the design, development, implementation, design of the informed consent process and monitoring of research, and in the dissemination of its results"*.[5] The CIOMS ethics guidance document also identifies stages in the life-cycle of the research that stakeholders could engage with – *design, development, implementation, design of the informed consent process and monitoring of research, and in the dissemination of its results.* These engagements are expected to be early, sustained throughout the lifecycle of the research[5,6,15] and even beyond the life-cycle,[15] using an iterative[4] or participatory approach[5] (A framework for Community Based Participatory Action Research was developed by a group of organisations and published in 2011. Information about how participatory approach to research can be facilitated is accessible at https://hc-v6-static.s3.amazonaws.com/media/resources/tmp/cbpar.pdf). Our study finding further enriches the statements of the guidelines as research advocates not only agree on the need for these forms of engagement, but also identify the roles advocates and their organisations can play in instituting these meaningful engagement processes.

Our study highlights that community advocates can help empower communities to maximize the possible outcomes of research for the benefit of participants and their community. However, Day *et al*.'s[1] systematic review identified that the main reasons for engaging, stakeholders, including community advocates, in biomedical HIV prevention trials was to enhance trial participants' recruitment and enhance the trial process. This disparity in expectations can be a source of conflict, which can be resolved when researchers and advocates engage in dialogues about the research before protocol design. The approach to dialogues should include innovative bottom-up engagement strategies complimented by research-driven top-down methods such as interviews and focus group discussions.[1,31]

With regard to another key normative document, the GPP guidelines, research participants identified its guidance document as useful for stakeholder engagement. We the authors, however, identified that there is no instituted mechanism to facilitate adherence to the GPP. One possible mechanism may be for researchers to submit their stakeholder engagement plans-inclusive of a budget[5]-along with other research-related documents, to ethics committee for review and approval with ethics committee members trained to use the GPP as standards for assessing the plans. This will enhance the proposals for ethics review of stakeholder engagement processes in biomedical research[4,15] as prescribed by CIOMS.[5] Laypersons on ethics committees can be trained to develop competencies to review and give constructive feedback for the submitted plans. Past capacity building efforts for laypersons on ethics committees have demonstrated their ability to acquire skills to make meaningful contributions to research protocol review.[32] The ethics committees should however, safeguard the dynamic responsiveness of the stakeholder engagement processes by allowing for real time review of engagement processes ahead of request for protocol amendment.[28] This suggests that training programmes for ethics committee members on their roles and responsibilities, should include assessment and monitoring of stakeholder engagement.

The GPP does not explicitly discuss the role of advocates in the design and implementation of biomedical HIV prevention research, although it notes that a *collection of individuals who*

have a stake in a biomedical HIV prevention trial should be engaged. The UNAIDS guidelines[4] however, acknowledges that need to engage civil societies as community members: *"the concept [of community] needs to be broadened to civil society so as to include advocates, media, human rights organizations, national institutions and governments, as well as researchers and community representatives from the trial site" (p. 18*). Individuals rather than biomedical HIV prevention research advocacy organisations working in low and middle-income countries are often engaged with the design and implementation of biomedical HIV prevention research. Organisations bring on a lot more traction to work than individuals can.

There are a few organisations exclusively working on biomedical HIV prevention research advocacy in Africa– AfrNI, Association for the Prevention of HIV and AIDS, New HIV Vaccine and Microbicide Advocacy Society– and a few others that have integrated biomedical HIV prevention research advocacy into their organisational programs.[33] Sadly, funding to enable these organisations work in this space in Africa– a region that hosts the majority of the biomedical HIV prevention research on the continent– is extremely poor and hard to come by. While MacQueen and Auebach[31] noted that stakeholder engagement processes receive funding, these funding opportunities are least accessible by African-led organisations for work in Africa. Yet, when African-led organisations are actively engaged with research implemented on the continent, the prospect of addressing the structural contexts and proximal factors associated with the clinical trial research is stronger. Without due recognition of the role that these organisations can play, and appropriate funding for their active engagement with biomedical HIV prevention research in Africa, the gaps created will increase the potentials for exploitation.[31]

Study participants also identified that advocates should also conduct research monitoring activities. We authors suggest that a role advocates can play is that of external monitors of stakeholder engagement at research sites. These roles can augment the works of trial monitors who evaluates compliance with the Good Clinical Practice guidelines and the sponsors who conduct clinical trial site audits. There is currently no formal mechanism identified for monitoring of stakeholder engagements during clinical trial conduct. Biomedical HIV prevention research advocacy organisations may have their capacity built to play this role. Researchers can facilitate the monitoring role of community advocates by including monitoring and evaluation frameworks for their stakeholder engagement plans. The Comprehensive Post-Acute Stroke Services (COMPASS) Study described one of such systems.[2] These are, however, propositions that require further discussions and deliberations with not only community advocates but also researchers and research regulatory agencies.

Monitoring of meaningful and ethical stakeholder engagement and ethical conduct of research is an innate role of advocates whose key skill is to play the watchdog roles. There are multiple examples of community advocates *calling out* unethical practices in the biomedical HIV prevention clinical research[34] many of which had resulted in the change of practices, including the development of the GPP guidance document so often referred too in this study. The monitoring role of advocates serves as an external assessment mechanism to safeguard the rights and welfare of community members. Sadly, this role is not identified in any of the ethical guidance documents despite its essence.

One of the strengths of this study was that the study participants were recruited from platforms that provided constant updates and education on HIV prevention clinical trials; and through HIV prevention research networks. We, therefore, anticipated that many participants will be familiar with HIV prevention study contexts and so were likely to share informed perspectives. Majority of the respondents were from regions in Africa that hosts a majority of the biomedical HIV prevention research conducted on the continent (Eastern and Southern Africa). The use of open-ended questions for this survey also helped elicit a lot more information that we could otherwise have generated through a quantitative survey.

The use of a questionnaire rather than the conduct of an interview may have however limited the ability to explore a number of issues raised in the responses. The data we collected was therefore limited in its depth. The relatively small number of respondents has implications for the generalisation of the findings as representative of majority of community stakeholders working in Africa. Furthermore, the online survey only engaged community advocates that have access to the internet. Internet access still remains a challenge for many in Africa.[35] The views shared here may therefore be more representative of the "elite" advocates who are more privileged through easy access to updates and information that could shape their perspectives. The study, therefore, may not represent the perspectives of community advocates with limited access to the information, whose views may differ somewhat from those of "elite" advocates.

Despite these limitations, the study was able to document the opinions of community members on "why" and "how" they can be involved with biomedical HIV prevention research design and implementation.[36-38] There is limited documentation of the perspectives of community members on their perceived role in the design and implementation of biomedical HIV prevention research. The GPP was an early attempt to guide researchers on how to conduct stakeholder engagement for biomedical HIV prevention research. Participants in this study highlighted that GPP comprehensively addresses the scope of what community advocates perceive as meaningful and ethical stakeholder engagement when conducting biomedical HIV prevention clinical trials-research question development, protocol development and research results' dissemination. Respondents, however, felt that beyond this, stakeholder engagement in research should include other roles like

monitoring and results translation to policies and programs, which community advocates can implement.

CONCLUSION

The GPP guidelines provide clarity about how stakeholder engagement can be meaningful and ethical. However, the guidelines do not identify the role of advocates in the monitoring of HIV prevention clinical trial conduct and translation of research to policies and programs. It also did not define the roles community advocates' organisations can play in facilitating the conduct of biomedical HIV prevention clinical trials. This increases the risk of organisations focused on biomedical HIV prevention research advocacy, being left out of meaningful and ethical stakeholders' engagement with biomedical HIV prevention research on the continent. While this study identified that community advocates perceive that organised advocacy organisations in Africa can play more roles by being engaged with biomedical HIV prevention research planning and conduct in Africa, another study is required to identify strategic approaches to enable advocacy organisations play those roles they identified they could play.

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Conflicts of interest

There are no conflicts of interest.

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