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Original Research Article

Is it fear or politics? A qualitative exploration of stakeholders' views on the failed Ebola vaccine trial in Southern Ghana

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ABSTRACT

Background: The negative meaning and rumours associated with the conduct of clinical trials regarding their experimental nature adversely affect trust and their conduct. A typical example of the challenges in conducting clinical trial studies was where Ghana was selected to conduct the ebola vaccine trials, which was not successful. This study explored the social and political perspectives on the unsuccessful implementation of the ebola vaccine trial in Ghana.
Methods: This was a cross-sectional exploratory study using qualitative research approach where 31 in-depth individual interviews and Key informant interviews were conducted with participants. The interviews were recorded, transcribed and coded into themes using Nvivo 12 software to aid thematic content analysis.
Results: The views expressed by participants suggested that lack of stakeholder engagement to create awareness on the Ebola vaccine trial led to doubts on the purpose for the trial. Also, media propaganda, negative influence and the perception that conducting the vaccine trial in Ghana could introduce the Ebola virus into the country created panic and fear, which affected public trust and support for the Ebola vaccine trial conduct in Ghana. Furthermore, political influence linked with site selection and timing for the study in particular, led to mistrust and the subsequent suspension of the trial in Ghana.
Conclusions: Based on the interpretation of our data, we conclude that the indefinite suspension of the Ebola vaccine trial in Ghana could largely be attributed to both fear and political influence as well as misinformation resulting from media propaganda leading to mistrust.

Keywords: Fear or politics, Stakeholders' views, Ebola vaccine trial, Southern Ghana

INTRODUCTION

Clinical trials play important roles in epidemic response and control.[1] Globally, 186 523 interventional registered clinical trials are reported to have been conducted between 2004 and 2013.[2] These clinical trials involve the use of human participants as volunteers.[3] A report by the World Health Organization (WHO) shows that clinical trials

research is shifting from high-income countries to middle and low-income countries.[4] During the last decade, the number of clinical trials conducted in sub-Saharan Africa has increased significantly.[5,6]

Increasingly, public health oriented clinical trials are conducted to address questions relevant to the health of the concerned population and very often, trial studies are conducted to ensure safety and effectiveness of new medicines before they are deployed for public use.[6,7] Further, it is demonstrated that the conduct of clinical trials has contributed significantly to improving healthcare services.[8] These include the introduction of additional critically-needed health personnel, and provision of laboratory facilities, which would otherwise not have been available in rural communities**,** thus contributing to improving healthcare delivery.[9,10] Additionally, previous studies have reported that the conduct of clinical trial studies offered the opportunity for community members to have access to prompt and proper medical attention, quality medicines and free treatment to improve health outcomes.[11,12]

Despite the potential benefits that could be derived from the conduct of clinical trials especially in sub-Saharan Africa, there are equally some challenges affecting clinical trials conduct[8]. For instance, lack of dedicated administrative staff, financial bottle necks, compensation issues and poor informed consent procedures have been reported as challenges affecting the conduct of clinical trial in low-income settings such as Ghana.[8,13] Again, evidence exists that there is lack of trust in the conduct of clinical trial studies.[14] The negative meaning and rumours associated with the conduct of clinical trial regarding their "experimental" nature adversely affect full involvement of community members in their conduct.[15] A typical example of the challenges in conducting clinical trial studies was the Ebola virus disease (EVD) outbreak in West Africa, where Ghana was selected to conduct EVD vaccine trial in the Volta Region, which was not successful.[16-18] The question however is whether this was as a result of public fear or political influence? Therefore, this study examined the social and political perspectives on the failed Ebola vaccine trial in Ghana. This could serve as scientific evidence on factors that led to the suspension of the trial, which could be used to guide the conduct of future clinical trials in Ghana and beyond.

METHODS

Theoretical foundations of the study

Kasperson's social amplification of risks framework was adopted and used to explain the issue of trust in terms of how information is transmitted and interpreted by various actors to influence trust in this case, the conduct of clinical trials. Trust is viewed as self-assured positive expectations concerning another person's conduct whereas distrust is having negative expectations about somebody's conduct.[19,20] Kasperson's risk framework explains the extent to which a particular risk event merges with psychological, social and cultural procedures to lessen feelings of risk.[21] The framework points out factors that influence risk perception and how risk events are interpreted and communicated by social actors in ways that may increase or decrease public reactions and trust to the risk event. The theory explains that amplification happens at two levels: in the transfer of information about the risk, and in the response mechanisms of society. These socially built risk messages are consequently interpreted and acted on by individuals based on their personal views and attitudes.[21] Social amplification of risk theory was used in this work because it provides the framework to analyse individual, community and geopolitical level actors pertaining to trust in clinical trials and how messages about trial studies are interpreted and communicated.

Study design

The study used qualitative research approach where in-depth interviews (IDIs) and Key informant interviews (KIIs) were conducted with participants between August and September, 2020. Qualitative research approach helps in capturing feelings, experiences and perceptions of individuals on the issue under investigation.[22] Therefore, this research method was deemed suitable in this study because the study aimed at gaining deeper understanding on the controversies and factors that contributed to the unsuccessful conduct of the Ebola vaccine trial in Ghana.

Study site

This was a multi sited-study conducted in the republic of Ghana. Specifically, interviews were conducted with stakeholders in the Kassena-Nankana East Municipality (Navrongo) in the Upper East Region, Kintampo in the Bono East Region, Hohoe in the Volta Region and Accra in the Greater Accra region of Ghana. The Kassena-Nankana East municipality (KNEM) is located in the Northern part of Ghana. The justification for selecting KNEM was that the Municipality falls under the research activities and catchment area of Navrongo health research centre (NHRC), which was established in 1989 to conduct high quality health research to inform policy. NHRC operates an institutional review board (IRB), which was established as an independent representative body to review, evaluate and decide on the ethical merits of NHRC research protocols and research proposals from other institutions. Clinical trial scientists working at NHRC and IRB members were selected and interviewed. Hohoe Municipality is located in the Southern part of Ghana and shares borders with the Republic of Togo to the east. The failed Ebola vaccine trial in Ghana was planned to be conducted in the Municipality. Thus, the area was selected to explore views of community members who were either consulted and/ or engaged about the failed Ebola vaccine trial.

The Greater Accra Region is the administrative capital of the republic of Ghana where most stakeholders, including

the members of parliament (MPs) live and work. Therefore, the Region was selected as one of the sites where some MPs, clinical trial scientists, regulators and monitors were selected and interviewed. Some of the interviews with clinical trial scientists were also conducted at the Kintampo Health Research Centre (KHRC) located in the Bono East Region of Ghana.

Study population

The study population comprised clinical trial scientists and monitors, clinical trial regulators (ethics committee members and Ghana food and drug Authority members), members of parliamentary and adult community members and opinion leaders. Clinical trial scientists who have led clinical trial studies in the three health research centres under the Health Research and Development Division of the Ghana Health Services (i.e. the Navrongo Health Research Centre, Kintampo Health Research Centre and Dodowa Health Research Centre) as well as clinical trial monitors were included in the study to share their views about factors that contributed to the unsuccessful conduct of the Ebola vaccine trial in Ghana. Clinical trial regulatory bodies such as the Ghana Health Service Ethics Review Committee and Ghana food and drug authority members (FDA) were also included in the study. These bodies are mandated to regulate the conduct of clinical trials (i.e review and approve clinical trial protocols for their conduct) in Ghana. They were included in this study to share their views on the reasons for the unsuccessful conduct of the Ebola vaccine trial in Ghana. Another category of participants in the study comprised members of parliamentary select committee on health. Ghana's parliament is the legislative arm of government and its mandate include promulgation of laws in addition to other oversight responsibilities. The parliamentary select committee on health was either directly or indirectly involved in the controversy around the Ebola vaccine trial that was to be conducted in Ghana. Therefore, MPs serving in the health committee of parliament were selected into the study because of their involvement in the failed Ebola vaccine trial in Ghana. In the Hohoe municipality, both male and female community members and opinion leaders (i.e. chiefs, elders and group leaders) were also included in the study to share their opinions on the failed Ebola vaccine trail that was planned to be conducted in the area.

Sampling techniques

Purposive sampling method was used to select participants in this study. Purposive sampling is where a researcher selects study participants who can provide appropriate information to help address the research questions or objectives.[23,24]

Selection of participants

Community members and opinion leaders: First, two communities (one community 5km within Central Hohoe and the other one 5kms away from Central Hohoe) were selected using purposive sampling method. The study team visited the selected communities and with the support of sub-chiefs and elders in the two communities, list of some community members and opinion leaders was obtained after the purpose of the study was explained to them. Using the list, these people were contacted by the study team and those who agreed to participate in the study were interviewed.

Clinical trial scientists, monitors and regulators: Various steps were followed to select clinical trial scientists, monitors and clinical trial regulators. First, official letters were written to the heads of the three-health research centers and the two clinical trial regulatory bodies to introduce the study to them. When permission was obtained, the study team visited these institutions and with the support of the heads, a list of members was obtained. Using the list, the study team contacted these individuals and those who were available and willing to participate in the study were included.

Members of parliament: Similarly, a letter was written to the Chairman of the health committee of parliament for permission to recruit some committee members into the study. Permission was received from the chairman, who further directed the Clerk of the health committee to make available the list of MPs serving in that committee to the lead investigator. These individuals were visited by the study team led by the lead authors and those who were available and willing to take part were interviewed.

Data collection techniques

The interviews were conducted by two trained graduate research assistants with previous experience in conducting qualitative interviews. The KIIs were conducted with clinical trial scientists, monitors and regulators while the IDIs were conducted with community members, opinion leaders and MPs. Appointments were booked with participants before the interviews were conducted. The interviews lasted between 35-50 minutes. English was used to conduct interviews with clinical trial scientists, monitors, regulators and MPs while the local language was used to conducted the interviews with community members and opinion leaders. With consent from participants, all the interviews were audio-recorded using digital voice recorders. A total of 31 interviews (i.e. 17 IDIs and 14 KIIs) were conducted with participants.

Data management and analysis techniques

The recorded interviews were transcribed verbatim after repeatedly listening to them. To ensure that qualitative principles of transcribing interviews were applied, two people with experience in qualitative research were also engaged to transcribe the recorded interviews. A codebook containing the main and sub-themes was developed. The transcripts were then prepared and imported into QSR Nvivo 12 software to facilitate data coding and analysis. Thematic content analysis was used to analyse the data.

The process of thematic content analysis means reading through textual data, identifying themes, coding the themes and then interpreting the content of the themes.[25] The transcripts were prepared and labelled based on variables such as age and category of participant. This method did help the authors to compare views on the issues across the different category of participants. The results were presented as narrative and supported by relevant quotes from the data.

RESULTS

The main themes discussed include inadequate stakeholder engagement, media propaganda, political influence, site selection and timing for the Ebola vaccine trial in Ghana. Table 1 contains summary of the main themes and key findings.

Inadequate stakeholder engagement

Views expressed by participants suggested that lack of stakeholder engagement to create awareness affected the conduct of the Ebola vaccine trial in Ghana. Participants perceived that ignorance played key role in influencing perceptions and trust of people regarding the conduct of the trial. They were of the view that stakeholders had doubts about the Ebola vaccine trials because they were not adequately informed to understand the rationale and design of the trial, which led to mistrust and lack of support for the study. Chiefs and community members were not educated about the trial and so, there did not trust the researchers (IDI-community member-Hohoe-04). The Ebola vaccine trial, there were so many hullabaloo (meaning so much noise) and people who were even educated did not understand what the study was all about. When it happens like that, everyone will interpret things the way they understand them and that could lead to mistrust and that was exactly what happened with the Ebola vaccine trial in Ghana (KII-ethics committee member-03).

Media propaganda and negative influence

Media propaganda was also reported as a key factor that affected public and stakeholders trust leading to the disagreement and indefinite suspension of the Ebola vaccine trial in Ghana. Most participants perceived that misinformation given to the general public by the media created panic and fear, which led to mistrust about the trial in the country. Views expressed by trial scientists and regulators suggested that people in Ghana had so much trust for media information and whatever the media said about the Ebola vaccine trial was taken seriously by the public. The media put fear on everybody because the way the media communicated the information scared a lot of people and that made it difficult for them to trust the vaccine trial (KII-clinical trial regulator-01). The media will start by saying that researchers are hiding information, they say this vaccine will do this and that, it is not true. The little thing that the media picks up and say, people turn to believe the media. So, once the media says do not take part, researchers are going to kill you, then people will believe them and that was what happened (KII-clinical trial scientist-02).

According to some community members, it was alleged that conducting the Ebola vaccine trial in Ghana could introduce the Ebola virus into the country and that created fear among the general public especially communities where the trial was planned to be conducted. As one community member expressed it: The chiefs and elders did not allow the Ebola trial to be conducted in the area because of the rumours that were going on. Some people were saying that the disease have not gotten to Ghana and so, why do researchers want to conduct the trial? So, the chiefs refused because they said that could actually bring the Ebola virus into the community (IDI-community member-Hohoe-04). According to the MPs, some individuals had the perception that clinical trial scientists involved in the Ebola vaccine trial in Ghana collected huge sums of money to use people as guinea pigs. This perception negatively affected trust and the conduct of the Ebola vaccine trial in Ghana as demonstrated in the conversation below with one of the MPs:

Question: What do you think contributed to the failed Ebola vaccine trial in Ghana? Reply: Our society has now become commercialized and people who opposed the Ebola trial were going round saying that the people (referring to sponsors of the Ebola vaccine trial) had brought plenty money and given to researchers who now want other people to be guinea picks (IDI-MP-03). Similarly, a conversation with one of the clinical trial monitors demonstrates how low trust resulted from panic affected the conduct of the Ebola vaccine trial in Ghana. Question: What would you say was the reason why stakeholders spoke against the conduct of the Ebola vaccine trial in Ghana? Reply: When people hear about Ebola, then their blood pressure starts going up including the stakeholders who spoke against the trial. So, it was largely fear resulting from misinformation that affected the conduct of the trial in Ghana. (KII-clinical trial monitor-05)

Political influence

Participants believed that political influence affected trust and the conduct of the trial in Ghana. Clinical trial scientists and regulators in particular perceived that it was the political contest or fight that drew in the other factors, which led to distrust and the indefinite suspension of the trial. It was more political because everything in Ghana is a bit polarized by politics. The politicians were saying that researchers are bringing this trial to my area so, what will happen? This influence by politicians led to distrust by community members (KII-clinical trial regulator-04). I think that the ebola vaccine trial was politically motivated. It was basically the political fight that drew in the other factors, which led to distrust (KII-clinical trial scientist-02). Some of the clinical trial scientists described the

agitations that led to the indefinite suspension of the trial in Ghana as intellectual dishonesty and mischief. According to them, the situation was not good for the country in future clinical trials conduct. As one of them expressed it. It was intellectual mischief and dishonesty on the part of those who were against the Ebola vaccine study and this is not the best for the country going forward (KII-clinical trial scientist-01).

Table 1: Summary of themes and key findings.

Theme	Key findings	Quotes
Inadequate stakeholder engagement	lack of stakeholder engagement to create awareness affected the conduct of the ebola vaccine trial in Ghana	Chiefs and community members were not educated about the trial and so, there did not trust the researchers (IDI-community member-Hohoe-04).
Media propaganda and negative influence	Misinformation given to the general public by the media created panic and fear, which led to mistrust about the ebola vaccine trials in Ghana. It was alleged that conducting the ebola vaccine trial in Ghana could introduce the ebola virus into the country, which created fear among community members	The media put fear on everybody because the way the media communicated the information scared a lot of people and that affected their trust on the ebola vaccine trial. (KII-clinical trial regulator-01). The chiefs and elders did not allow the ebola trial to be conducted in the area because they said that could bring the ebola virus into the community (IDI-community member-Hohoe-04).
Political influence	Participants believed that political influence affected trust and the conduct of the ebola vaccine trial in Ghana	I think that the ebola vaccine trial was politically motivated. It was basically the political fight that drew in the other factors, which led to distrust (KII-clinical trial scientist-02).
Site selection	Participants perceived that stakeholder from the site where the trial was to be conducted raised concerns about why the area was chosen for the study.	When the researchers wanted to conduct the Ebola vaccine study, they chose Hohoe in the Volta region and some people from the area were asking questions, why Volta Region was chosen for the study (IDI-MP-05).

Views articulated by community members and opinion leaders confirmed that political influence played a significant role in the failed Ebola vaccine trial in Ghana. They held that initially, community members did not have any problem about the trial, but the way some politicians especially those from the planned study area spoke about the trial, put fear in everybody, which affected community trust. The whole thing took a political dimension and you know, our MPs got involved. Some of the MPs came here (referring to Hohoe) to speak against the Ebola trial. I know our MP for instance was against it. She came down to Hohoe and was speaking against it, advocating against the conduct of the trial (IDI-opinion leader-Hohoe-07). The views expressed by clinical trial scientists, monitors, regulators and community members on how political influence affected trust in the conduct of the Ebola vaccine trial corroborated with opinions shared by some of the MPs when they were questioned. Question: Some participants interviewed earlier said that political influence affected the conduct of the Ebola vaccine trial in Ghana. Do you share the same view? Reply: Politics, why not? There is nothing that politics does not affect. For instance, there may be a good trial but people will bring politics to it and say let me label this good trial with bad name. Politicians will say researchers want to kill you, they do not like you, why is the study taking place here and not in other communities? When this happens, it could affect trust and I am sure that was what happened with the Ebola vaccine trial (IDI-MP-04).

Site selection and timing for the trial

Closely related to political influence, some of the MPs particularly mentioned site selection as one key factor that contributed to the unsuccessful conduct of the Ebola vaccine trial in Ghana. They maintained that stakeholders from the site where the trial was to be conducted raised concerns about why the area was chosen for the study to be conducted. Sometimes, researchers' choice of community could be a problem. I remember very well that when researchers wanted to do the Ebola vaccine study, they chose Hohoe in the Volta region and some people from the area were asking questions on why Volta Region was chosen for the study? So, the site selection contributed to the trust issues (IDI-MP-05). On the contrary, the clinical trial scientists, monitors and clinical trial regulators said site selected was not a problem. They perceived that the Ebola vaccine trial was not going to be conducted in Hohoe alone as was widely speculated. According to them, other communities in Ghana were also going to be included. These participants maintained that in conducting a clinical trial, a site needed to be selected to facilitate the conduct of the trial. Therefore, they believed that the site was not a problem that affected the conduct of the trial in Ghana. It was not only Hohoe that the trial was going to be conducted. Kintampo and Navrongo were going to be involved. I don't think the site selection affected the conduct of the trial (KII-clinical trials monitor-06). Closely related to site selection, some MPs and community members whom we interviewed

maintained that the timing for the conduct of the trials was not appropriate. They held that there was so much education on how dangerous the Ebola virus disease was, how people were dying in other countries resulting from the disease, and yet that was the time researchers wanted to conduct research to test a vaccine. They said the outbreak of the disease had put so much fear in people and this made stakeholders to raise concerns about why researchers were eager to conduct the vaccine trial in the country at that time. The trial was going to be conducted at a time people were educated negatively about Ebola and some people even thought that when they see Ebola patient, they will die. So, the time the researchers wanted to conduct that trial was not appropriate in my view (IDI-MP-02). The only problem was that researchers were trying to do the trial during the Ebola outbreak and the outbreak scared a lot of people. That is why the researchers were not able to gain trust of stakeholders (IDI-opinion leader-Hohoe-03).

DISCUSSION

This study explored views on the social and political debates that contributed to the unsuccessful implementation of the Ebola vaccine trial in southern Ghana. Study participants perceived that inadequate stakeholder engagement to provide appropriate information about the Ebola vaccine trial affected its conduct. This is largely so because people did not understand the rationale and purpose for the study and that could be the reason for the unsuccessful conduct of the trial in Ghana. These misconceptions, erroneous as they may be, contributed to widespread public mistrust and lack of support for the Ebola vaccine trial that was approved by relevant ethics and regulatory institutions in Ghana. Evidence exists that lack of information resulting from inadequate stakeholder engagement affected trust in the conduct of clinical trials.[26,17] More importantly, media propaganda, negative influence and misinformation about the Ebola vaccine trials caused fear and doubts in the minds of people. Views expressed by some participants suggested that people trust information coming from the media compared with what scientists could tell them. This supports Kasperson's social amplification of risks framework explains how risk events are interpreted and communicated by social actors, which could negatively influence public reactions and trust on public health interventions including the conduct of clinical trials.[21] No doubt, negative influence coupled with media propaganda were highly reported in this study as reasons that affected the conduct of the Ebola vaccine trial in Ghana. It is demonstrated in previous studies that the negative meaning and misinformation regarding risks associated with clinical trials seriously affected trust in clinical trials conduct.[7,27]

Political factor was also highly discussed in the current study that affected trust in clinical trials conduct. Opinions expressed by most participants across the different categories in this study showed that political influence led to the indefinite suspension of the Ebola vaccine trial in Ghana. A good number of participants indicated that there was no problem in communities where the study was planned to be conducted. The suspension was largely due to the campaign against the Ebola vaccine trial by some politicians especially MPs from the area where the planned study was to be conducted. Like in many low-income countries in Africa, politics has been perceived to affect every activity including health interventions and research. Therefore, clinical trials that pose real or existential threats to the public (and voters in the eyes of politicians) will likely attract the attention of pollical actors as was the case in the botched Ebola vaccine trial in Ghana. Although, political factor has not been reported in the literature to have a direct effect on biomedical research, evidence exists that political unrest in a country could jeopardize clinical trial research environment and that may discourage funders from sponsoring biomedical studies in such places.[28] Related to political influence, site selection was mentioned by some participants as one of the factors that negatively affected the implementation of the Ebola vaccine trial in Ghana. Key criteria for site selection to conduct clinical trials include investigator's experience in conducting clinical trials; high level of interest and commitment of investigator; investigator's track record, position and experience in conducting clinical trials; investigator's position (i.e. being a key opinion leader at the site); access to relevant patient population and timely recruitment as well as availability of equipment and facilities.[29] It is possible that study participants had no idea on the procedures used in selecting sites to conduct clinical trial studies. This could be the reason why some study participants maintained that the site selected for the Ebola vaccine trial in Ghana affected trust and its conduct. For instance, one of the criteria for selecting trial site is investigator's position and leadership role at the trial site. The lead investigator for the failed Ebola vaccine trial at the time was the head of a public University located in Hohoe, the proposed site for the trial. It was therefore prudent for the study to be conducted in the area to ensure close monitoring of study subjects and also to reduce traveling cost of key study personnel if the trial was going to be conducted elsewhere in the country. Though, site selection has been found in this study as one factor affecting trust and clinical trials conduct, study participants might not have an idea on the processes involve in sites selection for clinical trial studies. The mere fact that the Ebola virus was being described as very dangerous and the perception that conducting the trial was going to introduce the virus into the country made stakeholders especially those from the selected site to speak against its implementation.

Limitations

The study has the following limitations. The major limitation is that since the study used purposive sampling, a non-probability sampling method and also a small sample size, the views expressed by study participants are their personal opinions and may not necessarily represent

the views of the larger population. Another limitation is that some of the interviews with community members were conducted in the local language (Ewe), tape recorded, transcribed and translated into English. It is possible that the meaning of some statements made in the local language may have been lost in the English translation. However, the interviews were transcribed by people who were native speakers with experience in transcribing qualitative interviews. Any loss of meaning during the translation was thus minimized and therefore did not affect the findings of the study.

CONCLUSION

Based on the interpretation of our data, the indefinite suspension of the Ebola vaccine trial in in Ghana could largely be attributed to both fear and political influence as well as misinformation resulting from media propaganda. All these could be as a result of inadequate stakeholder engagement to create awareness about the trial in Ghana. The need for clinical trials to be successfully designed and conducted especially in low-income settings where the burden of new and emerging diseases especially infectious diseases is often high; is simply a pressing issue. Experiences from the 2014 Ebola outbreaks in West Africa and the current COVID-19 pandemic, there is need for concerted efforts to design and implement suitable clinical trial studies especially in sub-Sahara African with potential to addressing disease outbreaks. Therefore, providing information about the need for clinical trials studies to key stakeholders such as political and religious leaders, civil society organizations and key community members where the proposed clinical trial will be conducted, could help address community and stakeholders' concerns thus improving trust and their support in clinical trials conduct.

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