

A Qualitative Study on Experiences of HIV Vaccine Trial Participants in a Phase I/II Double Blinded, Randomized Placebo Controlled Clinical Trial in Tanzania: Lessons for COVID-19 Vaccine Testing

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Abstract

Background: HIV remains a major public health problem in Sub-Saharan Africa. More than half (54.5%) of all people living with HIV live in Eastern and Southern Africa where 700,000 new infections were reported in 2019. There is no HIV vaccine or cure available yet despite ongoing research to develop one. Uptake of vaccines, when these become available, is critical for its successful introduction in the global society. It is imperative to describe the knowledge, expectations, perceptions and experiences of the vaccines trial participants, as these may be indicative of future vaccine uptake, and may give lessons for COVID-19 vaccine development.

Methods: A phenomenological qualitative study was conducted to describe the experiences of volunteers who participated in the first HIV vaccine trial in Mbeya, Tanzania. A purposive sample of 20 of the 60 trial participants was interviewed. Interviews were audio-recorded, transcribed, translated, and subjected to thematic-content analysis.

Results: The study showed that trial participation was driven by positive expectations related to health and the realization of the need for an effective vaccine to combat HIV. However fear, concerns and worries about the safety of the trial vaccine were the frequently reported challenges to participation. Not only participants but also the significant others and community play an important role in the trial participation.

Conclusions: The success of a trial depends on direct and indirect participation in trials. Future trials, COVID-19 vaccine trials included, must promote positive expectations for trial participation and address fears and concerns related to vaccine safety.

Background

HIV pandemic and vaccine development

Since the start of the HIV epidemic, 75.7 million people have succumbed to the disease globally and in 2019 alone 690 000 lives were lost to HIV(1). As of 2019 38.0 million people were living with HIV including 1.7 million who were infected in that year alone (2). More than half (54.5%) of all people living with HIV (PLHIV) live in Eastern and Southern Africa where 700,000 new infections were reported in 2019. In Tanzania, there are an estimated 1.6 million PLHIV representing an adult prevalence rate of 4.6%; with 72,000 new infections and 24,000 AIDS-related deaths in 2018(3).

This suggests that the world now needs a vaccine more than ever to avoid further loss of lives since vaccines offer primary prevention to the population and offer the most cost-effective mechanism to tackle infectious diseases(4). While on average it takes at 10.7 years to develop a vaccine from preclinical phase to market registration, it is now decades before a vaccine is found for HIV pandemic (4). Previous trials such as one conducted in Thailand which found 31.2% efficacy brought with them promises for an effective vaccine although more work is still needed (5). While there are challenges in finding a vaccine, research has documented social implications and willingness to participate in HIV vaccine trials including knowledge about vaccine, hesitance, fear of side effects, perceived risks and benefits of participation, was social factors have often been mentioned as key socio-challenges in the development of vaccines(6–8).

Participants join vaccine trials both for altruistic and non-altruistic motives while safety, fear of being vaccinated with a live and actual HIV vaccine and time costs have been reported as barriers and concerns for participating in early HIV vaccine trials in Africa(9–11). Ongoing and new studies need to consider addressing these and other challenges in vaccine development efforts.

HIV vaccine development lessons for COVID-19 trials

As at 29 July 2020, there were 16,558,289 confirmed cases of corona virus and 656,093 confirmed deaths from COVID-19 in the world since January 2020 when the first cases of corona virus were confirmed outside of China (12). In Tanzania, the first confirmed case from COVID-19 was in March 2020(11). Scholars have linked the COVID-19 pandemic to the HIV pandemic in several ways including its devastating effects, high death rates, global nature and spread of the disease plus the lack of a vaccine or cure (13, 14). Therefore the lessons learnt from HIV vaccine development may be crucial in the development of a COVID-19 vaccine. Emerging knowledge of the association between HIV and COVID-19 also warrants not ignoring the other when one is analyzed (15, 16). As with the willingness to participate in HIV vaccine trials, close to two-thirds of research participants expressed willingness to participate in COVID-19 vaccine trials. Similarly, concerns in COVID-19 vaccine trials have been cited as individual safety, infection, and family members' concerns (17). As of 20 April 2020 there were five COVID-19 vaccine trials at the clinical stage and 71 trials at exploratory or preclinical evaluation stage (18). As in the development of H1N1 influenza, Ebola, Zika, and now SARS-CoV-2, the scientific community is required to urgently develop a COVID-19 vaccine (19) to stop the high morbidity and mortality. However, the COVID-19 vaccine development urgency must derive benefits from the history of HIV vaccine trial ethics including maintaining the public's trust and participation. As such knowledge of participants, expectations, views and experiences are important in COVID-19 as it has been in HIV vaccine development.

The case of Tanzania's HIV vaccine development

In 2005 the Tanzanian Ministry of Health and Social Welfare established and designated the National Institute for Medical Research- Mbeya Centre, formally known as the Mbeya Medical Research Programme (MMRP) to conduct HIV vaccine trials in Tanzania. Although the site had experience in conducting other clinical studies since 1996, it recognized enormous challenges in recruitment, enrolment and retention of HIV vaccine trial participants. One of the studies showed about 50% of the potential eligible volunteers expressed willingness to participate in HIV vaccine trials raising the need to conduct an exploratory sub-study to understand the experiences and challenges encountered by the study participants at the clinic and in the community (8). We adopted an ecological framework to explore the possible factors influencing participants' expectations, views and experiences at the individual, family, health system and community levels. We believe that these expectations and experiences may be helpful in finding a vaccine for a similarly infectious disease, COVID-19. The study aims to explore and describe the expectations or motivation for participating in the HIV vaccine trial, to understand the experiences and challenges encountered by respondents during participation in the HIV trial and discuss their relevance for COVID-19 vaccine development.

Methods

Study setting

The study was conducted in Mbeya region which has a population of 2,707,410 (National Bureau Statistics, 2013), and 16.6% HIV prevalence and an incidence of 7% in females and 5% in males at the time of the vaccine launch (20).

The Vaccine Trial

The first vaccine trial conducted by the Mbeya Medical Research Centre was "A phase I/II double-blinded, randomized placebo-controlled clinical trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine (VRC-HIVDNA016-00-VP) boosted by a multiclade HIV-1 recombinant adenovirus-5 vector vaccine (VRC-HIVADV014-00-VP) in HIV uninfected adult volunteers in East Africa" (RV 172 Protocol, 2004). This was part of a multicenter trial with other centers in Kenya and Uganda. The trial was sponsored by the U.S. Military HIV Research Program (USMHRP) and it started in July 2006 and completed in 2008. The data collection for this study was conducted between February and August 2009, the participants were still followed up for safety and immunogenicity.

The recruitment of participants for the vaccine trial involved inviting surrounding communities to the research centre to attend information seminars. The seminars briefed potential participants about the aim and objectives of the study, duration and eligibility criteria. Interested volunteers were registered to attend further briefing sessions where detailed information about the study including the number of visits, number of vaccinations, blood draw, HIV counseling and testing and medical examination were given. The trial involved inoculation of the candidate vaccine (Investigational product) into the participants and subsequent following up and monitoring of participants for immunogenic changes.

Study design and sampling

This was a descriptive qualitative sub-study of the HIV vaccine trial. The sub-study was underpinned by a phenomenological approach to describe the experiences of volunteers who participated in an HIV vaccine trial at Mbeya Medical Research Centre in their natural setting. This method was crucial to understanding participants' opinions, feelings and experiences as well as making sense of and interpreting the meaning of these experiences from the point of view of people exposed to the phenomenon (21) in this case the trial procedures. Purposive sampling was used to select 20 of the 60 trial participants. Respondents in this study were both male and female aged between 19 and 49 years. The selection, which used the study enrolment register and followed up reports, considered a mix of participants' demographic characteristics such as age, gender, education level, marital status and location within Mbeya town and participant participation levels.

Data collection

The first author conducted in-depth interviews (IDIs) with study participants using an unstructured interview guideline. The guide focused on the lived experiences of the respondents as participants in the trial. All interviews were conducted in private and quiet rooms. The interviews were conducted in Swahili, Tanzania's national language and were audio-recorded with the permission of the participants. Data were transcribed verbatim and then translated back from Swahili into English. The transcribed and translated interview data were subjected to cleaning and accuracy confirmation before analysis. This involved an independent transcriber randomly selecting and examining three transcripts and finally comparing with the original script to identify and edit any deviations.

Data analysis

Data were analyzed using thematic content analysis. The analysis of data started with ordering data into codes. We had pre-selected themes, but these were refined and new ones emerged as data showed different twists. The researchers discussed these to confirm alignment or divergence(22). Through an iterative constant comparison approach (23, 24), the researchers analyzed the data and resolved any disagreements by mutually agreeing. Voluntary informed written consent was obtained from each participant before any interviews were conducted.

Ethical Considerations

The study received ethics clearance from the Mbeya Regional Medical Research Ethics Committee (MMREC), Reference number MRH/E.10/10/2 and the permission to conduct the study was obtained from the local authorities at Mbeya Medical Research Centre. All study procedures were performed in accordance with the relevant guidelines and regulations in human subject research.

Results

Six themes related to expectation and experiences in HIV vaccine trial participation were found and these were categorized into the following sub-headings: 1) Expectation and motivation to participate; 2) Public health benefits to participants; 3) Safety of the vaccine; 4) Experiences with clinical procedures; 5) Experiences in the family and community; 6) Challenges to participation. We present each theme below. Table 1 shows the demographic characteristics

of the participants. Of the 20 participants 11 were males 12 were married, five were adolescents, 11 participants were between 25 and 45 years and only 5 participants had tertiary education

Table 1
Demographic profiles of the participants:

Characteristics variables	No of participants	Percentage
Gender	11	55%
Male	9	45%
Female		
Marital status	12	60%
Married	8	40%
Single		
Age	5	25%
Below 25 years	11	55%
Between 25–45 years	4	20%
Above 45 years		
Distance from the clinic	11	55%
Within 3 km	9	45%
More than 3 km		
Education level	1	5%
None or below Primary school	10	50%
Primary school level	5	25%
Secondary school	4	20%
College/other institution level		
Occupation	10	50%
Petty business	3	15%
Students	4	20%
Employed	3	15%
House wives		

Expectation and motivation

Some of the respondents, who believed they were at risk of acquiring HIV, believed they would be protected from HIV infection. This is despite that they were not aware if they were receiving a true vaccine or a placebo. A 25-year-old single female's assertion illustrates that: "I believe the vaccine must have some protective effect" and a 24 years old male college student who said, "...if we were allowed to choose I wanted to get the real vaccine... I know it will add some immunity in the body...". This illustrates that participants may have joined the study with the hope that if they were in the vaccine arm, they would be treated for HIV.

Public health benefits to participants

Participants' participation was driven by positive expectations related to health such as the need to conduct HIV testing. The study offered free HIV testing and through this, participants had an opportunity to know their HIV status. Related to this was that participants were motivated by receiving free medical care which was provided as part of the benefits of participating in the study. A 45-year-old married woman who did not have health insurance asserted; "My biggest motivation was free medical health care..."

Respondents appreciated the safety measures taken, the follow-up and health care services provided by the research team when the participants fell sick. For instance, a 49-year-old married father of three who lived on a shoe shining business had some serious health problems for which the study team provided the necessary medical care that he appreciated. He said:

If I were not a participant in [the] research centre I would have been dead by now, because with that sickness (seizures due to an infection in the brain), I would not have that amount of money needed to go to Dar-es-Salaam for treatment, but with the support of [the] research centre, look at me as you can see, I am healthy and feeling good again.

A 45-year married man explained "...the care we are getting here is not available in the public hospitals... so I see it as a big advantage for my being in the study".

Some participants joined the study with a motive to be part of the world's efforts in finding an effective vaccine for HIV which they viewed as beneficial to the future generation. "...I thought if the vaccine will be successful it will benefit me and if not me then my children or grandchildren". [Female, 45 years]. Another participant said "HIV is a difficult disease other prevention methods have failed... people are still acquiring the disease... if we get the vaccine it will be the solution to stop spread of HIV" [Male 44 years, street leader].

Safety of the vaccine

Despite the positive motivations described above, most participants had concerns about the safety of the vaccine that was being tested. Participants believed that all vaccines contained some formations of the virus or bacteria in question that would potentially infect them. A 44-year-old married men who was a street leader in one of the areas in town remarked,

"We used to know that vaccines are made from the bacteria or the virus responsible for the disease intended to be prevented... so we thought the same applies to [the] HIV vaccine...but the doctors explain[ed] everything".

This concern was raised by many participants in the consultation meetings to the extent that the trial management officers saw a need to clarify which they did. The same safety concern was echoed by a 33-year-old businessman,

"... Initially, I was worried about the safety of the vaccine... what if it harms me or I real[ly] get sick! ...But the seminar was good, it answered most of the questions I was asking myself".

Most respondents did not experience any serious side effects from the vaccination, apart from mild headache and pain at the site of injection, for example, a 40-year-old female petty trader remarked;

"...I did not feel anything apart from mild pain at the site of injection". A 42-year-old housewife stated that "...It was nothing seriousI had a headacheit lasted for like four hours... that was all".

Participants had different perceptions regarding vaccine-induced positivity (the false positive); many did not have problems with this situation while a few were concerned. A 31-year-old female secretary explained, "...I did understand well the seminar so I thought it was just fine, so long as it is not a real infection" Others felt that there was something hidden behind this positivity, for example, a 24-year-old young man said; False positive mmh! ... you never know...honestly, I was

worried ...three months after the vaccination I went to a VCT centre to test my blood, just to check if I will test positive or not”.

Experiences with clinical procedures

The time spent at the clinic to complete all procedures in a visit was described as “too long”, especially in the initial visits when participants had to consent to participate in the trial, go through medical examination and the counseling procedures. Normally participants would take about 6–8 hours to complete all procedures on the first day. A 45-year-old man raised the following complaint;

...waiting time was too long in some of the visits, like in one visit I remember coming at 08:00... and I left the clinic at 15:30...

Participants felt that the amount of time the trial was taking unfairly competed with their work demands as a working male remarked, “...this is not convenient for someone who is employed”. Although some felt it was okay as one young man, a laborer observed: “...Initially, appointments were like too long...though not to the level of inconveniencing my duties, but I knew it was for good intention”.

For participants who lived close to the clinic and were self-employed people who could structure their work activities alongside trial visits, there was no concern with time. A 33-year-old entrepreneur/business owner remarked... “It was fine with me... I just live behind the clinic and am not so busy in most of the mornings”.

A few participants expressed concerns with the amount of blood drawn for laboratory tests. A 34-year-old woman vending food expressed “... The blood taken is too much ...what if someone has low levels of blood! (The blood drawn per visit was about 140-150mls); these concerns from participants illustrate participants’ challenges with the clinical aspects of the procedures that required clear explanations. Many participants addressed their fears and concerns by using information they recalled from the information sessions.

Experiences in the family and community

Participants reported having difficult times with their spouses, families and friends as there was a stigma attached to participating in the trial. There were concerns about the trial being conducted in African countries. Participants’ significant others questioned why the trial was being conducted in Africa with some comparing participants with sacrificed guinea pigs.

A 23-year-old single lady reported that:

Friends and neighbors said we are being injected with HIV, we will soon fall sick, we are very stupid to involve ourselves in something very risky, why are the whites (the people coordinating the trial) not conducting this trial in their own countries! They are coming to Africa to kill us...”

The white race of the trial researchers was raised despite that black African investigators including the first author were directly involved in the research.

In some couples where one participated whilst the other partner did not, it lead them into serious problems in their marriages. A married 38-year-old male participant who was a vendor explained that;

My wife and I had a serious quarrel about my participation in this trial, especially after hearing the rumors concerning the vaccine; she would not allow me to touch her because she thought I am already infected by the virus from the vaccine... The PI explained to us and together we went through the informed consent form.... she understood and things went back to normal. But I tell you it was very tough at home... (laughter).

Challenges to participation

One of the challenges reported was the timing, coming in the morning hours for scheduled procedures was challenging for people who were employed and students. Although they were able to adjust their schedule, for example, a 24 years old college student reported:

...my appointments were mostly on Monday or Tuesday, these days we are busy at the college... so I would come late to the clinic... or choose to miss some sessions...

Participants mentioned that it was challenging to participate and remain in the study to the end, due to the rumors and misconceptions in the community about the vaccine.

“We were so much insulted by our neighbors...they said to us... You are even told not to become pregnant...but you are still blind ... actually, it needed one to be strong to stay in the study to the end”. [Female 27 years]

Some respondents pointed out that they did not care much about what other people thought or said, as long as their spouses supported them in participating in the trial. A 28-year-old man, a taxi driver explained:

“My wife and relatives had no problems because they know and trust me that, I would not put myself in danger ... that was all that mattered to me; other people were just talking... I just ignored them”.

Discussion

The study explored the expectations and experiences of HIV vaccine trial participants. Six themes emerged around positive and negative trial expectations, negative community interpretation of the trial, trial public health benefits to participants, safety issue and the impact of clinical procedures on participants' routine lives. We interpret the findings in terms of the ongoing HIV vaccine development and draw lessons for COVID-19 vaccine trial development. The findings help in understanding participants as vital contributors to vaccine development. We believe that the success of any vaccine trials hinges on the feedback of participation from participants without which results would be difficult to interpret.

We found that the success of a trial depends on direct and indirect participation in trials. That not only participants but also the significant others played a part in the trial participation requires more thought in view of the COVID-19 that the world is faced with. This demonstrates that the success of any vaccine trial is not solely on the drug but on a holistic consideration of participants including those who do not complete the trial, community members as well as the collaborators.

We learnt in our vaccine trial and other similar trials before (25–27) that it is important to understand that COVID-19 vaccine trial development has multiple players who are either direct and indirect and help to make the trial a success or a failure if not handled appropriately. Direct players include participants themselves while indirect players include spouses, family, community, dropped participants, organizers - local and international collaborators. COVID-19 vaccine trial investigators can learn from real and expected collaborative engagements from our study which participants and communities imagined and ideally imposed onto the trial.

We found participant and community misconceptions and myths about the vaccine trial such as that participants were infected with a live virus and others on false positivity. These were magnified by the participant's concerns on the safety of the vaccine on trial. Participants' and community's beliefs, concern and fear of being inoculated with a live HIV virus and the concern that the trial was sacrificing Africans as guinea pigs is not a new fear. Other studies reported the same concerns before (26, 27).

The fear that participants will be injected with a live vaccine should be debated in the context of human challenge studies which scientists including at the WHO consider as not outside the tools that should be deployed in the search for a vaccine for COVID-19 (28). Should such studies be implemented, detailed information sessions should be considered to enable ethically acceptable methods of conducting the studies. In this case, the launch of vaccine trials for COVID-19 has not been without the same challenges including hesitancy and fear of the unknown if one gets vaccinated(6).

Demystifying myths through a program of education is required to ensure participants and their communities are properly educated on trials (11) A lesson for current and future studies is that trust in the governments and research authorities are needed to dispel community and participant fears. Building communities of trust is crucial for the success of vaccine trials. As the world gears up for a vaccine for COVID-19 lessons learnt in the search for an HIV vaccine trial are hugely important today.

Those participants referred to investigators as foreigners to them suggest that trials' investigators must have a shared identity with participants. Previous studies in South Africa also reported on challenges of mistrust as a result of a racial identity that was not shared between participants and investigators (25) resulting in the black participants thinking that they may have been at risk of vaccine-induced infection into the participant of the other racial identity by another of the racial and foreign identity. This again is similarly shared in vaccine trials in South Africa (25). Continuous education of the community would go a long way clearing the misconceptions and avoiding such misconceptions from wrongly influencing participants. For example, vaccine trials for COVID-19 which some two French doctors suggested must be tested in Africa (www.bbc.com/news/world-africa-52192184) were actually conducted first in China and the developed world before any was launched in Africa (29). This was followed by an educational announcement by the WHO Director-General in setting the record straight that vaccine development would not be any racial but would follow established ethical protocols.

The researchers are urged to build communities of practice and meaningful collaborations with local settings and communities for proper information dissemination and for meaningful involvement of local people in trials. Examples of meaningful involvement include setting up community management and information dissemination teams in the communities where participants are recruited. This helps to bring communities to plan and contribute to the trial. Robust engagement with the study community and participants is required for COVID-19 vaccine trials. However, Shah et al encourages context-specific public engagement to minimize contact while maintaining social distancing regulations which can be through virtual platforms in well-resourced settings (30) or must be made available in resource limited settings. In addition, selecting sites must avoid mere convenience or vulnerability but to maximize trust between participants and investigators.

We also learnt that participants join the study for exterior motives such as to benefit humanity or in the words of the participants, to be part of the world's efforts to fight the HIV epidemic and protect future generations. A similar study in Kenya found that one-fifth of their participants were motivated by the need to find a vaccine for future generations (31). It is commendable that participants join trials for the benefit of others and not themselves. The ravaging effects of the HIV infection in the research community ignited participation out of altruistic. Likewise, the shocking death toll, excruciating pain with which COVID-19 brought may easily help to motivate participants to participate in the trial where they do not know if the vaccine will be safe to them or not. Such altruistic behavior is commendable and must be supported.

The COVID-19 will successfully rely on the commitment of participants to this important goal of benefitting humanity and not necessarily themselves. The public health benefits that were brought with the trial, such as free HIV testing and health insurance were not much cited by participants as motivations but benefits which came the way of participants. We cited the case of a healthy participant who accidentally fell ill and all his hospitalization and excellent care and bills were taken care of by the trial resources. Other studies in Tanzania have similarly reported participants being so grateful for medical insurance as a key benefit (Tarimo et al., 2019). This may be because of lack of health insurance among people in resource-limited countries and communities.

In the United States people of lower socioeconomic groups including those from Hispanic origin were more likely to volunteer to obtain better access to resources that they did not have (33). As a result, study investigators must ensure that such participants from low-income groups who volunteer are properly protected and understand the study aim, procedures and possible harm. Participants for COVID-19 vaccine trials may also have similar considerations of threats and benefits that they need to weigh in the trial. Providing best available health insurance to participants during the COVID-19 trials should be a priority during the COVID-19 pandemic even at a time when the health system is overwhelmed by challenges including laboratory, human resources, hospital bed shortages that are commonly reported in many countries affected by COVID-19.

The organization of the vaccine trials around community settings and the selection and monitoring of volunteers require careful analysis of participants and the needs of the trial. In our study, the timing of visits to the clinic (morning hours and weekdays) brought some inconvenience to participants like students, employees and other participants with competing for daily schedules. A similar challenge has been reported in the previous phase I/II trials in which as many as 29 clinic visits interfered with normal lives of participants (34). We recommend addressing such challenges beforehand in the best possible ways to avoid them influencing the safety and effectiveness of the candidate vaccine. Where possible, introducing some form of flexibility to participants such as weekend attendance for participants who cannot attend due to competing economic activities is crucial.

In this study, it becomes evident that more and detailed information or clarifications about the trial procedures and outcomes are needed during the educational and information seminars to deal with volunteers' worries and concerns on vaccine safety. This underlines the importance of improving the package of information to the volunteers, for example, information on the nature of the candidate vaccine to assure the volunteers that they will not get infection due to participation in the trial and also the vaccine-induced positivity due to antibodies from the vaccine. Information is power, if participants are empowered with the correct information, they withstand unnecessary misinformation, myths and misconceptions from community members and also help educate them including to accept trial procedures in future studies.

The study has its limitations. Firstly, the study was conducted three years post participation in the trial and the participant's stories may have been subject to recall bias. Participants may have only concentrated on what they remembered most, leaving other stories which may have been important to the researchers. However, participant responses during the survey did not show any signs of recall challenges. Secondly, the opinions and experiences gathered with regards to the rumors and misconception about the trial in the community were only collected from the people who participated in the study. The study should have also interviewed community members to triangulate information with that obtained from participants for a more understanding of issues related to participation in vaccine trials. Despite these, we believe that we obtained a balanced view of the expectations and experiences of participation in the study. We also believe that these expectations and experiences are crucial for COVID-19 vaccine trial development.

Conclusion

The study contributes to the understanding of HIV vaccine trial participants' experiences and challenges encountered during participation in the trial. Areas of concerns were identified and these need to be addressed by the research teams such as the provision of adequate information about HIV vaccine trial and also capacitating the communities with basic information about HIV vaccine trials. The information gathered is crucial in designing and implementing HIV and COVID-19 vaccine trial development. We recommend vaccine trial investigators to proactively address possible rumors and misconceptions, through a continuous education program to the communities where a vaccine trial takes place. Additionally, the use of media like television and radio programs for community education may be tested to help with information dissemination. The findings of this study are crucial to prepare for future HIV and COVID-19 vaccine trials.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Mbeya Regional Medical Research Ethics Committee (MMREC) on 13th July 2009 REF: MRH/E.10/10/2 and written informed consent for participation in the study was obtained from all study participants before any study procedure.

Consent for publication

Not Applicable.

Availability of data

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Competing interest

The authors have declared that no competing interests exist.

Authors' contributions

ES and SS. Wrote the main manuscript text; L.M and B.V Reviewed and commented on the manuscript; All authors read and approved the final manuscript

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