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Pregnant and breastfeeding women concerns during a group B Streptococcus phase ll clinical trial: A qualitative study in Kampala, Uganda

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ABSTRACT

Despite evidence that maternal vaccines can contribute to reduction of neonatal infections, vaccine hesitancy is a challenge in many low- and middle-income countries like Uganda.

We conducted in-depth interviews with pregnant women and focus group discussions with breastfeeding women who were part of a Group B Streptococcus (GBS) clinical trial. We explored the women's concerns about vaccination and their reasons for being hesitant to take vaccines before they joined the trial. Women aged 18–39 were randomly selected from follow-up lists during the study period. Data were analysed thematically.

All the women had been hesitant about joining the trial because of fear of possible vaccine side effects. A lack of knowledge on maternal vaccines, rumours and stigma in the community as well the need to follow study procedures were other concerns. Several women were concerned about their male partner view of their trial participation because using a trial vaccine meant taking a decision on behalf of the foetus.

Pregnant women's involvement in clinical trials of maternal immunisation requires engagement with their families and community stakeholders, including local leaders and health workers, to ensure people understand what maternal vaccines are and why trials with pregnant women are required.

1. Introduction

According to the 2021 WHO country report for Uganda, 60.5 % of infant deaths are caused by neonatal conditions [1,2]. Maternal vaccines given to pregnant women can reduce infections such as pertussis, tetanus and influenza in infants during their early months of life. Pregnant women are able to build up antibodies which are passed on to the infants providing some protection from diseases [3]. The introduction of vaccines for Group B *Streptococcus* (GBS) is a significant step in addressing neonatal mortality in low and middle income countries [4]. GBS has been reported as the main cause of neonatal sepsis and meningitis and is a leading cause of mortality and morbidity among infants.

Low uptake of maternal and childhood vaccines is linked to limited maternal knowledge [5]. Hesitancy to vaccines in general became more pronounced during the COVID-19 pandemic [6,7], including among pregnant women among whom uptake was slow [8]. Two recent reviews highlight the need to understand maternal vaccine hesitancy and develop context-specific policies to improve uptake [9,10]. The enablers to maternal vaccine uptake by pregnant women in rural and urban settings include social demographic characteristics such as literacy levels which support reading materials, vaccine knowledge by mothers, trust for health workers, male involvement and community perceptions and beliefs towards maternal vaccines [11,12].

To learn what the reasons for hesitancy about new vaccines for pregnant women we explored the concerns of women taking part in a GBS vaccine clinical trial in Kampala.

2. Methods

This cross-sectional, exploratory qualitative study was nested within an ongoing maternal vaccine clinical trial (CTA 0212) led by Makerere University and Johns Hopkins University (MU-JHU) in Kampala,

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Uganda. The clinical trial was a phase II study of a multivalent vaccine against the Group B streptococcus (GBS) capular polysaccharide (CPS) in pregnant HIV-infected and uninfected women. For the trial, women were enrolled from two main health facilities, Kawempe national referral hospital and Kisenyi health centre IV located in the Centre of Kampala city. The study protocol is available at Clinical trials.gov link.

2.1. Study population

We conducted 13 in-depth interviews with pregnant women and 3 focus group discussions with 23 women who took part in the trial, one of the Focus group discussions with 6 participants was held with pregnant women, 17 were women who were breastfeeding. The study was conducted at Kawempe National Referral Hospital, which serves women nationwide and nearby Kampala communities.

2.2. Theoretical background to the sampling

The socio ecological model of health [13] was used to structure our analysis for this paper. The model depicts layered structures that may influence an individual's decision.

The model portrays the relational influences on an individual. At the centre of the model is the individual woman, she is embedded in her family, around them are the community and wider society. A woman is influenced by her family members, as well as community views and societal beliefs which may also have an impact on the decisions of close family members. Importantly, the individual at the centre of the model is not alone - she is carrying a child which the family will feel responsibility for. In addition, she must follow systems that deliver services, there are decisions to make at this level too.

2.3. Recruitment

Pregnant women were recruited from the hospital after administrative permission. The social science team purposively sampled the pregnant and breast-feeding women in different age brackets (18–24 years, 25–32 years, 33–39 years) from the lists provided by the data management team from the Makerere University and John Hopkins University Research collaboration (MU-JHU) GBS trial. Eligible women were approached following contact from the clinic research team and those interested were then contacted by the social scientists by telephone and were informed about the study and requested to come to the hospital for detailed information during their follow up visits at the antenatal clinic. Breast-feeding women returning for a post-natal visit with their babies were also contacted. In-depth interviews (IDI) and focus group discussions (FGD) were scheduled after the clinical procedures for the participants.

2.4. Data collection

Data collection commenced in October 2022 and ended in February 2023. The IDIs were conducted to explore individual real-life experiences. The FGDs were conducted to explore the individual and community experiences and attitudes towards maternal vaccines. The women who took part in the IDIs did not take part in the FGDs.

In addition to written consent to take part in the study, individual verbal permission to audio record the IDI and FGD was requested before conducting the interview and FGDs. The interview guides for the IDI and FGD topic guide included topics on antenatal visit experiences, knowledge of vaccines in general and the specific vaccine in the trial, barriers and facilitators for taking part in the clinical trial among other topics. The IDI lasted between 30 and 60 min and were conducted in Luganda or English (depending on the participant's preference). The FGDs lasted between 60 and 90 min and were all in Luganda. The IDIs were conducted by two female social scientists. The FGDs were conducted by three female social scientists with one as an observer. The IDIs with individual pregnant women were conducted in a private space at the hospital. The FGDs were conducted within the hospital in large office spaces provided by the hospital administration.

2.5. Data management and analysis

Once a participant was interviewed and after an FGD had been conducted, the recording was uploaded onto an encrypted computer. The two social scientists who collected the data did the transcribing and translation. Luganda transcripts were translated and transcribed by the same social scientist into English. The two social scientists transcribed each other's interviews. This was helpful in generating questions to ask each other about the findings, check reliability and improve interviewing skills throughout data collection. The first author listened to a sample of audio-recordings throughout the study to follow up and discuss probes and emerging findings with the interviewers during weekly debriefing sessions.

All the transcripts were anonymized. Identification numbers were assigned to every transcript, and these were securely saved on the Medical Research Council /Uganda Virus Research Institute and London School of Hygiene and Tropical Medicine Uganda Research Unit (MRC/UVRI &LSHTM) server in Entebbe.

Thematic data analysis was employed for this study [14]. The team started with familiarizing themselves with the data by going through several transcripts each. The team then discussed the first five transcripts to come up with the initial code book, which was based on the interview guide themes as well as new themes from the data. The codes were then tested by reading additional transcripts until no new codes were being generated. The final code book was compiled after discussion among the team. This was used to code all the data.

Data were exported to NVivo 12 data analysis software to support the analysis process. The themes identified included: perceptions about vaccines in general, perceptions of the vaccine used in the overarching clinical trial, experiences at the antenatal clinic, decision making, barriers/concerns and facilitators to enrol in a maternal clinical trial and discussion of the elements of the consent process. In this paper we report on the concerns before and while taking part in a clinical trial.

2.6. Ethical considerations

The team sought permission from the administration of Kawempe national referral hospital to conduct this research at the hospital. The study was approved by the Makerere University School of Medicine Research and Ethics Committee Mak-SOMREC-2022-331, approved by the national regulatory body-Uganda National Council for Science and Technology (SS1278ES-UNCST) and the London School of Hygiene and Tropical Medicine ethics committee (28257-LSHTM).

After mobilizing the study participants, the research team provided detailed information in English or Luganda, the local language, depending on the language preferred by the participant. Participants were given an opportunity to ask questions about the planned study. All the participants gave their individual informed consent by giving written consent. If a participant was not able to read and write, the researchers involved a peer attending at the clinic on the same day, or male partner if he had escorted his wife to the clinic and could read and write. The partner or peer were part of the information sharing session and the peer or partner signed as a witness after the volunteering participant had given a thumb print.

The quotations are assigned identifiers, FGD or IDI indicate mode of data collection. For each FGD we provide the age group of participants.

3. Results

A total of 36 women took part in this study. 13 took part in In-depth interviews and the rest took part in the focus group discussions. The women who took part in this study were aged between 18 and 39 years,

sixteen (44 %) were aged below 30 years, nine (25 %) were aged between 25 and 29 years, and eleven (31 %) were aged between 30 and 39 years.

A table to show the breakdown is attached.

Age	IDI participants ($N = 13$)	FGD participants (N−23)
18–24 years	8	8
25–29 years	3	6
30–39 years	2	9

We did not get any refusals in this study, we recruited a few pregnant women who were not taking part in the trial but were receiving antenatal services from the same facility, to find out about their perspectives on maternal vaccines, their results are not presented in the results of this paper. Their perspectives even though hypothetical were not different from the women who took part in the trial, they would join a trial if they understood the reason for the trial.

There were no major differences around perspectives about vaccines in pregnancy and trial participation between the women who were pregnant and the women who were breastfeeding who took part in the qualitative study. All the women had been enrolled in the trial while pregnant, the difference in this qualitative study is that we interviewed the pregnant women who were in the trial and the breast-feeding women who had returned for a follow up visit of the trial. However, the breast-feeding women during the Focus Group Discussions would sometimes refer to themselves and the health of their babies while referring to vaccine experience, whereas pregnant women reported mainly about themselves.

All the women reported several factors which motivated them to take part in a maternal vaccine clinical trial ranging from an anticipation of disease prevention to the benefit of receiving special attention and a transport reimbursement once they joined. These are summarised in Table 1. (See Fig. 1).

The barriers included the influence of their immediate social network, including their family. There were several other areas of concern, which are summarised in Fig. 2.

In the Figure 2 we have shown different layers that influence decision making which range from what an individual believes, what the close family and close networks believe as social norms, next is how the community context may influence decisions and finally the barriers that may be experienced due to the institution processes. In the following section we share the barriers following these layers of the socio ecological model.

3.1. Concerns about participating in trials

The women who took part in the clinical trial, reported concerns and reasons for initial hesitancy to join the clinical trial and some concerns that they had during the trial. The concerns included fear of side effects because they took a vaccine for themselves and their babies, uncertainties about long term effects facilitated by peer reports and rumours, anxiety around a new vaccine, study procedures that involve follow up visits at their home which may lead to stigma in the community and the anxiety around blood draws for the pregnant women and the infants.

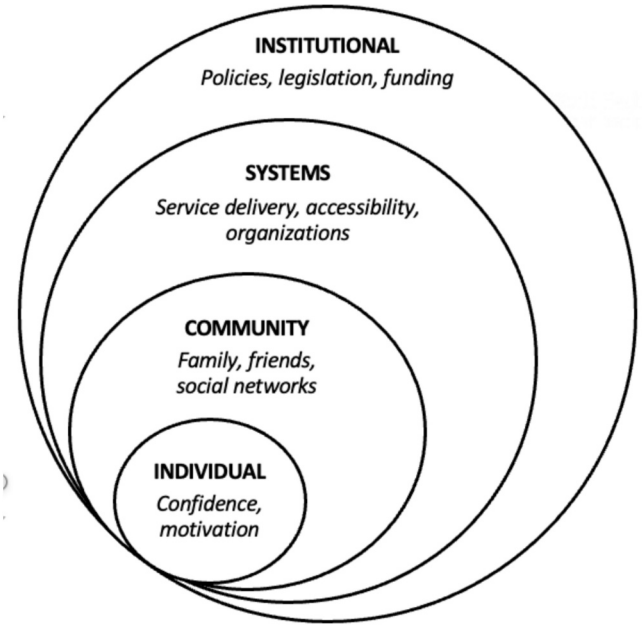

Fig. 1. The layers of the socio-ecological model.

Pregnant women reported that even after listening to the study information shared by the health workers including the benefits of the vaccine, they had concerns and fears about the trial vaccine. The main worry was the safety of the vaccine, and the possible side effects and their accountability to the family as the mother of an unborn baby reported that.

> *I made the decision to join the trial after understanding what the study was about and after asking my partner for permission to join. This is because I needed to be sure that I am not making a mistake, I have carried this pregnancy for nine months and then I take the vaccine and my baby gets a problem, what would I do? (*IDI, Preg 32 years).

Another mother said;

> *The only worry I had about this trial was getting a miscarriage after getting the vaccine. I was worried about the problems I would get (*IDI, Preg 22 years*).*

Another said:

> *Fear, honestly fear is there, because we are not so sure about the vaccines, for a moment I thought about the old people in the villages who have never taken their children for vaccination but they are healthy and just using local herbs, honestly with this medicine you are not so sure because you're not 100 % convinced about the safety*.(IDI, Preg, 22 years).

Table 1
shows common motivating factors reported by the women.

Motivating factors
Protection from Diseases
I joined the study because I believed the vaccine would protect me and my child from GBS infection (FGD-CONS-002-(30–35 years)
Health workers' approach
*The way the health worker talks to you is the one that inspires you to join the study. The things they give us aren't the ones that motivate us to join the study because they are mandatory requirements for a pregnant woman. (*FGD-25-29 years*)*
Support and influence from important people in their lives
*I didn't know what my husband would say, so I sat him down and explained to him everything, why I have decided to take part in the study and when he saw that it was going to be helpful for both me and the baby, he told me to join." (*IDI, Preg 24 years*)*
No payment required for the vaccine
*Joining a clinical trial is free of charge and the benefits of the trial. (*FGD, 25–29 years*)*

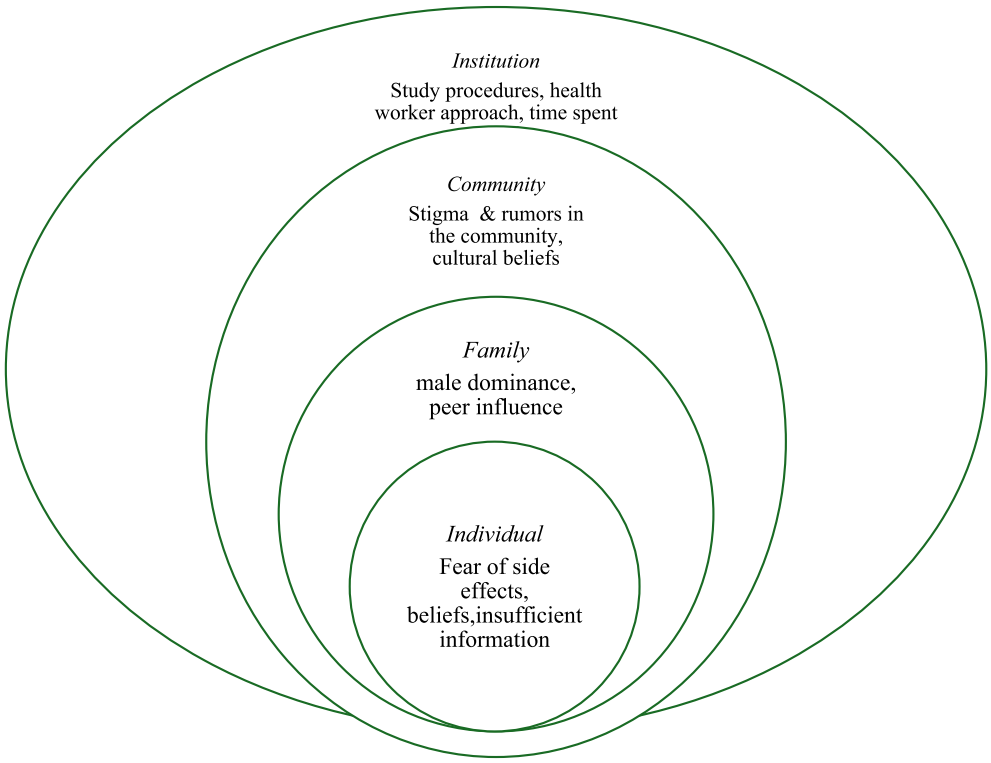

Fig. 2. Shows the summarised concerns.

The same concerns were expressed during the focus group discussions with the breasting feeding mothers.

> *We fear joining research studies especially clinical trials, because we are anxious about the safety of the vaccines, we think; first of all the vaccine is new it is not yet fully tested and proven, what if the vaccine is not right (False), what if they vaccinate us and we die for nothing, that's what scares most of us especially when the vaccine is new* (FGD- breastfeeding mothers (30–35 years).

Insufficient information about maternal vaccines was reported as another reason for hesitancy to taking part in maternal clinical trials. A first-time pregnant woman said;

> *As I told you this is my first pregnancy, I have never given birth, there is nothing that I know, so the HealthCare Workers are source of information and knowledge and when I come here, the healthcare workers must give me information.* (IDI, Preg 20 years).

Some pregnant women reported that they use herbal remedies as a preventive measure against infections, and one participant in a FGD mentioned that they did not see a reason to go for a vaccine. This belief could influence immunisation uptake in this group.

> *For us we use the local herbs they work for us, personally I trust that medicine because I see its effect in my life, if am to compare the two, I think I trust local herbals compared to conventional medicine because, am sure that my baby is safe.* (FGD- (30–35 years).

Pregnant women reported that their partners who are usually the household heads and who make financial decisions, influenced the decision that they made to take part in the clinical trial.

> *Some pregnant women are willing but it's their partners who stop them from participating, because like I told you, me I can't agree if my partner refuses me.* (IDI, Preg 25 years).

Peer talk while at the antenatal clinic, was reported as common and may influence decisions about joining clinical trials for some women,

> *"When we come for antenatal, I hear pregnant women talk about the use of herbal medicines, they were talking about witchcraft related practices, yes, basically illiterate related conversations, but they rely on them to give birth to healthy children."* (IDI, Preg 27 years).

The cultural belief in most cultures in Uganda that a child does not belong to one person and therefore a mother should not take the sole decision to join a clinical trial and should not offer consent without the partner's knowledge was a barrier for some pregnant women to join a clinical trial.

> *Me when I came and they gave me information about the study, I made a personal decision to join but also asked the doctor to allow me to go home and speak to my husband about it before I signed the papers, I explained to my husband, and he allowed me to take part in the study* (FGD 25–29 years*)*.

Pregnant women reported rumours that were spread within their communities about giving vaccines to mothers and these were usually a source of concern before joining a clinical trial. Rumours were mainly around women giving birth to a child with a deformity. Some of these concerns came through conversations with peers at the clinic that led to fear. A woman who was at the clinic during the recruitment process shared that: "*my child was vaccinated, and she got this defect, so don't try that vaccine". That kind of statement instils fear*.' (IDI). This had instilled fear about joining vaccine clinical trials while pregnant.

There were other concerns that relate to access to the facility and the frequency of visits once enrolled in the study. Some pregnant women mentioned that the distance to the facility had financial and practical implications on them, they find difficulty in the many movements they must make to attend follow up visits, yet they are pregnant.

There was a concern about the study procedures of sample draws that women and their infants needed to participate in. One woman shared her feelings and concern towards sample collection:

This is my last clinical trial. I have severe anxiety about blood draws—they trigger panic attacks. The frequent blood samples and rectal swabs are too distressing. (IDI, Preg, 23 years).

There was concern about baby blood draw, one mother mentioned this during a focus group discussion.

*After two weeks they tell us to bring the baby and they take off a blood sample from their little hand, that really hurt me and I thought to myself 'why do they take off all that blood from such a little baby', (*FGD 30–35 years*).*

Some women reported their concern about the frequency and extended time periods spent at the clinic which disrupt their daily routines.

*For me the only challenge I have is the continuous movements I have to make when am coming to the clinic for study visits, at this stage a pregnant woman needs to rest but, in this trial, they tell you to come to the hospital all the time." (*IDI, Preg 32 years*).*

Another woman expressed the discomfort with long stay at the clinic in this way.

Women usually reach the facility at around 7 am or 8 am but the health workers reach at 9 am or 10 am. When they reach the facility, they then go to take tea and people end up waiting for so long. By the time they start working on people, they start giving excuses again for going for lunch. So, women end up waiting for them like they are stupid. (IDI, Preg 22 years*).*

There is currently increased access to media for information including health information on vaccines. A pregnant woman reported that she watches media quite a lot and this had led to concerns when she heard of study recruiting pregnant women for maternal vaccination.

*Honestly, I think I watch very many movies, now I was thinking and remembering how people are given vaccines in the movies, and they give birth to aliens, I think it was just my childish mentality that made me think so negatively about these vaccines. (*IDI, Preg, 23 years*).*

Some women reported concern that health workers do not create a respectful relationship before introducing the information about the research. One woman in a FGD said:

When a health worker approaches the women, they should not start telling them about the research, that's what some health workers do but let them, first create rapport with the women, then tell them about the benefits of the research. (FGD- 30-35 years).

In another FGD women shared their perspectives.

"The health workers are usually busy since the people are so many" (FGD Preg 24–29 years).

"When you reach the facility, they make you seat at the waiting area and then after start giving out numbers. After giving out the numbers, they start being busy and so rude to people. (FGD Preg 24–29 years).

Some women do not want to be visited at their homes and yet it is usually mentioned as one way they can be followed during the study duration. During a focus group discussion, it was reported that.

Some pregnant women did not consider joining research because the health workers sometimes used to come at our homes for some visits say for visit 4 and 6, so some women didn't want to be visited at their homes for different reasons, and that could discourage them from joining the research (FGD- 30-35 years).

4. Discussion

The findings reveal multiple concerns driving hesitancy towards maternal vaccine trials, which may also affect participant retention. Factors like access to knowledge about maternal vaccination can be positive if correct information is shared to alleviate fears but can also have a negative effect when the woman gets information from the wrong sources, and this may lead the woman to decline to take a vaccine in a clinical trial. The relationship with the health workers which we report about in our study reflects the effect of mistrust of research in the communities.

Our previous research that was conducted in Kampala during the onset of covid disease in Uganda in 2022 revealed that pregnant women feared the vaccine but this was coupled with mistrust of the government systems [8]. However, the same study reveals that participants after witnessing the deaths that were occurring in the community, during their follow up interviews they reported that there was increased reception of vaccination for Covid 19. What pregnant mothers hear and experience according to our study findings can influence their choice to take part in a clinical trial.

Addressing information gaps and mistrust through community engagement could alleviate some concerns about maternal vaccines. A mixed methods study conducted in Kampala exploring reasons why parents would not take their children for immunisation, reported that parents mentioned the lack of adequate information about immunisation as one reason for incomplete vaccination for some children [15]. Therefore, continued sensitisation and knowledge sharing by health workers and sharing by the women who have taken part or had their children take part in clinical trials may be a useful strategy to reduce some of the negative perceptions, stigma related to procedures like visits at homes and rumours that individuals face in the community.

The main activity that women mentioned that could be foreseen to ensure sensitisation, information and knowledge sharing by health professionals to improve engagement of pregnant women into vaccines, is to give study information using different channels or methods besides reading study information, information could be shared using posters and video clips. Sharing information with male spouses /partners to the pregnant women would be helpful and reducing pressure on health workers at the public facilities who attend to the general population of pregnant women would help since they usually handle huge volumes of pregnant women at the public health facilities.

In most of the cultures in Uganda, there is the spirit of doing things together (Ubuntu) and this may involve close relations such as parents, in laws, spouses in the decision-making process [16,17]. Women are usually key in seeking for health care for themselves and their children and can make decisions sometimes, however in some situation's health seeking behaviour for women and children may be impacted upon by who makes the financial contribution and the final decision. There is therefore the need to involve men and key stakeholders like health workers and influential others in the community to understand issues of maternal immunisation [12].

Some of the reasons for male hesitancy towards maternal and child care including immunisation have been reported by Bagenda et al., [18] who studied the benefits of and barriers to male involvement in maternal health care, the barriers included lack of knowledge, lack of resources and alcohol among other individual behaviour factors. A systematic review conducted by khan [19] showed the importance of engaging the community so that men and women understand and get knowledge about maternal vaccines and avert fears and concerns about the outcomes of immunisation to the foetus of the participating women.

Women in our study reported concern over study procedures such as blood draws from their babies and themselves this is something that has been reported about even in health adult populations [20] who were requested to donate blood. The issue of blood draws during research will continue to require innovative ways to explain and describe the reasons for the blood draw, the amount drawn, the frequency and the need to draw blood from infants to detect infections early and control preventable diseases in each research context [21,22].

The main motivating factors for participation in vaccine trials are trust that is built with the research study and some government health workers who provide the health education and care services. Vaccine Information should be presented in simple language using some

education materials like charts and video clips if available. There is also need to give potential participants time to consult with people that they trust as they make decisions [23].

The findings of our study align with what is described in the social ecological framework, which situates an individual in several spaces that may influence their decision making. The influence may be from within an individual such as fear for self and babies' protection, but influence can also come in from other influencing factors from the community, access issues that relate to service delivery and structural factors that result from the policies in each context.

4.1. Study strength and limitation

The study was conducted in Kampala city and therefore may not be generalisable to rural areas, however the issues raised around pregnant women and infants' taking part in clinical trials are important learning points for all regions especially the sub-Saharan Africa region. The lessons will be useful to guide on how to manage hesitancy during enrolling of participants into planned clinical trials which will test new vaccines. If well embraced, immunisation of pregnant mothers has been reported to lead to the reduction of child mortality and morbidity.

5. Conclusion

Whereas the concerns that women in this study reported may be like what has been reported elsewhere in other African countries, there is need to uphold the contextual concerns and resolve them. This can be through an increase in sharing maternal vaccine information and educate communities, engage male partners as main household heads, empower and equip women with decision making skills, train health workers in handling pregnant women. Governments need to step up capacity building for the health care force which implements immunisation for pregnant women.

CRediT authorship contribution statement

Agnes Ssali: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Phiona Nalubega:** Writing – review & editing, Methodology, Investigation, Formal analysis, Data curation. **Rita Namugumya:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Mary Kyohere:** Writing – review & editing, Methodology, Investigation. **Kirsty Le Doare:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Janet Seeley:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Institutional review board statement

Ethical Considerations. The study was approved by the Makerere University School of Medicine Research and Ethics Committee MakSOMREC-2022-331), and National Council for Science and Technology (SS1278ES-UNCST) and the London School of Hygiene and Tropical Medicine Research and Ethics committee (28257- LSHTM).

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: A. S., P.N., R.N., M.K., K.L., and J.S. declare no conflict of interest.

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Data availability

Data will be made available on request.

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