Vaccine 63 (2025) 127627

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

A mix of views: Perspectives on pregnant women's participation in maternal vaccine trials

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ARTICLE INFO

Keywords:
Pregnancy
Maternal vaccination
Vaccine trials
Vaccine intentions

ABSTRACT

Background: The aim of this study was to investigate perspectives on participation in a Group B Streptococcus (GBS) maternal vaccine trial among pregnant women, their partners, family members, friends and other stakeholders in Kampala, Uganda.

Methods: We conducted focus group discussions, in-depth interviews and key informant interviews from October 2022 to February 2023 with 56 participants: 36 pregnant or breastfeeding women, 5 women not in the trial, 5 partners of women in trial, 5 healthcare workers, and 5 community stakeholders. This cross-sectional study was embedded within a GBS maternal vaccine trial conducted at the national referral hospital. All study participants were recruited after seeking hospital administrative approval and individual consent. Women taking part in the GBS trial were contacted by phone and invited to the hospital for detailed information during their follow-up visits. Eligible pregnant women were aged 18–39, and participating in a GBS maternal vaccine trial. Their identifiers were shared with the social science team after approval. With the support of the health visitors, the women were contacted. Non-trial participants with similar characteristics were recruited through antenatal clinic staff. Both groups were purposively sampled across age brackets (18–24 years, 25–32 years, 33–39 years) for discussion groups. Women's partners were recruited through contact information provided by the women, and community stakeholders were mobilized with assistance from a Community Advisory Board member. Healthcare workers involved in the trial, including doctors, nurses, and midwives, as well as a research ethics committee member, were directly approached and invited to participate. All participants provided informed consent.

Results: The participants expressed various concerns about participation of pregnant women in maternal vaccine trials. While family members, partners, friends, and community members, expressed concern for the safety of pregnant women and their unborn babies, the specific nature of these concerns and the focus on vaccine intentions differed. Pregnant women primarily focused on the safety of their babies, while partners and family members worried about both maternal and fetal safety. Friends were more concerned about the vaccine itself, community members were suspicious of vaccines in general, fear of possible harm and questioned the intent for vaccine development.

Conclusions: Building trust, providing accurate information, and engaging in transparent communication about the safety and intentions of maternal vaccines are crucial steps in fostering understanding and increasing participation in vaccine trials. Efforts to dispel myths, correct misconceptions, and address the underlying fears that contribute to hesitancy within these diverse stakeholder groups need to be discussed with targeted study populations.

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https://doi.org/10.1016/j.vaccine.2025.127627
Received 14 March 2025; Received in revised form 24 July 2025; Accepted 11 August 2025
Available online 31 August 2025

1. Introduction

Pregnancy is a prime time to prioritize care for both women and babies, given their increased susceptibility to infections [1]. Protecting pregnant women and their infants through vaccination against key diseases is a priority for the World Health Organization [2,3].

Historically, pregnant women were excluded from clinical trials throughout the entire pregnancy because of the strict standards that often prevented the testing of pharmaceuticals during labour and delivery. The strictness of these regulations reflected fears of potential teratogenicity and other harmful effects of pharmaceutical products, untested in pregnancy, on a developing embryo or fetus, although no such events have been found in any vaccine used in pregnancy to date [4].

There is a critical need to include pregnant women in vaccine development efforts where it is safe to do so and recent guidance offers an ethically sound path forward for the pregnancy vaccine research agenda [5]. The inclusion of pregnant women in trials is vital to the process of obtaining important information regarding the safety and efficacy of therapeutics or interventions to improve maternal health and pregnancy outcomes [6]. Research indicates that maternal knowledge, attitudes and beliefs play a substantial role in vaccine hesitancy [7]. Engaging with pregnant women through offering participation in vaccine research and respecting their rights to decide on their participation, can contribute to addressing information gaps and concerns. Such an approach is also central to woman-centred maternity care [8].The aim of this study was to explore views of the pregnant women and those around them (community leaders, partners and health workers) about perspectives on pregnant women's participation in Group B Streptococcus maternal vaccine trials to improve vaccine confidence.

2. Materials and methods

2.1. Study design

This qualitative study was a cross-sectional exploratory investigation that was conducted within a Group B Streptococcus maternal vaccine trial carried out by Makerere University- John Hopkins University (MUJHU) at a national referral hospital [9]. This was a phase II trial of a multivalent vaccine against GBS capsular poly-saccharide (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 was carried out at Kawempe National Referral Hospital, which serves as a national referral hospital for gynaecology and obstetrics, situated close to Kampala Uganda city centre. Kawempe administrative division, where it is situated, includes the neighbourhoods of Mulago, Kamwokya, Komamboga, and Kawempe, where the majority of the interviewed stakeholders reside. As a referral hospital women come from across the country, as well as from nearby communities.

2.2. Recruitment

Participants were enrolled from the hospital after receiving administrative permission and individual consent. Women who were participating in the Group B Streptococcus phase II vaccine trials were approached by the clinic research team. Interested participants were contacted by social scientists via phone and provided with information about the study. They were then requested to come to the hospital for detailed information during their follow-up visits at the antenatal clinic. The study specifically targeted women who were returning for their second follow-up visit during pregnancy or post-natal visits for breastfeeding women. These visits did not involve extensive clinical procedures and allowed ample time for discussion. Women were eligible for inclusion in the qualitative study if they were pregnant, aged 18–39 years, participating in a GBS maternal vaccine trial conducted by MUJHU and had to provide consent to participate.

Additionally, a separate group of women attending the same antenatal clinic at the referral hospital, who were not part of the clinical trial but shared similar characteristics such as age and trimester, were invited to participate in an interview. These women were recruited through the antenatal clinic staff. The midwife explained the main objective of the qualitative study and invited interested women to meet with the social scientists for a detailed discussion about the social science study. The social scientists provided the study details, and women who were willing to participate were invited to join the study, providing consent.

For both discussion groups the social science team purposively sampled pregnant women from different age brackets (18–24 years, 25–32 years, 33–39 years).

The women's partners were recruited with their support. The social scientists obtained the contact information of the partners from the women. The partners were then contacted by phone and invited to participate in the study after giving written informed consent.

Community stakeholders were mobilized with the assistance of a member from the Community Advisory Board (CAB). The CAB member provided the research team with the contact information of the stakeholders, who were then contacted by phone and later visited for a discussion about the participant information document. The stakeholders were asked to provide written consent before being interviewed at a mutually agreed upon time. The research ethics committee member was contacted directly by the social scientists and asked for consent to participate in the study.

The social science team purposively approached healthcare workers (doctors, nurses and midwives) who were involved in the trial processes and requested their participation in the study. These healthcare workers were selected because they had obtained consent from the women who participated in the trial, conducted home visits to the participants, administered vaccinations, and provided treatment and care. The healthcare workers also had to sign a consent form to take part in the study (Table 1).

2.3. Data collection

Data were collected from October 2022 to February 2023, from a total of 56 participants involved in the study. The women selected from the trial were either engaged in a semi-structured Individual Interview (IDI) or a Focus Group Discussion (FGD). We conducted individual interviews with women who were not part of the trial, health workers, spouses/partners of the women in the trial, and all stakeholders. Prior to conducting the interviews, verbal permission was obtained to audio record the interviews and FGDs. The interview guide and FGD topic guide covered topics such as: antenatal visit experiences, general knowledge of vaccines, the specific vaccine received, barriers and facilitators for participating in the clinical trial, the consent process, information shared, presentation format, and decision-making regarding joining a clinical vaccine trial. Individual interviews lasted between 30 and 60 min, while FGDs lasted between one and two hours. Two female social scientists conducted the individual interviews, while three female

Table 1
Table outlining the methods used to collect data for each category of participants.

Method of data collection	Category of people	Numbers of people
In-depth Interviews	Pregnant women in trial	13
In-depth Interviews	Pregnant women not in trial	5
In-depth Interviews	Partners	5
In-depth interview	Community stakeholders	5
Focus Group Discussions	Pregnant women in trial	6
Focus Group Discussions	Breast feeding women	17
Key Informant Interview	Healthcare workers	5

social scientists conducted the FGDs, with one serving as an observer. The interviews and FGDs were conducted in English and Luganda, depending on the participants' preferred language. Interviews with women in and outside the trial took place in designated office spaces at the hospital, while the FGDs occurred in large office spaces within the hospital. The location of the key informant interviews was chosen by stakeholders, with some conducted at the hospital premises and others in the participants' communities, based on their preferences. Health workers were interviewed at the study offices at Mulago hospital and Kawempe referral hospital. The interviews with stakeholders and health workers lasted between 30 and 50 min.

2.4. Data management and analysis

Once a participant was interviewed and after an FGD had been conducted, the recording was uploaded on an encrypted computer. Transcription was done by the research team and all transcripts were anonymized. Identification numbers were assigned to every transcript to allow for accountability, and these were saved on a secure server. For the analysis, the team began by discussing the first five transcripts to develop a coding framework. Data analysis was both deductive following the questions in the topic guides and inductive from within the data.

After developing the codes and the codebook, data were exported for management to NVivo 12, an electronic qualitative data analysis software. Themes identified during analysis were perceptions about vaccines in general, perceptions of the vaccine in the trial, experiences at antenatal clinic, decision making, barriers and facilitators to enrol in a maternal clinical trial and elements of the consent process which included study information and presentation, role of an impartial witness, confidentiality, compensation and strategies for information sharing. This paper only focussed on three themes: beliefs and perceptions around safety of the mother and the baby, suspicions/myths surrounding maternal vaccines and advise.

2.5. Ethical considerations

The team sought permission from the administration of Kawempe

Table 2
The demographic characteristics of the particicipants in the study without the health workers.

Characteristics	Pregnant women enrolled in trial-Interview. ($N = 13$)	Pregnant and Breast Feeding Women enrolled in trial-FGD. ($N = 23$)	Pregnant Women Not in trial ($N = 5$)	Male Partners. (N = 5)	Stakeholders. (N = 5)
Age					
17–24	8	8			
25–29	3	6	3		
30–39	2	9	2	4	1
40–49				1	
≥50					4
Sex					
Male				5	2
Female	13	23	5		3
Gestation					
6-7 months	2		2		
7-8 months	8				
8-9 months	1		2		
≥ 9 months.	1		1		
Marital status					
Married	11		5	5	
Single	2				
Level of education					
Primary	1		2	1	
Secondary	8		2	1	2
Diploma	1				
Tertiary/ Certificate.	2			3	1
Bachelors' Degree.	1		1		2
Occupation					
Religious leader.					1
Village Health Team					1
Local council Leader.					2
Business/Trader	6		1	2	
Peasant Farmer	1			1	
Saloon	2				
Tailor					
Health Professional					1
Housewife	2		3		
Teacher/librarian	1				
Electrician				1	
Office Attendant				1	
Unemployed	1		1		

national referral hospital to conduct this research at the hospital. The study was approved by the Mak-SOMREC-2022-331, SS1278ES-UNCST and 28,257-LSHTM.

3. Results

Of the 56 participants, 36 were pregnant or breastfeeding women, 5 were women not involved in the trial, 5 were partners of women in trial, 5 were healthcare workers (1 male, 4 female), and 5 were community stakeholders (2 males, 3 females) (Table 2).

Three main themes, related to women's participation in vaccine trials, emerged from the data during analysis; Safety of the mother and baby, Suspicions/myths surrounding maternal vaccines and suggestions.

3.1. Safety of the mother and baby

Participants expressed various concerns about the safety of pregnant women and their unborn babies in maternal vaccine trials. These concerns included:

3.1.1. Congenital abnormalities and still birth

Pregnant women's concern about participation in the maternal vaccine trial were predominantly on safety of their unborn babies and the effect of the vaccine on their pregnancy. They expressed worries such as the fear that the vaccines could lead to adverse outcomes for their babies, including death or congenital abnormalities. These concerns indicated that the primary focus was on protecting the well-being of their unborn children when making decisions about vaccination.

Pregnant women reported misconceptions and concerns regarding the safety of vaccines during pregnancy. They reported rumours within their communities that vaccines could harm their unborn babies, cause birth defects, or even lead to infertility. These beliefs, combined with a lack of information, created fear and hesitation towards participation in maternal vaccine trials.

I was scared because the nurse said it is research, it is a new vaccine and I thought the research was going to bring harm on my baby.I feared and thought to myself new vaccine, it's still under research how will it treat me and my baby. (IDI-Woman in trial).

Sometimes they [pregnant women] say that the vaccines might lead to the death of their unborn babies, sometimes they say that their babies might be born with some congenital abnormalities, sometimes they say that the vaccines may make them infertile. (IDI-Health worker).

Pregnant women carrying their first child expressed fear and anxieties that often accompany a first pregnancy. Their fear extended beyond the potential side effects of the vaccine itself, encompassing the additional responsibility and vulnerability associated with the first child. This vulnerability led to heightened concerns about potential harms, making them more susceptible to misinformation and negative stories circulating in their community. This fear, coupled with a lack of knowledge about the vaccine's safety during pregnancy, contributed to first time pregnant women's hesitation towards maternal vaccination trials.

I had fear because I was worried of what could happen to me after receiving the vaccine. […] At first I got scared being tried on a vaccine since I was carrying my first pregnancy. (IDI-Woman in trial).

Partners also expressed fear about the well-being of their unborn baby. They were worried about the safety of the maternal vaccine trial and the potential risks it may pose to the unborn child. They believed that the baby might be born with physical deformities or "damaged body parts." Additionally, they also expressed fear that the child might suffer from chronic health conditions or adverse effects as a direct consequence of the trial.

The fear I am having is delivering a baby with a health condition as a result of the clinical trial. The second fear I am having is having a still birth. The third fear I am having is my wife dying during delivery. (IDI-Male Partner).

Other family members also expressed similar fears and beliefs about the effects of the vaccine trial on the wellbeing of the unborn child.

They first discouraged me. My cousin sister told me that they might steal our children from us. They first asked me if I was sick and when I told them that I was fine, they then said, "take care because they might steal your children". (IDI-Women in trial).

Community members expressed similar concerns with that of the pregnant women and their family members about the impact of maternal vaccines on the well-being of both mothers and babies. Stakeholders expressed a concern that some vaccines may adversely affect the baby, emphasizing the need to understand the potential impact of the vaccine on both mother and baby's health.

My concern about the pregnant woman is the unborn child; some of these vaccines cross the placenta and affect the baby. So, the baby ends up getting the adverse events because of the clinical trial. Because some clinical trials don't look at the baby, they are only looking at the mother, how will the mother behave after being given the vaccine, but the baby is neglected. (IDI-Stakeholders).

3.1.2. Infertility

Pregnant women reported misconceptions and concerns regarding the safety of vaccines during pregnancy, including the belief that they could lead to infertility. Pregnant women including those not in the trial were concerned about the potential of vaccines to cause damage to the uterus, the organ where the baby grows, and to the brain of the developing child.

I think it might cause challenges in their reproductive parts. I mean inside like in the uterus where the baby grows from, then it might cause brain damage after some time for example, someone might get vaccinated and after two months or three they start changing and their brains start disconnecting slowly; that is what scares me about those clinical trials, I think for me I will just wait and see how the people who get vaccinated in those trials react and then think of accepting to join. (IDI-Woman not in trial).

Partners also expressed concerns related to the potential harmful effects of vaccines on the pregnancy and the wellbeing of their wives, including fears of uterine problems and infertility.

I have seen very many women who receive drugs during pregnancy and the drugs make them get still births. Secondly, a woman might lose her uterus as I earlier explained. (IDI- Male partner).

Community members believed that these vaccine trials might have harmful objectives, aiming to render women infertile, harm their ovaries, or even lead to birth defects, contributing to a prevalent fear within the community.

There are some people [community members] who say that those vaccine trials are aimed at making women infertile. They say that those vaccines burn women's ovaries and makes them stop giving birth. Some say that studies make women give birth to babies who are deformed. (IDI-Stakeholders).

3.1.3. Maternal mortality

Partners also expressed concerns related to the potential harmful effects of vaccines on the pregnancy and the wellbeing of their wives, including worries about maternal mortality during delivery and the perceived risks of medical interventions during pregnancy.

The third fear I am having is my wife dying during delivery. (IDI-Male Partner).

Community stakeholders also believed that vaccines would cause death and affect marriages of those who accept to take part in the vaccine trials especially to women whose participation never involved their husbands and other care takers.

Those clinical trials might cause death. They might even lead to marriage breakups. (IDI-Stakeholder).

Pregnant women expressed concerns and anxieties that they may face when considering participating in research studies. They highlighted the fear of exploitation and harm they might experience from the research team, emphasizing the importance of ethical research practices and building trust with potential participants.

Before a woman decides to take part in the study, she first gets scared. She could be having some fear. She may think they [researchers] want to sacrifice her or do something bad to her. (IDI-Woman not in trial).

Pregnant women highlighted their sense of caution and concern when making decisions that could affect their health and the well-being of their unborn child. Women emphasized the importance of prioritizing the safety of the mother and child during pregnancy and the need for thorough consideration of any potential risks associated with medical interventions or research participation.

Personally, if I am to take medicine, I first ask if it is healthy for the baby or myself. If you know you are carrying a person inside you, you just don't have to take any medication. According to my thinking, taking part in those trials may make a woman bring out a baby that has a [health] problem. (IDI-Woman not in trial).

One pregnant woman not in trial highlighted the fear of being subjected to an experimental treatment without definitive knowledge of its safety and efficacy.

What scares me most is that they are testing and trying to see if the vaccine works or not, it's not easy for anyone to accept to take part in such a study unless they don't know that the vaccine is still under research. (IDI-Woman not in trial).

Community members also expressed a broader doubt regarding vaccines, with a belief that they might have been invented to harm or even kill people, introduce unknown illnesses, and consequently, community members maintain a negative stance towards vaccines.

Community people don't believe in vaccines because they think these are things that have been invented to finish them [kill them]. They think it might introduce sicknesses they don't understand. (IDI-Stakeholders).

Despite these concerns, one of the men explained that his wife joined, and he benefited from reduced treatment costs: *People told me that they are going to put medicine in your child and they will not live for long, you know like the COVID -19 stories people said a lot, they tried to discourage me, […] right now it's very evident that if I had refused to take part it was me going to lose, because we have benefited a lot, I have saved a lot, and my [financial]situation was not good. (IDI-Male Partner).*

3.2. Suspicions/myths surrounding maternal vaccines

Pregnant women also raised suspicions about the origin and intentions behind the maternal vaccine trials. These included:

3.2.1. Vaccines are made to render women infertile

Community members believed that these vaccine trials might have harmful objectives, aiming to render women infertile, harm their ovaries, or even lead to birth defects, contributing to a prevalent fear within the community.

There are some people [community members] who say that those vaccine trials are aimed at making women infertile. They say that those vaccines burn women's ovaries and makes them stop giving birth. Some say that studies make women give birth to babies who are deformed. (IDI-Stakeholders).

3.2.2. Associating the trial with selling the unborn baby

Partners of pregnant women in the trial raised a concern that their wives' participation in the vaccine trial was associated with selling their unborn child. A pregnant woman in trial explained that:

My husband just commented that I might have sold my unborn baby off, so the health workers just give me money as a payment [referring to reimbursement for time] for that baby. By the time I give birth, the pay for the unborn baby will also be completed. (FGD-Woman in trial).

Pregnant women also reported that some of their relatives associated participantion in research with stealing of the babies.

My cousin sister told me that they might steal our children from us. They first asked me if I was sick and when I told them that I was fine, they then said, "take care because they might steal your children". (IDI-Women in trial).

3.2.3. Created by whites with unclear intentions

Pregnant women expressed a concern that vaccines might have been invented by a group (referred to as "whites") with a hidden agenda. The fear was that these vaccines might have been developed not for the well-being of those receiving them but with the intention to cause harm or negative effects in the bodies of the recipients. The fear expressed by the pregnant women is rooted in suspicion regarding the development and purpose of the vaccines rather than concerns about their immediate safety for herself or her baby.

Then I asked her [pregnant woman] why she fears and she told me that "You know whites have made so many drugs, it is possible that these whites have manufactured these vaccines to cause harm in our bodies" (IDI-Health Workers).

3.2.4. Government's intentions

The friends of the pregnant women were primarily preoccupied with suspicions regarding the safety and intentions behind the manufactured vaccines in the clinical trial, showing less regard on the impact of the maternal vaccine trial on the well-being of both the pregnant mother and the unborn child. The friends focussed on questioning the government's role in producing potentially harmful vaccines and using people as test subjects, which led to their discouragement and fear regarding the women's participation in the trial. Notably, their concerns were centred on the vaccines themselves rather than the health of the pregnant woman and her unborn baby, reflecting a strong emphasis on the perceived risks associated with the vaccine, rather than a consideration of the broader well-being of the participants.

The only challenge I got is that when l told my friends about the vaccine trial, they discouraged me that the government introduces harmful vaccines. So, they blamed me for participating in the vaccine trial. (FGD-Women in trial).

There were concerns about the blood draws and use brought up by friends and were reported by the women:

The people we consulted [friends] asked us how the research team are going to benefit from the blood they draw from us. They were concerned about where the blood is taken after drawing it from people. (FGD Women in trial).

3.2.5. Vaccines have been made to kill

Community members also expressed a broader doubt regarding vaccines, with a belief that they might have been invented to harm or even kill people.

Community people don't believe in vaccines because they think these are things that have been invented to finish them [kill them]. (IDI-Stakeholders).

3.2.6. Vaccines made to introduce illnesses

Community members also expressed a broader doubt regarding vaccines, with a belief that they might introduce unknown illnesses.

They think it might introduce sicknesses they don't understand. (IDI-Stakeholders).

Although there was a lot of negative attitudes from the different groups, the healthcare workers noted that the vaccines are not a problem [vaccines are safe] however there is need for sharing information clearly:

Yes, they have concerns and one of them asked me if the vaccine has any harmful effects to the baby, so we have to continue reassuring them and giving them information. (IDI- Health care workers)

3.3. Suggestions

Participants gave recommendations that would reduce their fears and negative attitudes towards vaccine trials as follows:

3.3.1. Consulting health workers

Participants indicated that having consultations with health workers who can provide thorough explanations about the trial could greatly reduce their anxieties. For instance, a *pregnant woman expressed concerns*

about potential risks like miscarriage after receiving the vaccine. However, after a health worker took the time to explain the study details, she felt reassured and decided to join the study.

3.3.2. Conducting more clinical trials

Health workers suggested that conducting more clinical trials involving mothers would help normalize the concept and reduce fear over time. They noted that "*historically, clinical trials were focused on diseases like HIV, but increasing the number of trials for other conditions would benefit mothers directly; as mothers become more accustomed to these trials, their willingness to participate increases, as familiarity breeds comfort and reduces apprehension*".

3.3.3. Partner involvement

Involving partners in the clinical trial process was reported crucial for increasing participation. Health workers in the study highlighted that encouraging male involvement in prenatal care was challenging but some facilities successfully managed to engage partners, with around 30 % of women attending antenatal visits with their partners. "*Promoting partner involvement would provide additional support and reassurance to the participants, making them more likely to take part in the trials*" as health workers put it.

3.3.4. Community engagement

Delivering study information within the communities, rather than solely at health facilities, would enhance understanding and improve perceptions of vaccine trials. Health workers suggested that outreach efforts in community settings, such as churches, markets, and universities, could reach a broader audience, including pregnant women and those planning pregnancies. Engaging with the community directly could dispel myths and misinformation about vaccines, promoting a positive attitude towards participation in clinical trials as health workers put it.

I think we can go to several places where we are most likely going to find pregnant women like churches and markets, these places have very many different people including men and women, we can also go to high institutions of learning like the universities, all these places have women who are pregnant and others are planning to get pregnant. (KII health worker)

Participants recommended that efforts to improve community sensitization about the benefits of research would help reduce negative perceptions and misinformation. Participants reported that they often harbor fears and misconceptions about clinical trials, viewing them with suspicion. By educating the community on the positive aspects and safety of research, the research team would alleviate these fears and encourage more people to participate.

My recommendation for this research is to improve sensitization of the research study. This is because most people think research is bad. They still think that research is a government deal. They think that maybe the government wants to make the pregnant women get miscarriage. You should also sensitize people about the benefits of research or clinical trials. (IDI stakeholder) (Table 3).

Table 3
The differences and similarities in the beliefs and perceptions of different parties involved in maternal vaccine trials.

Aspect	Pregnant Women	Partners/Family Members	Community Members
Safety Concerns	Primarily focused on the safety of unborn babies, potential adverse outcomes, congenital abnormalities, and fertility concerns.	Concerns about the potential harm to the unborn child, physical deformities, chronic health conditions, and adverse effects.	Similar concerns about the impact of maternal vaccines on the well-being of both mothers and babies, suspicions about vaccines' underlying intentions.
Fear and Anxiety	Fear extended beyond vaccine side effects to include anxieties about the vulnerability of first pregnancies and heightened concerns about potential harms and misinformation.	Worries about potential harm, fear of exploitation, and the importance of ethical research practices and building trust with potential participants.	Profound concerns about the impact of maternal vaccines on the well-being of mothers and babies, with suspicions about wicked objectives and negative beliefs about vaccines.
Concerns about reproductive and developmental health	Worries about potential damage to the uterus and brain of the developing child, reflecting a lack of complete understanding about the long-term effects of the vaccine.	Concerns about potential damage to the unborn baby's body parts, uterine problems, and infertility due to vaccines.	Similar concerns about vaccines causing harm, such as burning ovaries, making women infertile, and introducing unknown illnesses, reflecting a negative stance towards vaccines.
Reluctance to Participate in Trials	Reluctance due to concerns about unknown risks, potential personal sacrifice, and fear of being subjected to an experimental treatment without definitive knowledge of its safety and efficacy.	Similar reluctance based on fears of potential harm and exploitation, emphasizing the fear of being used as test subjects without sufficient understanding of the trial's safety.	Negative beliefs about vaccines and fear they are invented to harm or kill people, contributing to reluctance and suspicion towards vaccine trials.
Suspicions/ Myths about Vaccine Trials	Suspicions regarding the origin and intentions behind the maternal vaccine trials, with a concern that vaccines might have been developed with a hidden agenda to cause harm.	Beliefs that participating in vaccine trials is associated with selling unborn children and concerns about compensation for the baby, reflecting suspicions about the trial's intentions.	Broad doubt regarding vaccines as a whole, with a belief that vaccines might have been invented to harm or kill people, introducing unknown illnesses, maintaining a negative stance.

4. Discussion

Our study shows that there is concern for safety in vaccine trials for both the mother and baby from the different stakeholders in the community. The study also revealed that participants were as concerned about the vaccine itself as they were about the health of mother and child, emphasizing harm and potential malicious intent behind vaccine development that needs to be addressed.

Our study revealed that pregnant women's and community members' concerns about participation in maternal vaccine trial were around potential harm to women and their babies. This finding corroborates with findings from three studies which also revealed that participation of pregnant women in clinical trials entailed fears and worries mainly related to concerns about their risks for fetuses and how the vaccine would affect the unborn baby [10–13]. This study revealed that pregnant women including those not in the trial were concerned about the potential of vaccines to cause damage to the uterus, the organ where the baby grows, and to the brain of the developing child. These concerns reflected a lack of complete understanding about the long-term benefits of the vaccine. Findings from this study are similar to another study conducted in South Africa were pregnant women expressed low

understanding of maternal vaccines. [14].

Suspicions/myths surrounding maternal vaccines continue to exist about reasons for vaccine manufacturing by Europe and America, (referred to as "whites") with a hidden agenda. The fear is that these vaccines might have been developed not for the well-being of those receiving them but with the intention to cause harm or negative effects in the bodies of the recipients. This result is similar to another study that found that myths and misconceptions regarding immunization would affect pregnant women's decision to take up vaccines [15].

Research shows that involving partners and community members have an influence on the attitudes of pregnant women regarding immunization [16]. Some partners in our study believed that participation of their pregnant partners in the vaccine trial was associated with selling of their unborn child. Compensation for time spent at clinic was believed to be payment for the baby, although this is recommended by the Ugandan Council for Science and Technology. They were worried about the safety of the maternal vaccine trial and the potential risks it may pose to the unborn child. Community members believed that the research might lead to introduction of new illnesses. This finding is similar to a study conducted in Uganda which reported partners who believed that maternal vaccines would cripple their unborn children once taken [17]. It is therefore crucial to make sure that education programs on maternal immunization include different stakeholders including men to combat the negative attitudes about the maternal vaccine trials. We need to ensure that the different stakeholders are involved from inception of the study and the development of the protocol through to the conduct of the trial and its communication. We also need to constantly monitor what is happening in the community to make the trial a success.

5. Conclusions

We have highlighted the need for targeted and culturally sensitive communication strategies to address safety concerns around maternal vaccine trials. Building trust, providing accurate information, and engaging in transparent communication about the safety and intentions of maternal vaccines are crucial steps in fostering understanding and increasing participation in vaccine trials. Efforts should be made to dispel myths, correct misconceptions, and address the underlying fears that contribute to hesitancy within these diverse stakeholder groups through working together with communities to co-create tools to better communicate to the different stakeholders.

5.1. Limitations

There is a potential recruitment bias with the chosen healthcare workers for this study, as they were directly involved in the maternal vaccine trial.

CRediT authorship contribution statement

Phiona Nalubega: Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Ritah Namugumya:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Mary Kyohere:** Writing – review & editing. **Janet Seeley:** Writing – review & editing, Conceptualization. **Kirsty Le Doare:** Writing – review & editing, Conceptualization. **Agnes Ssali:** Writing – review & editing, Methodology, Formal analysis, Data curation, 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 Mak-SOMREC-2022-331), and National Council for Science and Technology (SS1278ES-UNCST) and the London School and Tropical Hygiene Research and ethics committee (28257- LSHTM). The research team signed a confidentiality agreement.

Funding

The study was funded through the training department at the MRC/UVRI and LSHTM Uganda Research Unit which is jointly funded by the UK Medical Research Council (MRC) part of UK Research and Innovation (UKRI) and the UK Foreign, Commonwealth and Development Office (FCDO) under the MRC/FCDO Concordat agreement and is also part of the EDCTP2 programme supported by the European Union under the grant number RIA2018V-2304-PREPARE. The clinical trial was conducted by Makerere University John Hopkins University and is sponsored by City St George's University of London through the EDCTP2 programme supported by the European Union.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgment

We thank the community and respondents for accepting to participate in this research.

Data availability

Data will be made available on request.

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