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RESEARCH ARTICLE

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Factors influencing mothers' decision to enroll their HIV-negative children in a hypothetical HIV vaccine trial

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Despite advances in preventive treatments for HIV, children continue to become infected with HIV. Research has investigated adult and adolescents' willingness to participate in hypothetical HIV vaccine trials; however, maternal willingness to enroll their infants in such trials remains underexplored. **Aim:** This study explored the factors influencing mothers' decision-making about enrolling their HIV negative infants in a hypothetical HIV vaccine trial. **Methods:** HIV infected and uninfected mothers (n = 22) were interviewed. **Results:** Several factors were identified as influencing the mothers' decisions, including perceptions and knowledge of HIV and vaccines. **Conclusion:** Maternal concerns about protecting their infants from HIV were also identified and mothers indicated that they were eager to vaccinate their children. Insufficient information and reassurance regarding vaccine trial safety and efficacy influenced maternal reluctance to enroll their child.

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Despite the success of existing prevention strategies such as prevention of mother-to-child transmission programs, exclusive breastfeeding and antiretroviral therapy (ART), new HIV infections in infants and young children persist. In South Africa, an estimated 360,000 children aged 0–14 years were living with HIV in 2013, representing close to 7% (16,000) of new infections globally among children in that age range during that year [1]. However, while the aforementioned strategies offer protection of HIV during infancy, HIV-exposed newborns who are not infected at birth or during breastfeeding remain at risk of HIV infection during adolescence and adulthood [2]. One approach to reduce HIV incidence is an effective and safe HIV vaccine.

The development of a safe, tolerable and effective vaccine for infants is lagging far behind those of adults [3]. In terms of adult vaccines, only one Phase III trial to date (RV144) has demonstrated modest efficacy [4]. Compared with adolescents and adults, infants stand to benefit the most from an HIV vaccine [ROSENTHAL KL, UNPUBLISHED DATA]. Preventative vaccinations would not only provide infants with life-long protection against HIV, but also allow HIV-positive mothers to breastfeed their infants without the risk of vertical transmission. Large numbers (thousands for Phase III trials) of infants will be needed to participate in HIV vaccine trials [5,6]. While the literature offers some insight into adolescents and adults' willingness to participate in HIV vaccine trials [7–10], less is known about the willingness of parents to enroll their infants and children in HIV vaccine trials and the factors that influence such a decision.

KEYWORDS

• children • HIV • vaccine trial

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In a study of hypothetical HIV vaccine trial acceptability, nearly all women reported (97%) that they would vaccinate their child once against HIV if this were an option [11]. This total decreased to 80% willing to vaccinate if vaccination was required every 3 months. Further, only 64% (513 out of 805) agreed to participate in a vaccine trial. Reasons for not wanting to participate included concerns about the side effects of the vaccine, partner objection, fear of discrimination by family and others and fear of contacting HIV through participation. These barriers to participation are similar to those found in the adult and adolescent literature [3,12–17]. However, as this study was based in Kenya, it is unclear whether similar results would be seen in other contexts.

Understanding the factors that influence pediatric trial participation is essential if large-scale trials are to proceed ethically and in a methodologically sound manner. Unlike adults, infants are unable to provide consent to participation in these trials. In this study, we expand on previous research [11] and report on the findings of a qualitative investigation into the factors that influence mothers' decision to enroll their HIV-negative infants in a hypothetical HIV vaccine trial.

Method

• Participants

Participants were HIV-positive and HIV-negative women enrolled at the Maternal Obstetric Unit (MOU) at Site B in Khayelitsha, a large peri-urban township in South Africa. The MOU is the largest of two public sector delivery units located within Khayelitsha, with more than 200 new clients booking appointments for antenatal care per week [18]. On average, Site B MOU provides antenatal care to approximately 350 patients per month [19] and recent estimates suggest that 30–32% of deliveries at this facility are to HIV-infected mothers [ROSENTHAL KL, UNPUBLISHED DATA]. To be included in the study, women had to be aged 18 years or older and be the mother of an HIV-negative infant. Women were excluded from the study if they had received a diagnosis of psychotic illness or developmental delay. Data were collected at two time points – October 2012 to January 2013 and October 2015 to March 2016. Mothers were only interviewed once at a single time point.

Purposive sampling was used to select participants [20]. MOU staff members informed enrolled mothers of the study, and those who

expressed an interest in taking part were invited to provide their contact details to the research team. Data collectors contacted all prospective participants and arranged a meeting to discuss the study in further detail. All participants were informed that they would continue to receive services offered at the MOU, regardless of whether or not they chose to participate in the study.

All participants were given an information sheet that they discussed with a bilingual data collector (in their preferred language, see **Supplementary Material**). Consent forms were read aloud to all participants, and participants were asked at regular intervals whether they had any questions. Participants were then asked to summarize the study in their own words and explain the rationale for their future participation. At this point, any misunderstandings relating to the study procedures or the potential benefits or risks of the project were addressed. Participants were then asked to sign an informed consent form, a copy of which was retained by participants along with contact information for the research team. All participants were informed that they could withdraw from the study at any time. Participants were given a R80 (US\$5.66) shopping voucher as a token of appreciation for their participation in the study.

• Assessments

Semistructured, face-to-face qualitative interviews were conducted by bilingual data collectors in Xhosa (the primary local language) or English as per participant preference at a research center in Khayelitsha (see **Supplementary Material**). All interviews were audio recorded (with participant permission) in full to ensure reliability. Interviews took place across two time points.

The interview guide was developed based on the research questions and the literature on parental attitudes toward enrollment of children in clinical trials. The interview guide was first piloted on several participants and interview questions were then refined based on participant responses. Interview questions focused on maternal understanding of HIV, experiences of vaccinations and perceptions of HIV vaccine clinical trials. Mothers were also asked for their views on whether they would enroll their child in an HIV vaccine trial and the factors that would influence their decision. All participants were informed that this research pertained to a hypothetical vaccine trial and that there are risks and

benefits to every vaccine. In line with qualitative research methods, data collection continued until saturation was reached.

Interviews were first translated and transcribed by an independent, bilingual transcriber who did not conduct the interview. The transcripts were reviewed by the data collector who conducted the interview for accuracy. Any disagreements in the translation of the transcripts were discussed between the researchers and resolved following a re-examination of the interview audio recording.

• Data analysis

To facilitate the organization and analysis of the data, transcripts were imported into NVivo 10 [21] and coded using thematic analysis [22]. Authors used the steps proposed by Braun & Clarke: repeated re-reading of the data, developing initial codes, searching for and generating candidate themes, and revising, defining and organizing themes. Themes were abstracted from the codes [23] with themes representative of repeated patterns of meaning across the dataset [22]. Authors V Williamson and B Coetzee coded all transcripts independently, with meetings held at regular intervals to discuss progress and agreement of codes as well as emerging themes. The credibility and trustworthiness of the findings were also ensured by peer debriefing [24]. Peer debriefing took place with feedback regarding the interpretation of the data from authors MT and AK, who have experience with maternal and child health research and qualitative methods.

• Ethics

The study was reviewed and approved by the Stellenbosch University Health Research Ethics Committee (S12/04/092).

Results

• Sample characteristics

A total of 22 women (12 HIV-infected and ten uninfected) participated in the interviews. The average age of the mothers was 32.4 years (range: 23–41 years), and the average age of their child was 4.5 years (range: 0–6 years). Of the 12 women who reported being HIV infected, only five reported that they were using ART at the time of the interview. Half of the participants (11 out of 22) were married and on average had two biological children and three household members.

• Results from thematic analysis

As delineated in **Box 1**, three overarching themes with accompanying subthemes were identified following thematic analysis of the data.

• Perceptions of HIV

Understanding & acceptance of HIV diagnosis

Both HIV positive and negative mothers perceived HIV to be an incurable but controllable illness. Many of the HIV-positive mothers in this study learnt about their status during pregnancy. Mothers stated that they understood and accepted their diagnosis, accepted the importance of adherence to ART and believed that individuals living with HIV were able to enjoy long and productive lives on ART. As such, mothers perceived HIV to no longer be a death sentence. Mothers' understanding of HIV and the subsequent acceptance of its manageability through ART was largely attributable to information received from nurses and counselors at the clinic. One participant stated:

“If you are diagnosed with HIV, it is not the end of the world. Because you are not sick or feel any pain. You are able to go and work for your children. You can't say just because you have got HIV, it is the end of the world... You can go anywhere as long as you treat it” (Fezeka, 27 years, HIV uninfected).

Understanding of HIV infection

Mothers stated that they could protect themselves from being infected with HIV by using condoms and wearing gloves when exposed to an infected person's blood or assisting a person with HIV. While most mothers perceived HIV to be contacted through sexual intercourse and contact with infected blood, some still held inaccurate beliefs about how HIV is contacted. For example, one mother stated.

“According to my knowledge, HIV is the virus inside human body in the blood. And when you have many diseases inside your body, they combine and make HIV” (Khethiwe, 47 years, HIV infected).

• Understanding of vaccines

Knowledge of vaccines

Mothers' knowledge and understanding of vaccinations generally were often limited. Primarily, mothers' knowledge of vaccines were restricted to their experiences of vaccinating their own child. Mothers often reported that they did not know what disease their child was being vacci-

Box 1. Themes and subthemes following thematic analysis.**Perceptions of HIV**

- Understanding of HIV
- Understanding of HIV infection
- Acceptance of diagnosis

Understanding of vaccines

- Knowledge of vaccines
- Vaccines as protective
- Knowledge of HIV vaccines and vaccine trials

Factors influencing decision to vaccinate

- Willingness to participate/interest in taking part
- Social influences
- Ultimately maternal decision
- Protectiveness (factor in altruism)
- Concerns of HIV vaccine side effects
- Distrust in vaccination trials
- Trust in medical staff
- Ease of access to vaccine

nated against and simply accepted vaccination of their children as per the basic instructions of medical staff (i.e. that they should bring their child to the clinic on a certain date for their immunizations).

Vaccines as protective

Mothers stated that they believed that vaccines served a protective function. Specifically, mothers reported that if their child received the necessary vaccinations, he or she would not experience illnesses or physical disabilities unlike children who had not been vaccinated. One mother stated:

“I think vaccines are made for the child to be right, I mean for the child to have a normal life. When they say maybe there will be a diseases coming, children usually go for the vaccine. for the child to be safe. When we grow up we would see children who are disable and wonder what happened, only to find out that they were not vaccinated when they were infants” (Mandisa, 33 years, HIV uninfected).

As such, vaccinations were considered vital to a child’s well-being and an act of maternal responsibility and caring. Neighboring children in the community who had not been vaccinated were often thought to have been irresponsible, unfit parents. This belief regarding the importance of vaccines is illustrated in the following excerpt:

“We grew up seeing this baby who is disabled, but we thought the baby was like that from

birth. It’s only my mother that told us that was the cause of not taking the baby for vaccine, because the (child’s) mother was busy drinking and careless about taking the child to the clinic for vaccine and the child ended up disabled” (Mandisa, 33 years, HIV uninfected).

Further, respondents stated that often children in the community were not vaccinated because their parents were unwilling to wait for long periods at medical clinics. Similarly, respondents reported that children whose parents were substance abusers were less likely to vaccinate their children.

Knowledge of HIV vaccines & vaccine trials

Mothers were unaware that a vaccine was being developed for HIV. Mothers often had limited knowledge of the purpose and procedures of a vaccine clinical trial, with many unable to comment as to how a trial would be undertaken. However, in some cases, mothers’ understanding of the hypothetical HIV vaccine trial was informed by their knowledge of ARV clinical trials. In these cases, mothers understood that ARVs were tested on individuals for effectiveness and potential side effects prior to their wider distribution, and the HIV vaccine trial was thought to follow the same process.

Interviewer: “Now let’s say the trials are about to start, would you bring your child?”

Mother: “Yes I would bring my child... I would bring her regardless. Even the ARVs were tested before being administered to people” (Fezeka, 27 years, HIV uninfected).

• Factors influencing decision to vaccinate
Willingness to participate

For the most part, mothers stated that they were willing and interested in their children participating in an HIV vaccine trial and that there was very little that would stop them from doing so. Mothers stated that their willingness to enroll their child in the trial would be increased after seeing other children successfully vaccinated against HIV. As stated by one mother:

“If it’s tested and proven that it is safe and working and the vaccinations are being conducted on other children, I must also take my baby” (Buhle, 31 years, HIV infected).

Even so, there were some who were concerned about confidentiality during participation. Another mother stated:

“Then, the one who told herself that I’m going to take my child to that place and found out that

her child has that thing, then comes back and tell her neighbour that girl I went to that place and I found out that my child has that thing” (Mandisa, 33 years, HIV uninfected).

Here, stigma and the possibility of being seen by others at a clinic acted as a potential barrier to participation. Mothers also stated that others within the community would be willing to vaccinate their children as it would mean not having to go to the clinic, where extensive waiting times existed, for regular HIV testing.

Social influences

Mothers stated that they would for the most part consult their child’s father on whether or not to enroll their child in the vaccine trial. For many, consulting their child’s father was considered necessary as important decisions regarding their children were often made together as a couple. Mothers also stated that, in addition to their child’s father, they would consult other members of their household and family with a view to receiving support for their decision to vaccinate the child. As one mother stated:

“I think getting a support might help me. I don’t want when I get home and discuss this and get a negative response. Support would help me a lot... It should come from our household. I don’t want to be alone in this, as if it’s my idea” (Fezeka, 27 years, HIV uninfected).

Individuals (e.g., fathers, household members, family) chosen by mothers as possible consultants in such a decision were considered to be understanding, trustworthy and capable of providing support.

Ultimately maternal decision

While mothers stated that they would consult others regarding trial participation, the final decision as to whether or not their child would participate reportedly rested with the mother. As stated by one mother:

“When you make decisions like this, it’s important to tell someone, that there is this thing and I would like to do it. That is important, although the decision is ultimately yours to take. But it’s good to get other people’s opinions as well” (Khanyiswa, 23 years, HIV uninfected).

Protectiveness (factor in altruism)

Mothers often believed that an HIV vaccine trial would be effective in preventing their child from contacting HIV. Mothers expressed a strong desire for their child to not contact the HIV

virus and took several steps to prevent their child from contacting HIV *in utero* and immediately following their birth. In line with this, the HIV vaccine trial represented a means for mothers to safeguard their child’s health and ensure they did not contact HIV later in life. As children were considered particularly vulnerable to contacting HIV, either while playing with other children and accidentally coming into contact with another child’s blood, or from later sexual intercourse as adults, participants stated that the vaccine offered reassurance and peace of mind for mothers that their child would remain HIV negative.

Mothers often perceived considerable stigma of HIV in their community and reported concerns that, should their child be HIV positive, they would be stigmatized by other children or ask their parents difficult questions about how they contacted the virus, neither of which the mother felt able to address. As a result, their child’s participation in the trial represented a means of protection, not only from the virus but from the associated stigma as well. As stated by one mother:

“Because at my house I am the only one who is infected. All I’m saying (is that) I wouldn’t love to have a child with HIV because it’s not nice to take treatment with your child. The child will grow with anger saying that ‘Mama, other children are laughing at me. Why me?’ You end up facing serious questions that you can’t answer. ‘Why did I get infected?’ Those are difficult questions” (Fezeka, 27 years, HIV uninfected).

Mothers also reported that their child’s participation in the hypothetical HIV vaccine trial could potentially result in wider community benefits. Children’s participation in the trial was thought to have the potential to lead to the reduction in the number of individuals with HIV. In these cases, mothers were particularly willing to enroll their child in the hypothetical vaccine trial. As stated by one mother:

Interviewer: “...Can you give me some reasons why you would let (your) baby take part?”

Mother: “I would let him take part so that we can see what will help children... and so that there could be a decrease on these diseases” (Babalwa, 32 years, HIV infected).

Concerns of HIV vaccine side effects

Attitudes toward the HIV vaccine trial were not all positive. A number of mothers reported concerns regarding the potential side effects of

the HIV vaccine trial. Mothers were concerned that their child could become sick, develop a rash or allergies which they did not have prior to the trial, or even die. In such cases, mothers did not want their child to take part in the trial, instead preferring for their child to participate once the vaccine had been proven safe. Moreover, mothers feared that if they took their child to be vaccinated against HIV, he or she would become infected with the virus. Given mothers' anxiety and distrust in clinical trials in these cases, the provision of information regarding the safety and efficacy of the vaccine was considered important. As stated by one mother:

Mother: "I mean people talk, like I would let my child to take part on these vaccines to be tested on him but some people will say no, white people are making money by using your children... your children will die and white people will make your children sick, things like that. People always talk bad things, you know, and those things will make me wonder" (Buhle, 31 years, HIV infected).

Other participants felt that members of the community would believe that receiving an HIV vaccination meant that the child was HIV positive. Nonetheless, as previously mentioned, mothers were often willing for their child to take part in the trial, despite the potential risk of side effects, as being vaccinated against HIV was thought to outweigh the risk of possible vaccine side effects.

Trust in medical staff

Mothers often desired the opportunity to discuss and receive guidance about the trial from medical staff or social workers. Mothers reported having additional questions about how the vaccine would work, who would be eligible to participate, and queries about potential side effects. Medical staff, including doctors and nurses, were largely seen as trustworthy, reliable sources of advice and mothers felt that they could approach medical staff for this support regarding the decision to enroll their child. As stated by one mother:

Mother: "I think I would go to a nurse or social worker. They know better than me. They can give me the best advice when it comes to health and can also tell me about the risks that are involved in the process. And how important is this to my child" (Khuthala, 33 years, HIV uninfected).

Ease of access to vaccine

Mothers were particularly knowledgeable about potential ways that healthcare workers could

increase trial participation in the community. Mothers stated that it was common for healthcare staff to drive around in the communities and promote vaccinations over a loudspeaker. The vaccinations would then be administered to children on site, and families could avoid the considerable waiting times experienced at clinics. Having vaccinations accessible at community level was deemed by mothers to be a necessary condition if HIV vaccinations were not a one-off treatment and needed to be administered routinely each year. As stated by one mother:

"Like with the polio ones, so vaccines are done in the same way, maybe they won't do it just once, (...) maybe they will say they must come again when they turn seven and maybe again at the age of 14, vaccines work like that" (Babalwa, 32 years, HIV infected).

Discussion

The aim of this study was to explore the factors influencing maternal willingness to enroll their HIV-negative infants in a hypothetical HIV vaccine trial. The narratives uncovered key themes relating to: maternal understandings of HIV; attitudes toward vaccination more generally; and the social, cultural and situational factors determining mother's decisions to enroll their child in the trial.

Our findings show that despite a fairly good knowledge of HIV, ART and vaccines in general, mothers tended to have little or no knowledge of HIV vaccines and HIV vaccine trials. Studies have shown that poor knowledge of HIV vaccines and trial methodology is associated with reduced willingness to participate [25], and this finding may represent a potential barrier to the enrollment of children in future vaccine trials. Of concern, vaccinations that mothers appeared to be more familiar with (e.g. polio), were reportedly often administered with limited communication between the parent and health worker. Instead, such vaccines were administered as an apparently routine act that required little mutual negotiation. The results of this study highlight the need for healthcare workers in future vaccine trials to ensure that parents are provided with accurate and sufficient information to maintain motivation to comply with and complete the trial.

Despite relatively poor maternal understanding of HIV vaccines and how they work, the majority of mothers were interested in enrolling their child in a trial, mainly because of anxiety

that their child could develop HIV in the future. The vaccine trial represented a means of reassurance that their child would be protected from contacting the virus. In such cases, the potential side effects and inherent risks of participation in the trial were reportedly outweighed by the possible benefits of participating. Notably, mothers believed that the vaccine would be protective despite receiving information from the study researchers that the effectiveness of the hypothetical vaccine trial had not been proven. This finding is in keeping with those of Otowombe *et al.* that adolescents were willing to participate in HIV research despite having knowledge of negative trial results [26].

Contributing to mothers' decisions to enroll in a trial were also beliefs that they could approach and trust medical staff for guidance about the trial as well as ease of access to the vaccination procedure. These results highlight the need for healthcare workers to be mindful of their position of trust and authority when providing information regarding vaccine trials. In particular, as mothers believed that the hypothetical vaccine would provide their child with lifelong protection against HIV, this may have implications for future trials. Thus healthcare providers should be aware of parental expectations and provide guidance regarding the potential need for booster vaccinations. Moreover, the findings indicate that healthcare workers must deliver information regarding the potential risks and benefits to child participation in a vaccine trial in a balanced fashion and ensure that parents fully understand the possible side effects of a trial before providing consent.

Mothers also reported several social harms associated with trial participation. Some mothers feared that others would assume that participation in the trial meant that their children were infected and that they would, therefore, be discriminated against. These results are in keeping with previous research that has found mistrust in vaccine trials to be an inhibitor of WTP [27–31]. A common misperception persists that HIV trial participants are in fact infected with HIV or at high risk of infection [32], which is in part due to the presence of HIV antibodies, a normal immunological response, after receiving the candidate vaccine [33]. Therefore, the guidance provided to parents who are considering enrolling their child in an HIV vaccine trial may be enhanced by the inclusion of information that would address these concerns.

Furthermore, these findings may also have implications for the Phase III trials (HVTN 702) that are expected to commence in South Africa in November 2016 (pending regulatory approval) amongst HIV-uninfected adults. Adults may avoid participating in HIV vaccine trials due to similar concerns, such as fear of discrimination or stigma from family members or the community. Education about vaccine trials delivered at a community level may serve to improve the acceptability of and willingness to participate in HIV vaccine trials by diminishing stigma and future research is needed to evaluate this response.

Mothers associated vaccinations with maternal qualities of care and responsibility and failure to vaccinate was considered to be irresponsible and indicative of parental laziness. This finding may have implications for future interventions that aim to improve uptake of routine vaccinations for young children. As such, future interventions may benefit from placing mobile vaccination units in the community or conducting home-based vaccinations within households. In this way, children whose parents/caregivers do not take them for vaccinations (for various reasons including parental laziness) will also be reached.

This study had several strengths and weaknesses. Among the strengths is the recruitment of both HIV-positive and negative mothers which allowed for the collection of a wide range of maternal views. However, a weakness of this study was the exclusive recruitment of mothers. As children often receive care from a number of other relatives in this context [34–37], the collection of views from other caregivers, such as grandmothers, and fathers would allow for a better understanding of the factors influencing caregivers' decision to enroll children in an HIV vaccine trial. Further, it was not possible to conduct member checking and provide participants with a copy of the interview transcripts and preliminary findings which must be acknowledged as a limitation. Given the nature of qualitative research which aims to explore participants experiences [22,38] these findings may not generalize to other samples; however, these results are in keeping with previous qualitative HIV trial research conducted in adolescent and adult populations. Moreover, it is possible that maternal responses in the present study may have been influenced by social desirability bias given the sensitive nature of

the interview topic. Finally, while women in this study indicated that they would be willing to enroll their HIV-negative infants into a hypothetical HIV trial, we do acknowledge that this willingness may not translate to actual willingness in a real trial. These limitations

EXECUTIVE SUMMARY

Background

- There is some evidence on adolescents and adults' willingness to participate in HIV vaccine trials. However, very little is known about the willingness of parents to enroll their children in HIV vaccine trials and the factors that influence such a decision.
- The aim of the present study was to explore the factors influencing mothers' decision to enroll their HIV-negative infants in a hypothetical HIV vaccine trial.

Methods

- A total of 22 women (12 HIV-infected and ten uninfected) from the Maternal Obstetric Unit at Site B in Khayelitsha participated in the interviews.
- Interviews were audio-recorded and transcribed verbatim. Transcripts were analyzed using thematic analysis in NVivo 10.

Results

- We identified three overarching themes: perceptions of HIV; understanding of vaccines; and factor influencing decision to vaccinate.
- Our findings showed that while women in this study had knowledge of HIV, ART and vaccines in general, mothers tended to have little or no knowledge of HIV vaccines and HIV vaccine trials.
- Our findings also showed that while mothers were familiar with vaccinations more generally, these were often administered with limited communication from healthcare providers as to the vaccines purpose and functioning.
- Mothers were for the most part eager to enroll their negative infants into vaccine trial research, as they considered this a valuable form of protection from future HIV infection.
- Some mothers reported concerns regarding the stigma associated with participation in HIV vaccine research.
- Also contributing to mothers' decisions to enroll in the hypothetical trial were beliefs that they could approach and trust medical staff for guidance about the trial as well as ease of access to the vaccination.
- Some mothers associated child vaccinations with maternal care and responsibility, while failure to vaccinate was considered to be irresponsible and indicative of parental apathy.

Discussion

- HIV vaccine trial participants require knowledge on the risks and benefits associated with vaccine research, as poor knowledge of HIV vaccines and trial methodology is associated with reduced willingness to participate. Such information could be provided by healthcare workers in future vaccine trials and is necessary in order to maintain motivation to comply with and complete the trials.
- The potential protectiveness of the HIV vaccine against the virus was a salient issue in this study. However, in the context of an experimental vaccine trial, research participants may need reminding of the risks and benefits associated with participation.
- Several inhibitors to participation, including mistrust of vaccine trials, were identified as important barriers to participation in this study which is consistent with previous research. The presence of HIV antibodies following HIV vaccination has been interpreted as deliberate infection. These results indicate that the provision of information to participants in HIV vaccine trial research that would address these concerns may be beneficial.
- At a community level, more information about HIV vaccine trials may improve the acceptability of trials and reduce the stigma associated with trial participation.
- This study identified several social, psychological, environmental and behavioral factors that influence HIV vaccine trial participation. In order to ensure that future HIV vaccine trials are conducted in a respectful and ethically sound manner, more research is needed to fully explore and understand barriers to participation.

notwithstanding, this study provides a novel exploration of the factors influencing mother's decisions on whether to enroll their child in an HIV vaccine trial.

Conclusion

In the context of vaccine trial acceptability and willingness to participate, the results of this research illustrate the concerns held by mothers and potential barriers to child participation in future vaccine trials. Our findings may be useful to vaccine trial investigators who are tasked with providing information to parents who are considering enrolling their child in future HIV vaccine trials. Our findings also suggest the need for healthcare providers to sensitively deliver trial information to parents. Taken together, this study highlights the social, psychological, environmental and behavioral factors influencing vaccine trial participation that are important to understand if we are to facilitate willingness

to participate in several thousands of eligible participants in future trials that are respectful and ethically sound.

Financial & competing interests disclosure

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No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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