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"If it benefits someone, it will be good:" perspectives on research participation from pregnant women living with HIV

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ABSTRACT

Pregnant women living with HIV (PWLHIV) are becoming increasingly involved in HIV research; however, the ethical concerns regarding their decision-making related to research participation are understudied. This qualitative study aimed to understand the perspectives and lived research experiences of PWLHIV, intending to identify important considerations to inform best practices. This study used semi-structured interviews (SSIs) of PWLHIV who participated in research studies in Eldoret, Kenya. All interviews were audio-recorded, transcribed, and translated. Qualitative analyses were performed, with line-by-line coding, constant comparison, axial coding, and triangulation to identify central concepts. Twelve PWLHIV participated**.** Overall, participants had positive experiences with HIV research. Most participants had difficulty distinguishing the differences between the research process and enhanced clinical care. They reported a willingness to participate in future HIV research studies and indicated altruism as the primary motivator. Participants identified their preferences and experiences with recruitment, consenting, reimbursement, and enrolment of infants in HIV research. The largest barrier for participating in HIV research was identified as a concern that participation would lead to HIV disclosure. By understanding the lived experiences of PWLHIV who participate in HIV research, future researchers can design studies and consenting processes to optimize ethical research practices.

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Introduction

Despite progress against the HIV/AIDS epidemic globally, young women are still disproportionately affected by HIV, with a prevalence rate three times higher than their male counterparts (Karim & Baxter, 2019). Over two million women of childbearing age live with HIV in sub-Saharan Africa (Avert, 2020). Pregnant women living with HIV (PWLHIV) are often excluded from clinical trials of new HIV treatments to minimize PWLHIV's risk of side effects or unintentional outcomes (Krubiner et al., 2016). This results in a paucity of data to guide the practice of evidence-based medicine and outcomes for this population. To optimize clinical care, PWLHIV and their young children must be engaged at the inception of novel research, rather than awaiting the results of trials involving non-pregnant populations. However, investigators may feel unprepared to manage the ethical considerations when engaging this population in research studies.

Research involving PWLHIV improves their care, but their experiences in research are often written by external entities, such as researchers or organizations. Only two published studies interview PWLHIV about their perspectives on research participation (Corneli et al., 2007; Sullivan et al., 2018). This reveals an urgent need to mediate the divide between inaccuracies in external perceptions and the true experiences of PWLHIV. The purpose of this study was to qualitatively examine the perspectives of Kenyan PWLHIV who participated in research. By understanding and addressing their ethical concerns for research, studies can be designed with appropriate ethical considerations to generate the data needed for evidence-based clinical care for this population.

Methods

Settings:

This study was set within the Academic Model Providing Access to Healthcare (AMPATH) program, a longstanding academic partnership between Moi University School of Medicine, Moi Teaching and Referral

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Hospital (MTRH), and a consortium of North American academic centers. PWLHIV were recruited from AMPATH's maternal-child health clinic (MCH) located at MTRH in Eldoret, Kenya. AMPATH is home to one of the world's largest HIV maternal and paediatric care programs, providing HIV-testing and care for approximately 80,000 pregnant women and 35,000 children (Indiana University School of Medicine, 2020). As of January 2022, 531 PWLHIV were actively enrolled in prevention-of-mother-to-child-transmission-of-HIV care at MTRH. During this time, 239 PWLHIV were engaged in research studies (M. Joy, personal communication, February 16, 2022).

Study Design:

This qualitative, cross-sectional study utilized a questionnaire to collect demographic information and semi-structured interviews (SSIs) to explore the participant's experiences. In SSIs, both the interviewer and study participants are able to pursue ideas or responses in greater detail (Gill et al., 2008; Proctor et al., 2011). The interviewer was an experienced facilitator and received additional training from one of the authors with expertise in qualitative interviewing.

Participants:

Participants for this study were recruited by convenience sampling. Inclusion criteria was as follows: (1) >18 years of age; (2) pregnant or <1 year since last pregnancy; (3) speak English or Kiswahili; (4) known to be living with HIV; (5) previously enrolled in a research study.

All individuals participated in one of two longitudinal studies that involved PWLHIV recruited from MTRH's MCH. Both studies took place in Eldoret, Kenya through AMPATH. One was a nested case–control study. Using laboratory studies, they investigated PWLHIV's risk of developing gestational diabetes. Two women from our study reported participating in this study. The other ten participants came from an epidemiological study observing the effects of dolutegravir implementation with prevention of mother-to-child transmission of HIV (publication forthcoming). Both studies required written informed consent.

Data Collection:

Twelve SSIs were held between November 12, 2019, and March 12, 2020. Recruitment was discontinued due to the COVID-19 pandemic. The facilitator conducted SSIs in Kiswahili or English. Interview guides were created by the authors, with questions informed by grounded theory, local healthcare providers, a Moi University sociologist, a U.S.-based paediatric infectious disease researcher, and a systematic review (Raciti et al., 2021). Questions included PWLHIV's perceptions of research, prior research experiences, community and cultural beliefs about HIV, pregnancy, and potential interventions. Interview guides are available upon request.

The SSIs lasted between 30 and 90 min and were audiotaped. The recordings were transcribed verbatim and translated into English by a trained translator, then verified by a separate bilingual (English-and Kiswahili- speaking) research assistant and deidentified. Written informed consent was obtained from study participants. Each participant received US$3 to cover travel expenses. This study was approved by the institutional review board of Indiana University School of Medicine in Indianapolis, Indiana, and by the institutional research and ethics committee of Moi University School of Medicine and MTRH in Eldoret, Kenya.

Data analysis

The transcripts were qualitatively analysed for contextualized understanding. A priori codes were created and extracted from the interview guide and used as frame for analysis. We employed constant comparison, axial coding, and triangulation to identify central concepts (Corbin & Strauss, 2014). Two investigators initiated constant comparative analysis, completing line-by-line analysis to elucidate the meanings and processes regarding the participants' perceptions of their previous participation, enrolment, and consent in research, using the qualitative analysis software Dedoose ("Dedoose," 2020). The same two investigators independently extracted and compared themes to high degrees of agreement. Three investigators performed axial coding—the process of relating categories to their subcategories and linking them together at the level of properties and dimensions—to organize themes into relevant relationships (Corbin & Strauss, 2014), which were developed inductively from the data. Quotes are edited minimally for clarity and provided throughout the results to add descriptive detail and highlight major themes.

Results

Description of study population

Twelve individuals (mean age 38.5 years, range 26–51 years) participated in this study. Ten had a prior

pregnancy before participating in research, and four had experienced a miscarriage or stillbirth. The majority (n = 7) lived with the father of their child, while others lived alone or with different family members. Just under half had jobs outside the home, and approximately 40% received education beyond primary school [Table 1].

Perspectives on research versus enhanced clinical care

Most were unable to identify specific differences between research and what they considered more attentive or enhanced clinical care, in which participants noted that clinical providers would spend more time talking with them, answering their questions, and ensuring appropriate referrals for services. Participants uniformly expected clinically relevant information regarding themselves or their baby to be disclosed. Some respondents viewed their research participation as attentive pregnancy care. One woman said, "*They told me that [they were] coming to see the baby and check how she is doing. So, I was not worried because it is helping since if the baby has any problem, they will discover it early.*" (Participant 5, 40 years old). Despite difficulties differentiating between research and care, many women noted only receiving reimbursement for transportation when participating in research. Only two women, both of whom received education beyond the primary level and participated in the epidemiological study, could distinguish between the investigative elements that classified research from enhanced clinical care.

Table 1. Participant characterisitics.

Variable	n (%)
Participant's Age (in years)	
25–30	2 (17%)
31–35	1 (8%)
36–40	3 (25%)
41–45	5 (42%)
46–51	1 (8%)
Education Level	
Some primary	1 (8%)
Completed primary	6 (50%)
Completed Secondary	2 (17%)
University or additional training	3 (25%)
Occupation	
Homemaker	2 (17%)
Business owner	1 (8%)
Teacher	2 (17%)
Casual Worker	1 (8%)
Farmer	2 (17%)
Unemployed	4 (33%)
Married to Father of Child	
Yes	7 (58%)
No	5 (42%)
Number of Previous Pregnancies	
0	2 (17%)
1	2 (17%)
2	3 (25%)
3	2 (17%)
4	2 (17%)
5	0 (0%)
6	0 (0%)
7	1 (8%)
Learned of HIV Status while Pregnant	
Yes	2 (17%)
No	10 (83%)

N = 12

Perspectives on motives facilitating participation

Participants expressed the benefits of research outweigh the risks. Altruism was identified as the primary motivator. One woman expressed, "*so long as [it] benefits someone, it will be good.*" (Participant 7). The women desired to help others through enhancing clinical treatment for all HIV patients and reducing the cultural stigma surrounding a positive HIV status.

Other motives for participation were accessible care, health education, reimbursement, and social support [Table 2]. Participants noted having access to medications and testing diagnostics through research and believed they would be referred if researchers were unable to provide the needed care. Many participants viewed discussions with researchers as teachings to gain knowledge, an influential factor in their decision to participate. Participants had varying thoughts on whether reimbursement impacted their decision: some viewing it to be very influential, while others were willing to participate without it [Table 2]. Primary reasons why reimbursement was desired were: (1) transportation issues, and (2) it allowed them to feed their family during participation.

Perspectives on concerns and barriers to participating

Confidentiality and privacy were identified as major concerns related to research participation. Several described the negative cultural sentiments towards HIV. Participants envisioned that community knowledge of their research participation would lead to status disclosure, resulting in discriminatory actions against their children and social stigmatization from the village. As one woman said, "*If you come to me [wearing an] AMPATH T-shirt, and I had never disclosed [my HIV status] to my friends, you will have come and disclosed me. If you disclose me to others, people will say, 'So and so has HIV.' People will point fingers at you. Others will discuss you. Others will find you and insult you.*" (Participant 8, 41 years old).

Three women expressed concerns that the internalized stress associated with being newly diagnosed or

Table 2. Facilitators and barriers for research Participation.

Facilitators	Illustrative quotes
Altruism	*"What they told me is that it will help many other people. So I accepted"* (Participant 5, 40 years old, Housewife) *"Yes. So long as [it] benefits someone, it will be good"* (Participant 7, 26 years old, Unemployed) *"Because it will help many people."* (Participant 4, 41 years old, Teacher) *"You are told to love yourself and your neighbor."* (Participant 11, 26 years old, Housewife)
Clinical care	*"I saw that they were helping us a lot because at times you are worried like; "do I have diabetes? Or what do I have?" but when you get [research], you are helped. Someone tells you; "I can do this for you, we want to know your diabetes status, let us check if you have it or not" so at least you see they are helping you."* (Participant 1, 38 years old, Housewife) *"I will expect the results first. When they tell me the results that is the most important thing."* (Participant 8, 41 years old, Businesswoman) *"You know others could have thought that the baby is [HIV] positive, maybe they have not known that there is medicine [to prevent HIV] because there are others who go to the local clinics; they don't come to the main hospitals. So, some of them do not even get tested and when they come to the hospital, they get tested. They had never been tested before."* (Participant 4, 41 years old, Teacher) *"You know during pregnancy, there are so many problems that we do undergo. So, they came there, it was free, and you were not forced. It was voluntary and you could join if you wished. So, I saw on my own that there is no need for me to refuse because it is my health, and I should know how I am. I was tested and given a card which I went home with."* (Participant 12, 32 years old, Housewife)
Teachings and lessons	*"You know one wants the knowledge, yes."* (Participant 9, 44 years old, Farmer) *"Understanding things better that [otherwise] I could not have understood."* (Participant 2, 41 years old, Businesswoman) *"What will make me agree to participate is wanting to know more about that thing."* (Participant 2, 41 years old, Businesswoman) *"Wanting to know more about new emerging things."* (Participant 3, 40 years old, Casual worker) *"You will have gotten to learn something because even if you were in the house, you would have been there keeping quiet or outside there looking after the baby. But here at least you get something, you learn something and gain certain knowledge."* (Participant 1, 38 years old, Housewife)
Reimbursement money	*"So, there are people who will participate because of the money, and there are those that will participate without asking for the money."* (Participant 11, 26 years old, Housewife) *"Yeah. Someone will say, "let me volunteer today. I will be given transport for coming and going back, I will be given lunch there". So even if I take this time, even if it is two hours, that is nothing to me."* (Participant 9, 44 years old, Farmer) *Yeah. It can make it easy. If you tell them that we will make some lunch, you will get lunch here and give you fare, one will make sure that they come. This is because most people come from far.* (Participant 2, 41 years old, Businesswoman)
Social support	*"I was to lose hope and then I come here you tell me; "you are not alone, I have worked with many and you are not alone" so if I was losing hope, maybe you hear others have lost hope and they don't want drugs. So through research, you come and they tell you; "we have done this study, you are not alone" they don't tell you names but they tell you they have done it for long and there are many people in that problem. So at least they will give me hope to feel like; "Oh, I am not alone, we are many" and you will take life normal and just continue."* (Participant 12, 32 years old, Housewife)
Barriers	Illustrative quotes
Confidentiality/ privacy	*"They fear for privacy. If there will be no privacy, many of them fear coming out because their information may come out there and they don't want to be known."* (Participant 12, 32 years old, Housewife) *"Let us say now you come with something that shows AMPATH and then you come to my home, I will refuse (laughs). I will not accept."* (Participant 11, 26 years old, Housewife) *"What I am saying is that anything that will make me refuse is something that will expose me either my face or my name and where there is any risk. I will not accept that one."* (Participant 11, 26 years old, Housewife) *"They will start gossiping saying; "so and so is like this and that" it is not good. If the research reaches a level that will make people know your [HIV] status, I will not participate."* (Participant 9, 44 years old, Farmer) *"They must give it to the doctor who works here. They cannot give it anyhow. They must go through the doctor."* (Participant 3, 40 years old, Casual worker) *"Yes. It even brings problems to the children. When you find my [HIV] status is like that and because somebody knew my status and my children are negative, you will even find that my children will be discriminated from other children."* (Participant 11, 26 years old, Housewife) *"They will spread the gossip. They will talk of bad rumors in the village. You see that is our secret, which we finish it here, and no one knows."* (Participant 1, 38 years old, Housewife)
Being pregnant	*"I think stress is usually brought about by the pregnancy itself because when you are not pregnant, you don't get stressed, but when you are pregnant you get a lot of stress. I don't know why."* (Participant 11, 26 years old, Housewife) *"Yes. It was taking around three hours and you had to persevere because you want your wellbeing to be good. For example, we were being told never to eat anything from morning yet you are pregnant and then you had to give out the first blood sample, then stay there and again give out the second blood sample and then the third one and you are expectant. Normally an expectant person would get hungry all the time, but you just had to persevere there so long as something has happened, you had to persevere."* (Participant 8, 41 years old, Businesswoman) *"Maybe if she is tired or the distance that person is coming from."* (Participant 9, 44 years old, Farmer) *"You know when one is expectant, they don't want a lot of things. It is tiredness"* (Participant 10, 51 years old, Casual worker)
Balancing family obligations	*"It will depend. Now I have the baby. [If] I came from my house when I had not planned for such, you see that will be a barrier. You see like now I came when it was almost lunch time and then when I come here I get that research that will take three hours and I have the baby, I will not agree."* (Participant 11, 26 years old, Housewife) *"You know everything will stand. For example, my husband is someone who looks for casual jobs. He does construction work. So, when he goes to work, he will come back for lunch, and I will not be there and he will not know how to organize himself."* (Participant 9, 44 years old, Farmer)

reminded of their HIV status during research may harm the fetus. Two of these participants were diagnosed with HIV during their pregnancies, and one mentioned feeling uncomfortable because she was "*still young in that challenge*." (Participant 6, 42 years old). Another woman mentioned being more tired during pregnancy,

hindering her desire to participate [Table 2]. Moreover, participants were challenged by balancing family obligations with research commitments, and would preference family obligation if required. However, most women expressed no concerns with participating in research while pregnant, and some preferred participating because of the "care" provided.

Perspective on logistical aspects of research

Recruitment

Researcher Demographics: All participants preferred that the primary contact be a known medical provider due to the sensitivity of their HIV status [Table 2]. A few participants noted they would be suspicious of status disclosure if not approached by their clinician. Furthermore, some participants would not refuse if their doctor told them about a research study. Participants desired the initial recruiter to be Kenyan, but the research team to be of mixed nationalities to allow for knowledge sharing and greater access to resources.

Location: As privacy was a significant concern, most women wished to be recruited while in the clinic or hospital [Table 2]. If researchers came to their villages, participants recommended approaching the chief for permission. Furthermore, participants felt strongly that all conversations regarding HIV-research happen privately.

Consenting

Most participants forgot or lacked an understanding of the research they participated in since being told at enrollment, with only three participants able to describe the study's objective. All participants expressed voluntarily enrolling, and two individuals had no memory of signing a consent form.

Participants expressed varying levels of understanding concerning the purpose of informed consent. Some women gave no explanation. A few women thought it was conducted to explain the study before enrolling, and one participant thought it was for the government to track the number of people living with HIV.

When participating in longitudinal studies, the women were supportive of reconsent. As one woman said, "It is like you started school, then you lacked fees [and left school], then you come back and stand on the door. When you come back, the teacher has the right to renew those things that you studied long ago." (Participant 7, 26 years old).

Additionally, many women expressed a desire to bring the papers home and think about the study before consenting. One participant desired signing them with the researchers present to answer her questions. Many preferred to read the forms themselves, and they all wanted the forms offered in Swahili or English.

Reimbursement:

Views regarding fair compensation for participation in research varied widely. Some women believed a flat rate was appropriate, whereas others thought that compensation should depend on the distance travelled, time commitment, and number of visits required. One participant stated that researchers should pay as much as possible, whereas another thought the minimum amount would be best.

Subsequent enrolment of infant in research:

All participants were willing to enrol their unborn children and infants in research. Although a few expressed hesitancies if injections or blood samples were needed. The majority (n = 9) still desired to enrol their newborn. As one participant said, "*when you take the baby's blood sample, it will help her because if she has a problem, you will find it out, and you will tell me so that we can help her early while she is still young.*" (Participant 5, 40 years old).

Additionally, the participants thought the mother should be the key decision-maker while the child is in the womb, but most (n = 8) noted that the decision to enrol an infant should be equally shared between the parents, unless the mother is single.

Discussion

Participant engagement and involvement in intervention development and evaluation are critical in improving health outcomes (Mkwanazi et al., 2017). Our qualitative study observed that PWLHIV in Kenya view research participation as beneficial with generally positive experiences. Despite participants' awareness of research's benefit to the community, the majority could not differentiate its purpose from receiving enhanced clinical care and expected to hear results of any tests performed on them. Altruism was the leading motivator for participation. Conversely, issues surrounding confidentiality dissuaded participation. Fear of unintentional disclosure of HIV status fuelled some women's desire to avoid contact with AMPATH staff members in public. By understanding participants' concerns and expectations, future studies can optimize the ethical conduct of research, which may inform and improve patient care and outcomes.

Many participants viewed research as synonymous with enhanced clinical care. These findings align with the therapeutic misconception recorded by studies in

different settings (Georgetown, n.d.). Therapeutic misconception exists when participants believe their healthcare is equally important to producing generalizable knowledge for medical advancements (Henderson et al., 2007). Historically, researchers differentiated research from enhanced clinical care by taking participants through the informed consent process to understand their role, the study's purpose, and the potential consequences of participating (Kadam, 2017). Therapeutic misconception should not exist given the definition of informed consent. Yet, our results show that the current consent process might not effectively distinguish the intended benefits of each.

Optimizing the informed consent process can be challenging for researchers to balance an adequate level of explanation for potential participants' rights to understand the complex risks and scope of research. Common challenges encountered are complex information, poor comprehension of consent forms, and patient competence (Kadam, 2017). National Bioethics Advisory Commission states that researchers must understand participants' expectations before participation. Formative research increases understanding of potential research participants' expectations and desires for research engagement (Georgetown, n.d.). Researchers may also consider clarifying why their research study is different from standard clinical care during recruitment, especially in laboratory-based research, which can easily be mistaken for routine care.

Fear of confidentiality breaches within research was a major barrier to participation. PWLHIV in low-resourced settings experience multiple social risk factors, prompting women to hide their diagnosis. Though confidentiality is a fundamental tenet of medical ethics, our findings emphasize a continued need to prevent HIV disclosure. Participants gave specific examples, such as research teams having to visibly de-identify their association with AMPATH when performing home visits, as the community closely associates the organization with HIV care in Kenya. Researchers must continue to remain cognisant of the distress that HIV stigma has on individuals. (McHenry et al., 2017).

Equally important during the recruitment process is building a good rapport between the participants and research team. In line with recent literature, our participants wanted the initial research contact to be a Kenyan healthcare worker who knew of their status (Kochhar et al., 2017; Newington & Metcalfe, 2014). This differs from how ethics boards want recruitment conducted, which highlights the need for community involvement in research design (Fregonese, 2018). The participants' recruitment desires are likely a result of the stigma associated with being a PWLHIV. Exploring the complexities between one's willingness to participate and potential power imbalances using this recruitment method will be an important area for future research.

Participants highlighted the importance of having internationally collaborative research teams. They perceived cross-cultural teams to have greater access to resources and ideas. Collaboration and partnerships ensure that research promotes global health and supports the appropriate health needs of each research location (Mercer et al., 2018; Millar et al., 2020). The involvement of AMPATH — who prioritizes reciprocity and mutual benefit among partners– likely influenced their desire to participate in research studies with internationally collaborative teams (Mercer et al., 2018). AMPATH holds a policy for international collaboration of research projects, which was likely noticed by the study participants.

Finally, our participants reported differing viewpoints on reimbursement. While researchers should reimburse for travel costs and time to prevent overall costs on participants (Molyneux et al., 2012), there is no universal consensus on what is acceptable. Researchers should work with local ethics committees to determine appropriate amounts to minimize any chance of inducement (Mngadi et al., 2017).

Limitations

This study was limited by its small sample, which was a result of COVID-19. Despite multiple attempts, we could not enrol new study participants safely within a reasonable timeframe. Thus, our findings are likely not representative of all PWLHIV. Furthermore, the current study relied on interviews, which can be subject to recall bias. Attempts were made to minimize the degree of recall bias by including participants whose research involvement occurred within the past year. Despite the limited sample size, this study brings up important considerations in an area with limited knowledge.

Through mapping the contextual realities of participating in research as a PWLHIV, we learn more about the interplay between cultural context and research. While these results may not be generalizable to all PWLHIV, important insights were gained, including the perceived benefits of research for both the participant and the larger community. Future work investigating the perception of PWLHIV who refused to participate in research could aid in our understanding of ethical considerations. The insights from this study can guide voluntary and ethical participation in future research involving PWLHIV.

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