A Qualitative Study on Experiences and Perceptions of Screening for Enrolment in HIV Clinical Research among Volunteers in Kenya

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Abstract

INTRODUCTION

Screening volunteers to determine their eligibility to enrol in clinical research is an important phase in clinical research. However, little is known about how volunteers view and experience this phase of research implementation. This study explored volunteers' perceptions and experiences of screening for enrolment into HIV clinical research studies.

MATERIALS AND METHODS

A qualitative study was conducted with 44 research participants purposively selected from a sample of 164 participants drawn from six research studies at the Kenya Aids Vaccine Initiative-Institute of Clinical Research (KAVI-ICR) in Nairobi, Kenya. Data was collected between March and June 2014, through in-depth interviews that were audio recorded and transcribed verbatim. Data were managed and thematically analyzed using the Atlas *ti* software.

RESULTS

Participants expressed mixed views and experiences about screening. A majority had initial fears about HIV testing and being screened for possible chronic diseases. Discomfort with physical examination, amounts of blood collected and associated pain were reported. On a positive note, participants were appreciative of the free comprehensive screening, and confirmations of being in good health. Those found with minor ailments reported receiving treatment before enrolment. HIV risk reduction behaviours following post-test counselling were also reported by some.

CONCLUSIONS

Evaluating participants' experiences of screening for enrolment is important for the design of research that meets ethical requirements and responds to research participants' fears and concerns for optimal enrolment and retention.

Keywords: *Screening, Clinical Research, Volunteers, Eligibility, Perceptions, Experiences*

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Introduction

HIV/AIDS remains a major public health concern globally with sub-Saharan Africa bearing close to half of the HIV-related deaths(1). An estimated 39 million persons were living with HIV by the end of 2022 with over 53% being from Eastern and Southern Africa(2). In Kenya, 1.4 million people were living with HIV in 2021. Kenya has a generalized epidemic with an adult prevalence of 4% and a concentrated epidemic of 5.4 % among women aged 15-49 and 30% of new infections have occurred among the most at-risk populations (MARPS)(1,3).

Global scientific efforts to combat the epidemic have included the development of treatment options and prevention awareness has resulted in reduced prevalence rates, a decline in AIDS-related mortality and improved quality of life for people living with HIV(3,4).

However, these gains have suffered the aftermaths of the COVID-19 pandemic and the Russian-Ukraine war, leading to economic disruptions and shifting funding priorities from HIV programming (5,6), thus exacerbating the impacts of HIV among vulnerable populations. Finding a safe and efficacious vaccine is needed to bring HIV to a halt(7–9).

To date over 250 HIV vaccine trials have been conducted, yet none has shown success for licensing (7,10). With the war not yet won, current and future vaccine and drug studies will require thousands of volunteers willing to be recruited, enrolled and retained to trial completion(11). Before participants are enrolled in studies, they are screened to determine their eligibility and this often involves the capture of medical history, physical examination and collection of samples that include blood and urine for laboratory analysis as per study protocol. Evaluating participants' experiences of clinical research participation is important in unearthing their fears and concerns around participation. Nonetheless, little is known of how they experience the screening for enrolment yet this information may provide answers as to why several research sites are continually unable to meet recruitment goals(12–14). Elsewhere, studies evaluating the screening phase of research have focused on data accruals of screening outcomes such as screen failures(15–17) while others have been on sex differences and outcomes of screening and enrolment(18) and clinical research management(19).

In Kenya, KAVI-ICR has over the last two decades, conducted phase 1 HIV vaccine trials, drug trials, epidemiological studies and lately Ebola and COVID-19 vaccine trials. Available clinical data have shown KAVI-ICR to successfully recruit and retain volunteers in HIV vaccine trials. However, little is known of why eligible volunteers declining enrollment. For example, one study evaluating screening outcomes found that of 59.4% of eligible participants, 18.6 % had declined enrolment(20). In an observation study that screened and enrolled 100 participants for future HIV vaccine trial participation, 86 agreed to be contacted. On contact, only 26 (30%) were willing to be screened and enrolled in a 40-person HIV vaccine trial forcing the trial to recruit and screen more participants (21). Studies evaluating recruitment challenges in clinical research have overly focused on pre-screening challenges (22,23) and less attention on screening experiences. Therefore, this study aimed to investigate the experiences and perceptions of screening for enrollment into HIV clinical research studies among volunteers at the KAVI-ICR.

Materials and Methods

Study design and site

We conducted a cross-sectional qualitative study with 44 research participants at the KAVI-ICR trial sites in Nairobi, Kenya. KAVI-ICR has two sites namely: KAVI-KNH situated at Kenyatta National Hospital, Faculty of Health Science, University of Nairobi, and the KAVI- Kangemi at Kangemi Health Centre, a Nairobi County government community health facility. Both trial sites have dedicated teams that handle various aspects of clinical research implementation.

Study population

Study participants were males and females aged between 18-49 years. They were drawn from six KAVI-ICR studies conducted between the years 2009 and 2014. The studies included four phase 1 HIV vaccine trials, one drug trial and an epidemiological observation, thus three studies from each site as shown in Table 1 below. The participants had mixed sexual behavioural characteristics.

Those in the vaccine-based trials (B002, B002, S001 and HIVCORE 004) were low–risk and sera-negative; the Protocol J observation study had a mix of low to high-risk uninfected and sera-positive participants, while the PrEP drug study had high-risk HIV uninfected males recruited from the men having sex with men (MSM) population.

Sampling

A purposive sample of 44 participants was drawn from 164 participants who had

responded to a survey questionnaire on volunteers' experiences and perceptions of clinical research participation mixed methods study. Due to the small size of qualitative samples, a sample range of 15%-20% was considered adequate for in-depth analysis of the subject matter (24,25). Participants were selected if they had consented to be contacted for the in-depth interviews, their knowledge of the subject matter and willingness to share their experiences(26) of screening for enrolment. Table 1 contains the distribution of the participants across the six studies.

Data collection

Participants were recruited by the lead author with the help of the trial staff. In-depth interviews were conducted by the first author with the assistance of three experienced research assistants between March and June 2014. Research tools were pre-tested among 10 female sex workers drawn from a double-blind randomized trial of a monthly treatment of Metronidazole and Miconazole Co-formulated suppositories versus placebo for preventing vaginal infections study at the Sex Workers Outreach Program (SWOP), Kariobangi, in Nairobi.

Interviews were conducted in private quiet rooms at the trial sites. English and Kiswahili languages were used per participant preference. Participants were asked to share their views about the screening requirements, and procedures and further describe their experiences of being screened. Interviews lasted approximately one hour and were audio recorded, nuances were captured and detailed notes were taken. All interview notes were written out after every interview and assigned unique identifiers corresponding to those of the audio recordings.

Data analysis

The audio-recorded data was transcribed verbatim and translated into the English language where the Kiswahili language was used. A descriptive phenomenological approach was used to analyze the scripts. Analysis was performed by the lead author, co-author (JO) and a research assistant, who co-jointly first read and re-read three scripts to identify elements of discourse and themes for the development of the codebook. The three transcripts were independently coded using Atlas *ti* software, for agreement. The remaining transcripts were shared and coded accordingly.

Ethical considerations

Ethical approval was obtained from the Kenyatta National Hospital Ethics Research Committee (KNH-ERC-ref P298/05/2013). Participants were consented before data collection. To ensure data confidentiality, personal identities were replaced with unique identifiers. Participants were reimbursed a sum of Kshs. 500 (Approx. USD 4) for their transport to and from the research sites.

Results

Characteristics of the participants

Participants were males and females aged between 20 and 49 years. A majority were heterosexuals (38), while the rest were homosexuals (6) and bisexuals (2).

Table 1:
Distribution of Study Participants

Study Site	Study Name	In-depth Interview Sample		
		Females (n=22)	*Males* (n=22)	Totals (n=44)
KAVI-KNH	B002	5	3	8
	S001	4	2	6
	Protocol J	3	3	6
KAVI-Kangemi	HIVCORE 004	6	6	12
	B003	4	4	4
	PrEP	0	4	4
Total		**22**	**22**	**44**

Most were of low socioeconomic status with no income or low wage earners through petty trades or domestic work.

Screening requirements and procedures

Participants described their experiences and views of the screening phase that entailed the capture of medical histories, physical examinations and collection of samples for laboratory analysis. Table 2 below provides information on the various samples and procedures performed.

Experiences of screening

Participants had positive and negative perspectives and experiences about screening for enrollment that are explained in the following emerging themes:

- Free comprehensive medical check-ups
- Treatment for minor ailments treatment
- HIV Risk Reduction
- Discomfort with physical medical examinations
- Fears about taking tests and providing samples
- Fear of being found with major illnesses

Positive aspects of screening

Free comprehensive medical check-ups. Given the range of tests and screening of chronic diseases, a majority of the volunteers equated the screening to receiving a free comprehensive medical check-up. They considered themselves privileged as the procedures and tests performed are typically expensive for their meagre incomes to afford. Other benefits included knowing their blood groups, and haemoglobin levels, and reports of good health were mentioned as explained by two male volunteers:

"I had never gone for a urinalysis … and blood tests, I knew my blood grouping----- I was able to know the level of blood, my health condition. Those are some of the things that I enjoyed" (Male Participant, BOO3)

"There are health benefits like your blood is screened and told how your kidneys are if you are healthy or not. I was told about my body, my heart and I knew my health was good" (Male Participant, B002)

Treatment for minor ailments. Those found with minor ailments reported receiving treatment before enrollment while those who tested HIV positive were referred to a support group as explained:

"We had HIV testing and STIs screening, and other medical conditions …. those who tested positive were referred to support groups, and if one had STIs, treatment was provided' (Male Participant, PrEP)

Table 2:
Screening procedures and samples collected

Study Type	Study Names	Samples collected	Procedures Performed
Vaccine	*B002, B003, S001, HIVCORE*	*Blood* *Urine* *Sputum*	• *HIV test counselling and testing* • *Test for Hepatitis B&C and other STIs* • *A chest X-ray and sputum test to rule TB* • *Kidney function test by use of urine* • *Pregnancy test* • *Eye examination (specific to B002)**
Observation	*Protocol J*	*Blood* *Urine*	•*Pre and Post HIV test counselling* •*HIV test and results* •*Pregnancy Test*
Drug	*PrEP*	*Blood* *Anal swabs* *Urine*	• *HIV test counselling and testing* • *Test for Hepatitis B&C and other STIs* • *Anal swab to check for STIs* • *Kidney function test by use of urine*

Data Source: Study protocols

"I had candidiasis, which they gave me some medicine but I could not continue because of family planning" (Female Participant, HIVCORE)

HIV risk reduction counseling. Receiving negative HIV test results and post-test counselling was appreciated and for some, this had resulted in risk reduction behaviours. Two participants explained:

"I knew I did not have any STIs, no HIV; at least it made me careful as to how I was living my life…… To have safe sex and to be careful though am active."

(Male Participant Protocol J)

"I saw it had a lot of benefits. We were taught how to protect ourselves" (Female Participant, B003)

Negative aspects of screening

Discomfort with physical examination. Male participants more than females had experienced discomfort with physical examinations which they said required them to undress:

"I found it weird when I was told 'remove all the clothes we examine your body' and provide your history of diseases" (Male Participant, HIVCORE)

"*No, because he even asked whether he could do the screening down there (meaning vagina) and I accepted because I had no fear"*
(Female Participant, HIVCORE)

Fears and misgivings about testing. Several participants reported fears and misgivings around providing samples and undergoing HIV testing. These fears were more apparent among participants who had never tested and of high-risk behaviour, whose questions of "*what if the test is positive?"* weighed heavily on:

"I was scared at first of the tests but they told me what to expect…especially the HIV tests since it was the first time I was being tested"
(Male Participant, HIVCORE)

Fear of being found to suffer from chronic illnesses was common. Like for HIV, these fears were marked with "*what if*?" and were said to emanate from personal health experiences or knowledge of family members with chronic disease burden:

"I was a little bit scared. The fact that they were screening for any other diseases, some of which you may have and you don't know"
(Female Participant, B003)

"I feared I might be found with a health problem since at times I would have headaches or feel weak, so I was like if I don't have the HIV, so then what is my problem?"
(Male Participant, B003)

"I had lots of fear regarding the result. There is diabetes in our family and I thought I might be affected" (Male Participant, S001)

In the midst of the unknown, some participants reported adopting a '*wait and see'* attitude. A female volunteer explained:

"About the serious conditions, I was not worried because I have never had any serious disease. But you don't know about your health until it is tested. So, I was just waiting"
(Female Participant, B002)

Discomfort with sample collection. Experiences of pain resulting from blood sampling were reported. Despite the experiences of pain, some participants felt obligated to stay on because of the signed informed consent. One participant recounted:

"I was not comfortable with the blood, I felt like a mouse in a laboratory, but I had already signed the consent form and everything had started, you could withdraw but now, it's good you complete wholeheartedly" (Male Participant, PrEP)

Fears of blood draws and concerns about the amounts of blood collected were expressed:

"I got scared when blood was being drawn from me. What could I do I just took courage and they told me everything will be fine."

(Female Participant, HIVCORE)

"The blood that they were draining was too much unlike the one for smearing they were taking many tubes" (Male Participant, PrEP)

Although painless, urine sampling was problematic for some as it often requires one to

have a full bladder at the time of collection

"I was used to giving blood. You just give my arm but for urine, it was hard as there had to be urine in my bladder and you are not prepared" (Male Participant, B003)

Discussion

The present paper provides insights into research volunteers' perceptions and experiences of the screening phase of HIV clinical research implementation. Findings reveal participants had mixed feelings and experiences about screening. In the beginning, there were fears about HIV testing, and screening for chronic diseases which were bypassed by receiving results of being in good health.

Findings showed that while screening helps researchers determine the eligibility of participants before enrolment, fear of HIV test outcomes can be a deterrent to participation. In our study more male than female participants had not tested before for fear of positive test results. Recent studies conducted in Kenya and other settings have reported low uptake of HIV counselling and testing particularly among men, where some choose to rely on partners' test outcomes (27–31).

While knowing one's health status is important, the fear of being screened for chronic illnesses was imminently felt before screening. For some, the fear was due to knowledge of close relations suffering chronic conditions or their own risk behavioural factors. These findings suggest the potential impact of fear on the uptake of health services particularly among males as reported in reported in one review(32). The findings also suggest that while screening for diseases outside of the clinical trial settings may offer health promotion and disease prevention opportunities, many low-income earners are unlikely to afford the services(33).

Tied to the fears of testing, were reservations about sample collection. Some volunteers expressed fears and anxiety about the amount of blood drawn and the pain of the blood draw. Blood sampling concerns in clinical research studies and allegations of blood being collected for sale and rituals are not new in Kenya and other countries(34–36). Our study indicates the need for researchers to reassess the amounts of blood collected, guarantee participant safety, and adopt painless methods of blood sampling for enhanced clinical research experience(37). Findings further revealed that although the informed consent provided for their right to decline or discontinue participation in the of safety uncertainty or other concerns, participants stayed on. This decision was due to the fear of breaking the informed consent agreement thereby assuming a sense of obligation to the research. The findings point to the persistent challenges of achieving the goals of informed consent, similar to those reported in other studies(38–40).

Findings also revealed concerns about undressing during physical examinations and genital sample collection, influenced by clinician sex. Although less expressed by females, the level of intrusiveness, comfort and the sex of the attending clinician were considered. The findings highlight the significance of sex balance among clinical research practitioners in addition to growing attention to factors that impede women and minority groups' optimal participation in HIV clinical research studies(41).

The study showed how research benefits, such as free tests, being found to be of good health and receiving treatment for minor ailments, can influence individuals' decision to participate in research, despite initial discomfort with screening and potential outcomes. Studies conducted in Kenya and elsewhere have shown, that participants' decision making to be driven by various factors that range from personal, health needs to economic benefits among others(15,22,40,42). The huge health inequities and inequalities among low-income earners who rely on public healthcare, make free medical care in research centres attractive (43). Further, findings suggest that, while participants may be drawn to research for potential benefits, research

demands may also lead to hesitancy, as reported by a Tanzanian study(44).

Overall study findings, showed that despite the fears held about screening, the pre and post-test counselling offered to participants coupled with receiving HIV negative test had resulted in behaviour change among participants. Other studies have also shown counselling to positively influence sexual risk reduction among key populations(45,46). Further, although participants may initially have fears and anxiety, supportive clinical staff counselling and explaining research processes results in a better understanding of research information, building trust, acceptance and tolerance of trial processes(44). The findings further underscore the need for researchers to continuously engage and re-consent research participants in every level of participation period to be able to manage their fears and expectations around research participation.

Limitations of the Study

This paper examined experiences of screening for enrolment in research among volunteers who participated in six KAVI-ICR studies conducted between 2009 to 2014. A key limitation of this study is the recall and selection bias of the information shared here. This anomaly is due to the time-lapse of when participants were screened into their respective studies and when we interviewed them for this study. The other limitation is the exclusion of screening failures, whose views may be important in managing volunteers' expectations. Despite the stated limitations, the findings respond to the gap in knowledge on how experiences of screening may influence decision-making for research uptake.

Conclusions

Screening volunteers to determine their eligibility for enrollment in HIV clinical research is an important ethical requirement in human protection. In this study positive and negative aspects of screening which may act as motivators and deterrents of research participation were shared. Therefore, understanding research volunteers' fears and concerns regarding screening for enrolment may aid researchers in mitigating enrolment and retention challenges while improving participants' overall experiences in research.

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Data Availability. All relevant data collected and analyzed for this study are included in the publication.

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