

CLINICAL SCIENCE
MEETS
SOCIAL SCIENCE:
**GENDER AND
AIDS VACCINE
RESEARCH**

The successful development of an HIV vaccine depends in part on recruiting adequate numbers of women and men in vaccine studies. However, enrolling and retaining women in vaccine studies can be challenging in some settings. For example, in East Africa, women's past involvement in vaccine research has been uneven. Earlier phase I and II trials had a female to male ratio of 1:8. More recent studies have met targets for women's participation, but anecdotal evidence suggests recruiting women remains a challenge.

Women and men have distinct considerations that affect their decisions to participate in AIDS vaccine research. Gender norms influence participation of women and men. These dynamics manifest in social barriers and consequences that must be understood and addressed to ensure equitable participation, mitigate potential harm and ultimately lead to an effective vaccine. Recruitment and retention strategies should therefore address these gender issues.

This research brief summarizes the results of one study on how gender issues influenced volunteers' decisions to participate in AIDS vaccine research in Kenya and their experience of participation – information that may help facilitate the integration of women in vaccine research in settings facing similar gender dynamics. The study was conducted in Kenya in 2007 as a collaboration between the International AIDS Vaccine Initiative (IAVI), the International Center for Research on Women (ICRW) and the University of Nairobi.

Why Women?

There are a number of reasons why both women and men need to be recruited, enrolled and retained in vaccine studies. For one, a vaccine must be tested in the population in which it will be used to ensure licensure. Biological differences between women and men, such as the difference in viral load and rates of male-female versus female-male transmission also may impact a vaccine's effect. And it is important to test the vaccine in both sexes to know whether it will have the same efficacy and/or side effects in women and men. From an ethical and health equity perspective, the benefits of trial participation, which include education, counseling and care, should be available to equal numbers of women and men.

Moreover, an effective AIDS vaccine would be a prevention option that a woman could use regardless of her partner's cooperation.

Current prevention approaches, such as condoms, are insufficient for many women, given the gender-power dynamics in many relationships that limit women's autonomy and restrict their ability to protect themselves. As HIV prevalence and incidence continue to rise globally among women, and in some countries surpass rates among men, new and better female-initiated and controlled prevention tools, such as vaccines or microbicides, are needed.

METHODS

Male and female study participants were recruited in late 2006 and early 2007 through two sites where the Kenya AIDS Vaccine Initiative is conducting vaccine research. One site is at the Kenyatta National Hospital (KAVI-KNH) in Nairobi, an urban, mixed income area where phase I/II (safety) trials are conducted. The second site is the low-income, informal settlement of Kangemi, Nairobi (KAVI-Kangemi), where epidemiological studies are ongoing in preparation for efficacy trials. These sites were purposively selected to understand concerns across study contexts and among both higher risk populations recruited for HIV incidence studies and lower risk populations recruited for phase I studies.

To understand issues related to various stages of recruitment and enrollment, in-depth interviews were conducted with 65 past and current participants and with volunteers who were screened out for health reasons or chose not to participate. Key informant interviews were held with 21 vaccine research staff members including principal investigators, community mobilizers, community leaders, doctors, nurses and counselors. Focus group discussions included 18 community advisory board members, peer leaders and community members. Analysis identified differences and commonalities between respondent groups and sites given the differences in education and risk status between participants at the two sites. Issues that commonly emerged across sites and respondent categories are described in this brief.

Results

The data show that the three stages of vaccine study participation – recruitment, enrollment and retention – are gendered, meaning that women and men experience them differently. The results presented here highlight key themes that emerged from the data – access to information, decision-making processes, costs of participation as well as benefits – which deepen our understanding of specific gender-related factors that influence women's and men's participation in vaccine research, their particular experiences as study participants, and their ability to complete the study.

ACCESS TO INFORMATION

Accurate information about vaccine studies is crucial during all stages of research. Where, when and how information is shared can influence a participant's ability and willingness to engage in learning more and progress from recruitment to enrollment and participation.

Women face unique barriers to accessing information about vaccine studies. More than men, women often lack the autonomy, mobility and time necessary to participate in informational sessions. With little control over their schedules, women are challenged to find time to travel to and attend seminars. They are particularly pressed for time because of their multiple responsibilities, which include household duties, caring for family members and income generation. The constraints on women's time and mobility have implications not only for their ability to access information but also to participate in vaccine research.

"...men have more free time than women. So much as women would like to attend they cannot since they are ever busy."

— Female recruitment seminar participant

Gender dynamics also hinder information seeking, particularly in the group settings used to educate potential volunteers about vaccine research. Both women and men can be uncomfortable asking sensitive questions in large groups of mixed ages and sexes. Men tend to dominate discussions with their questions and comments, while women are more reserved and less inclined to ask questions, especially in large groups or a new environment.

"Women are a bit shy in any new environment. I have realized that when I bring women here to KAVI, they do not ask as many questions as they did when the KAVI nurse counselors came to their community. Another thing is that if the language is too technical, they do not know what to ask, hence, they do not understand and they go home with their questions and assumptions."

— Female peer leader

When participants leave sessions with unanswered questions, rumors and misperceptions about vaccine research can be spread and reinforced throughout the community. These misperceptions are a continual challenge to vaccine research and cover a range of issues about vaccine safety, clinical procedures such as drawing blood and the experimental nature of trials.

DECISION-MAKING PROCESSES

Decision making is a distinctly different process for men and women. Men have more autonomy and authority to make independent choices. Women seek permission from partners, significant others including family and household members as well as community members. And the expectation that a woman will secure permission from a male figure is not limited just to married women. Single women with one or multiple partners also felt the

need to seek permission. Consequently, a woman's decision requires more time to engage in this consultative process, time they do not necessarily have as they juggle multiple responsibilities.

"Culturally, from the community level, the wives are supposed to consult in whatever they are doing with their husband; but the husbands do not need to consult with the wives. This is what is culturally accepted."

— Community advisory board member

Women expressed concerns about how to raise sensitive topics such as fertility and pregnancies with male authority figures when securing their approval. Women who concealed their study participation risked discord in relationships when male partners or fathers learned the reason for a woman's routine absences. Even when women were able to discuss sensitive issues with a partner, men often did not give their wives or partners permission to participate in studies.

"If a woman is married, she has to consult her spouse... if she was not on a method [contraception] she has to tell the husband that she wants to be on a method and the husband will ask why? And she has to disclose and maybe the husband will object."

— Trial staff

Women are seen as having central roles in the lives of their families and their communities. Members of the community, therefore, are highly influential in encouraging or discouraging a woman's participation in vaccine studies. Community support is more important to a woman's participation than for men. Consequently, women seemed more sensitive to how their community might perceive her participation. If the community does not support vaccine research or women's participation in vaccine studies, the information and consultation process is even more challenging for women.

"In my community, a woman is married to the community, so she belongs to the community. She requires permission not only from her husband but her community as well."

— Female community advisory board member

COSTS

Trial volunteers weigh the costs and benefits of participation in their decision-making process. For women, whose decisions are greatly influenced by others, there are numerous social and economic costs to their participation in vaccine trials.

PREGNANCY

Culturally, a woman's value is intricately tied to childbearing. The requirement to avoid pregnancy and use contraception during part of the trial can be too high a cost for many women. Concerns about future fertility also arose among women and men.

“In my community, people uphold the traditional values of getting married, having children and making something out of your life. When you approach a lady and tell her about KAVI and the requirement that they should not get pregnant, they ask you where KAVI will take them in the long run. They tell you that they shall look for a husband and continue with life. They cannot afford to put their life on hold even for six months.”

— Male peer leader

DISRUPTION OF RELATIONSHIPS

Both women and men were concerned that their trial participation may lead to the potential loss of a relationship. But for women who are economically dependent on men, the loss of these relationships most often leads to the loss of material and economic support as well. For example, a study staff member encountered this problem when a woman participant did not consult with her partner before enrolling in the study. When her partner became aware of her participation, he began to withhold food and material support. The study staff member intervened by visiting the husband, sitting with him for two hours explaining the study, and allaying his fears of health and vaccine safety concerns.

TIME

Time also was a concern for both men and women. Men viewed the time spent for vaccine research encroaching primarily on income-earning activities. But women have less free time because of their multiple roles as mothers, caregivers, household managers and income earners.

“So when the volunteers hear that it may take the whole morning, it becomes an obstacle. Some say, ‘I have to go and take food to my children in school over lunch hour,’ and yet at lunch hour they are here. So you find that some go away and leave the study; they do not finish it.”

— Trial staff

The sense that a woman “belonged” to her partner, her family or her community meant time away from her household responsibilities had the potential for a social cost if partners and significant others were not aware of, or supportive of, participation.

“...There are also those husbands whose wives are participating ...[who] complain their wives are spending much of their time in being in the study at the expense of their children.”

— Female research site community resident

STIGMA

The stigma that surrounds HIV also pervades vaccine research. Participants that were associated with vaccine trials or study sites often were perceived as being infected with HIV, which in turn implied they had engaged in “inappropriate,” “bad” or “sinful” behavior. Women were more vulnerable to stigma and seemed to experience more of its consequences in the forms of gossiping, name calling, finger pointing and shunning.

“People were saying that KAVI is for prostitutes and for those with AIDS. So she saw that people were taking her to be sick. Since she didn’t want her reputation to be damaged further she decided to drop out.”

— Male current study participant

HEALTH CONCERNS

Many volunteers considered the unknown health effects of an experimental vaccine as a potential cost to participation. Women’s health concerns differed from those of men. Men thought about how the vaccine might effect sexual functioning or promote the growth of diseases such as cancer. Women were more focused on how the vaccine would affect future fertility, and both men and women were concerned about the effect of the vaccines on pregnancies, including the possibility of birth defects. Some women worried about short-term side effects of the vaccine and how these effects would impact their ability to manage their caregiving responsibilities.

FEAR OF HIV STATUS

HIV testing is a requirement for study participation, and the fear of knowing one’s status was evident among women and men. Women expressed concerns that testing positive would affect not only their individual health but also their ability to care for their children.

“Before I was tested, I feared what will happen to my children if I’m tested positive and how I will suffer with the disease.”

— Female current participant

BENEFITS

Several benefits of trial participation, for individuals and communities, motivate volunteers to enroll and remain in vaccine research.

INDIVIDUAL BENEFITS

Access to health care

Men and women mentioned the free, quality health care that comes with participation as both a motivator and benefit. Participants noted the presence of good quality health care, which may not be available elsewhere; the availability of free medicines; non-judgmental care; and being screened/tested on a regular basis, particularly for HIV.

HIV testing

Although knowing one’s HIV status was fraught with anxieties about a positive test result, HIV testing also was viewed as a benefit of vaccine participation because testing was free, repeated regularly, and included counseling.

“...it is not many places that you go to and you are tested free of charge.”

— Female current participant

“...especially knowing my status all the time. Continuously.”

— Male current participant

“...and you know before you are done the HIV test there is counseling, such that even if you are tested positive, you will know how to live with it.”

— Female current participant

Interestingly, women from the low-income, higher-risk population site were much more likely to view HIV testing as a benefit to participation. Conversely, women in the lower-risk population site did not mention HIV testing as a benefit.

Accurate information

The ability to access information about HIV/AIDS transmission, prevention, treatment and care, as well as learning how to share that knowledge with others, was mentioned as both a motivation for participation as well as a benefit. Women were motivated by being able to access knowledge they could share with their children. Men were more focused on learning about vaccines, though some did note the benefit of other types of information.

“I wanted to help myself because when you have children you must be able to teach them yourself, because young boys these days, even to tell them to protect themselves is hard, so you as a parent must learn so you can teach your children.”

— Female current study participant

Behavior change

Reductions in risk behavior were cited as an individual and community-wide benefit. Both men and women reported increased male – and occasionally female – condom use, often citing the availability of free condoms through KAVI. A few female volunteers mentioned that they had learned how to negotiate condom use with their partners.

“On a positive note, I am more keen on my health than when I started. Today I can comfortably tell a guy to use a CD [condom] if he wants sex with me.”

— Female past trial participant

“...the only thing that has changed is the fact that we use condoms. If I decide not to wear one, she wears hers, and if she won't wear one, she asks me to wear one. But before,[we] were not this informed, we used to go 'skin to skin.'”

— Male current study participant

Being part of the solution

Many female volunteers discussed purely altruistic reasons for their participation. This decision often was inspired by their experience with HIV in some way, either personally through the loss of a family member or friend or more generally because of the effect of HIV and AIDS on the community.

“[volunteering provides] a positive...feeling good...about contributing to the community.”

— Female current participant

There were some gender differences in the nature of the altruism. While some women discussed their volunteerism as a way to help their families, some men emphasized potential heroism and future fame if the vaccine trial succeeds.

“I did not hope to gain anything, but I at least wanted to be one of the volunteers who tried to get the vaccine, so even in the future if I am not there, maybe my son will say my father was a volunteer for this vaccine.”

— Male recruitment participant

COMMUNITY BENEFITS

Respondents at the Kangemi research site reported community-level benefits, but no gender differences were noted. The most commonly mentioned community benefit was that participation has and will lead to a reduction in risk behaviors, such as multiple partners, and drug and alcohol use, thereby benefiting the community as a whole. Respondents also mentioned an increase in helpful behavior, such as tending to people living with HIV through home-based care, skills acquired as research volunteers, and the sharing and diffusion of the information volunteers learn through participation. While it is clear from the data that stigma is present and feared, a few respondents in Kangemi felt that the vaccine research was helping to chip away at stigma, in particular by helping those living with HIV through treatment, counseling, home-based care and living “positively.”

“The support has changed because KAVI has now involved a lot of the youth who [are more educated], and this has resulted in less stigma for the disease and the people involved. The information has now continued to enlighten people, I being one of them.”

—Female community resident

Conclusion

Women and men undergo distinctly different processes when it comes to participation in clinical trials. As the results show, social science research can improve understanding of the needs, motivations, fears, enabling factors and constraints to participation and retention in trials; key gender factors that might shape differential participation and retention of women and men; and the experienced social costs and benefits of participation in vaccine trials and related studies. This information can strengthen mobilization, outreach, recruitment and retention support systems, and thus improve chances of achieving the desired outcome – the ethical development and delivery of safe, effective and accessible vaccines.

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