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ORIGINAL PAPER

Perceptions of a Community Sample about Participation in Future HIV Vaccine Trials in South India

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Abstract Focus group discussions were conducted to assess factors that might impact participation of subgroups in Chennai for future HIV vaccine trials. The participants were 112 men and women representing the following: (1) transport workers; (2) clients who attended a sexually transmitted disease clinic; (3) injection drug users; (4) men having sex with men; (5) women in sex work; and (6) monogamous married women. Participants expressed an intense interest in future HIV vaccine trials. Willingness to participate in future trials included altruism and the desire to have a protective vaccine for the future. Assurances regarding stigma and confidentiality, and compensation for families in the event of a poor outcome with a future HIV vaccine trial were reported. Concerns also centered on the impact of seroconverting, and a possible increase in risk behaviors. The need for education and counseling about the dangers of engaging in risky behavior during and after participating in a future HIV vaccine trial is discussed.

Keywords Community-based research · HIV vaccine trials · High-risk populations

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Introduction

Although AIDS was diagnosed for more than 20 years, currently, no effective HIV preventive vaccine exists. In India, efforts to develop an HIV vaccine are being coordinated by the Indian Council of Medical Research, the National AIDS Control Organization, and the Department of Biotechnology. These joint efforts have led to the selection of the Tuberculosis Research Centre in Chennai, India, as one of two Indian Council for Medical Research centers of excellence to begin a Phase I Human HIV vaccine trial with Modified Vaccine Ankara. Qualitative research to identify factors that might limit participation of clients at risk for HIV/AIDS is needed to ensure the quality of this trial and maximize the generalizability of the findings.

The purpose of this study was to conduct a community-based participatory research study, using a qualitative design, to assess: (1) willingness of high-risk groups to participate in a HIV vaccine trial; (2) factors that might impact these individuals' participation in a vaccine trial; and (3) potential impact of HIV vaccine trial participation on risky drug and sexual behavior.

With a population of over a billion persons, India is second in total number of people living with HIV/AIDS (UNAID, 2004); an estimated 5.1 million Indians were

affected in 2004 (National AIDS Control Organisation, 2004). As in Africa, the major mode of HIV transmission is through sexual intercourse; sexually transmitted diseases appear to facilitate the transmission and acquisition of HIV infection (UNAID, 2004).

According to the Tamil Nadu State AIDS Control Society (2004), the seroprevalence rate was 8.4% among persons diagnosed with a sexually transmitted disease, 4% among women in sex work, 40% among injection drug users, 6.8% among men having sex with men, and 0.65% among ante-natal. A previous report in 2003 revealed a seroprevalence of 15.8% among clinic patients with sexually transmitted diseases in this same city (Thilakavathi et al., 2003).

Truckers are another group that may be targeted in the Phase I Modified Vaccine Ankara trial since many of them are normally exposed to unprotected sex with multiple partners. The truckers are mostly mobile, often driving long distances wherein multiple opportunities for casual sex with different partners abound. As the prevalence of HIV infection rises, the likelihood of acquiring HIV through these casual encounters increases.

As India prepares to take part in a preventive vaccine trial against the HIV virus, the future use of HIV vaccines poses unique biological, social and geographical factors relevant to HIV/AIDS that may affect individuals and communities who participate in HIV vaccine development activities. While antiretroviral drugs have reduced mortality from AIDS in developed nations, their availability is still limited in India due to the cost and limited distribution. Effectiveness of behavioral programs to control HIV spread are uncertain. Thus, the need for novel preventive strategies, such as HIV vaccines, is paramount.

Qualitative studies conducted in the United States and elsewhere provide an indication of the concerns that may be voiced by Indian participants. Generally, a sense of altruism appears to motivate persons willing to enter HIV vaccine trials (Strauss et al., 2001). For example, in a study of Ugandan military (Hom et al., 1997), over 88% of the participants expressed a desire to participate in a future HIV vaccine trials. However, U.S.-based studies revealed low interest (21%) in participation when enrollees, men having sex with men were informed that they might receive a portion of the HIV virus (WHO-UNAIDS Report, 2001). Additionally, concerns about the safety of the vaccine dampened the interest of Kenyan participants (4%), along with the possibility that the vaccine might result in an HIV positive test (Vlahov et al., 1994). Yet, persons who perceived themselves to be at greater risk, perceived a vaccine to have greater efficacy, or were provided higher monetary incentives (Ringwalt, Greene, Robertson, & McPheeters, 1998) were more willing to participate in HIV vaccine trials than their respective counterparts not experiencing these factors.

The impact of the vaccine on participants' continued or increased high-risk behaviors is a potential drawback to participation in HIV vaccine trials. U.S. studies have indicated that high-risk populations may continue to engage in risky behaviors after receiving the HIV vaccine (Hom et al., 1997; Nyamathi et al., 2004; Vlahov et al., 1994).

Methods

Design

A Phase I qualitative study consisting of focus group discussions was conducted in two communities in South India. Focus group methodology uses in-depth, open-ended group discussions, 1–2 h long, centered around a specific set of pre-defined issues of limited focus (Robinson, 1999). This strategy has been successfully used to examine public attitudes related to health behaviors.

Participants and Setting

The study sample consisted of the following groups: (1) transport workers such as truckers and cleaners; (2) clients who attended a sexually transmitted disease clinic at Government General Hospital in the last three months; (3) injection drug users; (4) men having sex with men; and (5) women in sex work. In addition, a sample of monogamous married women from self-help groups in the local communities was included in the study. The samples were recruited by approved flyers that were posted in these respective sites. All groups were gender specific due to highly sensitive nature of content discussed. Men having sex with men, injection drug users, and truckers were male-only groups; while women in sex work and married women were female-only groups. In addition, persons recruited from sexually transmitted disease clinics were separate groups of men and women.

A total of 12 focus groups were conducted, with 6–7 eligible participants per group. Two focus groups were conducted with each subgroup, resulting in a sample size of 112. Community members were considered eligible if they reported themselves to be a member of one of the six subgroups and were 18–55 years of age. Eight focus groups were conducted at Chennai and four at Madurai.

The setting for the study included four non-governmental organizations working with clients at risk for HIV/AIDS. They were the Association of Rural Mass in India, Address Centre, the Indian Community Welfare Organisation in Chennai, and Institute for Mass Awareness, Guidance and Education at Madurai. Chennai is an urban area since it is the capital of Tamil Nadu as well as one of the metropolitan cities of India whereas Madurai is more of an rural agglomeration situated at the southern part of Tamil Nadu.

Community Advisory Board

A community advisory board was formed so community members could contribute to the research process. This process ensures that the phenomena of interest are understood from the prospective of the clients themselves (Israel, Schulz, Parker, & Becker, 1998). The community advisory board members included representatives of the non-governmental organizations, medical officers, a representative from Tamil Nadu State AIDS Control Society, and people living with HIV/AIDS. The role of the community advisory board was to assist the investigators in formulating the research design, designing the study protocols, revising the study's semi-structured interview guide, and designing a recruitment process that would facilitate client participation. In particular, community advisory board members assisted the research staff in designing the flyer for posting the study, and discussed and revised selected items of the semi-structured interview guide to make sure they were clear, culturally relevant, and simple. Discussion was also held regarding best times to conduct the focus groups, how to enroll participants from each of the groups, and an education on cultural nuances that were critical for the research team to appreciate.

Procedure

Participating non-governmental organizations informed their clients about the study by means of posted flyers with dates that the research staff would be available at the site. After a description of the study was provided by a study investigator, interested participants signed informed consent and filled out a screener to determine whether they belonged to one of the pre-selected subgroups. Eligible participants were taken to a private room and given additional details about the study. After a more detailed written informed consent was obtained, the focus groups were conducted by a well-trained research facilitator in a private area of the non-governmental organization site. The research staff were trained extensively on focus group methodology, transcription, and content analysis. In particular, the second author has had extensive experience with research studies both in TB and HIV/AIDS and has received a number of training sessions in qualitative and quantitative analysis. In addition, the second author, and the field investigators including three project staff recruited for the project and two social workers from Tuberculosis Research Centre/Madurai Unit underwent two days intensive training on focus group methodology. The training included components of focus group design, sample selection, institutional review board safeguards, and the conduct of focus group design. Training was conducted by Dr Panda, a consultant for National Institute of Epidemiology, Chennai.

All focus group discussions were conducted in Tamil, the local language of Tamil Nadu. During pilot study it was determined that very few participants knew about randomized clinical trials or that HIV vaccine trials were being planned in India. Consequently, the focus group discussion guides began by educating participants about the basics of a clinical trial. This education included the double blind assignment of participants into an intervention and a control group, and the possibility of testing seropositive in a non-infected person due to the production of vaccine-related HIV antibodies. Care was taken to inform the interested participants that enrollment in the current study would not guarantee enrollment in a future HIV vaccine trials. Moreover, participants were informed that the current study was a first step in assisting researchers to prepare for a future Phase III trial. The participants were compensated monetarily; the total of which was equivalent to one day of wages. Refreshments were provided after the sessions were completed.

To assure the validity of the focus group discussions, two participants from each focus group session were invited to participate in one of two follow-up interviews at a mutually convenient location after all discussions had been conducted and transcribed. These study participants validated the content of the transcribed sessions.

Semi-structured Interview Guide

A semi-structured interview guide was pre-tested and modified in a culturally sensitive and linguistically appropriate manner by the community advisory board. The semi-structured interview guide guided each session, using open-ended questions which were initiated about the participants' familiarity of general vaccines

and then specifically about the HIV vaccine. These questions then led participants to think aloud about factors that might facilitate or impede participation in HIV vaccine trials and the impact of vaccine participation on risky behavior. Finally, we assessed factors that would be critical for acceptance of a future vaccine, such as vaccine efficacy, duration of protection and delivery format. At the end of each focus group, a socio-demographic profile was completed, along with other instruments; descriptive information on participants' responses are published elsewhere (Suhadev et al., in press).

Data Analysis

The focus group discussions were audiotaped for subsequent transcription. The audiotapes of each session were transcribed into computer files. Upon completion of the focus group sessions, the investigators oversaw transcription and content analysis of the taped recordings; content analysis was performed using the constant comparative method (Glaser, 1978). This method involves a line-by-line analysis of the transcribed interviews by coding data into relevant sentences and phrases. Concurrent coding and analysis continued until unique categories were no longer identified. Intercoder reliability was assessed by two independent coders who had experience in content analysis. Trustworthiness of the data (Lincoln & Guba, 1985) and control for naturalistic inquiry were ensured by credibility, transferability, dependability, and confirmability.

Socio-demographic Information

Questions were asked regarding date of birth, gender, religion, education, employment status, income assistance and the occurrence of high-risk behavior.

Results

Demographic Profile

A total of 112 respondents participated in the focus group discussions; 67 (60%) were male and 45 (40%) were female (Table 1). The subgroups represented included truckers ($n = 20$), men having sex with men ($n = 20$), injection drug users ($n = 19$), women in sex work ($n = 17$), sexually transmitted disease clients ($n = 15$) and married women ($n = 21$). The mean age of the respondents was 32.4 years ($SD = 8.5$). Respondents were primarily Hindus (81%) and employed full time (56%). More than half (68%) completed high school and 7% completed higher studies. Almost half of the sample was married (42%); 38% were never married and 13% were separated/divorced/widowed.

Table 1 Demographic profile

S. no	Characteristics	Male (67)		Female (45)	
		No	%	No	%
I	*Focus group participants*				
	1. CSWs	–	–	17	37.8
	2. IDUs	19	28.4	–	–
	3. MSMs	20	29.9	–	–
	4. STD attendees	8	11.9	7	15.6
	5. Truckers	20	29.9	–	–
	6. Married women	–	–	21	46.7
II	*Age*				
	Mean	31.04		34.24	
	SD	7.86		9.18	
III	*Education*				
	No formal education	13	19.4	15	33.3
	School education	47	70.1	29	64.5
	College/Technical	7	10.5	1	2.2
IV.	*Martial status*				
	Never married	41	61.1	1	2.2
	Married	24	35.8	31	68.9
	Separated/Divorced/ Widowed	2	2.9	13	28.9
V.	*Religion*				
	Hinduism	58	86.6	32	71.1
	Islam	4	5.9	2	4.4
	Christianity	5	7.5	11	24.5
VI.	*Nature of work*				
	Full time	43	64.1	20	44.5
	Part time	16	23.9	2	4.4
	Unemployed	2	3	5	11.1
	Retired	1	1.5	–	–
	Others	5	7.5	18	40

Almost half (42%) of the respondents perceived themselves to be at no risk of HIV/AIDS. Of the remainder, 47% reported unprotected sex with multiple partners, 28% shared unclean needles, 9% reported male-to-male unprotected sex and 17% reported other risk behaviors.

Knowledge about HIV/AIDS and Vaccines

All the participants were knowledgeable about HIV/AIDS, how it spreads and how to protect oneself from the infection. While they did not have all the scientific facts, they were aware of the impact of AIDS on the immune system. For example, one married woman said, ''If a door is left ajar anyone may enter it. Similarly, when the body's immune status is low, all diseases may invade it.'' The participants were aware of the many standard vaccines used in India, such as polio, BCG, hepatitis and others. They had a basic

understanding of vaccines and why vaccines were given to the public.

Awareness of the HIV Vaccine Trials Preparations in India

Few participants were aware that an HIV vaccine trial was under consideration in India. Virtually all participants learned about HIV vaccine and clinical trial basics through introduction to the study. However, they felt they needed more information about HIV vaccines. While they were concerned that the vaccine contained a part of the virus, almost all participants hoped that a HIV vaccine would become available in the next few years. For example, one participant from the transport worker group commented ''the way science and technology are advancing, the chances of an HIV vaccine being available in the next five or ten years are good.'' A participant who self-reported himself as a man having sex with men added, ''HIV/AIDS is a killer disease. It would be wonderful if there is going to be a vaccine for it. We are confident that it would come.'' Thus, hope was expressed by many participants in all of the subgroups.

Despite frequent endorsement of a HIV vaccine, there was variation in the responses, especially from the transport worker and the married women subgroups, regarding the need to have a HIV vaccine. One transport worker expressed his position ''There is no need for this research if each individual takes a vow that he will not indulge in any high-risk behavior.'' Others strongly protested by saying that it would not be possible in this modern world to abstain from high-risk behaviors. Another transport worker condemned the publicity about safer sex by saying ''It is wrong to advertise that it is safe to use condoms and have sex. Is a condom 100% safe? It is better to advertise 'Do not have illicit sex' rather than say 'Practice safe sex'.''

The participants were clear on whom to consult before considering future participation in an HIV vaccine trial. The four most common responses were non-governmental organizations, medical personnel, family and vaccine researchers.

Level of Protection

The groups also varied in their perceptions of protection level. For example, at least one person from most of the subgroups felt that the vaccine should be fairly protective. Two participants from the men having sex with men cohort insisted that the vaccine needed to be 100% protective against the HIV virus. However, many other participants felt the vaccine would not be fully protective, initially. One transport worker verbalized. The protection might be for 3–6 months.'' Another commented, ''Initially it (the HIV vaccine) will give 75% protection. At the end of the research, it will be 100%, hence there is no harm.'' Mostly, the participants believed that inclusion in the trial would get them a powerful vaccine when one became available.

Awareness of Vaccination Priorities

While several participants questioned who should be eligible for the vaccine, injection drug users verbalized the need for ''HIV positive people to be vaccinated, persons having sex with a known HIV-infected person, those who visit women in sex work, those with immoral behavior, those planning to go out of town (out of station), lorry (truck) drivers, (truck) cleaners, and those who are in the family.'' Married women thought all women should be vaccinated, as well as all those aware of their own risk behavior, drivers and sweepers, children, sex workers and their families, and husbands and couples.

Married women and females who attend sexually transmitted disease clinics expressed a greater willingness to participate in a future HIV vaccine trials than their counterparts; they felt the disparity was due to their desire to protect themselves and a fear of infection from their spouses. As one married woman verbalized, ''We may be unaware of the behavior of the men folk. If they had gone astray, there are chances of us also to get infected. By taking the vaccine, this can be prevented.''

General Concerns

When asked about concerns they might have about participating in a future HIV vaccine trial, a lively debate ensued in all focus groups producing a wide variety of responses. Several participants reported general apprehensions regarding participation in a HIV vaccine trial; the impact of others finding out that a person has become HIV seropositive was particularly salient. As one participant eloquently informed others in the focus group,

> ''People do not consider HIV/AIDS as an ordinary/another disease. The stigma attached to the disease is persisting still. Other people may get to know about the result when the trials are being conducted. No one will come forward to take part in the vaccine trial if there are going to be chances that others/outsiders may know the result. Why?

> Even I shall not come. Men having sex with men are not given/accorded status in society. We agree that you are working for a worthy cause. But if everyone (public/outsiders) is going to know about their HIV status, none of the men having sex with men will agree for the trial. It would be better if the stigma attached to HIV/AIDS were removed from the minds of the public before the vaccine is introduced.''

Another participant from the group of men having sex with men strongly protested about the stigma experienced by saying,

> ''As it is, there is stigma for the men having sex with men group. In addition, if they happen to be HIV positive, the scenario will only change for the worse. People will not accept men having sex with men at all. People have the notion that men having sex with men only have HIV/AIDS and they infect the public. This attitude should go. People should be made aware that a number of males have HIV. They spread the infection to their wives.''

Despite this strong sentiment, other participants considered ways in which the concern about becoming HIV antibody positive might be mitigated. As one married women verbalized, ''The ELIZA test will be positive due to vaccination. We should tell those persons who had taken the vaccines that the positivity would disappear after some time'' and ''If we go separately to the doctors and get tested, there will not be any problems. When the husband and wife go together, there will be a problem due to positive result.'' Moreover, a few married women and women in sex work wanted to know whether their seropositivity from the HIV vaccine would be transmitted to their sexual partners. Another issue was confidentiality about HIV testing; this fear was expressed as ''Friends will suspect us if we undergo HIV testing.''

Surprisingly, many of the participants in each of the subgroups verbalized few concerns about side effects of the vaccines, as faith in the government was profound. As one trucker affirmed, ''The government is never wrong. Therefore, if the government endorses a vaccine, it will surely be safe. So we can take the vaccine without fear.'' Women who identified themselves as women in sex work also voted to take the vaccine courageously. While a few sequelae, such as fever, allergic reactions and swelling were recognized, they were not considered serious. Polio vaccination is a success story and participants quoted the government efforts to eliminate polio in India. One married women said, ''The advertisement for the polio vaccination is widespread and educative. HIV vaccination may be done on similar lines. It would be beneficial if HIV vaccine is also given in railway stations and bus stops.''

Additional comments about how reservations could be mitigated were offered by other participants. For example, several participants brought up the need to inform knowledgeable persons, such as physicians or elders in the family, about taking the vaccine. A participant, who identified himself as a man having sex with men, stated he would agree to take the vaccine if identification cards were issued and monetary compensation granted in the event of serious adverse effects leading to death. He stated, ''We want a written guarantee plus insurance policy. The document should specify that, in the event of death (of the person after taking the vaccine), his family would be given full support.'' Men having sex with men also verbalized their desire for the researcher to provide a 100% guarantee that the vaccine would be safe, a list of provisions one would get if they volunteered, and full support for the family in the event of death. Additional considerations included the desire for frequent HIV testing (transport workers and men having sex with men) and careful selection of persons who would become aware of one's HIV serostatus.

Facilitators of Participation

Low cost for the vaccines was considered important by all groups. ''The price of the vaccine should be less and it be affordable for every one.'' Free vaccines were also requested by several participants. Additional facilitators included having the government handle the HIV vaccine trial. ''If it is done through the government, many people would come forward to take it.'' ''...the government is never wrong. Therefore, if the government endorses a vaccine, it will surely be safe. So, we can take the vaccine without fear.'' Faith in the research team was also pervasive across all groups. Nevertheless, one transport worker opined that, ''For people who live by Indian culture, it is difficult to enroll them into HIV vaccine trials. So the research team must mix the medicine in drinking water or some such simple measure and administer it on large scale.''

Several participants also mentioned additional facilitators researchers should consider to bolster recruitment in future HIV vaccine trials. Their suggestions included the need to inform future participants

that ''being HIV positive is a part of the vaccine trial and be so declared, if necessary,'' and that prior testing had been conducted in animals and a few people.

Finally, a few participants emphasized that education was critical to have people participate in the trial.

> ''Community members would want to know about the frequency of the vaccines and the site administered, how it might impact marriage, how long the HIV positive result will last, how long will the vaccine protect for, and will the vaccine be effective.''

Risk Behavior Change after Participation in a HIV Vaccine Trial

The majority of participants expressed the belief that people would increase their risky behavior after receiving the HIV vaccine. Married women, in particular, feared ''those in the sex industry will not have any fear after taking the vaccine'' and '' They will become bold. They will not change their high-risk behavior.'' One transport worker thought that persons vaccinated would use the vaccine like a condom and continue risky behaviors. Most of the negative comments came from transport workers, and to a lesser extent, from clients who attended a sexually transmitted disease clinic, injection drug users, and women in sex work. As another transport worker expressed, ''Now there is a fear that AIDS is a deadly disease and death is certain if you go astray. But in the future, this fear will disappear and everyone will think that they can indulge in high-risk behavior after taking a vaccine.''

Several participants were concerned that behaviors were not considered easy to change, particularly as condoms were not always available (sexually transmitted disease clinic attendee), and that it was just hard to change immoral behavior as ''people will revert to their illicit relationships.'' However, a number of participants also voiced reasons why people could change. The sentiments expressed were that people with families would not get into illegal behavior, and that people would change behavior due to fear. Married women felt that all persons who loved their life would change high-risk behavior.

When asked about percentage of people increasing or maintaining their high-risk behavior, responses ranged from 10% (transport workers and some injection drug users) to 80% (injection drug users). Clients of sexually transmitted disease clinics and some injection drug users believed greater numbers of people would make wrong choices. Married women, along with a few participants in all other groups, expected that about 50% would continue their high-risk behaviors.

Education was emphasized by many. In particular, participants felt that when the vaccines are given, safe sex should be emphasized. When questioned on what instructions would help to prevent high-risk behaviors, scattered responses across the groups included advice on safe sex, the possibility that one could lose their life should they engage in high-risk behavior, the need to listen to the doctors and non-governmental organizations, and the fact that people should follow a one-on-one relationship. However, realities of life came through as one person noted, ''Condoms should be used regularly. But we cannot tell our regular customers to use condoms nor can we be without a job.''

Retention in HIV Vaccine Trials

Participants agreed that retention in HIV vaccine trials would best be achieved if future volunteers were to be ''properly looked after.'' Transport workers requested leave without loss of pay, a venue close to home, and information about the short-term effects of the vaccines. Sexually transmitted disease clinic attendees requested frequent meetings with the researcher, while injection drug users requested compensation in the form of rice. Men having sex with men requested ''security assurance that in the case of amiss, families would be taken care of.'' Married women thought cards with posted dates and identification cards would be helpful. They also requested facilities, such as those used for the old polio programs, and thought that the use of incentives would be helpful. Finally, married women thought that messages of any impending HIV vaccine trial should be announced in visual form to educate the rural masses. They felt that advocacy done through television advertisements and the use of mass media would be most effective. A final suggestion from a married woman was that ''students may be introduced to the facts about HIV/AIDS from an early age onwards through lessons in their curriculum.''

Discussion

This study provided important information on factors affecting decision-making of select subgroups in Southern India about participating in a future HIV vaccine trial, as well as the potential impact of HIV vaccination on future high-risk behavior. Particular strengths of this study included assessments conducted across diverse high-risk populations at Chennai and

Madurai, thus representing both urban and rural areas in Tamilnadu.

Findings revealed that a lack of knowledge about HIV vaccines was widespread among participants in this study. In fact, these participants came to know about HIV vaccine development efforts and preparations for Phase 1 trials in India through this study as it would have been difficult for these participants to contemplate issues that might arise from future participation in a hypothetical HIV vaccine trial had they not received basic information, such as double-blind selection, vaccine-induced seropositivity, and the experimental nature of HIV vaccines, at the outset of the focus group discussions.

Nevertheless, we found that participants were familiar with the concept of vaccination. This probably reflects the high childhood immunization coverage in the state and nation-wide immunization campaigns conducted for polio eradication. These participants tried to apply their appreciation of the government efforts regarding polio vaccine to ways to encourage HIV vaccine trial participation; many indicated that the comprehensive health education by the mass media has been successful for the polio vaccine would be helpful for HIV vaccine trial as well.

Although protection from HIV infection and altruism were the main motivators for participating in efficacy trials, monetary incentives, health insurance, accountability, and assurances of confidentiality by the government in the event of any serious adverse reaction or any vaccine death were additional facilitators for HIV vaccine trials. The data also indicated that the community would rely on government agencies for vaccine trial information. Thus, the information dissemination on HIV vaccine trials should be done through government agencies at the national level to address vaccine-induced seropositivity, safety, confidentiality, protection from the vaccine, and other key vaccine trial concepts.

A major concern that came across in all study subsamples was vaccine-induced seropositivity. This study finding is consistent with findings from other hypothetical vaccine preparedness studies (Koblin et al., 1998; Nyamathi et al., 2004; O'Connell et al., 2002; Strathdee et al., 2000). In particular, questions were raised about the stigma and discrimination due to post-vaccination seropositivity, as well as issues of confidentiality.

Clearly, participants thought that involvement of sexual partners would facilitate recruitment and retention, since vaccine-induced seropositivity could create problems among marital partners. Hence, partner counseling was thought to be an essential prerequisite for a vaccine trial, in addition to collective education involving family and peers.

Almost unanimously, participants stated that high-risk behavior would increase if a HIV vaccine were made available. This assumption is consistent with prior literature assessing perceptions of high-risk behaviors and HIV vaccines (Jackson et al., 1995; Nyamathi et al., 2004; Vlahov et al., 1994). Safe sex education and counseling after participation in a future HIV vaccine trial was initiated to reduce risk behavior (Sahay et al., 2005), and it will have to be an inherent aspect of HIV vaccine trial designs in the pre-trial and trial phase. Comprehensive counseling will be critical, along with frequent reinforcement during the course of clinical trials, to counteract assumptions about protection by a vaccine of yet unproven efficacy.

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