AIDS RESEARCH AND HUMAN RETROVIRUSES
Volume 25, Number 2, 2009

DOI: 10.1089/aid.2007.0312

Factors Associated with Willingness to Participate in HIV Vaccine Trials among High-Risk Populations in South India

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Abstract

Successful conduct of any HIV vaccine trial (HIVVT) requires a high level of preparedness in the community. A cross-sectional study was conducted in Tamilnadu, India among 501 participants from six different risk groups to investigate their willingness to participate (WTP) in future preventive HIVVTs and to explore their knowledge and attitude toward preventive HIV vaccines. In total, 82% were willing to participate and the desire to be protected from HIV was the main reason for WTP. Perception of not being at risk was the major reason for refusal among married women. The knowledge scale showed a significant increase in scores after vaccine education. In all, 76% revealed the hope that there would be an effective vaccine in a few years and 71% hoped that the HIV vaccine would protect them from HIV infection. The main concern was the unknown efficacy of the vaccine (50%) and the effects of an HIV vaccine on participants' lives (51%). Overall, 76% agreed that sex without a condom would not be safe whether or not there was an HIV vaccine. To conclude, it is likely that high-risk volunteers will be willing to enroll in preventive HIVVTs. Addressing barriers and concerns by providing information through appropriate agencies will spell out success for preventive HIVVTs in India.

Introduction

A preventive HIV vaccine is a substance that teaches the body's immune system to recognize and protect itself against HIV, the virus that causes AIDS. A vaccine goes through a series of clinical trials before it can be used to protect people from infection or disease. Phase I trials focus on safety, Phase II trials focus on safety/immunogenicity, and Phase III trials focus on safety, immunogenicity, and efficacy. India, among other countries, is in search of a preventive AIDS vaccine. The AIDS Vaccine program in India exists under a Memorandum of Understanding between the Ministry of Health and Family Welfare (Government of India) through NACO, the Indian Council of Medical Research (ICMR), and the International AIDS Vaccine Initiative (IAVI). Currently, two Phase 1 clinical trials of a preventive AIDS vaccine are underway, one at the National Research Institute in Pune and the other at the Tuberculosis Research Centre in Chennai.[1] These Phase I trials involve healthy HIV-uninfected adult volunteers with a low risk of contracting HIV infection. The results will yield important data on the safety of the vaccine.

Before a large-scale Phase III trial can be launched in a community, feasibility studies need to be carried out to assess whether populations at risk are accessible and willing to participate by gathering data on knowledge, attitudes, perceptions, and practices and misconceptions about HIV vaccines and preventive HIV vaccine trials (HIVVTs) among targeted populations. Eliciting trial preferences and concerns prior to trial implementation may enable accommodation of participant's preferences and support tailored intervention to address concerns and misconceptions to facilitate enrollment in safe and ethical trials among vulnerable communities.[2] Such information will help in identifying factors such as stigma, misconceptions about vaccines, negative/hostile campaigns from groups opposing HIV vaccines that may influence participation in trials, assessing acceptability of the vaccine or placebo in a trial, and designing public information counseling and education messages in vaccine trials.[3] HIV vaccines should benefit all those in need, but it is imperative that they benefit the populations at greatest risk of infection.

As it is important to address all these sociological problems before starting efficacy trials by enlisting the cooperation of highly vulnerable groups who feel that they are stigmatized in the Indian community, a comprehensive multisite cross-sectional study was designed (1) to assess the demographic characteristics of the high-risk groups who are vulnerable to

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HIV infection and their knowledge of and attitudes toward HIV vaccine trials (preventive HIVVTs), (2) to investigate their perceptions about willingness to participate (WTP) in a future vaccine trial and factors that enhance or diminish their willingness to participate, and (3) to describe the potential impact of preventive HIVVT participation on risky drug and sexual behavior.

Materials and Methods

Design

A two-phased qualitative–quantitative design was employed. In Phase I, in-depth qualitative assessments were conducted by focus group methodology with 100 participants from HIV at-risk adults. A semistructured interview guide that was developed, pilot tested, and revised in a culturally sensitive manner by the Community Advisory Board (CAB) was used to direct the focus groups. On the basis of the qualitative data collected and analyzed, the interview schedules with the measurement scales were designed and administered to 501 healthy individuals representing six different study groups during Phase II, which was quantitative by nature.

Study setting and population

In Chennai, a capital city, and in Madurai in Tamilnadu, South India, the Tuberculosis Research Centre (TRC) conducted this study in collaboration with the UCLA Schools of Nursing and Medicine between October 2004 and September 2005. During phase I (qualitative), 12 focus group discussions (FGDs) were conducted, the findings of which are presented elsewhere.[4] During the Phase II (quantitative) study, 501 study participants were enrolled. These included five high-risk groups composed of the following: transport workers (TWs), persons diagnosed with a recent sexually transmitted infection (STI) from government hospitals and NGOs (STIs), injection drug users (IDUs), men having sex with men (MSMs), and female sex workers (FSWs).

Based on the revised estimates, the adult HIV prevalence in 2006 was estimated to be 0.36% in India. However, HIV continues to be concentrated among the poor and marginalized sections of the society and as per the National AIDS Control Organisation (NACO), HIV prevalence is estimated to be 4.62% among FSWs, 24.2% among IDUs, 5.6% among MSMs, 8% among persons with sexually transmitted illness, and 0.25% among antenatal women in Tamilnadu, a southern state of India.[5] India has perhaps 5 million truck drivers. About half drive long distance routes that keep them away from home for a month or more. Truck drivers are more likely than other men to be clients of sex workers, and sex work is common along major truck routes.[6]

Further, as there are indications that the HIV epidemic has moved into the general population and the number of women infected is steadily rising, a representative sample of monogamous married women from self help groups (SHGs) was included. The study population was mainly drawn from four different NGOs at Chennai and Madurai, which were closely working with the targeted population at the grass root level. They were the Association of Rural Mass in India (ARM), the Address Centre and Indian Community Welfare Organisation at Chennai, and the Institute for Mass Awareness, Guidance and Education (IMAGE) at Madurai.

Study instruments

Prior to the onset of the study, the study protocols were extensively reviewed by the CAB and discussed and further modified in the Scientific Advisory Committee meeting and the Institutional Ethics Committee meeting. After receiving the approval of the Indian Council of Medical Research (ICMR), NACO, the Institutional Review Board (IRB) of UCLA, and the participant's individual informed consent, the interviews were conducted in the local language (Tamil) after screening. The interview schedule was developed in English, translated into the local language Tamil, and validated by back translation. Multiple tests before beginning the study were conducted in a similar setting outside the study area before finalization of the study instrument. The research staff participated in special training on focus group discussions, data collection, and data analysis. On the basis of information available from the FGDs, interview schedules were developed. The interview schedules consisted of open as well as closed questions on sociodemography, measurement scales on Knowledge of HIV vaccines and preventive HIVVTs, attitudes about HIV vaccines and preventive HIVVTs, and social support. Willingness to participate (WTP) in a preventive HIVVT was measured by a yes/no response: "Would you be willing to participate in a future HIV vaccine trial?"

Procedure

During pretesting, the researchers came to know that the different high-risk groups in the study area had not heard of clinical research and they were not aware of recruitment of volunteers for research involving healthy human subjects or about voicing their opinions on health-related matters during an interview taking a vaccine as part of a trial.

Hence, after the baseline assessment on HIV vaccines and preventive HIVVTs by a 10-item scale developed by Koblin *et al.*,[7] health education was provided to each individual about the meaning of a preventive HIV vaccine trial, specifically about the double-blind selection of participants into the vaccine or placebo groups, the possibility of testing seropositive due to the production of antibodies after taking an HIV vaccine, and the experimental status of the HIV vaccine. Again, the Koblin scale was administered to determine the knowledge retained about preventive HIVVT participation among the study participants.

Participating NGOs informed their clients about the study. Interested participants completed a screener to assess whether the individual was a member of one of six selected groups being assessed. Eligible participants were taken to a private room and the trained staff provided details about the study. The interview was structured around a given hypothetical scenario in which the participants would be willing to participate in a preventive HIV vaccine trial. Written informed consent was obtained prior to data collection. The eligibility criteria for the study were that the participants should be above 18 years and willing to participate in the study. In addition, they should be a member of the high-risk groups by practicing high-risk behavior such as IDU or sex with multiple partners; the exception was for married women. The participants were compensated for their time and travel expenses and refreshments were provided after the sessions.

Statistical analysis

The interview schedule included both open and close-ended questions and measuring different scales, which were previously tested and modified according to the cultural and linguistic pattern of South India, did the quantitative assessment. The structured questions were precoded and analyzed using SPSS 13.0 version software (SPSS, Inc, Chicago, IL). Sociodemographic information included sex, age, education, marital status, religion, and occupation.

A 10-item Koblin scale at two time points assessed knowledge of HIV vaccines and preventive HIVVTs before and after vaccine education. This scale had been previously tested in the United States and was further modified for the Indian community after pretesting. The participants were asked to respond "yes" or "no" to each item in the scale. Comparisons between pre- and post-Koblin scale responses were made for each item in the scale.

Attitudes about HIV vaccines and preventive HIVVTs were assessed by an 18-item CDC Vaccine Attitude Survey[8] that showed how much they agree or disagree with each item. Subscale clustering included trial benefits, concerns and barriers, and impact of vaccines on sexual behavior. Subscale clustering included benefits of participation, barriers and concerns, and postvaccination condom use. For each statement, the study participants were requested to respond as "agreed" or "disagreed."

Multivariate logistic regression was applied to determine the pattern of willingness of the study respondents with respect to sociodemographic factors and the type of high-risk group.

Social support for the study respondents was measured by a 16-item 5-point Likert scale that was used in the RAND Medical Outcomes Study[9] to elicit information about how often respondents had friends or family members available to offer support.

Results

Demographic profile and high-risk behavior of the participants

Out of the total of 501 respondents, 55% were males, 59% were from the age group of 31–50 years, 64% were married, 79% were school educated, and 73% were working. Generally the participants came from a low socioeconomic background and most of them were not knowledgeable about the current Phase I trials for preventive HIV vaccines in India. Because the majority of the high-risk groups are at risk for HIV due to risky sexual behavior and drug and alcohol use, the respondents were asked about their sexual activity, alcohol use, drug use, needle sharing, and condom use. The findings revealed that 51% used alcohol, 15% used Ganja (marijuana), 17% used heroin, 13% used tablets such as Nitravet and Nitrogen, 16% used injections, and 5% used mild tranquilizers such as Librium and Valium.

Out of 501 respondents, only 16.4% always used condoms with their regular sexual partners in comparison to 24.4% who used condoms with other sexual partners.

Knowledge of preventive HIVVT concepts before and after health education

The participants' baseline knowledge of preventive HIVVTs was assessed by the Koblin scale before and after the educational session. The topics discussed covered the research/testing processes, including the use of a placebo, that any potential vaccine would undergo, the possibility of testing seropositive due to the production of antibodies after taking an HIV vaccine, and the current experimental status of the HIV vaccines. From Fig. 1 it is clear that there was a significant improvement in all 10 Koblin knowledge items from pretest to posttest. The level of knowledge at baseline ranged between 26% and 86%, whereas at posttest this increased from 63% to 93%. The participants had difficulty in understanding that the initial HIV vaccines may only be partially efficacious. Thus, only 63% of respondents answered the question "Early vaccines tested will not be 100% effective in preventing HIV" correctly at posttest. This was still an improvement, as 26% had correctly responded to this item at baseline. It is noteworthy that participants believed that the vaccine would be powerful despite our emphasis on the experimental nature of HIV vaccines. Likewise, the participants could understand issues such as double-blind selection of the trial volunteers into vaccine and placebo groups only after the educational session. This was apparent from their pretest and posttest responses to items 5, 8, and 10 (38%, 75%; 32%, 90%; 37%, 90%).

Attitudes toward HIV vaccines and preventive HIVVTs

The CDC HIV Vaccine Attitudes Scale was administered to the study participants to assess their attitude to HIV vaccines and preventive HIVVTs. The 18 items in the Questionnaire were clustered into (1) Benefits of Participation, (2) Barriers and Concerns, and (3) Postvaccination Condom Use (Table 1).

The number of participants who agreed and disagreed with each item is given in the table. In addition, the percent of respondents willing to participate in a preventive HIV vaccine trial both for the agreed and disagreed groups was also provided to determine the relationship between the attitude of the respondents and their WTP in HIVVTs.

Benefits of participation. Eight items were clustered on personal as well as social benefits of trial participants in a future hypothetical preventive HIVVT. More than 70% voiced positive sentiments about a future vaccine; they believed that their participation in a preventive HIVVT would lead to the development of a vaccine that would protect them from HIV infection. Similarly, additional benefits included a reduction in their likelihood of getting HIV (76%), altruism (74%), future prevention of HIV (73%), and help for researchers in finding an effective HIV vaccine (68%).

Barriers and concerns about preventive HIVVT participation. Although protection from HIV infection and altruism were the main motivators for WTP for the study participants, the respondents expressed several concerns about their participation in a hypothetical preventive HIVVT. Using the CDC scale of seven items that assessed concerns about and barriers to preventive HIVVT participation, the most common concern was how the vaccine would affect the trial participant's life (51%). Other common concerns were whether the vaccine would be powerful enough to prevent the infection (50%) and effects on marriage, job prospects (38%), and travel (39%). Additional concerns

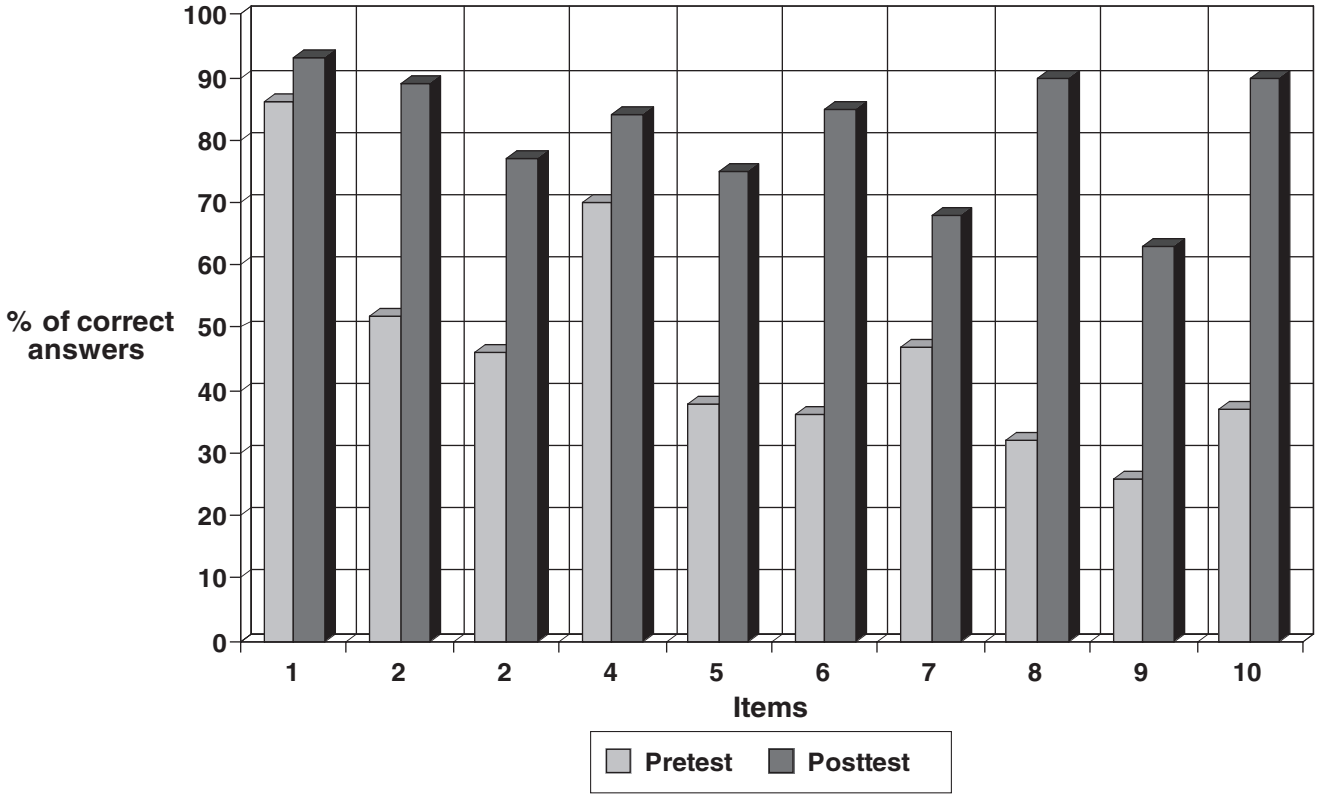

FIG. 1. Pretest and posttest knowledge of vaccine trial concepts. 1, Vaccine safety; 2, strengthens immunity system; 3, enrollment of both HIV^+ and HIV^- persons; 4, provision of health care for study-related medical problems; 5, information about vaccine or placebo at the end of the study; 6, guaranty for participation in a future HIVVT; 7, no effect on participants' HIV status; 8, randomization into vaccine or placebo groups; 9, early vaccine will be 100% effective; 10, study nurse will select the vaccine or placebo.

included physical side-effects (34%) and uncertainties involved with preventive HIVVTs (32%).

Postvaccination condom use. Three items on the CDC HIV Vaccine Attitude Scale also revealed concerns about the possible increase in HIV risk behavior. Seventy-six percent of participants agreed that sex without condoms would not be safe regardless of whether an HIV vaccine was available. Likewise, 68% had refuted the statement "An effective vaccine will make safer sex less important" and 62% of them had disagreed with the statement that they would have more faith in a vaccine rather than the practice of safer sex for protection from HIV.

WTP in preventive HIVVTs

Of the 501 respondents, 82% were willing to participate, 16% were not willing, and 2% were undecided about their participation in future preventive HIVVTs. About 32% of 501 participants wanted to seek advice from others before giving their consent for participation; of these 46% wanted to consult with their spouse/sexual partner, 26% with their friends/colleagues, and 13% with NGOs, counsellors, or other knowledgeable people. In addition, 57% preferred to consult the community groups or organizations on this issue, such as NGOs (62%), health personnel (17%), and researchers (1%).

A multivariate logistic regression was applied to determine the pattern of willingness with respect to sociodemographic factors (Table 2). Women expressed their desire to protect themselves from their infected husbands and were willing to participate in preventive HIVVTs. Respondents under 30 years of age were reluctant to participate. Logistic regression after adjustment for the covariates revealed that married women as compared to other high-risk behavior groups were less willing to participate in preventive HIVVTs. About 95% of CSWs, 92% of IDUs, 74% of MSMs, 88% of STIs and truck drivers, and 58% of married women were willing to participate in future preventive HIVVTs. The respondents with less education were less willing to participate in future HIVVTs than women in the highly educated group.

Social support

The MOS Social Support Survey is a 16-item scale used in the RAND Medial outcomes study[9] and was modified according to the cultural and linguistic patterns of the local community. The items elicit information about how often respondents had relatives and friends available to provide health care or show love and affection on a five-point Likert scale. An additional question enquires about the number of close relatives and friends available to participants for companionship, assistance, and other types of support.

For the purpose of analysis, the items were subclustered into two main domains: (1) physical help and advice and (2) love and affection. Table 3 shows whether these forms of support and assistance are available none of the time, some of

Table 1. Participant's Attitude toward HIVVTs and Their Willingness to Participate[a] ($n = 501$)

	Agreed (%)		*Disagreed (%)*	
Statements	*No. of respondents*	*WTP in HIVVTs (%)*	*No. of respondents*	*WTP in HIVVTs (%)*
Benefits				
Less chance of HIV infection	361	95	104	57
Willing for the common good of India	369	93	112	55
Hope for an effective HIV vaccine	362	86	59	81
Protection from HIV infection	356	94	117	62
Help researchers prevent HIV/AIDS	361	94	119	82
Will reduce the threat of HIV infection	380	86	101	77
Even if the vaccine does not work, help researchers find an effective vaccine	339	93	140	61
HIV will become preventable like polio	364	86	90	92
Concerns and barriers				
Uncertainties	322	89	158	73
Unknown long-term side effects	170	70	294	90
Not willing unless vaccine is given	139	68	337	90
Whether the vaccine is powerful enough to prevent the infection	249	89	228	78
Effect on participants' life	257	88	214	77
Effect on insurance, marriage, and job	192	80	247	90
Effect on travel	196	82	236	90
Condom use				
More faith in vaccine rather than safer sex	130	87	311	87
Vaccine will make safer sex less important	104	78	341	90
Never safe to have sex without condom whether or not there is an HIV vaccine	380	88	76	80

[a]HIVVT, HIV vaccine trial; WTP, willingness to participate.

Table 2. Logistic Regression for Willingness to Participate in Preventive HIV Vaccine Trials ($n = 489$)

			95.0% CI for OR	
	Significance	*Odds ratio (OR)*	*Lower*	*Upper*
Gender				
Female		1.000		
Male	0.362	0.479	0.098	2.331
Age				
≤30	0.633	0.869	0.489	1.546
>30		1.000		
Marital status				
Unmarried		1.000		
Married	0.022	0.385	0.170	0.870
Separated/divorced/widowed	0.592	1.838	0.198	17.052
Education				
Illiterate		1.000		
Schooling	0.024	.304	0.108	0.854
College and above	0.005	.130	0.032	0.536
High-risk groups				
Married women		1.000		
Commercial sex workers	0.003	16.128	2.551	101.973
Injecting drug users	0.065	5.037	0.907	27.989
Truck drivers	0.000	13.085	3.505	48.848
Persons with sexually transmitted infections	0.002	17.693	2.818	111.070
Men having sex with men	0.002	6.392	1.981	20.621

Table 3. MOS Social Support Survey (%)

Statements	*None of the time*	*Some of the time*	*Most/all of the time*
Physical help and advice			
Someone to listen to you	6.1	46.5	47.4
Someone to give you good advice	7.8	44.9	47.4
Someone to take you to the doctor	6.9	41.1	52.0
Someone to have a good time with	6.5	46.8	46.8
Someone to give you information	9.9	46.3	43.8
Someone to get together with for relaxation	9.9	44.2	45.9
Someone whose advice you really want	7.3	47.8	44.9
Someone to turn to for suggestions	18.9	46.3	34.8
Someone to help you if you were sick	6.7	43.0	53.3
Someone to help with daily chores	5.9	53.9	40.3
Love and affection			
Showing love and affection	7.8	43.6	48.6
To love and make you feel wanted	6.9	43.8	49.3
To confide in	9.0	49.1	41.9
To share your private worries and fears	18.4	46.8	34.8
To do something enjoyable	6.9	47.2	45.9
Understanding your problems	8.0	45.1	47.0

the time, or most/all of the time for the study respondents. Their responses indicate that most receive the required support some of the time or most of the time; very few said that they receive support none of the time.

The level of social support was determined for both gender groups and risk groups and this difference is statistically significant ($\chi^2 = 13.1$, $p = 0.000$). Among male respondents, 47% had five or fewer close relative and friends, whereas 72% of female respondents had five or fewer close relative and friends. On the other hand, 26% of male respondents compared to 9% of female respondents had 11 or fewer close relatives and friends. Furthermore, MSMs had the highest number of close friends followed by truck drivers, STDs, CSWs, IDUs, and married women. When the scores were given for all 16 items in the scale and were related to gender and risk behavior, it was found that truck drivers among men and married women among women enjoyed greater social support whereas among the STD group both men and women had poor social support.

Discussion

The present study attempted to assess the different factors associated with WTP among the potential beneficiaries in South India. Knowledge and attitude toward HIV vaccines are among the factors that may influence participation in trials and the eventual acceptability of efficacious vaccines.[10–15] We found a significant difference in the level of knowledge before and after vaccine education in our study sample. However, only 63% of the participants understood that initial HIV vaccines are expected to be only partially efficacious. This might be due to their previous experience with preventive vaccines in the effective control of polio, smallpox, malaria, and nationwide immunization programs in India. Prior research suggests that low to moderate efficacy vaccines can make substantial contributions to controlling the epidemic and can yield significant benefits among populations with high HIV seroprevalence.[16–20]

During this initial stage of vaccine research, most people in the community had not heard of clinical research using placebos, double blind studies, and randomization. They had also not heard of volunteers for research involving healthy human subjects, that healthy persons could voice their opinion on health-related matters during an interview, or about taking a vaccine or drug as part of a trial. Hence, the baseline knowledge of placebos for two statements was as low as 32% and 33%, which increased to 90% and 75% after the information session.

Of the 501 original participants, 82% were willing to continue to participate. In another Indian study conducted at Pune in Western India by Sahay *et al.*,[21] nearly 80% of the participants, consisting of sex workers and patients with sexually transmitted infections and their spouses, were willing to continue to participate in preventive HIVVTs. Previous studies suggest that sociodemographic characteristics and risk behavior are associated with WTP.[10,11,13–15,22] According to a report from a WHO–UNAIDS consultation,[23] WTP in trials varies depending on educational level, perception of risk, and age. Altruism and a desire for protection are common motivations for participation and vaccine safety is usually the major concern. Likewise, altruistic reasons were reported by 41% of high-risk men at Pune, India by Sahay *et al.*[21] Our findings revealed that about 58% of married women as compared to 95% of CSWs were willing to participate in preventive HIVVTs, which shows the difference in the self-perception of HIV risk. Despite the fact that an increasing number of married women are becoming infected, generally due to their husband's high-risk behavior, they do not consider themselves at risk. Protecting married women from infection in India is a major problem.[24] Therefore, the possibility of a preventive HIV vaccine holds tremendous promise for women. Involvement of men in the social movement for women may be helpful as our study findings reported that 46% of the participants wanted to consult their spouses before deciding whether to participate in preventive HIVVTs. Furthermore, the majority also wanted to discuss the issue with NGO workers. NGOs can play a crucial role in recruitment and retention of volunteers since they know the pulse of the community and they provide a vital link between researchers and the community.

In the case of preventive HIVVTs, participants should understand that the vaccine is experimental and has not yet been proven to be protective; hence they must always practice safe sex behavior. However, there is some evidence that high-risk behavior would increase if an HIV vaccine were available. Among 48 participants in Phase 1 and 2 preventive HIVVTs, the percentage engaging in unprotected sex increased from 9% before the trial to 20% after 1 year.[25] Evidence of increases in risk behavior among HIVVT participants was also reported in other studies.[25–27]

However, we found that our participants expressed more faith in condoms rather than in HIV vaccines. Other studies done at Pune and Chennai[21,28] reported that condom use would not decrease in spite of an approved vaccine. Safer sex education and counselling after volunteering have been reported to reduce the risk behavior[21] and hence will have to be an inherent aspect of HIV vaccine trial designs.

The study findings revealed that almost all participants received social support sometimes or most of the time, but there was a gender difference in the number of close relatives and friends for men and women that was found to be statistically significant ($\chi^2 = 13.1$, $p = 0.000$). About 26% of male respondents in comparison to 9% of female respondents had 11 or more close relatives and friends. In the traditional culture of India in which women usually rely on men for economic subsistence as well as for access to information, men receive more healthcare and support. The number of relatives and friends decreased in descending order from MSMs, truck drivers, STIs, CSWs, IDUs, and married women. MSMs and truck drivers have wider social networks as compared to IDUs, who are more introverted and isolated, and married women, who confine themselves to their small family circle. In terms of availability of support, truck drivers and married women enjoyed the maximum support.

To conclude, although 82% of the study participants with risk factors for HIV infection were willing to participate in future preventive HIVVTs, only 58% of married women were willing to participate. The main reason for their refusal was their belief that they were not at risk for HIV infection. Hence, there is a need for more education on the benefits of vaccine trials for all groups due to the increasing number of HIV-infected married women. Addressing barriers and concerns through appropriate agencies will result in success for preventive HIVVTs in India.

Acknowledgments

The authors are grateful for a grant from the international core of the University of California, Los Angeles AIDS Institution CFAR program to the UCLA School of Nursing for carrying out the study. Dr. P.R. Narayanan, Director, Tuberculosis Research Centre, provided guidance and constant encouragement throughout the study. We thank the nongovernmental organizations, both in Chennai and Madurai, for their help in the recruitment of study participants. The fieldwork could not have been completed without the active cooperation of Mr. Ramesh, Ms. Jaya Lenitta, and Ms. Anuradha. We are also indebted to the study participants who contributed their personal information without which we could not have conducted the study.

Disclosure Statement

No competing financial interests exist.

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