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A pilot study on willingness to participate in future preventive HIV vaccine trials

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***Background & objectives*: In India, phase-I human clinical trials for a preventive HIV vaccine are being conducted at Pune and Chennai Centres. In order to find out the willingness of populations at risk to participate in future preventive HIV vaccine trials (HIVVTs) and to assess the factors that enhance or deter them from participation, a study was conducted at Chennai and Madurai in Tamil Nadu.**

***Methods*: This cross-sectional study was conducted among transport workers, people attending sexually transmitted infection clinics, injection drug users, men having sex with men, women in sex industry and a representative sample of monogamous married women, by employing measurement scales. A structured questionnaire on knowledge and attitudes about the HIV vaccine was used to measure the participants' knowledge and attitudes about HIV vaccine and HIVVTs.**

***Results*: Of the 112 participants, 67 (60%) were men. Mean age of the respondents was 32 yr; 68 per cent were high school educated. Majority of respondents were willing to participate in a future HIVVT and the reasons were altruism, protection from HIV, and support for the researchers. Major concerns were vaccine efficacy, side effects of the vaccine and the impact of a HIV vaccine on the participants' lives. Majority (85%) agreed that sex without condom would not be safe despite the availability of an HIV vaccine.**

***Interpretation & conclusion*: It is likely that high-risk volunteers will be willing to enroll in HIVVTs. Barriers and concerns should be dealt with carefully by providing correct information. Also there is a need for more education to ensure participants' understanding of key concepts of HIV vaccine trial.**

Key words High-risk groups - HIV vaccine trial concepts - India - willingness to participate

India has more than 5 million people living with HIV/AIDS, the world's second highest number of infections after South Africa; thus representing a high public health burden. Almost one-fourth of India's AIDS cases are among children and young people below 25 yr of age. According to the National AIDS Control Organisation(NACO), 68 new cases of HIV occur every hour[1]. As the HIV epidemic has been spreading from high to low risk populations and from urban to rural areas over the last decade[1,2-6], HIV vaccine offers the best long-term hope to control the AIDS epidemic.

Efforts to develop an HIV vaccine are being co-ordinated by the Indian Council of Medical Research (ICMR), NACO and the Department of Biotechnology in India and their partner, the International AIDS Vaccine Initiative (IAVI)[2]. The first phase I trial of an HIV candidate vaccine was conducted in the United States in 1987[7]. Phase I trials provide initial safety and immunogenicity data and are conducted among small numbers of healthy volunteers(30-50). Phase II trials provide information on additional safety and immunogenicity in different populations usually among hundreds of volunteers. Phase III trials are designed as large scale, double-blinded, controlled trials including thousands of volunteers and conducted to assess the efficacy of the candidate vaccine in preventing HIV infection or disease[8].

Currently, preparations for phase-I HIV vaccine trials in India are underway. In 2002, a multiple HIV vaccine candidate strategy approach was adopted and two centers of excellence for the HIV vaccine clinical and laboratory evaluation were set up at two ICMR institutes at Pune and Chennai. India started its first phase-I human clinical trial for a preventive HIV vaccine with the Adeno-Associated Virus (AAV) in February 2005 at the National AIDS Research Institute (NARI) at Pune. The second phase-I trial is being conducted at Tuberculosis Research Centre (TRC) at Chennai, with Modified Vaccine Ankara (MVA).

Clearly, HIV vaccines need to be delivered as a part of an overall HIV prevention strategy, as initial vaccines will be far from fully effective. Prior to any vaccine trial, it is important to assess the concerns of and perceptions about barriers and facilitators of the community who might be participating in a future HIV vaccine trial (HIVVT). Currently, little is known about the challenges the community of participants may experience as a result of engagement in a HIVVT. Researchers preparing to initiate these trials need to be adequately informed of the issues raised by highly vulnerable groups who may already feel stigmatized in the community. Therefore a sociological study was conducted to investigate HIV vaccine readiness among the high-risk groups in Tamil Nadu for future HIV vaccine trials.

This study assessed factors that might impact the decision of future participants to enroll in a HIVVT. These individuals include subgroups who typically engage in high risk activities, such as injection drug users (IDUs), those engaged in unprotected sexual activity with multiple partners, such as men having sex with men (MSM), women working in the sex industry, transport workers and those who report a recent sexually transmitted infection (STI). Further, as there are indications that HIV epidemic has moved into the general population and the number of women infected is steadily rising, a representative sample of monogamous married women has also been included for the study. The specific objectives of the study were to assess the knowledge and attitude towards HIVVT participation among groups at risk for HIV as it relates to (*i*) willingness to participate in a future HIVVT; (*ii*) factors that enhance or deter these individuals from participating in a future HIVVT; and (*iii*) the potential impact of HIVVT participation on risky drug and sexual behaviour among these persons.

Material & Methods

Design: A two-phased qualitative-quantitative design was employed in collaboration with the UCLA

Schools of Nursing and Medicine, USA. The original study was a mixed method design in which participants first completed focus group discussions and then assisted in piloting several instruments which have been previously modified in a culturally sensitive manner by the community advisory board (CAB). Structured scales were administered to the participants at the end of the phase I qualitative study during October 2004 to January 2005 in which focus group discussions were conducted. These structured scales, Knowledge of HIV/AIDS Vaccines Scale[9] and the Centers for Disease Control HIV Vaccine Attitude Scale[10] enabled the researchers to assess the targeted community' s current state of knowledge and attitude towards participation in HIVVTs.

Participants and setting: The study population consisted of several subgroups that were considered at higher risk for HIV as compared with the general population. These subgroups included transport workers (TWs) such as truck drivers and cleaners, persons diagnosed with a recent STI at Government Hospital, IDUs; MSMs, and women in commercial sex work (CSWs). In addition, a representative sample of monogamous married women from the self-help groups (SHGs) in the local communities was included. The eligibility criteria for the study were that the participants should be above 15 yr and willing to participate in the study. Besides, they should be a member of the high-risk groups by practicing high-risk behaviour except for married women.

The study population was mainly drawn from 4 different non-governmental organizations (NGOs) working in the field of HIV/AIDS at Chennai and Madurai. They were the Association of Rural Mass in India (ARM), Address Centre, Indian Community Welfare Organization (ICWO), at Chennai and Institute for Mass Awareness, Guidance and Education (IMAGE) at Madurai.

Procedure: Prior to the onset of the study, the study protocols were extensively reviewed by CAB and discussed and further modified in the Scientific Advisory Committee Meeting and Institutional Ethics Committee Meeting at the Tuberculosis Research Centre (TRC), Chennai. 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 focus groups were conducted in the local language (Tamil) after screening. The research staff consisting of the Indian investigators and their facilitators underwent in special training on focus group discussions (FGDs), data collection and data analysis.

Participating NGOs informed their clients about the study. Monogamous married women were included from the local self-help groups (SHGs), which were encouraged by the government organizations for women empowerment. Interested participants completed the initial consenting process and completed a screener, which assessed that the individual was a member of one of six selected groups being assessed. Written informed consent was obtained prior to data collection.

During pretesting, the researchers came to know that the knowledge on HIVVTs was very minimal among the study participants. Hence, at the opening of the FGDs, participants were educated about the meaning of a vaccine trial, particularly 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 a HIV vaccine, and the current experimental status of the HIV vaccines. Care was taken to inform the participants that there was no HIV vaccine immediately available in India and that the current study was a first step in assisting researchers in preparation for a future trial. This was followed by the FGDs in which questions were asked on vaccines, facilitators or barriers to participate and the impact of vaccination on risky behaviour (findings not presented here). At the end of the focus group interviews, a socio-demographic profile was completed along with other instruments by interviewing each participant separately by the

research staff to know his or her level of retention on HIV vaccine concepts. On the basis of information available from this pilot study, interview schedules were developed to collect data from a large sample. The participants were compensated for spending their time, and travel expenses and refreshments were provided after the sessions.

The structured questions were precoded and analyzed in SPSS 10.0 for windows (SPSS, Inc, Chicago, IL, USA). Proportions, means with standard deviations are used in appropriate places. Chronbach alpha was used to test the reliability of the scales.

Socio-demographic information: Information was collected regarding the date of birth, gender, religion, education, employment status, income and the nature of high-risk behaviour.

Knowledge of HIV/AIDS: Knowledge of HIV/AIDS was assessed by an 11 item scale developed by Koblin *et al*[9]. This scale measured the participant's knowledge on HIV vaccines and concepts about participation in a HIVVT. The participants were asked to respond 'yes' or 'no' for each item in the scale. This scale had been previously tested in the US and was further modified for the Indian community after pretesting. Chronbach alpha was 0.5441.

HIV vaccine attitude: Attitudes about the HIV vaccine was assessed by a 19 item HIV vaccine attitude scale[10] which reflects different beliefs or attitudes towards HIVVTs. Subscale clustering included trial protection, HIV altruism, trial protection, tolerance for ambiguity and safer sex after vaccination. For each statement, the study participants were requested to respond as "disagree strongly", 'disagree', 'undecided', 'agree', 'agree strongly', 'refuse to answer' and 'don't know', which will show how much they agree or disagree with each statement. Chronbach alpha revealed 0.7096 regarding the reliability of the scale.

Results

Demographic profile: A total of 112 respondents participated in the study of which 67 (60%) were men. The subgroups included TWs (n = 20), MSMs (n = 20), IDUs (n = 19), CSWs (n = 17), STI clinic clients (n = 15) and married women (n = 21). The mean age of the respondents was 32.4 ± 8.52 yr. More

Table I. Demographic and behavioural characteristics of trial participants

Characteristics	Male (n=67) No. (%)	Female (n=45) No. (%)
Focus group participants:		
CSWs	-	17 (37.8)
IDUs	19 (28.4)	-
MSMs	20 (29.9)	-
STD attendees	8 (11.9)	7 (15.6)
Transport workers	20 (29.9)	-
Married women	-	21 (46.7)
Age (yr)*:	31.04 ± 7.86	34.24 ± 9.18
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)
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)
Religion:		
Hinduism	58 (86.6)	32 (71.1)
Islam	4 (5.9)	2 (4.4)
Christianity	5 (7.5)	11 (24.5)
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)

CSWs, commercial sex workers; IDUs, injection drug users; MSMs, men having sex with men
*Values are mean ± SD

than half (68%) completed high school and 7 per cent completed higher studies. Almost half of the sample was married (42%); 38 per cent were single; 13 per cent were separated/divorced/widowed. The samples were primarily Hindus (81%) and employed full time (56%) (Table I). Forty two per cent of the total respondents perceived no risk of HIV/AIDS. Of the remaining participants; 47 per cent reported unprotected sex with multiple partners, 28 per cent shared unclean needles, 9 per cent reported male-to-male unprotected sex and 17 per cent reported other risk behaviours.

Knowledge retained about HIVVT participation: Findings of knowledge scale revealed that approximately 90 per cent of the respondents answered correctly regarding the safety of HIV vaccines, and the ability of the vaccine to boost the body's immunity. These participants were also convinced that health care would be provided for those experiencing vaccine-related medical problems. These respondents were also aware that some participants in a clinical trial would receive the vaccine, while others would receive the placebo. Knowledge about vaccine-induced HIV positivity, the less than desired efficacy of early vaccines, and the fallacy that the study nurse did not decide the random assignment of the vaccine *vs* the placebo ranged from 60-80 per cent. Fewer respondents were aware that only HIV negative participants (as compared with both HIV positive and HIV participants) were to be solicited in the future HIVVT trials being planned, that they would receive information about the substance they received (vaccine or placebo), that one would not receive a guarantee on participation in future HIVVTs, and the vaccine might have an effect on their current negative HIV antibody status.

Gender difference was observed in relation to the item on trial randomization and the difference was statistically significant ($P<0.05$). For example, 82 per cent of the male respondents as compared to 100 per cent of female respondents were aware that some participants would get the real vaccine and some would get placebo (Table II).

HIV vaccine attitude scale: Three major domains were identified: willingness to participate due to altruism and other reasons, concerns and barriers for

Table II. Gender-wise distribution of responses of participants understanding on HIV/AIDS vaccine trial concepts

Items	Percentage of correct responses		
	Male=67 No. (%)	Female=45 No. (%)	Total=112 No. (%)
Healthcare for vaccine-related medical problems	65 (97)	43 (96)	108 (96)
Proven safety of vaccines through large scale HIVVTs	62 (93)	42 (93)	104 (93)
HIV vaccine strengthens the immune system	60 (90)	41 (91)	101 (90)
Some get the real vaccine, and some get a placebo	55* (82)	45 (100)	100 (89)
Post-vaccination seropositivity due to vaccine/infection	46 (69)	26 (58)	72 (64)
Study nurse will select the vaccine/placebo	42 (63)	29 (64)	71 (63)
Early vaccines - not 100% effective	39 (58)	30 (67)	69 (62)
Participants told whether they got the vaccine or placebo	34 (51)	31 (69)	65 (58)
People in these studies will be in future vaccine studies	34 (51)	31 (69)	65 (58)
No effect on participant's HIV test results	39 (58)	30 (67)	69 (56)
Preventive trials enroll both HIV+ and HIV-	33 (49)	26 (58)	59 (53)

*$P<0.05$; compared to females

Table III. Gender-wise responses on personal and social benefits of HIV vaccine

Statements	Agreed (%)		Disagreed (%)		Undecided (%)		Don't know (%)	
	M	F	M	F	M	F	M	F
Personal benefits:								
Less chance of getting infected with HIV	90	98	6	-	4	2	1	-
Protection from HIV	92	89	3	9	5	2	-	-
Social benefits:								
There will be an effective HIV vaccine in a few years	90	96	6	-	3	2	1	2
Vaccines will reduce the threat of. HIV infection	93	93	6	5	1	-	-	2
HIV will become preventable like polio	87	96	4	2	6	-	-	2
Willingness is important for the common good of India	97	100	2	-	-	-	1	-
Help researchers prevent HIV/AIDS	97	96	3	4	-	-	-	-
Even if the vaccine does not work, help researchers find an effective vaccine	82	91	9	7	8	2	1	-
Number of participants = 112								

participation, and future sexual behaviour change after receiving an approved vaccine. The responses did not show much variation between 'disagree strongly'and 'disagree' as well as between 'agree' and 'agree strongly', hence they were merged into 'disagree' and 'agree' for the purpose of analysis.

Benefits of participation in a future HIVVT: The majority of participants voiced positive sentiments about the future vaccine; in fact, 92 per cent revealed the hope that there would be an effective vaccine in a few years (Table III). A majority (93%) also responded that their participation in a HIV vaccine trial would reduce their chances of getting HIV infection and hoped that the HIV vaccine would protect them from HIV infection. Many believed that HIV would be preventable similar to the polio vaccine preventing polio.

A number of participants expressed altruism as a rationale for their willingness to participate in a future HIVVT. Almost all the participants (98%), agreed that their participation in a HIVVT is important for the common good of India.

Perceived barriers and concerns about HIVVT participation: A total of 7 items covered concerns or barriers participants perceived should they become involved in a future HIVVT (Table IV). A majority of concerns (61%) revolved around the unknown efficacy of the vaccine, such as whether the vaccine is powerful enough to prevent the HIV infection. Additional concerns related to the effects of a HIV vaccine on participant's lives (50%), possible unknown long-term side effects of the vaccine (32%), and the impact of the vaccine on the participants' ability to get insurance, marriage and job prospects (31%). Less than 30 per cent of the responses worried about whether they would be given the vaccine or placebo (26%); 27 per cent were concerned about restriction on travel due to participation in a HIVVT (Table IV).

Sexual behaviour change after receiving a HIV vaccine: The HIV vaccine scale also assessed participants' likelihood of sustained safe behaviour subsequent to vaccination. The participants were asked about their perception regarding possible risk behaviour change if an actual HIV vaccine was available, and whether behaviour would change positively or negatively.

Overall, 85 per cent of respondents agreed that sex without a condom would not be safe whether or not there was a HIV vaccine available illustrating the participants' faith in condom use even after receiving an approved vaccine. The response pattern clearly emphasized the level of motivation prevalent among each group on condom use. All MSMs (100%) had agreed that condoms were necessary followed by transport workers (95%), CSWs (94.1%), STIs (86.7%), married women (76.2%) and IDUs (57.9%). Approximately one-third of respondents agreed that if they were to participate in a vaccine study, they would have more faith in the vaccine to protect them from HIV rather than safe sex. Similarly, about a third agreed that an effective vaccine would make safe sex less important and they would be less worried about having unprotected sex.

Table IV. Concerns/barriers regarding trial participation

Statements	Responses (%)			
	Agreed	Disagreed	Undecided	Don't know
Uncertanities-uncomfortable	43	55	2	
Unknown long-term side effects - uncomfortable	32	61	5	2
Not willing unless l knew I was getting the vaccine	26	71	3	
Comfortable if I knew the vaccine is powerful enough	61	35	3	1
Comfortable if I knew how it would affect my life	50	46	4	-
Effect on insurance, marriage or getting a job	31	53	6	10
Effect on travel - uncomfortable	27	55	7	11
No of participants = 112				

Discussion

We attempted to assess the knowledge and attitudes of targeted subgroups in a community in Chennai and Madurai by sensitizing them through focus groups discussions and obtaining the feedback by using structured questionnaires. Findings revealed that the overwhelming majority of participants were willing to participate in a future HIVVT. In addition, the majority of participants were confident about the availability and safety of the vaccine and understood basic mechanisms of action of the vaccine. This high level of awareness of the vaccine was similar to that a study conducted in Thailand[11].

Majority (over 90%) of participants believed that the HIV vaccine was the best hope for controlling AIDS; these persons were also confident that such vaccines could be produced. However, a major concern across all study populations was the lack of knowledge about which persons would be eligible to enroll. For example, 47 per cent of the participants believed that both HIV positive and HIV negative people were appropriate for participation in HIVVTs, despite the education on preventive vaccines. This is also reported for a Ugandan cohort where they conflate whether vaccines cure or prevent disease[12,13].

Altruism was found to be a main motivation for participating in efficacy trials across all study populations. Overall, over 90 per cent of participants indicated that their willingness to participate in an

HIVVTs was for the common good of India and for the researchers to find an effective vaccine. In addition, participants hoped that the vaccine would be of personal benefit in terms of protection from HIV infection. Similarly, in the study by Koblin *et al*[14] social benefit was rated most frequently as very or somewhat important in the respondents' decision-making about participation in vaccine trial as participation was based upon "helping to find a vaccine that works", followed closely by "helping to stop the epidemic". Almost 70 per cent of volunteers from a cohort of high-risk homosexual men in Rio de Janerio reported their willigness to participate, with altruism being the main reason[15,16]. In a study of a random household sample of 890 Kenyans from Nairobi and rural Thika[7], findings revealed that willingness increased with number of sexual partners and level of education. The most common reasons for refusing vaccinations were not being at risk of HIV infection (47%), concern about the safety of the vaccine (4%), and probability of already being infected (3%). However, these findings differed in other countries. In an Ugandan study, 88 per cent of military personnel reported willingness to participate in trials[7]. Similarly in Pune, India, over 80 per cent of 349 patients attending sexually transmitted disease clinics reported positive feelings about the HIV vaccines in general; 48 per cent reported willingness to participate in future HIV vaccine trials[17].

The most frequently rated concern or barrier regarding the future HIVVT was vaccine efficacy and safety. Another Ugandan study reported that the desire to be protected from HIV/AIDS was a common reason for being willing to participate in a hypothecated vaccine trial and concern about side-effects was a common reason for being unwilling[18]. Majority (91%) believed participation in a HIVVT would provide protection from HIV infection and wanted an assurance that the vaccine would be powerful enough to prevent the infection; they also wanted to know about the consequences of vaccination on their life.

In United States (US)-based studies conducted with MSMs, findings revealed that willingness to participate in trials declined from 37 per cent at baseline to 21 per cent at 12 and 18 months when participants were informed that they might receive a portion of the HIV virus[7]. Vlahov *et al*[19] found that 85 per cent IDUs initially expressed interest in participating in a future HIVVT. However, interest declined to 47 per cent when participants were informed that the vaccine might result in a HIV positive test. While research does indicate altruism as a predominant factor in willingness[20], persons who perceived themselves to be at a greater risk, those who received information about the greater per cent efficacy of vaccine, and those who were given higher incentives[21] were more likely than their counterparts to be willing to participate in HIVVTs.

To date, no studies have assessed the potential impact of vaccine trial participation on continuation of risky behaviour. Vlahov *et al*[19] revealed that 37 per cent of IDUs would not maintain safe behaviour and would rely on the vaccine for protection. Similar intentions were prevalent among military personnel in Uganda[22], and in high-risk women[23]. This information among future vaccine participants in India is critical as ongoing engagement in such activities could increase their chances of becoming infected with the HIV virus.

One of the ethical concerns about the HIV vaccine is the possible increase in the risky behaviour or decreased use of condoms among vaccine participants due to the notion of "chance" protection. However, we found that our participants had more faith on condoms than with on the HIV vaccine. This attitude might be attributed to the priority given by the government agencies and NGOs on regular condom use for prevention of HIV infection.

This study had its own strengths and limitations. The cross-sectional study was done among different types of high-risk populations and did not find any significant difference in the responses of high-risk

groups. But, it was interesting to note that women were more willing to volunteer than men and the reason quoted was the possible protection from HIV infection from their husbands. Besides, CAB comprising people from NGOs, PLWAs, medical officers assisted the study team at all steps and this process ensured that the phenomena of interest were understood from the perspective of the clients themselves. The small sample and one time assessment of the participants willingness are the study limitations. Further, the results of this study may be limited in reasons of predicting actual patterns of willingness once recruitment for a vaccine efficacy trial begins. The hypothetical vaccine trial presented did not refer to any specific vaccine product of strategy and we do not know the actual proportion of study population who might be willing to participate once presented with a specific vaccine product and trial. Another possible limitation of the study was the structured nature of the measurement scales, and hence, our inability to probe on negative responses. Moreover, no baseline assessments were done prior to the focus groups since the knowledge about HIV vaccines and HIVVTs was very minimal and the participants were not able to understand and answer the items in the scale without knowing the vaccine concepts.

In conclusion, though majority of the study participants with high-risk behaviours were willing to participate in future HIV vaccine trials there is a need for more education to ensure participants understanding of key concepts. The information, education and communication (IEC) materials for HIV vaccine trials should focus on concepts such as preventive vaccines, trial participants, double-blinding, vaccine efficacy, safety and importance of continuing safe sex behaviour among volunteers.

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