

# SOCIOLOGICAL RESEARCH



## Studies Completed:

### Knowledge and attitude on HIV vaccine trials and willingness to participate among persons at risk in south India

#### Background:

The TB Research Centre is conducting a phase-I HIV Vaccine Trial (HIVVT). Prior to any HIV preventive vaccine trial, it is important to assess the concerns, knowledge gaps, attitude towards HIV vaccines and willingness to participate in future HIVVTs among populations at risk of HIV infection. The triangulation of qualitative and quantitative data, will give meaningful information about HIVVT participation. To address these issues, a sociological study with a two-phase qualitative-quantitative approach, was conducted. This was performed to find out the HIV vaccine readiness at Chennai and Madurai. The study was done in collaboration with the University of California, Los Angeles, USA.

#### Objectives:

1. To determine the willingness of populations at risk of HIV infection to participate in future HIVVTs.
2. To evaluate the knowledge levels of vaccine trial concepts.

#### Methods:

The participants were 112 men and women representing the following subgroups:

1. Transport workers, such as truckers and cleaners;
2. Clients who attended a STD clinic at Government General Hospital in the last three months;
3. Injection drug users;
4. Men having sex with men;
5. Women in sex work.

In addition, representative samples of monogamous married women from the self-help groups in the local communities were included. The study participants were mainly drawn from four major non-governmental organizations (NGOs) - both at Chennai and Madurai. A Community Advisory Board assisted in the design of the semi-structured Interview Guide that guided the focus group questions and the revision of measurement scales. For Phase II, interview schedules along with modified measurement scales were administered to 501 study participants, 83 approximately from each group.

#### Findings of Phase – I (Qualitative Research)

A total of 12 Focus Group Discussions (FGDs) were conducted with six – seven eligible participants per group. Two focus groups were conducted with each subgroup resulting in a sample size of 112. During the pilot study, researchers came to know that the knowledge on HIVVTs was very minimal among the study participants. Therefore they were educated about HIVVTs, particularly about the double-blind selection into the vaccine or placebo groups, the possibility of vaccine induced sero-positivity, the partial efficacy of experimental vaccines and the need to practise safer sex. A Semi-Structured Interview Guide (SSIG) guided each



session using open – ended questions. All FGDs were audio taped, transcribed and translated into computer files. Content analysis was performed using the constant comparative method (Glaser, 1978).

Participants expressed keen interest in future HIVVTs. Factors facilitating willingness to participate in future trials included altruism and the desire to have a protective vaccine for the future. Despite expression of trust in the Government, participants still felt that specific requirements would be necessary to ensure adequate recruitment of participants. The requirements included, assurances regarding stigma and confidentiality, compensation for families in the event of a poor outcome with a future HIVVT. Additional concerns centered on the impact of the vaccine on the recipient's physical health and the implications of seroconverting. Participants were worried about the possibility of risk behaviors increasing after the receipt of vaccination.

The critical need for ongoing education and counseling to make people aware of the dangers of engaging in risky behavior during and after participating in a future HIVVT has been discussed, and implications for mass media have been suggested.

### **Findings of Phase II (Quantitative Research):**

Out of the 501 respondents, 55 per cent were males, 59 per cent from the age group of 31–50 years; 64 per cent married; 79 per cent school educated and 73 per cent working. The participants' baseline knowledge on HIVVTs was assessed before educating them about the vaccine concepts. The same scale was administered again to assess their level of understanding. The difference was statistically significant for all 10 items in the Koblin scale and the attitude about the HIV vaccine was assessed by an 18-item CDC Vaccine Attitude Scale, which showed how much they agreed or disagreed with each statement.

Attitudes about the HIV vaccine was assessed by an 18-item HIV Vaccine Attitude Scale, and subscale clustering included benefits of participation, concerns and barriers for participation and future sexual behavior change after vaccination. More than 70 per cent agreed that the HIV vaccine would protect them from HIV infection and hoped that HIV could become preventable like polio.

About 51 per cent worried about the effects of a HIV vaccine on their lives and 46 per cent were concerned about whether "the vaccine was powerful enough to prevent the HIV infection." Additional concerns were the restriction on travel due to participation (39 per cent) and the impact of the vaccine on the participants' ability to get married, insurance and job prospects (38 per cent). Less than 30 per cent of them worried about whether they would be given the vaccine or placebo. Overall, 76 per cent of the respondents agreed that sex without a condom is not safe, whether there was a HIV vaccine available or not. Overall, willingness to participate for HIVVTs was 82 per cent. The main reason was protection from HIV infection and altruism. Many participants said that their participation in a HIVVT was important for the common good of India. Besides, the research might help in the eradication of the HIV infection.

Women participants expressed their desire to protect themselves from infected husbands. The reasons for refusal to participate were perceptions about not being at risk of the HIV infection; fear of stigma; uncertainty about the receipt of vaccine or placebo; concern about the safety of the vaccine.

Difference in the level of knowledge (% correct responses) at base-line and after vaccine education is shown in Table 6. About 57 per cent wanted to seek advice



from others before giving their consent for participation and the majority of them wanted to consult their respective NGOs. It is interesting that the pattern of willingness is different when we assess the association between the participants' demographic variables and the willingness to participate in HIVVTs. Willingness was 84 per cent among the males and 81 per cent among females. It was more among those who had never married, separated, widowed than those married (89 per cent, 96 per cent, 100 per cent vs. 77 per cent), not educated than the highly educated (63 per cent vs. 94 per cent), and those employed than the unemployed (84 per cent vs. 79 per cent).

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. The local NGOs play a crucial role in motivating trial volunteers.

### Verbatims during FGDs:

"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" (MSM)

"Developing a vaccine itself is wrong" (TW)

"For people who live by Indian culture standards, it is difficult to enroll them" (TW)

"Other people may get to know about the result. No one will come forward due to stigma attached to HIV/AIDS"

"Following vaccination, is it safe to have sex with wife? Friends? Will they show positive result?"(MSM)

"Among the sexual partners, if one is vaccinated and the other one is not vaccinated, will they get the infection due to sexual relationship?"(CSW)

"People will solicit improper relationships with gusto" (MW)

"There is a fear that AIDS is a deadly disease and death is certain. This fear will disappear in the future" (TW)

"We cannot tell our regular customers to use condoms nor can we be without job" (CSW)

"No one would want to catch the disease-most would use the opportunity & reform themselves" (MSM)

**Table 6: Difference in the level of knowledge (% correct responses) at base-line and after vaccine education**

Items	Pre-test (%)	Post-test* (%)
Vaccine safety	86	93
Strengthens immunity	52	89
Enrolls both HIV+ and HIV-	46	77
Healthcare for volunteers	70	84
Be informed about Vaccine/Placebo	38	75
Guarantee for future HIVVTs	36	85
No effect on HIV test results	47	68
Get vaccine or placebo	32	90
Not 100% effective	26	63
Study nurse will select	37	90
No. of responses = 501		

\* There is a statistical difference between the pre and post-test at 95% confidence interval for all items