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Correlates of HIV vaccine trial participation: an Indian perspective

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Abstract

Successful conduct of HIV vaccine trials in a population of great cultural diversity like India could be a challenge. Concerns, knowledge gaps and willingness to participate in future HIV vaccine trials were studied among 349 patients attending three sexually transmitted infections clinics and one reproductive tract infections clinic. Overall willingness to volunteer for HIV vaccine trials was 48%. Women and men at risk of HIV infection were willing to participate in the HIV vaccine trials. Factors associated with increased willingness to participate in these trials were awareness of current HIV vaccine efforts, realization of importance of vaccine for self, concern about adverse events and altruism.

Keywords: Willingness; HIV vaccine; Trial

1. Introduction

Current effort for HIV prevention focuses on achieving a sustainable change in sexual behavior to minimize the risk of HIV infection. Even after intense interventions, this approach may be ineffective and/or unaffordable [1]. Other strategies including barrier contraceptives and microbicides are being extensively evaluated [2–5], but their efficacy remains to be proved. A possible cost-effective prevention approach could be vaccination. Therefore, development of HIV vaccines and conduct of human trials gain importance, especially in the context of developing nations where both counseling facilities and anti-retroviral therapies are expensive and not readily available.

Genetic diversity of HIV may necessitate evaluating various candidate vaccines in different regions of the world. Locally relevant co-factors for HIV transmission might influence vaccine-induced protection in the developing countries [6]. Additionally, trial volunteers might face challenges like inaccurate information, lack of access to healthcare and stigma as well as discrimination. Thus, as the developing countries with large young susceptible populations and high HIV incidence rates are planning for HIV vaccine trials [7], the preparedness of the local communities needs to be assessed.

The HIV epidemic in India has spread to the general population and in the rural areas [8–11]. There are an estimated 4.65 million HIV-infected individuals [12]. Preparations for phase-I HIV vaccine trials in India are underway [13]. Advocacy and a high level of preparedness at scientific, technical, socio-cultural and community levels will facilitate the conduct of HIV vaccine trials.

Pune is an industrial city with a population of nearly 3 million, situated in the high-HIV prevalence state of Maha-

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rashtra in India. Baseline feasibility studies on high-risk cohort (sexually transmitted infections (STI) clinic attendees, sex workers) in Pune have reported high-HIV prevalence (18–26%) and provided information on the associated biological and behavioral risk factors in the study population [14]. HlV-l C is the most common subtype [15]. The sentinel surveillance among pregnant women attending government clinics in Pune city indicated HIV prevalence ranging from 2.5 to 3.7% (unpublished data from National AIDS Research Institute, Pune, India), and that in the rural areas around Pune was 1.2% [8].

The present study attempts to explore the concerns and the level of preparedness for HIV vaccine trials among the persons with low- and high risk for HIV infection.

2. Methods

2.1. Study population

The study was conducted in Pune city in western India between April 2002 and June 2003. In all, 349 respondents who were a part of an ongoing cohort were included in the present study. The participants included 286 attendees of STI clinics including STI patients, sex workers, spouses of STI patients, persons with high-risk behavior, and 63 women attending reproductive tract infections (RTI) clinic who had no reported risk or risk behavior.

2.2. Survey instrument

A twenty-two items semi-structured questionnaire was utilized. Multiple options were given for all the questions. Owing to the low level of literacy, the counselors administered the questionnaire after the participants made informed decision to participate in the study. Prior to the interview, each respondent was explained the meaning of a 'clinical trial' and the 'experimental nature of the HIV vaccine' that may be used in the future trials. The instrument had a specific focus on assessing the general understanding about vaccines, immunization, willingness and concerns pertaining to participation in HIV vaccine trials in future. Additionally, open-ended responses were collected from those who chose the option 'others'. Descriptive qualitative responses for barriers to participation, expectations about incentives, understanding of window period and preferences about vaccine-endorsing agencies were also recorded verbatim.

2.3. Statistical analysis

The structured questions were pre-coded and analyzed in SPSS 10.0 version software. Hypotheses were tested at 5 and 1% level of significance. Pearson χ^2-test was used to test the association between potential factors and willingness to participate in HIV vaccine trials. Factors found to be significant in the univariate analyses were included in the logistic regression model to test the degree of independent association between these factors and willingness to participate in HIV vaccine trials.

Willingness to participate in the vaccine trial was categorized as 'yes' for those who were 'definitely' willing to participate and all other responses, such as 'very likely, somewhat likely, not likely and definitely would not join' with a variable degree of uncertainty were categorized as 'no' (best case scenario analysis). We also expanded the definition of 'willingness' to include those with 'very likely' response and re-ran the analysis.

To understand the respondents' knowledge about vaccine users, seven different categories of the population (infants, children 1–5 and 6–15 years, youth, pregnant women, adult men and women) were given as multiple options. The question was oriented to assess their understanding about vaccines in general and not HIV vaccine in particular. A score of 0 indicated total lack of knowledge about the probable vaccine users. We used the score of 5 as cut-off for 'high awareness' about vaccine recipient categories, as it was more likely to capture the concept of adult vaccination. We studied the relationship between the knowledge of vaccine users (score ranging from 0 to 5) and the knowledge of therapeutic or preventive use of the vaccines.

A content analysis of the qualitative responses was done to identify barriers to participation and frequencies were tabulated to analyze such responses.

3. Results

3.1. Demographic profile and knowledge about AIDS and vaccines in the study population (data not shown in the tables)

Out of the total 349 respondents, 205 (58.7%) were men and 144 (41.3%) were women. Of these, 161 (46.1%) were STI patients, 15 (4.3%) female sex workers and 110 (31.5%) had other known risks for HIV acquisition like being a partner of STD patient, having multiple sexual partners or recent visits to sex workers. The remaining 63 (18%) were women attending RTI clinics for complaints like backache or white discharge and no reported risk behavior. All the study participants had a low socio-economic background and a low level of education. The mean age of the respondents was 29.9 years (S.D. = 7.89 years).

Most of the respondents (74%) felt that HIV is a severe problem in India, but 19.7% considered it less severe and 3.4% thought it was not a problem at all. The majority (82.2%) had heard about the term vaccine; 69.6 and 10.6% were aware that vaccines were preventive and therapeutic respectively. Nearly 96% of the respondents, who had heard of vaccines, knew that vaccines were useful for infants and children. Although 57% participants knew possible use of vaccines for pregnant women, only 32% were aware of the concept of adult vaccination. The participants with a higher