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# Willingness to participate in preventive HIV vaccine trials in a community-based cohort in south western Uganda

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**Summary**

OBJECTIVES To assess willingness to participate in HIV vaccine trials and possible barriers to participation.

METHODS Questionnaire survey of participants completing a 2-year community-based HIV Vaccine Preparedness Study, followed by cross sectional analysis of data.

RESULTS 95% of participants were willing to participate in a trial with similar attributes to the Vaccine Preparedness Study. Certain hypothetical trial attributes significantly reduced willingness to participate: The requirement to delay pregnancy (for females) had the largest effect, reducing willingness to participate from 97% to 23% ($P < 0.0001$). Larger blood draws had the second largest effect: 95–55% ($P < 0.0001$). The possibility of receiving either candidate vaccine or placebo had the third largest effect: 95–73% ($P < 0.0001$). Monthly study visits had the fourth largest effect: 95–92% ($P < 0.0001$). Trial duration longer than 2 years had the least effect: 95–93% ($P = 0.0025$). Combined attributes reduced willingness to participate from 95% to 43% (McNemar's $\chi^2 = 521.00$; $P < 0.0001$) overall and 97–11% (McNemar's $\chi^2 = 531.00$; $P < 0.0001$) for female participants. Physical harm concerns (adjusted OR = 34.9; 95% CI, 10.4–118) and a low risk behaviour index (adjusted OR = 0.09; 95% CI, 0.01–0.73) were associated with unwillingness to participate.

CONCLUSIONS We found a high level of willingness to participate in HIV vaccine trials in this population. However, certain HIV vaccine trial requirements were associated with reduced willingness to participate. Community as well as individual concerns will have to be carefully addressed in planned HIV vaccine trials.

**keywords** HIV vaccine trial, willingness, community-based, barriers

## Introduction

HIV/AIDS continues to be a significant cause of morbidity and mortality worldwide particularly in Africa, in spite of many efforts in HIV prevention, treatment and care (UNAIDS/WHO 2007). The development of an efficacious vaccine appears to be one approach that might have significant impact on the epidemic (International AIDS Vaccine Initiative 2006). Assessment of willingness to participate is important in assessing the suitability of populations for potential HIV vaccine efficacy trials.

Several willingness-to-participate studies have been conducted among high risk populations (Sherr *et al.* 2004; Sahay *et al.* 2005; Van de Ven *et al.* 2005; Yin *et al.* 2008) with high HIV incidence, but only few in general populations (Kiwanuka *et al.* 2004). Though populations with high HIV incidence are ideal for HIV vaccine efficacy trials because trials in such populations require relatively small sample sizes, follow up and retention are often challenging. We need to explore how to effectively conduct efficacy trials in general, lower-risk populations, although these would require larger sample sizes. In preparation for such efficacy trials, the MRC/UVRI Uganda Research Unit on AIDS in collaboration with the International AIDS Vaccine Initiative conducted an HIV Vaccine Preparedness Study (VPS) to determine HIV incidence among adults in rural south west Uganda. As part of this work we assessed the willingness of this population to participate in HIV vaccine trials. The VPS was conducted in a community-based cohort with an HIV incidence of 1.4 per 100 person-years (Ruzagira *et al.* 2006).

## Methods

The objective of this study was to assess willingness to participate in HIV vaccine trials among volunteers completing 2 years of follow up in a community-based VPS in Masaka district, Uganda. The VPS activities did not target a specific HIV vaccine candidate or trial.

### Study population

Adult men and women living in three rural communities were invited for screening and enrolment into the 2-year prospective vaccine preparedness study. The inclusion criteria were: being clinically healthy, age 18–60 years, being HIV negative, being able and willing to give informed consent and to provide adequate locator information, agreeing to participate in repeated HIV counselling and testing and to receive the results and for women to undergo repeated pregnancy testing.

## Procedures

### Screening and enrolment visit

Screening and enrolment procedures were performed on the same day. After obtaining informed consent, information on demographics, residence, comprehension of HIV and HIV vaccine research and sexual risk behaviours was obtained using a structured questionnaire. A medical history was taken, a full physical examination performed and HIV counselling done. 15 ml of blood were drawn for HIV and syphilis serology and to store plasma and serum. Women were asked to provide a urine specimen for pregnancy testing.

### Follow up visits

At each of the 3 monthly follow up visits, a medical history was taken, a symptom-directed physical examination performed and HIV counselling given. Collection of specimens and laboratory tests followed the same procedures as at the enrolment visit. At 6-monthly intervals, we also assessed comprehension of HIV and HIV vaccine research and sexual risk behaviour. Information on willingness to participate in HIV vaccine trials was elicited at the final visit, 24 months after enrolment.

### Comprehension of HIV and HIV vaccine research

We ascertained knowledge of HIV transmission and prevention, of the difference between HIV infection and AIDS, of Voluntary Counselling and Testing (VCT), of prevention of mother-to-child transmission and of HIV vaccine research.

### HIV risk assessment

This included collection of data on reported symptoms of sexually transmitted infections, number of sexual partners, casual sex partners, condom use, alcohol consumption and HIV risk perception.

### Willingness to participate

Interview questions were drawn from literature on willingness to participate in HIV vaccine trials (Jenkins *et al.* 2000; Mcgrath *et al.* 2001; Kiwanuka *et al.* 2004). Questions were translated to Luganda (the local language) and the questionnaire was pre-tested. The questionnaire was administered by experienced interviewers to assess volunteers' willingness to participate in an HIV vaccine trial in general (designed to be similar to the current vaccine preparedness study) as well as participants' motivations and concerns. Willingness to participate in an HIV vaccine efficacy trial with certain more demanding hypothetical attributes that did not feature in the VPS was also assessed. These attributes included the chance of receiving candidate vaccine or placebo, the need for larger blood draws i.e. about 8–10 tablespoons compared to 1.5 tablespoons drawn in the VPS per visit, monthly study visits for about 2 years, trial duration longer than 2 years and for female participants, the requirement to delay pregnancy for the duration of the trial.

### Community preparedness activities

A number of activities were conducted to support the vaccine preparedness studies. First, a Community Advisory Board (CAB) composed of local leaders, study participants and representatives of community based organizations was formed. The CAB met quarterly throughout the study period to discuss study progress and communicate any community concerns. Second, free VCT and treatment for common illnesses were provided to the general community at fortnightly clinics that were conducted at public health centres located within the study area. Persons found to be HIV infected were referred to receive HIV care and support services. HIV infected pregnant women were referred to receive prevention of mother to child HIV transmission services. Third, the community liaison team conducted monthly village health education seminars at which selected health topics were discussed. The seminars also provided an opportunity for the study team to talk about and answer questions relating to the vaccine preparedness

studies. The health education seminars did not target a specific HIV vaccine candidate or trial.

### Ethics

The VPS protocol was reviewed and approved by the Uganda Virus Research Institute Science and Ethics Committee and the Uganda National Council of Science and Technology. Before enrolment, a detailed discussion of the study information was conducted with each participant, and written informed consent obtained. We did not conduct formal assessments of informed consent understanding although these would be required in an actual HIV vaccine trial. The VPS and assessment of willingness to participate might have raised hopes of participation in an actual HIV vaccine trial among participants. To reduce the chances of this happening, participants were informed that the VPS activities did not target a specific vaccine trial or candidate and that participation in the VPS did not mean that one would participate in future trials.

### Statistical methods

Data used for this analysis are from the enrolment visit (demographics and circumcision status) and from the final visit of the VPS (willingness to participate in HIV vaccine trials, comprehension of HIV and HIV vaccine research and risky sexual behaviour data).

For this analysis, in order to construct meaningful variables on risk behaviour and HIV related knowledge, we combined related items into composite indices by additive scaling. Cronbach's alpha ($\alpha$) was used to compute the internal consistency of the responses. The risky sexual behaviour index ($\alpha = 0.71$) was constructed from data on the number of sexual partners, history and consistency of condom use. The HIV knowledge index ($\alpha = 0.46$) was constructed from data on participants' awareness of the role of faithfulness and of condom use in HIV prevention, the difference between HIV infection and AIDS, HIV voluntary counselling and testing, highly active anti-retroviral therapy and prevention of mother to child transmission. This index was included in the analysis despite its low internal reliability. The HIV vaccine research knowledge index ($\alpha = 0.61$) was constructed from data on voluntarism, risks and benefits, safety of vaccines and availability of a preventive HIV vaccine.

With the exception of evaluating the effect of hypothetical trial attributes on willingness to participate, the outcome measure was considered as 'unwillingness to participate'. In this cohort, unwillingness was a rare outcome; therefore the odds ratios would approximate the rate ratios. Univariate odds ratios and their 95% confidence intervals were used to characterize associations of individual potential factors with unwillingness to participate. A multivariate logistic regression model of unwillingness to participate was constructed from variables that were significantly correlated with unwillingness in the univariate analysis. The McNemar's test for paired binary data was used to compare the proportions of participants willing to participate in a trial with and without the hypothetical attributes described above. All data analyses were done in Stata 9.0 (StataCorp, College Station, TX, USA).

## Results

### Background characteristics

A total of 1184 participants were recruited into the vaccine preparedness study. The median age was 32 years (IQR: 25–41), 62% were female and 70% were married. Only 13% had attained some secondary school education. Of those enrolled, 1013 (86%) completed the willingness to participate and 878 (74%) the HIV and vaccine research comprehension and risk assessment questionnaires at their last study visit. There were no differences in key baseline characteristics (age, marital status, education level and HIV risk perception) between those who completed the willingness to participate questionnaire and those who did not. All participants who completed the willingness to participate assessment knew that there is no effective HIV vaccine yet and most (84%) understood that the VPS was in preparation for actual HIV vaccine trials. About 90% were aware that participation in an HIV vaccine trial may not reduce their risk of contracting HIV. Majority of participants (91%, $n = 878$) perceived themselves as being at risk of HIV and 63% of these mentioned perceived partner unfaithfulness as the reason.

### Influence of trial attributes on willingness to participate in HIV vaccine trials

95% of participants said they would be willing to participate in a trial of similar attributes to the vaccine preparedness study. Key motivators for participation were hope of being protected from HIV (47%), regular HIV VCT (36%), altruism (28%) and health care (16%), whereby more than one response was permitted. In Table 1, we report changes in willingness to participate when participants were asked to state their willingness to participate in an HIV vaccine trial with five hypothetical attributes. The requirement to delay pregnancy (for females) during a trial had the largest effect on willingness to participate, reducing initial willingness to participate

**Table 1** Influence of hypothetical vaccine trial attributes on willingness to participate

| Hypothetical vaccine trial attribute | *n* | Willingness to participate in a trial without the hypothetical attributes listed below* | Willingness to participate in a trial with hypothetical attributes (%) | McNemar's chi-square value; *P*-value |
|---|---|---|---|---|
| Possibility of receiving either candidate vaccine or placebo | 1013 | 95 | 73 | 209.44; <0.0001 |
| Larger blood draws | 1013 | 95 | 55 | 391.09; <0.0001 |
| Monthly study visits | 1013 | 95 | 92 | 18.29; <0.0001 |
| Trial duration longer than 2 years | 1013 | 95 | 93 | 9.80; <0.0025 |
| Delay of pregnancy (women) during the trial | 630 | 97 | 23 | 428.08; <0.0001 |
| All attributes except delay of pregnancy (women) during a trial | 1013 | 95 | 43 | 521.00; <0.0001 |
| All attributes including delay of pregnancy (women) | 630 | 97 | 11 | 531.00; <0.0001 |

*Meaning a trial similar to the vaccine preparedness study that participants had been involved in for the past 2 years.

from 97% to 23% (McNemar's $\chi^2$ = 428.08; $P < 0.0001$); larger blood draws had the second largest effect: 95–55% (McNemar's $\chi^2$ = 391.09; $P < 0.0001$); the possibility of receiving either candidate vaccine or placebo had the third largest effect: 95–73% (McNemar's $\chi^2$ = 209.44; $P < 0.0001$); monthly study visits during the trial had the fourth largest effect: 95–92% (McNemar's $\chi^2$ = 18.29; $P < 0.0001$); and trial duration longer than 2 years had the least effect: 95–93% (McNemar's $\chi^2$ = 9.80; $P = 0.0025$). Combined hypothetical trial attributes (excluding the requirement for women to delay pregnancy) reduced overall willingness to participate from 95–43% (McNemar's $\chi^2$ = 521.00; $P < 0.0001$). Among female participants, combined hypothetical trial attributes (including the requirement for women to delay pregnancy) reduced willingness to participate from 97% to 11% (McNemar's $\chi^2$ = 531.00; $P < 0.0001$).

### Unwillingness to participate in HIV vaccine trials

Participants who said they were unwilling to participate in HIV vaccine trials had concerns about vaccine safety (40%), blood draws (27%) and time requirements (10%). The associations of selected factors with unwillingness to participate in HIV vaccine trials are shown in Table 2. Unwillingness to participate did not differ by gender, religion, marital status, level of education, circumcision status (males) and knowledge about HIV and HIV vaccine research. In univariate analysis, higher age, concerns about potential physical harm due to the trial and a low risk behaviour index were positively associated with unwillingness to participate. Perceived risk of HIV infection due to expected partner unfaithfulness was associated with reduced unwillingness to participate. In the multivariate logistic regression model, only concerns about potential physical harm and a low risk behaviour index were positively associated with unwillingness to participate in HIV vaccine trials; participants who had one or more physical harm concerns were much more likely to be unwilling to participate (adjusted OR = 34.9 95% CI 10.4–118), while the higher the risk behaviour index (i.e. the more risky the participants behaviour), the less likely they were to be unwilling to participate (adjusted OR = 0.09 for a 1 point increase on the risk behaviour index; 95% CI 0.01–0.73) – thus participants with lower risk behavior were more likely to be unwilling to participate.

## Discussion

The proportion of participants in this study willing to participate in HIV vaccine trials if these were similar to the VPS was about 95%. This was higher than the 77% willingness to participate in HIV vaccine trials reported in a population-based study in Rakai, Uganda (Kiwanuka *et al.* 2004). Assessment of willingness to participate in the Rakai study followed a community-based education program on potential HIV-preventive vaccines. In contrast, assessment of willingness to participate in our study was conducted among participants who had completed a 2-year

**Table 2** Factors associated with unwillingness to participate in HIV vaccine trials

| Characteristic | Subcategory | *n* | Unwillingness (%) | Unadjusted OR (95% CI) | Adjusted OR (95% CI) |
|---|---|---|---|---|---|
| Age (years) | 18–24 | 214 | 1.9 | 1.00 | 1.00 |
| | 25–34 | 362 | 1.9 | 1.04 (0.30–3.58) | 1.44 (0.31–6.62) |
| | 35–44 | 233 | 5.2 | 2.85 (0.90–9.03) | 3.90 (0.98–15.61) |
| | 45+ | 204 | 5.9 | 3.28 (1.03–10.40) | 2.13 (0.51–8.95) |
| Sex | Male | 383 | 3.9 | 1.00 | 1.00 |
| | Female | 630 | 3.2 | 0.80 (0.54–1.59) | 0.71 (0.29–1.73) |
| Marital status | Single | 44 | 4.6 | 1.00 | _ |
| | Married | 722 | 3.5 | 0.75 (0.17–3.29) | _ |
| | Others (steady partner, separated, divorced, widowed) | 247 | 3.2 | 1.42 (0.14–3.44) | _ |
| Religion | Anglican & Catholic | 830 | 3.3 | 1.00 | _ |
| | Muslim | 124 | 5.7 | 1.80 (0.76–4.20) | _ |
| | Others | 59 | 1.7 | 0.351 (0.07–3.85) | _ |
| Education level | Complete primary school or less | 881 | 3.4 | 1.00 | _ |
| | Complete secondary school or higher | 132 | 3.8 | 1.12 (0.43–2.93) | _ |
| Knowledge about HIV vaccine research† | No errors | 769 | 3.8 | 1.00 | _ |
| | 1 or more error | 109 | 2.8 | 0.72 (0.22–2.41) | _ |
| Knowledge about HIV† | No errors | 146 | 3.4 | 1.00 | _ |
| | 1 or more error | 732 | 3.7 | 1.08 (0.40–2.85) | _ |
| Physical harm concerns | None mentioned | 991 | 2.7 | 1.00 | 1.00 |
| | 1+ mentioned | 22 | 36.4 | 20.4 (7.61–54.67) | 34.9**(10.4–118) |
| Circumcised (male) | No | 332 | 3.6 | 1.00 | _ |
| | Yes | 51 | 6.0 | 1.70 (0.45–6.13) | _ |
| Perceives oneself as being at risk of HIV infection‡ | No | 70 | 3.6 | 1.00 | _ |
| | Yes | 796 | 4.3 | 0.84 (0.25–2.85) | _ |
| Perceived risk of HIV infection due to expected partner unfaithfulness | No | 294 | 6.1 | 1.00 | 1.00 |
| | Yes | 502 | 2.2 | 0.34 (0.16–0.74) | 0.47 (0.20–1.1) |
| Risk behaviour index (low to high risk)§ | _ | NA | NA | 0.31 (0.11–0.84) | 0.09* (0.01–0.73) |

*$P < 0.05$; **$P < 0.0001$.

†878 participants completed the comprehension of HIV and HIV vaccine research and risk assessment questionnaires.

‡Response for 12 participants was 'not sure'.

§The risk behaviour index was constructed from six variables each with two or three level responses: [Number of sexual partners in the past 7 days, Number of sexual partners in the past 3 months, Number of sexual partners in the past 12 months (responses = none, one or two or more); Ever use of a condom, condom use in the past 12 months (responses = yes, no); Frequency of condom use in last 12 months (responses = rarely, sometimes, always)].

follow up period in a VPS. The fact that our participants had already demonstrated an ability to participate in the VPS for a long time may explain the high level of willingness to participate in a vaccine trial similar to the VPS. However, as discussed below, certain hypothetical vaccine trial attributes had a strong negative effect on the observed level of willingness to participate in our study.

Consistent with other studies (Jenkins *et al.* 2000; Mcgrath *et al.* 2001), hope of being protected from HIV infection was an important motivator for willingness to participate in HIV vaccine trials, although the majority of participants clearly understood that participation in a vaccine trial might not reduce one's risk of contracting HIV. Even when protection is not guaranteed, the desire to be protected may be a motivator for participation in vaccine trials (Mcgrath *et al.* 2001). Access to regular HIV VCT was an important motivator for willingness to participate in HIV vaccine trials. This is encouraging since

HIV VCT is necessary for HIV vaccine trials. Unlike studies among high-risk populations (Périssé *et al.* 2000; Souza *et al.* 2003), altruism was not a major motivator for willingness to participate in our study. Although free health care was provided during the vaccine preparedness study, few study participants mentioned it as a motivator for willingness to participate.

Certain hypothetical HIV vaccine trial attributes had a strong negative effect on willingness to participate in HIV vaccine trials. Among female participants, the need to delay childbearing during a trial had the largest negative effect on willingness to participate. Unwillingness to delay or prevent pregnancy may negatively impact enrolment and retention of young women in HIV vaccine trials. Efforts to address pregnancy prevention concerns during trials are especially important in Africa where high pregnancy rates have been reported in microbicide trials (Moodley 2007). Knowledge about pregnancy prevention practices and access to effective contraception should be assessed as part of preparations for conducting HIV prevention trials (MacQueen *et al.* 2007). In populations with limited access to effective contraception, family planning counselling should be integrated in informed consent processes and contraceptive services provided at the trial sites.

Underlying concerns about blood draws may explain the large negative effect of larger blood draws on willingness to participate. Concerns might include the perceived risk of blood volumes extracted during research and uncertainty about what happens to the stored samples (Molyneux *et al.* 2005a,b). Investigators will need to continuously educate volunteers on the importance of obtaining blood samples during a vaccine trial, emphasize the safety of the proposed blood volumes and address any other concerns.

The possibility of receiving either candidate vaccine or placebo also had a large negative effect on willingness to participate. This effect could be due to unwillingness to be allocated to the placebo arm of a trial, since hope of being protected from HIV was a main motivator for willingness to participate in this study. These results are consistent with findings in the Ugandan military study (Mcgrath *et al.* 2001), where willingness to participate was lowest for trial conditions that reflected features of a placebo controlled design. It would appear that potential volunteers hope they receive the vaccine and that it works despite the fact that they know that the vaccine may turn out not to be effective.

Some studies (Newman *et al.* 2006, 2007) have reported concerns about time commitments during a trial with participants preferring trials of shorter duration. In our study willingness to participate remained high for a trial with monthly study visits and duration longer than 2 years. This suggests participant time commitments may not be a major issue for trials in this population.

Our study confirmed others that have shown a relationship between risk behaviour and willingness to participate (Sherr *et al.* 2004; Sahay *et al.* 2005). In our study, low risk behaviour was associated with unwillingness to participate in HIV vaccine trials. Similar to findings in other willingness to participate studies (Périssé *et al.* 2000; Souza *et al.* 2003), physical harm concerns were associated with increased unwillingness to participate. The most cited concern was safety of candidate vaccines. The vaccine safety concerns in our study were of general nature as participants were not given information about a particular candidate vaccine. The recent closure of the STEP (HVTN 502) and Phambili trials (HVTN 503) that used Ad5 vector may have raised concerns about the safety of HIV vaccine vectors (HIV Vaccine Trials Network 2007). Investigators in future VPS studies may have to explore knowledge of proposed HIV vaccine vectors, explain their nature and why they believe that the vectors will be safe.

Findings from this study highlight the need for HIV vaccine researchers and sponsors to invest in pre-trial community education and formative research. The aim of pre-trial education should be to improve communities' understanding of vaccine trial processes, address communities' concerns and ensure balanced assessment of trial related risks and benefits. The formative research should focus on knowledge of HIV vaccine trials, local perceptions and concerns about medical research, cultural norms and practices. During actual HIV vaccine trials, investigators will need to ensure that potential trial participants are in fact fully informed and do understand issues such as the fact that they may be assigned to a control (placebo) arm and that the candidate vaccine may not be efficacious. This could be partly achieved by administering a quiz to assess understanding of the informed consent document information. In addition, HIV prevention should be emphasized through regular risk-reduction counselling and provision of free condoms during trials.

Our study had the following limitations. First, although it was a VPS, questions on willingness to participate were hypothetical as no specific information about a trial or candidate vaccine was given. Participants may be less willing to participate once presented with details of an actual vaccine trial. In a study to describe the relationship between hypothetical and actual willingness to enrol in a preventive HIV vaccine trial, 29% of participants who had previously stated definite willingness to enrol in a future phase II trial refused enrolment in the trial, as did 49% of those who had stated probable willingness to enrol in a future phase II trial (Buchbinder *et al.* 2004). Second, our participants might have been inclined to express

willingness to participate in vaccine trials as they had been enrolled in a VPS for 2 years at the time the willingness to participate questionnaire was administered. The fact that participants in this study had successfully participated in the VPS for 2 years, is a potential source of bias as participants would have been more likely to accept participation in a trial of similar attributes. Therefore, the level of willingness to participate in HIV vaccine trials observed in this study may be different in other settings. Third, there is a possibility of response bias for certain items in our willingness to participate questionnaire as measures were not psychometrically evaluated. In addition, we did not use a standardized instrument to collect sexual risk behaviour data. The limitations of self-reported sexual behaviour are well recognized and there have been efforts to develop standardized instruments for sexual risk behaviour assessment (Weinhardt *et al.* 1998). Standardized self-report instruments will be required to track risk behaviours in actual HIV vaccine trials, hence should be used in vaccine preparedness studies.

In Summary, we found a high level of hypothetical willingness to participate in HIV vaccine trials in this community-based cohort. However, certain HIV vaccine trial requirements may be associated with reduced willingness to participate. Successful recruitment into HIV vaccine trials will require that community and individual concerns and misconceptions are sought and addressed.

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