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Willingness to participate in HIV vaccine efficacy trials among high risk men and women from fishing communities along Lake Victoria in Uganda

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Abstract

Introduction—HIV vaccine efficacy trials conducted in suitable populations are anticipated in sub-Saharan Africa. We assessed the willingness to participate in future vaccine trials among individuals from fishing communities along Lake Victoria, Uganda.

Methods—From July to October 2012, we described a hypothetical vaccine trial to 328 (62.2% men) adults (18–49 years), at risk of HIV infection within 6 months of enrolment in a cohort and assessed their willingness to participate in the trial. Chi-square and logistic regression models were fitted to assess associations between vaccine trial attributes, participants' characteristics and willingness to participate.

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Results—Overall, 99.4% expressed willingness to participate in the hypothetical HIV vaccine trial. This decreased marginally with introduction of particular vaccine trial attributes. Delaying pregnancy for 10 months and large blood draw had the largest effects on reducing willingness to participate to 93.5% ($p=0.02$) and 94.5% ($p=0.01$) respectively. All the vaccine trial attributes in combination reduced willingness to participate to 90.6%. This overall reduction in willingness to participate was significantly associated with gender and exchange of gifts for sex in multivariable analysis; women were more than three times as likely to have expressed unwillingness to participate in future vaccine trials as men ($aOR = 3.4$, 95% CI: 1.55, 7.33) and participants who never received gifts in exchange for sex were more than four times as likely to have expressed unwillingness as those who received gifts for sex ($aOR=4.5$; 95%CI 1.30, 16.70). The main motivators of participation were access to HIV counselling and testing services (31.9%), HIV education (18.0%), hope of being prevented from acquiring HIV (16.6%) and health care (12.5%).

Conclusion—Our study identifies an important population for inclusion in future HIV prevention trials and provides important insights into acceptability of trial procedures, differences in decisions of women and men and areas for further participant education.

Keywords

willingness to participate; vaccine trials; fishing communities; Uganda

Introduction

The sub-Saharan Africa region has continued to contribute the majority of new HIV infections worldwide despite the existing prevention and treatment efforts [1]. The best hope for controlling the epidemic in this region is a safe, effective and affordable preventive vaccine tailored to the local epidemic [2]. Despite considerable efforts in vaccine research over the last three decades, no vaccine is yet available for HIV prevention. The RV144 (“Thai” vaccine) trial efficacy results provided the first indication that a prophylactic HIV vaccine may be possible [3], and has regenerated the quest to find suitable populations to participate in future HIV vaccine trials. These trials will require thousands of participants who are representative of the populations targeted to benefit from the vaccines. In order to conduct efficient efficacy trials, the study population should have a high HIV incidence and a high likelihood of study retention [4].

Fishing communities in sub Saharan Africa and elsewhere have been characterised with high HIV infection rates from the onset of the epidemic making them possible populations for evaluation of HIV prevention strategies including vaccines [5–10]. In Uganda, over 2.5 million people are engaged in fishing as a means of gainful employment for unskilled workers such as fishermen, fish processors, traders and barmaids who often travel away from home for long periods, moving between temporary fishing camps [11]. This mobility has been linked to high risk sexual behaviour and bridges sexual networks into the general population [7]. Mobility could also pose a challenge to successful retention of individuals from fishing communities and it is not known if fishing communities can make a commitment to participate in trials. An earlier study to assess feasibility of retaining individuals from these communities demonstrated study retention of 76% during an 18 months follow-up and provided the first evidence that the fishing communities could be

retained in future trials [12]. However, volunteers from this study attended visits every 6 months at clinics located within the fishing sites. Future vaccine trials will require more frequent visits and are unlikely to be conducted within the fishing sites that are remote and with no infrastructure to support trials. Sufficient information is therefore needed to specifically ascertain if fishing communities are willing to participate in trials conducted at sites far away from their places of work. Previous research has shown different proportions of willingness to participate (WTP) among individuals at risk of HIV infection [13–18]. In Uganda, so far three studies have reported WTP in HIV vaccine trials with one of these among high risk populations [19–21]. To our knowledge, no study has documented WTP among high risk individuals from fishing communities. WTP studies conducted elsewhere cannot be generalised to fishing communities. We therefore assessed WTP in future HIV vaccine trials among high-risk individuals from fishing communities being enrolled in an observational cohort.

Methods

Study setting and population

This cross sectional study was conducted within an ongoing open cohort study of HIV-uninfected adults at risk of HIV infection recruited from fishing sites. The fishing sites are along Lake Victoria in Masaka, SW Uganda about 40km away from the MRC/UVRI clinical research centre (Figure 1), with an estimated population of 3000 adults and HIV prevalence of 29% [11]. Two public health centres located within 5km radius serve these communities with basic health services including HIV counselling and testing and provision of anti-retroviral treatment. Other local non-government organisations offer similar services occasionally through outreach posts.

The cohort study was established in January 2012 to estimate HIV incidence and volunteer retention. Participants are identified through facility and home-based voluntary counselling and testing (VCT) and referred to the clinical research centre for screening and enrolment. To be enrolled into the cohort, participants have to be healthy sexually active adults (18–49 years) at risk of HIV infection and willing to be interviewed on HIV risk factors and undergo HIV VCT and urine pregnancy testing (women). HIV risk was defined by at least one of the following; i) history of unprotected sex with more than one partner in the previous month, ii) a new partner in the previous month, iii) history of sexually transmitted infection within three months, iv) use of recreational drugs and/or alcohol use (at least weekly) in the past three months, v) absence from home for at least two nights a week in the past three months.

Study procedures

At enrolment, baseline socio-demographic characteristics and HIV risk behaviour data were collected by trained interviewers and medical assessments by physicians using standard structured questionnaires. Participants were followed every three months with HIV testing repeated during all visits and HIV risk assessment done every six months.

Data collection for the WTP study

Between July and October 2012, we consecutively enrolled participants from the cohort study within their first six months in the cohort. Those enrolled in the parent cohort for more than six months and those lost to follow up were excluded from the WTP assessment. Detailed information on a hypothetical vaccine trial with characteristics similar to the “Thai” vaccine trial [3] was provided to participants by trained interviewers. These characteristics are summarised in table 2. Information on vaccine induced sero-positivity and their implication on future HIV testing was also included. Participants were then asked if they would participate in the described hypothetical trial. Their responses were assessed on a five-point scale coded as; “definitely yes=1”, “probably yes=2”, “definitely no=3”, “probably no=4” and “not sure=5”. For those with responses “1” or “2”, further questions were asked regarding their willingness to participate in the trial and undergo each of the given vaccine trial characteristics. Those with responses “3”, “4” or “5” were asked to give reasons for refusing to participate and free responses from the participant were checked against a pre-coded list of multiple choice responses which included vaccine safety concerns, vaccine induced sero-positivity, low risk perception, HIV vaccine trial stigma and time or transport constraint. The WTP questionnaire was developed from published literature in the general population [22]. Demographic and risk profile data were obtained from the parent study.

Statistical analysis

Participants’ socio-demographic and HIV risk variables were summarised by gender. We combined participants who said “definitely yes” or “probably yes” as WTP and those who responded as “definitely no”, “probably no” and “not sure” as non-WTP. Proportions for overall willingness to participate and for each vaccine trial characteristic were determined using counts and percentages. Using overall WTP proportion as a reference, we assessed the relationship of WTP with each trial characteristic using the Chi-square test. Overall unwillingness was determined as the sum of all participants who declined to participate under any of the given vaccine trial characteristics described. Associations between unwillingness to participate and participants’ socio-demographic characteristics and behavioural risk variables were examined using odds ratios, with 95% confidence Intervals (CIs), by fitting logistic regression models. Only factors for which the association attained statistical significance at the 10% level using a likelihood ratio test (LRT) were considered for the multivariable model [23]. Only age was included as apriori confounder. In the multivariable model, factors were removed from the model using a backward elimination algorithm if removing the term did not make the fit of the model significantly worse at the 5% level (on an LRT).

Ethical considerations

This study was approved by the science and ethics committee of Uganda Virus Research Institute and Uganda National Council of Science and Technology. All participants provided a written informed consent before being interviewed. Participants diagnosed with sexually transmitted infections and other acute infections were treated in the research clinic. Those

diagnosed with HIV infection had baseline CD4 counts measured and were referred to the local service providers for appropriate care.

RESULTS

Participant characteristics

Overall, of 443 participants enrolled in the cohort study, 328 (74.0%) completed an assessment of WTP in a future HIV vaccine trial and 207 (63.1%) were assessed during their month- six visit, 93 (28.4%) at month-three and only 28 (8.5%) during their enrolment visit. A total of 115 participants were not assessed because 15 had spent more than six months in the cohort and were ineligible for WTP study, 28 were lost to follow-up and 72 who attended their routine visits were not interviewed due to time constraint. However, these did not differ from those enrolled in the WTP study regarding demographic characteristics or behaviour.

Among participants in the WTP study, the median age was 28 years (range 18- 48 years), 204 (62.2%) were men, 144 (43.9%) were from the Baganda indigenous tribe, 172 (52.5%) were married, 252 (76.8%) were Christians and 234 (71.3%) had a primary education. While most (78.9%) participants had lived in the study area for more than one year, more than a third of participants (36.3%) reported frequent travel away from home in the past month.

A quarter of participants (24.4%) reported having one or more new sex partners in the past month, 47.0% reported experiencing either genital discharge or genital sores (44.2%) and one third (33.5%) reported exchange of gifts for sex in the past three months. While reported use of recreational drugs such as khat and marijuana were low in this population, alcohol consumption was much higher with 63.2% of participants reporting alcohol consumption. Nearly half of participants reported alcohol consumption prior to sex (table 1).

As shown in the table 1, some participant characteristics varied by sex. More women than men were divorced separated or widowed (38.7% vs.19.8%); attained secondary education (25.8% vs. 16.2%); reported new sex partners in the past month (62.3 vs. 0.5%); and reported genital discharge (66.1% vs. 35.3%) or genital sores (51.6% vs. 39.7%). Women were also more likely than men to have lived in the fishing site for less than one year (35.5% vs. 12.3%), although they were less likely to travel away from home than men (26.6% vs. 42.4%). While most men (62.5%) were engaged in fishing, women carried out fishing related businesses such as fish processing and selling fish (16.1%) and other business such as restaurant and bar work (53.2%).

Associations between vaccine trial characteristics and willingness to participate

Overall, 99.4% of study participants expressed willingness to participate in a hypothetical HIV vaccine trial (table 2). Vaccine trial characteristics did influence willingness to participate somewhat. Willingness to participate was significantly reduced by the trial requirement to delay pregnancy in women (93.5%; $p=0.02$), and to draw large volumes of blood (94.5%; $p=0.01$). When all six characteristics were combined, willingness to participate was reduced to 90.6% overall. Length of study, frequency of study visits, trial

arm and vaccine administration by injection did not appear to have a significant influence on participants' willingness to participate in a future trial.

Factors that motivated potential participation in a trial

Primary motivations for participation in a trial were health-care related. They prioritised access to HIV counselling and testing services (31.9%), HIV education (18.0%), hope of being prevented from HIV infection (16.6%) and access to quality general health care services (12.5%). The desire to be among the first to participate in a vaccine trial (14.3%) and altruism (6.7%) were other reasons listed for participation. No participant reported monetary incentive as a motivator.

Factors that deterred potential participation in a trial

Reasons given for refusing to participate were time commitment (4 participants), transport challenges (1 participant) and fear of vaccine safety (1 participant). None of the participants reported vaccine induced sero-positivity as a reason for refusing to participate.

Consultations prior to taking a decision to participate

Only 105 (32%) participants expressed a preference for consulting with others before participation, 54 (51.4%) of whom said they would seek advice from a family member who could be their spouse (61.1%), parent (31.5%) or other family member (7.4%). The remaining 51 (48.6%) participants identified health care workers, friends and community or religious leaders in equal proportions as important sources of advice regarding participation in a vaccine trial. Making a decision to participate varied between men and women. Women were more likely than men to consult spouses before participation (47.7% vs 13.6%). More men than women were likely to consult health workers (47.5% vs 37.3%), parents (18.6% vs 11.8%), other family member (8.5% vs 3.9%) and religious or community leaders (1.7% vs 0.0%).

Participant characteristics associated with unwillingness to participate in future HIV vaccine trials

In the adjusted analysis, gender and receiving gifts in exchange for sex were independent predictors of unwillingness to participate in a future trial. Women were more likely to express unwillingness to participate in future vaccine trials than men (adjusted odds ratio [aOR]=3.4; 95%CI: 1.55 to 7.33), and participants who never received gifts in exchange for sex were more likely to be unwilling to participate in future vaccine trials than those who received gifts for sex (aOR=4.5; 95%CI 1.30 to 16.7). While borderline associations were observed between reporting a new sex partner, a history of alcohol consumption always before sex, reporting genital discharge, and unwillingness to participate in the unadjusted analysis, these associations did not remain significant in the multivariable analysis (table 3). Other factors investigated but not found to be associated with unwillingness to participate were reporting genital sores, duration of stay in the fishing village, travel away from home in the past month and time spent in the cohort. Proportions of participants unwilling to participate were 10.7%, 8.6% and 9.7% ($p=0.93$) respectively for those interviewed at cohort entry, three months and six months in the cohort.

Discussion

In this study among HIV- uninfected adults from fishing communities along Lake Victoria in Uganda, we found an overwhelming willingness to participate (99%) in a hypothetical HIV vaccine trial comparable with the finding of 95% of the general inland population in Masaka [22]. Two earlier studies in Uganda found a lower WTP (77%) in the neighbouring district of Rakai and 79% in the Ugandan military [20,21]. From 2008, HIV Vaccine Awareness Day has been observed annually on May 18 in Uganda with extensive media coverage[24]. This might have contributed to increase in awareness on HIV vaccine trials leading to higher WTPs in the latter studies. In the Rakai study, hypothetical trial characteristics were not described to participants before being assessed for willingness to participate [20]. Another major difference is that our study interviewed newly enrolled volunteers while these studies [20,22] assessed volunteers after a two year follow-up.

Overall, there was a modest influence of vaccine trial characteristics on WTP in a future trial. Concerns about delaying pregnancy in women and having to undergo large-volume blood draws were the major factors associated with a reduced willingness to participate. Surprisingly, for this mobile fishing population, length of study and frequent study visits did not affect WTP. These findings are encouraging for a mobile population such as this one which might otherwise be difficult to retain in a trial. Participation also did not appear to be influenced by the notion of randomisation to a placebo unlike in a study among the military in Uganda [21]. This however, could have resulted from lack of understanding on the placebo concept, highlighting the importance of participant education to ensure full understanding of the implications and the potential for allocation to a placebo arm.

While not trial characteristics specifically, a substantial proportion of the population cited access to high quality health services as an important motivator for participation in a future trial. Provision of health services is an important entry point into studies, and must therefore be integrated into all planned trials in these communities as this may also influence continued participation. It is worrying that participants may falsely perceive the vaccine to be protective since some (16%) mentioned the hope of being protected from acquiring HIV as a motivator. For any future clinical trials conducted in the fishing communities there will be need to reinforce counselling messages on the possibility of the trial vaccine not being protective. Although altruism is frequently cited as a motivator for participation among other high risk populations, [22,25–28], this was not the case for our study. Personal health gains outweighed altruism perhaps due to the limited access to high quality services. Individuals from the fishing communities could have also perceived themselves as high risk and as primary beneficiaries of vaccines over others.

There was also some evidence to suggest that participant characteristics might influence future trial participation. In particular, female gender and not receiving gifts in exchange for sex were important factors associated with unwillingness to participate in a trial. Women's willingness to participate appeared to be influenced by the requirement to delay or defer pregnancy, and women placed a greater emphasis on spousal consultation prior to deciding to participate. These findings are in keeping with the reported structured gendered roles within these communities, where most women perform lower income- generating activities,

making them more dependent on men [29,30], from whom they might have to seek approval to participate in a vaccine trial. Recruiting women from the fishing communities will require sensitisation of their spouses or sex partners and dialogue regarding women's pregnancy concerns. There is also need to increase HIV vaccine trial awareness among health care providers, since so many people may consult them for their opinion about participating in vaccine research.

Since women constitute more than 50% of any HIV infected adult population in sub Saharan Africa and gender may influence critical vaccine efficacy endpoints [31], It is important that focused strategies are put in place to particularly motivate them to ensure similar rates of trial participation among women and men..

Our finding that participants who received gifts in exchange for sex were more willing to participate in future vaccine trials is in agreement with results of other studies showing a positive correlation between high risk sexual behaviour and willingness to participate [32,33]. There was also a tendency towards this association shown in the unadjusted analysis for other parameters for high risk assessment such as alcohol consumption before sex, number of new sexual partners and genital discharge.

There are some limitations to this study. Participants were selected for enrolment on the basis of their HIV risk profile. This may have limited our ability to discern sufficiently the influence of risk behaviour perception on willingness to participate. This study only assessed willingness to participate in volunteers within six months of enrolment into a cohort by a face to face interview. This shorter duration of follow-up together with the direct interviews might have biased participant responses in favour of willingness to participate because of social desirability. Being new to the research process, individuals may be more optimistic or less critical than individuals who were long-term research participants.

However, we found no association between the willingness to participate and period of enrolment in the cohort. In an actual vaccine trial, participants would similarly need a minimum period from screening to enrolment in a trial to take a decision to participate. We also acknowledge that this assessment reflects hypothetical interest which may not translate into actual participation in a trial [34]. Although WTP has been reported to have a modest ability to predict actual participation [35], the very high willingness reported here bodes well for future recruitment in this population. We provided information on occurrence of vaccine induced sero-positivity which is commonly reported in HIV vaccine trials [36–38], but only views of participants who had refused to participate were assessed on this. Some studies have reported vaccine induced sero-positivity as a concern raised by trial participants [39,40], which we could not sufficiently explore with the small numbers that refused to participate.

Despite these limitations, our study has several strengths. The study enrolled a high-risk, under-researched population that is ideal for HIV vaccine efficacy trials, and has a representation of both men and women. The few WTP studies in sub-Saharan Africa have been conducted in either low-risk populations [20,22], or populations that do not offer the diversity by gender and age seen in this fishing population [41,42]. A further strength of our

study is that we modelled our typical vaccine trial on the real Thai trial providing an opportunity to evaluate participants' willingness to participate in an actual trial.

In conclusion, WTP in a hypothetical HIV vaccine trial in this high risk cohort was very high. Our study provides important insights into acceptability of trial procedures and areas of further participant education. The study also highlights the important differences in the decisions of men and women to participate in the trials in this population. These encouraging results pave the way for more research on the strategies of recruiting women, in particular and this population in general into future HIV vaccine and other HIV prevention trials.

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Key Messages

- Fishing communities have high willingness to participate in future vaccine trials
- Large blood draws and pregnancy delays influence their decisions to participate
- Decisions for trial participation differ between men and women in this population
- Highlights the acceptability of trial procedures and areas of participant education
- Paves way for more research on recruitment and retention for future efficacy trials

Figure 1.
Map of study the area showing fishing sites of recruitment along Lake Victoria and the Masaka MRC/UVRI Clinical Research Centre in Uganda

Table 1

Baseline socio-demographic characteristics of men and women from fishing communities enrolled in a study of willingness-to-participate in HIV vaccine efficacy trials in Masaka, SW Uganda (N=328)

Characteristic	All participants N (%)	Men n (%)	Women n (%)	p-value ^d
Total	328 (100)	204 (100)	124(100)	
Age group in years				0.48
18–24	114 (34.7)	66 (32.4)	48 (38.7)	
25–34	138 (42.1)	90 (44.1)	48 (38.7)	
35+	76 (23.2)	48 (23.5)	28 (22.6)	
Ethnic group				<0.01
Baganda	144 (43.9)	83 (40.7)	61 (41.2)	
Banyankole	38 (11.6)	28 (13.7)	10 (8.1)	
Banyarwanda	75 (22.9)	38 (18.6)	37 (29.8)	
Other	71 (21.6)	55 (27.0)	16 (12.9)	
Marital status				<0.01
Single	88 (26.8)	65 (31.9)	23 (18.6)	
Married	172 (52.5)	119 (58.3)	53 (42.7)	
Divorced/Separated/Widowed	68 (20.7)	20 (9.8)	48 (38.7)	
Main source of income ^a				<0.01
Fishing	133 (40.5)	133 (65.2)	0 (0.0)	
Fish related business ^b	38 (11.6)	18 (8.8)	20 (16.1)	
Bar attendant/Commercial sex worker	32 (9.8)	0 (0.0)	32 (25.8)	
Other business ^c	125 (38.1)	53 (26.0)	66 (58.1)	
Religion				0.25
Christian	252 (76.8)	161 (78.9)	91 (73.4)	
Moslem	76 (23.2)	43 (21.1)	33 (26.6)	
Education				0.03
None	29 (8.8)	15 (7.4)	14 (11.3)	
Primary	234 (71.3)	156 (76.4)	78 (62.9)	
Secondary	65 (19.9)	33 (16.2)	32 (25.8)	
Number of years lived in fishing communities				<0.01
Less than one year	69 (21.1)	25 (12.2)	44 (35.5)	
1–5 years	149 (45.4)	153 (50.5)	46 (37.1)	
More than 5 years	110 (33.5)	76 (37.3)	34 (27.4)	
Away from home >2days/week in the past 3 months				<0.01
Yes	119 (33.6)	86 (42.4)	33 (26.6)	
Number of sex partners in the past one month				<0.01
None	248 (75.6)	202 (99.5)	46 (37.7)	
One or more	80 (24.4)	2 (0.5)	78 (62.3)	
Received gifts in exchange for sex in the past 3 months				<0.01
Yes	68 (20.7)	23 (11.2)	45 (36.3)	

Characteristic	All participants N (%)	Men n (%)	Women n (%)	p-value ^d
Gave gifts in exchange for sex in the past 3 months				<0.01
Yes	110 (33.5)	105 (51.7)	5 (4.0)	
Frequency of alcohol consumption in the past month				<0.01
None	121 (36.9)	63 (30.9)	58 (46.8)	
Weekly or less frequently	175 (53.4)	116 (56.9)	59 (47.6)	
Daily	32 (9.8)	25 (12.2)	7 (5.6)	
Alcohol consumption before sex in the past month				0.02
Never	168 (51.2)	92 (45.1)	76 (61.3)	
Sometimes	105 (32.0)	72 (35.3)	33 (26.6)	
Always	55 (16.8)	40 (19.6)	15 (12.1)	
Marijuana use in the past month				0.02
Yes	17 (5.2)	15 (7.4)	2 (1.6)	
Khat use in the past month				0.01
Yes	27 (8.2)	23 (11.3)	4 (3.2)	
Reported genital discharge in the past 3 months				<0.01
Yes	154 (47.0)	72 (35.3)	82 (66.1)	
Reported genital sores in the past 3 months				0.04
Yes	145 (44.2)	81 (39.7)	64 (51.6)	

^aTwo men and 6 women were unemployed

^bFish related business included boat rental, selling fish, fish processing,

^cOther businesses included selling food, shops for general merchandise, transporters, loaders, mechanics, barber shops, farming, entertainment (film shows), selling charcoal, brewing alcohol and hair dressing.

^dp-value; Chi square probability value comparing column proportion (%) between men and women for each variable category as a group.

Table 2

Associations between vaccine trial attributes, and willingness to participate

Vaccine trial characteristics	N	WTP n (%)	^g p-value
Baseline assessment	328	326 (99.4)	Ref
Vaccine trial attributes considered ^e			
Study duration of 3 years	326	326 (100.0)	0.16
Study visits at 0,1,3,6 months and 3 days after every vaccination	326	325 (99.7)	0.57
Vaccine administration by injection	326	321 (98.4)	0.25
Randomisation to any study arm including placebo	326	319 (97.9)	0.09
Large volumes (8–10 teaspoons) of blood drawn	326	308 (94.5)	<0.01
Women required delay or deferring pregnancy for 10 months ^f	124	116 (93.5)	0.02
All trial attributes combined	326	295 (90.6)	<0.01

^eWTP was assessed for vaccine trial attributes among those who expressed WTP and all were multiple response questions (each participant had a chance to respond on each attribute)

^fOnly assessed among women who were willing to participate at baseline assessment.

^gp-value; Likelihood ratio test (LRT) probability value comparing reduction in willingness to participate by each vaccine attribute to the baseline (Willingness before introduction of attributes).

Table 3

Associations between participant characteristics and unwillingness to participate in an HIV vaccine trial, among fishing communities along Lake Victoria, Uganda

Participant characteristics	Not willing n (%)	Unadjusted OR (95%CI)	Adjusted ^h OR (95%CI)	p-value
Age group in years				
18–24	11 (9.7)	Ref	Ref	
25–34	11 (8.0)	0.8 (0.34–1.94)	0.9 (0.36–2.15)	0.79
35+	9 (11.8)	1.3 (0.49–3.20)	1.4 (0.52–3.51)	0.53
Sex				
Men	11 (5.4)	Ref	Ref	
Women	20 (11.8)	3.4 (1.56–7.31)	3.4 (1.55–7.33)	<0.01
Received gifts in exchange for sex in the past 3 months				
Yes	3 (4.4)	Ref	Ref	
No	28 (10.7)	2.6 (0.83–9.09)	4.5 (1.30–16.70)	0.02
Alcohol consumption before sex in the past month				
Never	13 (7.7)	Ref		
Sometimes	9 (8.6)	1.1 (0.46–2.71)		
Always	9 (16.6)	2.3 (0.93–5.80)		
Number of new sex partners in the past month				
None	20 (8.1)	Ref		
One	9 (15.0)	2.0 (0.87–4.67)		
Two or more	2 (11.7)	1.5 (0.32–7.12)		
Reported genital discharge in the past 3 months				
No	12 (6.9)	Ref		
Yes	19 (12.3)	1.9 (0.89–4.00)		

^h Factors adjusted for include those listed in the table and the following; i) education, ii) ethnicity, iii) marital status iv) number of years spent in the fishing sites, iv) frequent travel away from home in the past month, v) frequency of alcohol consumption, vi) reported history of genital sores in the past three months, v) time spent in the cohort study