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Willingness to participate in biomedical HIV prevention studies after the HVTN 503/Phambili trial: A survey conducted amongst adolescents in Soweto, South Africa

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Abstract

Objectives—Adolescents may be appropriate for inclusion in biomedical HIV prevention trials. Adolescents' overall willingness to participate (WTP) in biomedical HIV preventive trials was examined, including after the prematurely discontinued phase IIB HVTN 503/Phambili HIV vaccine trial, in Soweto, South Africa.

Methods—An interview-administered cross-sectional survey was conducted among 506 adolescents (16–18 yo) between October 2008 and March 2009. The assessment included WTP in HIV prevention trials, sexual and substance use behavior, and related psychosocial constructs. Multivariate logistic regression analyses examined predictors of WTP in biomedical prevention trials.

Results—The sample was primarily female (n=298, 59%) and 50% of all participants were sexually active. WTP in general was high (93%), with 75% WTP in a vaccine trial after being informed about the HVTN 503/Phambili trial. Less exposure to stressors (OR 2.8, CI: 1.3–6.3) was associated with adolescents' WTP in HIV biomedical prevention trials overall. Those with less exposure to stressors (OR 1.7, CI: 1.1–2.8) and not sexually active (OR 2.1, CI: 1.4–3.3) were predictive of WTP after the HVTN 503/Phambili trial. A higher number of sexual partners was associated with unwillingness to participate more generally ($p=0.039$) and specifically after the HIV vaccine trial ($p=0.0004$).

Conclusions—The high level of adolescents' WTP in biomedical prevention trials is encouraging, especially after the prematurely discontinued HVTN 503/Phambili HIV vaccine trial. High risk youth were less likely to be WTP, although those not yet sexually active were more WTP. Future biomedical HIV preventive trials should address challenges to enrollment of high-risk adolescents who may show less WTP.

Keywords

willingness to participate; HVTN 503/Phambili trial; Biomedical; HIV prevention

Introduction

Recent efficacy trials show promise for a number of biomedical HIV prevention interventions, such as male circumcision, microbicides, pre-exposure prophylaxis and

vaccines.¹⁻⁴ Although there have been many phase I/II HIV vaccine trials, very few HIV vaccines have been tested for efficacy, and only one study conducted in Thailand from 2003 to 2005 demonstrated modest efficacy.⁵ The HVTN 503 or Phambili trial was a large scale Phase IIb test-of-concept HIV vaccine trial conducted in South Africa that tested the MRK Ad5 HIV vaccine.⁶ The study aimed to evaluate the efficacy of a subtype B vaccine in populations where the predominant circulating clade is C, and had two co-primary endpoints: HIV infection and/or impact on disease progression.^{7,8} Enrollment and vaccination of participants into the HVTN 503/Phambili trial was prematurely stopped in September 2007 because of results obtained from a companion trial called STEP, which was conducted in North America, Australia, South America and the Caribbean. The STEP trial showed that the MRK Ad5 HIV vaccine did not prevent HIV infection and^{8,9} further, the vaccine appeared to cause increased susceptibility to HIV acquisition in a sub-group of participants (uncircumcised men who had sex with men, with pre-existing Ad5 immunity).

The development of an efficacious HIV vaccine continues to be a vital research area that hopefully will contribute toward a biomedical HIV prevention intervention. An HIV vaccine that is developed and shown to be efficacious will have a major impact on the HIV epidemic,^{10,11} particularly in sub-Saharan Africa where majority of the HIV positive people live. There are approximately 5.7 million people living with HIV in South Africa, more than any other part in the world.¹² The HIV prevalence rate among 15–19 year olds in South Africa is 6.7% among females and 2.5% among males with an incident rate of about 1%.¹³ Adolescent females are disproportionately affected by HIV and become infected at a younger age compared to adolescent males.⁹ The burden of HIV on adolescent females is highly influenced by those in coital relationships with older males in higher risk profiles for HIV.^{14,15}

Adolescence is characterized by biological, neuro-developmental, cognitive and social changes which heralds exploration and higher risk taking behavior.^{3,15,16} Sexual and reproductive health programs aimed at reducing risk for HIV are often not effective and few behavioral HIV prevention programs in South Africa are able to facilitate sufficient behavior change despite extensive campaigns to increase awareness of HIV and to increase correct and consistent condom use at every sexual act.¹⁷ Adolescents continue to engage in behaviors that place them at risk for HIV including initiating sex at an early age, increased sexual activity, low or inconsistent condom use and multiple partners.^{14,18} To address the adolescent population more effectively, HIV prevention efforts will have to take a multi-faceted approach which includes individual level behavioral interventions, community level change, and biomedical interventions such as vaccines.³

Biomedical scientists argue that the development of an efficacious and affordable preventative HIV vaccine is an important component of prevention tools to eradicate the impact of HIV/AIDS among adolescents.^{19,20} From a public health point of view, it is predicted that a preventative HIV vaccine will be most effective with adolescents if it is given prior to sexual initiation.²¹ Adolescents become a future population of interest to test candidate vaccines after one is found to be efficacious with adults. In preparation for future biomedical prevention trials, including HIV vaccine trials, it is critical to determine the level of awareness, understanding, willingness as well as barriers to participation by prospective adolescent participants.^{22,23} Inclusion of adolescents in biomedical trials will require a large number of HIV negative adolescents. The willingness of adolescents to participate in future vaccine trials will impact on the recruitment of adolescents for such trials.²⁴

This study seeks to determine the predictors of willingness to participate in biomedical HIV prevention trials in general and specifically in vaccine trials after the prematurely discontinued HVTN 503/Phambili HIV vaccine trial. Researchers found high levels of

willingness to participate in future vaccine trials among adolescents in Soweto before HVTN503/Phambili.²⁵ To our knowledge, this is the first paper reporting on willingness to participate in HIV preventive trials post-HVTN 503/Phambili among adolescents.

Methods

Setting and participants

Between October 2008 and March 2009, adolescents (16–18 years old) living in Soweto, an urban setting in Johannesburg, South Africa, completed a face-to-face interviewer administered survey. The Soweto area is made up of approximately 40 townships. Each township formed a stratum where fifteen adolescents were recruited. More females (60%) were recruited into the study by design because females are disproportionately affected by HIV. Potential participants were approached in schools, youth organizations and public places like malls and informed about the study. Contact information was obtained and appointments scheduled. Those with cell phones received reminders through text messages. 852 potential participants were approached; 152 refused to participate, 193 did not show up for appointments or gave incorrect telephone numbers, and one was dropped because of missing data. Participants were informed prior to the interview that they will be asked about participation in trials related to biomedical HIV prevention research. The interview was conducted in English, the preferred language for almost all participants, and where necessary clarifications were made in the local language. Parental consent and participant's assent was sought for those below 18 years of age in accordance with the Ethical Review Board guidelines. The 18 year old participants provided evidence to prove their age in the form of an identity document or birth certificate. Those who accepted to participate in the survey were invited for interviews at the Perinatal HIV Research Unit (PHRU) and were compensated \$7 to cover their transport costs. Interviews lasted approximately one hour and were conducted by research assistants in a quiet office within PHRU.

The study protocol was reviewed and approved by the University of the Witwatersrand Human Research Ethics Committee and the Duke University Institutional Review Board.

Assessment Measures

Demographic Information—This section consisted of twenty-four items related to gender, age, grade in school, family structure, parent/guardian information, socio-economic status, the household structure and composition, and decision making related to the adolescent's household.

Willingness to participate (WTP) in future biomedical HIV preventive trials was assessed by four separate items. Survey instructions stated that these items were about future HIV trials to test whether interventions were effective in preventing HIV infection, including an explanation of biomedical trials with examples (HIV vaccine, microbicide and male circumcision trials) clearly defined. Participants were informed about the results of the vaccine (including Phambili) and male circumcision trials prior to the interview. The items asked about general WTP, female participants WTP in microbicide trials, male participants WTP in male circumcision trials and WTP in HIV preventive trials after the prematurely discontinued HVTN 503/Phambili HIV vaccine trial. See Table 2 for the detailed questions. A Likert response format was used ranging from “very willing” to “very unwilling” (1=“very willing”, 2=“somewhat willing”, 3=“willing”, 4=“somewhat unwilling” and 5=“very unwilling”). Per item, responses were categorized as “willing” or “unwilling”, with those who responded “very willing”, “somewhat willing” and “willing” classified as WTP.

Parent Adolescent Communication Scale (PACS) assessed frequency of communication between parent and child in the past six months regarding five specific items: sex related issues, how to use condoms, sexually transmitted infections, HIV/AIDS, and pregnancy/getting someone pregnant.²⁶ A 4-point Likert response format was used: never, rarely, sometimes and often ($\alpha=0.79$).

Self-efficacy scale for condom use and sexual risk reduction²⁷ comprised of five items (e.g. “would you be able to avoid sex anytime you didn’t want it?”) scored on a four-point Likert scale (1=no, 2=probably no, 3=probably yes and 4=yes). Higher total scores indicated higher self efficacy ($\alpha=0.51$).

Attitudes about sex—Attitudes towards sex and condom use were measured by a 9-item scale ($\alpha=0.62$).²⁸ Participants were asked to state whether they agreed or disagreed with statements on attitudes about sex. Example items include “it is okay to have a person with whom you have sex so that they will buy you things”, “condom use is a shared responsibility for both partners” and “it is okay to have many sexual partners”.

Exposure to stressors scale—Exposure to stressors scale was adopted from a previous adolescent study²⁵ in Soweto and was made up of 15 items that asked about stressful events that might have happened to the participants while growing up. Examples include whether “they had been separated from their mums for more than three months”, “if their parents were separated” or “if a close family member had HIV or had died of HIV” ($\alpha=0.65$).

The *Social Support Scale for Adolescents (SSAS)*^{27,28} measured emotional support, instrumental support and relationship satisfaction, assessed with three items: talking to people about personal problems, needing money and having fun with people ($\alpha=0.74$).

Risk behavior—Adolescents were asked whether they had used tobacco in the last six months, ever had alcohol, ever used drugs to get high, ever had sexual intercourse, the number of partners in their lifetime and whether they had ever been pressured by their partners into a coital relationship. The legal age in South Africa for drinking alcohol is 18 years while that for purchasing tobacco products is 16.

Coping strategies—The Kidcope is a 19 item scale of potential ways to cope with a stressful situation.²⁹ Three subscales; active ($\alpha=0.47$), avoidant ($\alpha=0.43$) and destructive coping ($\alpha=0.57$), were scored with item responses 1=“yes” and 0=“no”. Six items formed the active coping subscale (e.g. “try to see the good side of things” and “try to solve the problem by thinking of answers”). The avoidant subscale consisted of 9 items including; “try to forget it”, “blame yourself for causing the problem” and “do nothing because the problem could not be sorted anyway”. A destructive subscale was developed to reflect context specific strategies and was made up of 4 items; “try to physically hurt myself”, “hurt someone verbally/put someone down”, “break or throw objects” and “use alcohol, cigarettes or other substances”.

Statistical Analysis

The level of WTP was examined using frequencies and presented by gender. Descriptive statistics were determined for age, number of people living in a household, number of rooms in a household and the psycho-social measures. The distribution by gender of categorical predictive variables were compared using the Fisher’s exact and chi-square tests while the continuous variables were compared using the student’s *t*-test. Four logistic regression models were run to determine predictors of WTP in future HIV preventive trials. The first model identified correlates of WTP in biomedical prevention trials more generally, whereas

the second model examined WTP following the prematurely discontinued HVTN 503/Phambili trial. The third and fourth models determined predictors of WTP in male circumcision and microbicide trials in males and females respectively. Predictor variables were demographics, psychosocial factors and behavioral items. Multivariate logistic regression analyses were conducted using the stepwise selection procedure to identify variables predictive of WTP. All items were considered for entry into the multivariate model on the basis of two criteria: (1) if a variable attained a p-value ≤ 0.1 at the univariate level and (2) if the inclusion resulted in a non-significant p-value in the Hosmer and Lemeshow goodness of fit statistic.³⁰ For each model, odds ratios and their 95% confidence intervals were determined. The number of sexual partners between the willing and the unwilling to participate was compared using the Poisson regression model adjusted for age and gender. The statistical tests were two-sided at 5% level of significance. All data analysis was conducted using Statistical Analysis Software (SAS, version 9.2).

Results

Demographics

A total of 506 adolescents (41% male, 59% female) completed the study (Table 1). A significantly higher proportion of males reported being sexually active compared to females ($p < 0.0001$) and the proportion of females proceeding to the next grade in school without repeating a class is higher than that of males ($p < 0.0001$). Nearly all ($n = 498$) were enrolled in school at the time of the study.

Willingness to participate

Nearly all participants indicated general WTP in future HIV prevention trials (Table 2). WTP after learning of the general outcome of the prematurely discontinued HVTN 503/Phambili trial remained high with 73% of males and 77% of females responding favorably towards participation. Among males, 79% reported their WTP in a HIV prevention study like male circumcision, while 92% of females indicated their WTP in a microbicide trial (Table 2).

Distribution of predictive variables

A number of variables differed by gender (Table 3). Females were less likely to be sexually active ($p < 0.0001$), reported higher levels of parental communication ($p = 0.012$) and self efficacy ($p < 0.0001$), and stronger attitudes against high risk behavior ($p < 0.0001$). Males were more likely to report tobacco ($p < 0.0001$), alcohol ($p < 0.0001$), and drug use ($p < 0.0001$).

General predictors of WTP (Model 1-Table 4)

Demographics, psychosocial and behavioral variables were examined as predictors of WTP in biomedical prevention trials, such as vaccine trials (Table 4). The age of participants was tested at the univariate and multivariate level producing no significance. At the univariate level, being female (OR 2.6, CI: 1.3–5.3), high self-efficacy for condom use and sexual risk reduction behavior (OR 2.2, CI: 1.02–4.6), less exposure to stressors (OR 2.8, CI: 1.3–6.2), not using tobacco in the last six months (OR 2.6, CI: 1.3–5.1) and those who have never consumed alcohol (OR 3.4, CI: 1.2–9.7) were significantly associated with general WTP; never having used drugs and use of destructive coping were sufficiently related for inclusion in the multivariate model. However, in the multivariate model, only less exposure to stressors (OR 2.8, CI: 1.3–6.3) predicted WTP.

Predictors of WTP post-HVTN 503/Phambili trial (Model 2-Table 4)

At the univariate level, those who were not sexually active (OR 2.19, CI: 1.44–3.3), had less exposure to stressors (OR 1.58, CI: 1.05–2.39), had not recently used tobacco (OR 1.6, CI: 1.06–2.43) and never had alcohol (OR 1.87, CI: 1.15–3.05) were significant predictors of WTP after specifically noting the general outcome of HVTN 503/Phambili trial (Table 4). At the multivariate level, only those not sexually active (OR 2.1, CI: 1.4–3.3) and those with less exposure to stressors (OR 1.7, CI: 1.1–2.5) predicted WTP.

Number of partners

A higher number of sexual partners was associated with unwillingness to participate more generally ($p=0.039$) and specifically after the prematurely discontinued HIV vaccine trial ($p=0.0004$).

Predictors of WTP in future HIV preventive trials like male circumcision among males (Model 3-Table 5)

Univariately, those who have never had alcohol were predictive of WTP (OR 5.4, CI: 1.24–23.3). Adolescents under pressure from peers to be sexually active were marginally predictive (OR 2.0, CI: 1.001–4.0). In the multivariate model, male adolescents who reported lower levels of self efficacy for condom use and sexual behaviour (OR 2.4, CI: 1.14–4.9) were predictive of WTP in HIV preventive trials like male circumcision studies (Table 5). Those who have never used alcohol were marginally predictive (OR 4.5, CI: 1.0–20.3).

Predictors of willingness to participate in future HIV preventive trials like microbicide studies among females (Model 4-Table 5)

Less use of avoidant (OR 0.77, CI: 0.59–1.0, p -value 0.054) and active coping (OR 0.69, CI: 0.47–1.0, p -value 0.06) strategies were marginally associated with WTP at the univariate level. None of the items tested at the multivariate level were significant (Table 5).

Discussion

To date, little to no data are available on South African adolescents' WTP in future biomedical HIV prevention trials following the premature discontinuation of enrollment and vaccination into the HVTN 503/Phambili trial. Interestingly, adolescents living in Soweto reported very high levels of WTP in biomedical trials more generally, including vaccine trials, but also specifically after the STEP study demonstrated no efficacy with the possibility of increased susceptibility to HIV acquisition in a sub-group of individuals, *and* the public announcement of halting enrollment and vaccination into the HVTN503/Phambili study.

Less exposure to life stressors was associated with adolescents' WTP in biomedical trials more generally, including HIV vaccine trials. With regard to WTP in the context of the prematurely discontinued HVTN 503/Phambili trial, in addition to lower levels of stressful life experiences, adolescents who were not yet sexually active were more willing to participate in a future vaccine trial. Higher levels of WTP among those not yet sexually active could be related to adolescents' desire for an HIV prevention method to become available as their risk increases, concerns about ability to negotiate sexual risk reduction and rather rely on a biomedical method, or naiveté with regard to implications of the current status of HIV vaccine trials. Taking the halting of the Phambili trial into account, higher risk adolescents were less likely to be WTP. While some research suggests the importance of an HIV vaccine prior to sexual initiation,²¹ less WTP among higher risk youth presents a challenge for efficacy trials targeting high risk youth. Strategies would need to be identified

to encourage participation of high risk youth. This is consistent with findings from a previous adolescent study in South Africa that found sexually active participants were predictive of WTP.³¹

A limited number of studies exist in literature on WTP in HIV prevention trials among adolescents in sub-Saharan Africa.^{23,25,31–35} Of those trials done in sub-Saharan Africa, all prior to the outcome of the STEP and Phambili studies, the majority are from South Africa where a high proportion of adolescents indicated their WTP. In contrast, other risk groups such as gay and bisexual men in Canada and injection drug users (IDUs) in the US reported low levels of WTP.^{36,37} A more recent study comparing IDUs and non-IDUs post-STEP showed high levels of WTP in both groups.³⁸ Our finding provides a unique perspective into WTP in HIV preventive trials among adolescents after the HVTN 503/Phambili HIV vaccine trial stopped enrolling and vaccinating participants. The HIV vaccine trial findings were presented to participants, yet three-quarters still indicated their WTP. Although we did not explore the reasons for this high WTP, it would be important to further examine adolescents' understanding of the details of the trial findings and the implications. Although factors influencing WTP vary across previous adolescent and adult studies, possible explanations for WTP include altruism, knowledge of current information about HIV, and the extent of prior training about HIV vaccines prior to study enrollment.^{25,31,32} It cannot yet be ascertained as to why adolescents reported a high level of WTP, but given the context of this study, a high level of awareness about HIV and perceived knowledge about HIV vaccines due to ongoing HIV biomedical trials in Soweto and surrounding regions likely contributed to interest among these youth.

With regard to gender specific prevention trials, adolescent females showed more WTP in a microbicide trial than adolescent males in a male circumcision trial, although a large majority of males were willing to participate. Interestingly, lower self efficacy for condom use and risk reduction sexual behavior was associated with higher levels of males WTP in adolescent male circumcision trials. It may be that males with stronger confidence in their ability to use condoms are less likely to seek out male circumcision, or it may be that since findings from the male circumcision trials have been made widely available,^{39–41} adolescent males with lower levels of self efficacy perceive a protective effect against HIV in male circumcision. Hence they see no need to use condoms, and thus their confidence with regard to condom use and sexual risk reduction less consequential. In females, none of the variables tested were associated with WTP in microbicide trials. This is most likely due to the high level of WTP and thus lack of variability in the data hence affecting the predictive power.

Several limitations of the study should be noted. Questions regarding WTP in this study were hypothetical and it remains to be seen whether adolescents will participate in biomedical trials, if the opportunity arises in the future. All the measures were self-reported and possibly influenced by social desirability (providing answers that the adolescent thinks the interviewer is seeking) bias. In addition, some assessment measures had low reliability values and the predictive power was likely weakened by the high proportion of participants willing to participate. While some assessment measures have been used in this setting, all measures were not psychometrically validated, which could improve reliability of study findings.²⁸ Lastly, all participants were from Soweto and the results are not necessarily generalizable to other regions.

Although the majority of the adolescents indicated their WTP in HIV preventive trials following the outcome of the HVTN 503/Phambili trial, there is a need to further assess their knowledge and understanding of the vaccines and trial methodology. Future research should also assess parental willingness for adolescent children's involvement in biomedical HIV

prevention trials. Regulatory authorities and other stakeholders need to utilize this window of opportunity and consider the inclusion of adolescents in future HIV vaccine trials.

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Table 1

Demographic characteristics

Variable	N (%) [#]	
Mean age (IQR)	17.1 (16–18)	506 (100)
Mean no. of people living in household (IQR)	5.7 (4–7)	506 (100)
Mean no. of rooms in household (IQR)	4.8 (4–6)	506 (100)
Source of drinking water	Tap water in home	497 (99)
	Community tap	7 (1)
	Other	0 (0)
Gender	Male	208 (41)
	Female	298 (59)
Schooling history*	Repeated classes	158 (31)
	Not repeated	348 (69)
Parental status	Both parents alive	299 (59)
	Single parent	167 (33)
	Orphan	40 (8)
Parental marital status	Married	174 (39)
	Never married	182 (40)
	Other	95 (21)
Head of household (Age bracket in years)	Female (18–60)	253 (50)
	Male (18–60)	167 (33)
	Female (>60)	62 (12)
	Male (>60)	22 (5)
Age	16	154 (30)
	17	167 (33)
	18	185 (37)
Sexually Active*	Yes	255 (50)
	No	251 (50)

[#]The totals may not be equal to sample size due to missing values

* Significant by gender

Table 2

Distribution of responses to the WTP scale by gender

Item	Males (%)	Females (%)
If there was a study taking place that could prevent HIV infection in teenagers such as a vaccine study, how willing would you be to take part?		
<i>Very willing</i>	119 (57.77)	212 (71.38)
<i>Somewhat willing</i>	31 (15.05)	36 (12.12)
<i>Willing</i>	34 (16.50)	36 (12.12)
<i>Somewhat unwilling</i>	6 (2.91)	3 (1.01)
<i>Very unwilling</i>	16 (7.77)	10 (3.37)
In a recent HIV vaccine trial, some participants were found to be more susceptible to HIV infection after receiving the HIV vaccine when exposed to HIV through high risk behaviour. How willing would you be able to participate in a future trial knowing this information?		
<i>Very willing</i>	50 (24.04)	91 (30.64)
<i>Somewhat willing</i>	51 (24.52)	80 (26.94)
<i>Willing</i>	50 (24.04)	58 (19.53)
<i>Somewhat unwilling</i>	15 (7.21)	21 (7.07)
<i>Very unwilling</i>	42 (20.19)	47 (15.82)
If there was a study taking place that could prevent HIV infection in teenage females, such as a microbicide study, how willing would you be able to participate?		
<i>Very willing</i>	N/A	179 (60.47)
<i>Somewhat willing</i>		43 (14.53)
<i>Willing</i>		49 (16.55)
<i>Somewhat unwilling</i>		7 (2.36)
<i>Very unwilling</i>		18 (6.08)
If there was a study taking place that could prevent HIV infection in teenage males such as a circumcision study, how willing would you be to participate?		
<i>Very willing</i>	101 (49.03)	N/A
<i>Somewhat willing</i>	28 (13.59)	
<i>Willing</i>	33 (16.02)	
<i>Somewhat unwilling</i>	9 (4.37)	
<i>Very unwilling</i>	35 (16.99)	

Table 3

Descriptive statistics for predictive variables by gender

Variable	Male (N=208)	Female (N=298)	p-value
PACS			
High (%)	83 (39.9)	153 (51.3)	0.012
Low (%)	125 (60.1)	145 (48.7)	
Self efficacy			
High (%)	66 (31.7)	163 (54.7)	<0.0001
Low (%)	142 (68.3)	135 (45.3)	
Attitudes about sex			
Low risk (%)	86 (41.4)	75 (25.2)	<0.0001
High risk (%)	122 (58.6)	223 (74.8)	
Exposure to stressors			
Less (%)	103 (49.5)	161 (54)	0.32
More (%)	105 (50.5)	137 (46)	
Social support			
High (%)	113 (54.3)	140 (47)	0.12
Low (%)	95 (45.7)	158 (53)	
Sexually active			
No (%)	70 (33.7)	181 (60.7)	<0.0001
Yes (%)	138 (66.3)	117 (39.3)	
Pressure from peers			
Yes (%)	109 (52.7)	131 (44.9)	0.10
No (%)	98 (47.3)	161 (55.1)	
Tobacco use in the last six months			
No (%)	108 (51.9)	228 (76.5)	<0.0001
Yes (%)	100 (48.1)	70 (23.5)	
Ever had alcohol			
No (%)	35 (16.8)	112 (37.6)	<0.0001
Yes (%)	173 (83.2)	186 (62.4)	
Ever used drugs to get high			
No (%)	150 (72.1)	269 (90.6)	<0.0001
Yes (%)	58 (27.9)	28 (9.4)	
Mean active coping score (std)	4.3 (1.3)	4.4 (1.3)	0.38
Mean avoidant coping score (std)	5.2 (1.8)	5.3 (1.7)	0.68
Mean destructive coping score (std)	0.63 (0.9)	0.58 (1.0)	0.53

* standard deviation

Table 4

Univariate and multivariate analysis of predictors of WTP in vaccine trials in general and after the HVTN 503/Phambili HIV vaccine trial

Variable	General WTP						WTP after HVTN 503/Phambili trial					
	Univariate		Multivariate*		Univariate		Multivariate*		Univariate		Multivariate*	
	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value
Gender												
Female	2.6(1.3–5.3)	0.0081	1.9(0.9–4.2)	0.1	1.3(0.85–1.9)	0.25	-	-	-	-	-	-
Male	1	1	1	1	1	1	1	1	1	1	1	1
PACS												
High	1.7(0.8–3.6)	0.14	-	-	1.02(0.7–1.5)	0.93	-	-	-	-	-	-
Low	1	1	1	1	1	1	1	1	1	1	1	1
Self-efficacy												
High	2.2(1.02–4.6)	0.043	1.8(0.8–3.99)	0.14	1.1(0.75–1.69)	0.58	-	-	-	-	-	-
Low	1	1	1	1	1	1	1	1	1	1	1	1
Attitudes about sex												
Low risk	1.5(0.77–3.06)	0.22	-	-	1.4(0.9–2.07)	0.13	-	-	-	-	-	-
High risk	1	1	1	1	1	1	1	1	1	1	1	1
Exposure to stressors												
Less	2.8(1.3–6.2)	0.009	2.8(1.3–6.3)	0.011	1.6(1.05–2.09)	0.0285	1.7(1.1–2.5)	0.02	1.7(1.1–2.5)	0.02	1.7(1.1–2.5)	0.02
More	1	1	1	1	1	1	1	1	1	1	1	1
Social support scale												
High	0.8(0.41–1.64)	0.57	-	-	1.3(0.84–1.89)	0.27	-	-	-	-	-	-
Low	1	1	1	1	1	1	1	1	1	1	1	1
Sexually active												
No	1.5(0.73–2.97)	0.28	-	-	2.19(1.44–3.3)	0.0003	2.1(1.4–3.3)	0.0015	2.1(1.4–3.3)	0.0015	2.1(1.4–3.3)	0.0015
Yes	1	1	1	1	1	1	1	1	1	1	1	1
Pressure from peers												
Yes	0.98(0.5–2.0)	0.96	-	-	0.85(0.6–1.28)	0.44	-	-	-	-	-	-
No	1	1	1	1	1	1	1	1	1	1	1	1
Tobacco use in the last six months												

Variable	General WTP				WTP after HVTN 503/Phambili trial			
	Univariate		Multivariate*		Univariate		Multivariate*	
	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value
No	2.6(1.3–5.1)	0.008	1.5(0.7–3.5)	0.3	1.6(1.06–2.43)	0.027	1.2(0.75–1.8)	0.5
Yes	1	1	1	1	1	1	1	1
Ever had alcohol								
No	3.4(1.2–9.7)	0.024	2.2(0.73–6.9)	0.16	1.9(1.15–3.05)	0.012	1.5(0.9–2.5)	0.12
Yes	1	1	1	1	1	1	1	1
Ever used drugs to get high								
No	2.1(1.0–4.5)	0.06	1.1(0.46–2.8)	0.8	1.5(0.92–2.54)	0.104	-	-
Yes	1	1	1	1	1	1	-	-
Active coping	0.86(0.6–1.1)	0.29	-	-	1.06(0.9–1.23)	0.49	-	-
Avoidant coping	0.84(0.7–1.04)	0.10	-	-	1.07(0.95–1.2)	0.29	-	-
Destructive coping	0.77(0.6–1.1)	0.09	0.99(0.7–1.5)	0.95	0.86(0.7–1.05)	0.15	-	-

* The multivariate Odds ratios are adjusted for all other variables in that column

Table 5
Univariate and multivariate analysis of predictors of WTP in future HIV biomedical trials by gender

Variable	Males (circumcision trials)				Females (microbicide trials)			
	Univariate		Multivariate*		Univariate		Multivariate*	
	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value
PACS								
High	1.06(0.54–2.1)	0.86	-	-	1.65(0.7–3.8)	0.24	-	-
Low	1	1			1	1		
Self-efficacy								
Low	1.86(0.94–3.7)	0.076	2.4(1.14–4.9)	0.0216	0.5(0.2–1.2)	0.12	-	-
High	1	1	1	1	1	1		
Attitudes about sex								
Low risk	1.3(0.65–2.59)	0.46	-	-	1.2(0.47–2.96)	0.72	-	-
High risk	1	1			1	1		
Exposure to stressors								
Less	1.3(0.68–2.59)	0.41	-	-	1.6(0.67–3.67)	0.3	-	-
More	1	1			1	1		
Social support scale								
High	0.88(0.45–1.7)	0.71	-	-	0.79(0.35–1.8)	0.57	-	-
Low	1	1			1	1		
Sexually active								
No	1.37(0.7–2.87)	0.4	-	-	0.69(0.3–1.7)	0.4	-	-
Yes	1	1			1	1		
Pressure from peers								
Yes	2.0(1.001–4.0)	0.0497	2.0(0.96–4.17)	0.065	0.5(0.23–1.3)	0.17	-	-
No	1	1	1	1	1	1		
Tobacco use in the last six months								
No	1.24(0.64–2.4)	0.53	-	-	1.04(0.4–2.7)	0.93	-	-
Yes	1	1			1	1		
Ever had alcohol								

Variable	Males (circumcision trials)				Females (microbicide trials)			
	Univariate		Multivariate*		Univariate		Multivariate*	
	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value	OR(CI)	p-value
No	5.4(1.24–23.3)	0.0249	4.5(1.0–20.3)	0.0503	1.1(0.45–2.5)	0.9	-	-
Yes	1	1	1	1	1	1	-	-
Ever used drugs to get high								
No	0.95(0.5–1.99)	0.88	-	-	0.39(0.05–3.0)	0.37	-	-
Yes	1	1	1	1	1	1	-	-
Active coping	0.89(0.68–1.2)	0.39	-	-	0.69(0.47–1.0)	0.06	0.7(0.5–1.1)	0.14
Avoidant coping	0.94(0.78–1.1)	0.5	-	-	0.77(0.59–1.0)	0.054	0.8(0.6–1.1)	0.24
Destructive coping	0.7(0.5–1.03)	0.074	0.79(0.55–1.1)	0.19	0.8(0.55–1.15)	0.23	-	-

* The multivariate Odds ratios are adjusted for all other variables in that column