Willingness to Participate and Enrollment in a Phase III Preventive HIV-1 Vaccine Trial

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Background

- T rials of preventive HIV-vaccines require large study populations with a high incidence of HIV infection, and individuals who are capable of adhering to study protocols, and are willing to participate.
- Other issues that need to be taken into account in study design, include appropriate education about trial concepts prior to enrollment and throughout the trial, optimizing recruitment and retention of high-risk individuals, and taking all reasonable actions to reduce risk behaviours in trial participants.
- Characterizing high-risk populations willing to participate in HIV vaccine trials is important for assessing the feasibility of large-scale efficacy trials. However, self-reported willingness to enroll may not translate into actual enrollment into a trial.

Objectives

- To assess the extent to which HIV-negative Vanguard Project participants would be willing to participate in future HIV vaccine trials,
- To identify independent predictors of willingness to participate
- To explore reasons why willingness to participate may not translate into enrollment into the ongoing AIDSVAX B/B phase III vaccine trial.

Methods

Vanguard Project

- Since May 1995, young (15-30) gay and bisexual seronegative men (MSM) have been recruited into an ongoing prospective study of HIV incidence and risk behaviors in the Greater Vancouver region.

Instruments

- Sociodemographic characteristics , sexual risk taking, depression (CES-D), beliefs about HIV-issues, and beliefs surrounding and reasons for not participating in the AIDSVAX B/B trial were collected from self-administered questionnaires.

Willingness to Participate

- *"If an HIV vaccine were tested in Canada on people who don't have HIV, would you be interested in participating in a study to see if it works?"* (definitely, probably, don't know, probably not, and no). Subjects responding "definitely" or "probably" were considered to be willing to participate.

Statistical Analyses

- Contingency table analysis compared willing versus unwilling participants , according to sociodemographic and risk-taking variables.
- Logistic regression models identified independent predictors of willingness to participate in an HIV-vaccine trial.
- All possible two-way interactions were examined.

Results

Of 474 respondents, a greater proportion of participants were willing (214/474 or 45.1%) than not (97/474 or 20.5%). Almost a third were unsure (129/474 or 27.2%), and only a very small percentage were ineligible as they were HIV-positive (13/474 or 2.7%) or were already in the AIDSVAX, B/B vaccine trial (21/474 or 4.4%).

Table 1 - Participants willing to participate were younger, more likely to be living in unstable housing, and more likely to have injected drugs in the past year or in their lifetimes (all p<0.05).

Table 2 - Being willing to participate in an HIV vaccine trial was also associated with having had more sex partners and engaging in more sexual risk behaviours (all p<0.05).

Table 3 - Although willing participants were more likely to be depressed, and to believe they had been infected with HIV in the past year, they also reported being more optimistic about new HIV treatments (all p<0.05).

There was no association between willingness to participate and ethnicity, involvement in the sex trade, education, income, sex with HIV+ partners, or sexual behaviours with regular partners.

Table 4 - Only a third of willing participants (80/214 or 37.4%) had heard of the phase III trial. Among participants who gave a reason for not participating in the AIDSVAX" B/B trial, participants who were willing to participate were most likely to cite having missed the deadline for enrollment. Participants not willing to participate cited fear of health problems and concern for being denied health insurance as reasons for not participating in the AIDSVAX"B/B trial (all p<0.05).

Table 5 - In multivariate analysis, having had a regular sex partner was a negative predictor of being willing to participate, whereas having a high perceived HIV risk in the past year was a positive predictor of being willing to participate in a future vaccine trial.

Table 1: Sociodemographic factors associated with willingness to participate (WTP) in an HIV vaccine trial

	WTP (n=214)	Not-WTP (n=97)	p-value
Unstable housing	35 (16.4%)	4 (4.3%)	0.003
Injected drugs (ever)	45 (21.0%)	9 (9.3%)	0.011
Injected drugs (in past year)	35 (16.4%)	6 (6.2%)	0.014
Median age (IQR)	27 (24-31)	29 (26-31)	0.041

Table 2: Sexual behaviour in past year associated with WTP in an HIV vaccine trial

	WTP (n=214)	Not-WTP (n=97)	p-value
Casual sex partners	165 (81.7%)	67 (71.3%)	0.043
Insertive anal sex with a casual partner*	97 (58.8%)	50 (74.6%)	0.023
Unprotected anal receptive sex with a casual partner*	35 (42.1%)	7 (21.9%)	0.043
Regular sex partners	152 (73.8%)	80 (84.2%)	0.046
Median # of male sex partners in past year (IQR)	4.5 (3-15)	3.5 (1-12)	0.040

* among those with casual partners

Table 3: Depressive symptoms and perceived risk of HIV infection associated with WTP in an HIV vaccine trial

	WTP (n=214)	Not-WTP (n=97)	p-value
Median CES-D score (IQR)	7 (3-11)	5 (2-8)	0.012
"New HIV treatments will take the worry out of sex"	31 (15.1%)	6 (6.5%)	0.035
"If every HIV-positive person took the new treatments, the AIDS epidemic would be over"	16 (7.9%)	1 (1.1%)	0.021
"People with undetectable viral load don't need to worry so much about infecting others with HIV"	19 (9.3%)	2 (2.2%)	0.027
"Possibly, probably or most likely infected with HIV in the past year"	31 (14.7%)	5 (5.3%)	0.018

Table 4: Beliefs surrounding and reasons for not participating in the AIDSVAX B/B phase III HIV vaccine trial

	WTP (n=214)	Not-WTP (n=97)	p-value
Ever heard of the AIDSVAX trial (n=445)	80 (37.4%)	57 (59.4%)	< 0.001
Perceived likelihood that AIDSVAX trial will lead to engaging in unsafe sex:*			
1. For others:			
Much more likely	15 (19.0%)	6 (10.7%)	0.115
Somewhat more likely	41 (51.9%)	25 (44.6%)	
Not more likely	18 (22.8%)	15 (26.8%)	
Unsure	5 (6.3%)	10 (17.9%)	
2. For self:			
Much more likely	3 (3.8%)	0 (0.0%)	0.593
Somewhat more likely	6 (7.6%)	5 (8.9%)	
Not more likely	67 (84.8%)	47 (83.9%)	
Unsure	3 (3.8%)	4 (7.4%)	
Reasons for not enrolling in the AIDSVAX trial:*			
Might cause health problems	8 (10.1%)	27 (48.2%)	< 0.001
Can't be sure the vaccine won't infect	10 (12.7%)	25 (44.6%)	< 0.001
Missed the deadline for eligibility	26 (32.5%)	3 (5.4%)	< 0.001
Concern for being denied health insurance	1 (1.3%)	7 (12.5%)	0.009

* among those who had heard about the trial

Table 5: Independent predictors of WTP in an HIV vaccine trial

	Odds Ratio	95% C.I.	p-value
Regular partner in past year	0.48	(0.25-0.92)	0.027
"Possibly, probably, or most likely infected with HIV in the past year"	5.35	(1.57-18.25)	0.007

Conclusions

- Riskier and socioeconomically disadvantaged men, and men with a high perceived HIV-risk were more likely to be willing to participate. This population could be difficult to retain, and may require careful monitoring and appropriate education and counseling to maximize retention and safety for participants.
- Participants who have a regular sex partner were also less likely to be willing to participate in a trial. Vaccine trials have excluded men in relationships however recent data show that these men may be at high risk for HIV infection. Therefore, vaccine trial design and education may look to include these men.
- Self-reported willingness to participate in an HIV vaccine trial did not translate into actual participation in a phase III efficacy trial among Vanguard participants. From these findings, however, a comprehensive approach to educating communities and trial participants may help to improve community and participant's knowledge base about preventive HIV vaccine trials - especially of ongoing trials - and inform perceptions of trial related risks and benefits.
- As knowledge of HIV vaccine trial concepts changes over time due to education and community input, perhaps willingness to participate will more readily translate into actual trial participation.