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COGNITIVE FACTORS AND WILLINGNESS TO PARTICIPATE IN AN HIV VACCINE TRIAL AMONG HIV-NEGATIVE INJECTION DRUG USERS

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Abstract

This cross-sectional study involving a cohort of injection drug users (IDU) examined the relationship between cognitive factors (HIV treatment optimism, self-efficacy and knowledge of vaccine trial concepts) as well as risk factors for seroconversion, and willingness to participate (WTP) in a preventive phase 3 HIV vaccine trial. Willingness to participate overall was 56%. In a multivariate analysis, for a 20-unit increase in a 100-point composite scale, self-efficacy was positively related to WTP (adjusted odds ratio [AOR] = 1.95, 95% CI = 1.40–2.70). HIV treatment optimism and knowledge of vaccine trial concepts were unrelated to WTP. Aboriginal ethnicity (AOR = 3.47, 95% CI = 1.68–7.18) and a higher educational level (≥high school) (AOR = 1.96, 95% CI = 1.07–3.59) were positively related to WTP. This study provides information on WTP for an HIV vaccine trial. Limitations and future directions are also discussed.

Keywords

HIV vaccine preparedness; Cognitive factors; Injection drug users; VIDUS; Vancouver

INTRODUCTION

While considerable progress has been made towards identifying factors that predict willingness to participate (WTP) in HIV vaccine trials [1] and [2], the relationship between cognitive factors such as optimism, self-efficacy, and knowledge of vaccine trial concepts, and WTP in a phase 3 trial in injection drug users (IDU) deserves further study. For

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example, to our knowledge there is currently no self-efficacy scale pertaining to WTP in an HIV vaccine trial in IDU.

Optimism is the “hopefulness and confidence about the future or the success of something” [3]. In two previous studies examining optimism in relation to WTP, people who were optimistic about HIV vaccines/vaccine trials (MSM [men who have sex with men]) [4] and HIV treatment (IDU) [5] were more willing to participate in HIV vaccine trials than those who were not optimistic.

Self-efficacy is concerned with “not with the skills themselves but with the judgments about what one can do with those skills” [6]. Self-efficacy is important for HIV vaccine trials because adherence is necessary in a multi-dose regimen trial. Little work has explored the predictive value of self-efficacy to WTP, though one study found that self-efficacy (Giocos called this perceived behavioral control) did not predict WTP in adolescents [7], pointing out that further research is required in this area.

Among male HIV-negative IDU with a high knowledge score for vaccine trial concepts (for example, seven of 10 answers correct), increases in knowledge reduced the likelihood of becoming unwilling at 18 months (AOR [adjusted odds ratio] = 0.90, 95% CI = 0.83–0.96) [8]. However, Halpern et al. found no relationship in IDU between declining WTP and trial knowledge [9] and [10].

One methodological challenge concerns the distinction between WTP in a hypothetical vs. an actual trial. Several studies have examined actual compared with hypothetical WTP. In one study, stated WTP in IDU was the single best predictor of actual enrollment[9]. However, in an extension of this study, only 20% of those stating hypothetical WTP during the vaccine preparedness study (VPS) actually enrolled in the HIVNET 014 trial[11]. In one study in Vancouver, Canada, self-reported WTP in MSM did not translate into enrollment into the AIDSVAX B/B (VaxGen) trial [12]. HIV VPS also indicate that concerns about vaccine-induced infection, side effects, false HIV-positives, and trial-related discrimination are associated with lower WTP in actual trials and that addressing barriers may improve WTP [13] and [14].

For future vaccine trials in IDU, HIV clades, HIV incidence rates (IR) and cohort retention are important factors. The HIV-1 virus has genetic diversity, although it is mainly infection with subtype B that occurs in IDU [15]. The HIV IR in our IDU population was 1.25 per 100 person-years with a retention rate of 82% for the period of 2007–2008. In a vaccine trial, an IR of >2% and a retention rate of >90% are important for trial feasibility [16], as otherwise a larger sample size required would be required for an effect to be shown.

MATERIALS AND METHODS

Data were collected using the Vancouver Injection Drug Users’ Study (VIDUS), a prospective cohort study that began in May 1996 and has been described in detail elsewhere [17]. In 2005, VIDUS became a cohort of HIV-negative active injectors, and between October 2007 and May 2008, 276 HIV-negative IDU were recruited for participation. Participants completed an interviewer-administered questionnaire, and a set of

supplementary questions on cognitive factors was also administered. Participants were reimbursed $20 for the visit, and referrals were provided for universal medical and HIV/AIDS care, and available drug and alcohol treatment. The study has been approved on an annual basis by the Providence Health Care/University of British Columbia (UBC) Research Ethics.

Data collection for the present study took place within the larger context of VIDUS. In terms of sample size, opportunities to administer the questionnaire used to collect current data yielded a sample size of 276 participants. This sample size afforded sufficient statistical power to examine the associations between the dependent and independent variables of interest.

Predictor variables

Variables were based on a previous VPS by Strathdee et al. who examined factors such as sociodemographics, drug use and risk behaviors, measures of health service utilization, and psychosocial variables in relation to WTP in an HIV vaccine trial [18](Table 1). In our study, Aboriginal ethnicity was defined as: First Nations (native), Métis, or Inuit. A Center for Epidemiological Studies Depression Scale (CES-D) standard cutoff of ≥16 was used [19].

Measurement scales

Interviewers administered three measurement scales addressing HIV treatment optimism (two items) (Table 1), self-efficacy (five items) (Table 2) and knowledge (10 true/false items). Items measuring HIV treatment optimism were already part of the main VIDUS questionnaire.

In terms of validation of the optimism scale, Van De Ven et al. developed a 12-item optimism scale consisting of HIV treatment optimism items in gay men, in which the scale was shown to have predictive validity and generalizability [20]. In addition, the HIV treatment optimism scale had good reliablity, with items specifically about HIV therapies having item-total correlations ranging from 0.38 to 0.56 [20]. For the present study, the two HIV treatment optimism items were summed to obtain an HIV treatment optimism total score (Table 1). HIV treatment optimism in our study referred specifically to optimism of treatment of HIV on transmission of the virus.

The self-efficacy scale, administered supplementally after the main VIDUS questionnaire, was modified from a study that examined determinants of highly active antiretroviral therapy (HAART) continuation among IDU in which the scale had predictive validity and high internal consistency (Cronbach's $\alpha = 0.82$) [21]. In our study, composite self-efficacy scores were calculated by adding sub-scale scores and dividing the sum by the total number of sub-scale items [21].

The 10 true/false knowledge items were also administered as supplemental items [8](with permission, Koblin) and focused on concepts such as randomization, blinding, placebos, safety, adverse reactions, and vaccine-induced seropositivity. These knowledge items were taken from two studies that used a common knowledge scale[8] and [9]. Although there was

no specific validation that was conducted with the knowledge questions that we used from Koblin's study, the focus was on areas that those authors thought were most critical for participants to know with regards to vaccine trial concepts (Koblin, personal communication). If participants were unsure what a vaccine was, the definition was explained by the interviewer. The knowledge questions were categorized as correct vs. incorrect/do not know.

Outcome variable

Willingness to participate was the outcome variable and was asked by "If an HIV vaccine study were available, would you be willing to participate in it?". Five possible answers were provided: "definitely not", "probably not", "do not know", "probably", "definitely". For our analysis, the outcome variable was dichotomized into "definitely/probably" vs. "definitely not/probably not". The results were obtained with "do not know" for WTP excluded from the analyses.

Analyses

Data were analyzed using SPSS (Statistical Package for Social Scientists) Version 17.0. Contingency table analysis was used to compare willing with unwilling subjects (Table 1), and variables associated with WTP at $p < 0.05$ in a univariate analysis were analyzed in a multivariate logistic regression analysis.

RESULTS

The mean age of participants was 42.3 years (standard deviation [SD] = 8.5 years) (Table 1). The number of people "definitely willing" to participate in an HIV vaccine trial was 79 (29%), "probably willing" was 75 (27%), "probably not willing" was 42 (15%), and "definitely not willing" was 47 (17%). Thirty-three people (12%) responded "do not know", leaving 243 participants for our analysis. Sixty-five percent of the sample analyzed was male; 29% were of Aboriginal ethnicity. Overall, 56% of these 243 participants indicated they were willing to participate in an HIV vaccine trial.

In a univariate analysis, the entire group of variables along with self-efficacy were assessed in relation to WTP (Table 1). Participants tended to be low in HIV treatment optimism for both WTP and non-WTP (most values <4/10 for both) while high in self-efficacy (most values ≥80/100 for both). The Mann-Whitney test showed that HIV treatment optimism was not significantly related to WTP ($p = 0.40$) (Table 1), while self-efficacy was related ($p < 0.01$). The correlation of the two HIV treatment optimism items with each other was 0.62. The self-efficacy items were also highly correlated with each other (range = 0.42–0.86) and Cronbach's α was 0.86. The individual knowledge items assessed in the chi-square analysis were not significantly related to WTP. Cronbach's αfor the knowledge scale was 0.61.

In a multivariate analysis, the variables assessed in relation to WTP were self-efficacy, Aboriginal ethnicity and educational level (i.e. ≥high school vs. <high school). For a 20-unit increase in a 100-point composite scale, self-efficacy was positively associated with WTP (AOR = 1.95, 95% CI = 1.40–2.70, $p < 0.01$). Aboriginal ethnicity (AOR = 3.47, 95% CI =

1.68–7.18, p < 0.01), and a higher educational level (≥high school) (AOR = 1.96, 95% CI = 1.07–3.59, p < 0.05) were positively related to WTP (Table 3).

DISCUSSION, INCLUDING FUTURE DIRECTIONS

In previous studies, generally low educational levels (<high school) were positively related to WTP [1] and [2]. The opposite relationship in our study may be due to unmeasured confounders including vaccine awareness or motivation, with the former referring to knowledge of childhood immunizations, the purpose of vaccination, and some knowledge of HIV vaccine development [22].

HIV treatment optimism was unrelated to WTP, though specific vaccine optimism was not examined. Given the improved predictability of cognitive factors related to more specific behaviors [23], the examination of vaccine-specific optimism may be warranted. A positive relationship between vaccine optimism and high-risk behavior would underline the need for ongoing risk-reduction counseling and behavioral interventions.

As demonstrated in our study, self-efficacy was positively related to WTP. Our results suggest that the relationship of self-efficacy to WTP in our study may be relevant in an actual vaccine trial in IDU in our setting where recruitment strategies are similar. The sparse data at lower values makes it difficult to comment on the relationship between self-efficacy and WTP at these values. Generalizability would be expected assuming that the relationship between self-efficacy and WTP is similar in those different populations and settings. The scale or a modified version should also be tested in other populations and settings to examine its validity in relation to WTP.

The present study found no relationship between knowledge of vaccine-related concepts and WTP in an HIV vaccine trial. At the same time, low educational levels (<high school) have been positively related to WTP [1] and [2]. In contrast, vaccine awareness has been correlated with WTP [24], [25] and [26], and educational programs to address lack of knowledge or misconceptions may improve WTP [14]. Further investigation is needed, therefore, to more clearly understand the relationship between knowledge and WTP. This understanding can inform the need for and nature of interventions to increase that knowledge.

High-risk variables

Aboriginal ethnicity was found to be positively related to WTP. A potential confounder in the relationship between Aboriginal ethnicity and WTP is educational level (i.e. ≥high school vs. <high school. However, with or without educational level in the final multivariate model, the strength of the association between Aboriginal ethnicity and WTP in an HIV vaccine trial was similar. Perceived risk (of HIV seroconversion) could be another potential confounder, but this variable was not available in the questionnaire. Therefore, exactly what explains the difference between Aboriginals and non-Aboriginals in terms of WTP is not clear in our dataset. Further research is needed, therefore, into the relationship between factors that place one at high-risk for HIV infection and that individual's WTP in an HIV vaccine trial.

Comparison of studies

The present study reports a lower WTP of 56% than has been reported elsewhere [18]. In the Strathdee study in IDU in Vancouver, Canada, 83% of participants were willing to participate, but were given little information beyond the definition of a vaccine [18]. Moreover, the possible answers only consisted only of a yes/no response option, and only 8% of the sample was Aboriginal. Participants could be more optimistic about vaccine development [27], although optimism was not linked to WTP in our study. The lower WTP may also be due to the STEP study results [28] although one knowledge item in the present study "Once a large-scale HIV vaccine trial begins, we can be sure the vaccine is completely safe" was responded to correctly by only 37% of participants.

Limitations

The non-random nature of the VIDUS sample may affect the generalizability of these findings. This cross-sectional study also precluded the examination of changes in cognitive factors over time. The oral interviews could have resulted in socially desirable reporting, and there may have been recall of information from the educational points, raising the possibility that the answers on knowledge were not based on true understanding, but on rote memorization. Finally, some subsets of questions did not have a large number of participants, limiting power to detect interactions. Lastly, hypothetical WTP may not correlate with actual enrolment.

CONCLUSIONS

This study addresses gaps in knowledge regarding cognitive factors and WTP in HIV vaccine trials. To our knowledge, the relationship between self-efficacy and WTP in injection drug users has not previously been examined. In our particular setting in injection drug users, the self-efficacy result may be useful for identifying participants who would be WTP in an HIV vaccine trial. The cognitive factors examined in this study deserve further exploration in other settings and populations such as MSM and heterosexuals, and also using items that relate more specifically to vaccine trials. Finally, in spite of the recent positive results of the Thailand HIV vaccine trial [29], the potential impact of the STEP study on WTP needs to be assessed.

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Table 1

Factors associated with willingness to participate in an HIV vaccine trial among injection drug users (n = 243).

Variable	WTP (n=154) n (%)	Not WTP (n=89) n (%)	p-Value[a]
Sociodemographics			
Age mean (median)	42.1 years (42.9)	42.8 years (44.9)	0.51 (t-test)
IQR[b]	36.8–47.7	35.8–50.4	
Gender			
Female (reference)	60 (39)	26 (29)	0.13
Male	94 (61)	63 (71)	
Aboriginal ethnicity[c]	54 (35)	17 (19)	0.01
Education ≥high school	90 (58)	38 (43)	0.02
Employment	46 (30)	22 (25)	0.39
Unstable Housing[d]	107 (69)	59 (66)	0.61
Risk variables			
Borrowed needles[d]	9 (6)	6 (7)	0.79[f]
Lent needles[d]	4 (3)	6 (7)	0.18[f]
Injection heroin ≥daily[e]	43 (28)	27 (30)	0.69
Injection cocaine ≥daily[e]	13 (8)	7 (8)	0.88
Smoking crack ≥daily[e]	58 (38)	36 (40)	0.67
Sex trade involvement[d]	25 (16)	8 (9)	0.11
Incarceration[d]	31 (20)	12 (13)	0.19
Health service utilization			
Attended needle-exchange program (ever vs. never)	118 (77)	63 (71)	0.32
Needle-exchange program ≥1/week	68 (44)	35 (39)	0.46
Injecting in Insite (ever vs.never)	109 (71)	70 (79)	0.18
Injecting in Insite[d]	89 (58)	65 (73)	0.81
Drug/alcohol treatment[d]	75 (49)	47 (53)	0.54
Psychosocial variables			
Depression (≥16)[g]	87 (66)	53 (65)	0.88
Cognitive factors			
Treatment optimism			
By taking HIV medicines, an HIV+ person reduces the chance of infecting someone with HIV through sharing needles[h]			0.95
By taking HIV medicines, an HIV+ person reduces the chance of infecting someone with HIV through unprotected sex[h]			0.14
Treatment optimism sum			0.40
Knowledge items correct vs. incorrect/do not know			

Variable	WTP (*n*=154) *n* (%)	Not WTP (*n*=89) *n* (%)	*p*-Value[a]
1	35 (23)	27 (30)	0.19
2	44 (29)	21 (24)	0.40
3	77 (50)	36 (40)	0.15
4	90 (58)	52 (58)	1.00
5	19 (12)	13 (15)	0.63
6	94 (61)	49 (55)	0.36
7	52 (34)	39 (44)	0.12
8	71 (46)	40 (45)	0.86
9	76 (49)	33 (37)	0.06
10	125 (81)	71 (80)	0.71

[a] Two-tailed probability.

[b] IQR, interquartile range.

[c] First Nations, Métis, or Inuit.

[d] Activities in past 6 months.

[e] Current activities.

[f] Fisher's exact test.

[g] CES-D (20 item 4-point scale) standard cut-off score of ≥16.

[h] 5-Point Likert optimism scale ranging from “strongly disagree” to “strongly agree”

Table 2

Self-efficacy items

a. Remember to keep appointments for the time of each vaccination, which may be frequent for the first several months
b. Remember to keep all appointments for the rest of the study, which may be every three months, and up to four years in total
c. Remember to also take HAART medications if HIV-positive
d. Remember not to obtain HIV antibody tests outside of the study
e. Take the vaccine when using intravenous drugs

Participants were asked to indicate their level of confidence in their ability to perform the specified behaviors. Responses were given using an 11-point scale ranging from 0 to 100 (i.e. 0, 10, 20, …, 100), with 0 anchored as ‘Could not do it at all’ and 100 anchored as ‘Certain could do it’. HAART refers to highly active antiretroviral therapy.

Table 3

Multivariate logistic regression model showing independent predictors of WTP in an HIV vaccine trial among injection drug users (n = 243).

Variable	AOR	95% CI	p-Value
Self-efficacy	1.95	1.40–2.70	<0.01
Aboriginal ethnicity	3.47	1.68–7.18	<0.01
Educational level (higher vs. lower)	1.96	1.07–3.59	<0.05

AOR, adjusted odds ratio; CI, confidence interval.