



## Short communication

## Cognitive factors and willingness to participate in an HIV vaccine trial among HIV-negative injection drug users

Shayesta Dhalla<sup>a,\*</sup>, Gary Poole<sup>a</sup>, Joel Singer<sup>a,b</sup>, David M. Patrick<sup>a,c</sup>, Evan Wood<sup>d,e</sup>, Thomas Kerr<sup>d,e</sup>

<sup>a</sup> School of Population and Public Health, University of British Columbia, Vancouver, BC, Canada

<sup>b</sup> Canadian HIV Trials Network, St. Paul's Hospital, Vancouver, BC, Canada

<sup>c</sup> BC Centre for Disease Control, Vancouver, BC, Canada

<sup>d</sup> BC Centre for Excellence in HIV/AIDS, St. Paul's Hospital, Vancouver, BC, Canada

<sup>e</sup> Division of AIDS, Department of Medicine, University of British Columbia, Vancouver, BC, Canada

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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 ( $\geq$ 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.

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### 1. Introduction

While considerable progress has been made towards identifying factors that predict willingness to participate (WTP) in HIV vaccine trials [1,2], 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 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 [9,10].

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 AIDS VAX 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 [13,14].

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

\* Corresponding author at: School of Population and Public Health, University of British Columbia, James Mather Building, 5804 Fairview Avenue, Vancouver, BC, Canada, V6T 1Z3. Tel.: +1 604 321 4116.

E-mail address: [shayestadhalla@yahoo.com](mailto:shayestadhalla@yahoo.com) (S. Dhalla).

**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 <sup>a</sup>
<i>Sociodemographics</i>			
Age mean (median) IQR <sup>b</sup>	42.1 years (42.9) 36.8–47.7	42.8 years (44.9) 35.8–50.4	0.51 (t-test)
Gender			
Female (reference)	60 (39)	26 (29)	0.13
Male	94 (61)	63 (71)	
Aboriginal ethnicity <sup>c</sup>	54 (35)	17 (19)	0.01
Education ≥high school	90 (58)	38 (43)	0.02
Employment	46 (30)	22 (25)	0.39
Unstable Housing <sup>d</sup>	107 (69)	59 (66)	0.61
<i>Risk variables</i>			
Borrowed needles <sup>d</sup>	9 (6)	6 (7)	0.79 <sup>f</sup>
Lent needles <sup>d</sup>	4 (3)	6 (7)	0.18 <sup>f</sup>
Injection heroin ≥daily <sup>e</sup>	43 (28)	27 (30)	0.69
Injection cocaine ≥daily <sup>e</sup>	13 (8)	7 (8)	0.88
Smoking crack ≥daily <sup>e</sup>	58 (38)	36 (40)	0.67
Sex trade involvement <sup>d</sup>	25 (16)	8 (9)	0.11
Incarceration <sup>d</sup>	31 (20)	12 (13)	0.19
<i>Health service utilization</i>			
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 <sup>d</sup>	89 (58)	65 (73)	0.81
Drug/alcohol treatment <sup>d</sup>	75 (49)	47 (53)	0.54
<i>Psychosocial variables</i>			
Depression (≥16) <sup>g</sup>	87 (66)	53 (65)	0.88
<i>Cognitive factors</i>			
Treatment optimism			
By taking HIV medicines, an HIV+ person reduces the chance of infecting someone with HIV through sharing needles <sup>h</sup>			0.95
By taking HIV medicines, an HIV+ person reduces the chance of infecting someone with HIV through unprotected sex <sup>h</sup>			0.14
Treatment optimism sum			0.40
Knowledge items correct vs. incorrect/do not know			
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

<sup>a</sup> Two-tailed probability.<sup>b</sup> IQR, interquartile range.<sup>c</sup> First Nations, Métis, or Inuit.<sup>d</sup> Activities in past 6 months.<sup>e</sup> Current activities.<sup>f</sup> Fisher's exact test.<sup>g</sup> CES-D (20 item 4-point scale) standard cut-off score of ≥16.<sup>h</sup> 5-Point Likert optimism scale ranging from "strongly disagree" to "strongly agree".

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.

## 2. 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 sta-

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