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

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Abstract

There are gaps in our knowledge of the role cognitive factors play in determining people's willingness to participate (WTP) in therapeutic HIV vaccine trials. Using a cross-sectional design in HIV-positive injection drug users (IDU), we determined the role of three cognitive factors: HIV treatment optimism, self-efficacy beliefs, and knowledge of vaccine trial concepts in relation to WTP in a hypothetical phase 3 therapeutic HIV vaccine trial. Willingness to participate was 54%. Participants tended to be low in HIV treatment optimism (mean = 3.9/10), high in self-efficacy (mean = 79.8/100), and low in knowledge (mean = 4.1/10). Items pertaining to HIV treatment optimism and knowledge of HIV vaccine trial concepts were generally unrelated to WTP. An increase in self-efficacy had a statistically significant positive association with WTP (OR = 1.61, 95% CI = 1.04–2.46, $p<0.05$). Furthermore, most of these HIV-positive participants had high levels of self-efficacy, so we are most confident about this relationship at such levels.

INTRODUCTION

Currently, there is a need for the development and implementation of both a therapeutic and prophylactic HIV vaccine (Perrin, 2002). Therapeutic vaccination has been investigated with the aim to increase immune responses in order to delay or reduce highly active antiretroviral therapy use (HAART) and prevent disease development (Puls & Emery, 2006).

At present, there is no licensed therapeutic vaccine for HIV. Only one phase 3 therapeutic HIV vaccine trial (Study 806) has been conducted in 77 centers in the United States (US) using the Salk HIV-1 immunogen (Remune) in the presence of antiretroviral therapy (ART) or no ART (Kahn, Cherng, Mayer, Murray, & Lagakos, 2000). This trial was unsuccessful with respect to HIV progression-free survival and overall mortality.

A recently conducted therapeutic HIV vaccine phase 2 study in HIV-positive individuals incorporated a psychological substudy as part of a 3-arm trial (ALVAC+Remune vs. ALVAC alone vs. placebo) (Balfour et al., 2010). A goal of the substudy was to examine

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HIV patients' baseline motivation for participating in a therapeutic HIV vaccine trial using a risk/benefit analysis. It was found that patients enrolled in the trial felt that potential social and personal benefits of participating outweighed potential social and personal risks. For example, 81% of people felt that participating in an HIV vaccine trial was a way to honor people who died of AIDS, while 69% cited side effects and 34% cited future health problems as potential risks.

More vaccine research is needed in HIV-positive individuals, and their willingness to participate (WTP) in such research must be better understood. Cognitive factors can be examined as predictors of WTP in an HIV vaccine trial, and the present study focused on such factors, including HIV treatment optimism, self-efficacy beliefs, and knowledge of HIV vaccine concepts. To our knowledge, these cognitive factors have not previously been examined in the context of a therapeutic HIV vaccine preparedness study (VPS), specifically in injection drug users (IDU).

Cognitive factors

Optimism has been defined as the "hopefulness and confidence about the future or the success of something" (Soanes & Stevenson, 2005). Optimism in the context of a therapeutic trial would be important to examine as HIV treatment optimism (hopefulness and confidence in the success of treatment, e.g., HAART) may potentially be associated with high or low vaccine/vaccine trial optimism.

Self-efficacy is concerned not with the existence of specific skills, but with the one's judgements about what one can do with those skills (Bandura, 1986). Self-efficacy is important because a person's belief that he/she can comply and adhere to a protocol could be important in a multi-dose regimen vaccine trial. To our knowledge, there has been no self-efficacy scale developed in IDU for an HIV vaccine trial.

Knowledge is defined as the "information and understanding of a specific topic or of the world in general, usually acquired by experience or by learning" (Vandenbos, 2007). Knowledge is ethically necessary for informed consent and may be associated with WTP in a vaccine trial. Various knowledge scales exist for these purposes (Koblin et al., 1998; Koblin, Holte, Lenderking, & Heagerty, 2000; Smit, Middelkoop, Myer, Seedat, Bekker, & Stein, 2006; Starace, Wagner, Luzi, Cafaro, Gallo, & Rezza, 2006).

Objectives and Hypotheses

The present study examines the relationship between selected cognitive factors and WTP in a hypothetical HIV therapeutic vaccine trial in IDU in the Downtown Eastside of Vancouver, Canada. We sought to determine the effects of HIV treatment optimism, self-efficacy regarding a vaccine trial, and knowledge of HIV vaccine trial concepts in relation to WTP in an HIV vaccine trial. We also examined the effects of sociodemographic variables, drug use and risk behaviors, measures of health service utilization, and psychosocial factors in relation to WTP. We hypothesized that higher self-efficacy would be positively related to a greater WTP. We also hypothesized that treatment optimism and knowledge would be associated with WTP, though we could not predict the direction of this relationship.

METHODS

Procedure

Participants in the present cross-sectional study were IDU who were also part of the AIDS Care Cohort to Evaluate Exposure to Survival Services study (ACCESS), a prospective cohort study in HIV-positive IDU that began in December 2005. A detailed description of

this cohort is provided elsewhere (Uhlmann et al., 2010). Participants completed an interviewer-administered questionnaire collecting demographic data, information about recent drug use patterns, HIV risk behaviors, and experiences in addiction treatment. Participants were reimbursed $20 Canadian (CDN) dollars for the study visit, at which time referrals were provided for universal medical care, 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 Board.

Data collection for the present study took place within the larger context of the ACCESS study. A sample size of 85 participants was made available. Notably, a similar study with a larger sample size of 276 HIV-negative participants yielded close to equivalent results for the cognitive factor data in relation to WTP (Dhalla et al., 2010).

Presentation of information

After the conclusion of the main ACCESS study questionnaire, trained interviewers administered eight items pertaining to knowledge of HIV vaccine trial concepts (with permission, Koblin, November 2007) (Koblin et al., 2000) (Appendix 1). These items focused on concepts such as randomization, blinding, placebos, safety, adverse reactions, and vaccine-induced seropositivity. If participants did not know what a vaccine was, the definition was explained by the interviewer. Previous work in this area presented the prospect of vaccine trials as being likely without giving respondents the impression that they were being invited to a specific trial and our script was written to be consistent with this precedent (Koblin et al., 2000).

Measurement scales

As part of the larger interview, trained interviewers administered three measurement scales addressing HIV treatment optimism (2 items) (Table 1), self-efficacy (5 items) (Appendix 1 [SQ1]), and knowledge of vaccine trial concepts (10 true/false items) (Table 1, Appendix 1 [SQ2]). The HIV treatment optimism items were already part of the main ACCESS study questionnaire.

Appendix 1 shows the order of items presented to participants after the main ACCESS study questionnaire.

In terms of validation of the optimism scale, Van De Ven et al. (2000) developed a 12-item treatment optimism scale in gay men (15.2% reported they were HIV-positive) which was shown to have predictive validity and generalizability (Van de Ven, Crawford, Kippax, Knox, & Prestage, 2000). For the present study, the two HIV treatment optimism items, similar to those used by Van de Ven et al. (2000), were summed to obtain an HIV treatment optimism total score (Table 1).

The self-efficacy scale was a supplemental scale administered after the conclusion of the main ACCESS study questionnaire (Appendix 1 [SQ1]). The self-efficacy items were based on a previous self-efficacy scale in HIV-positive individuals that had predictive validity for HAART continuation and high internal consistency ($\alpha = 0.82$) (Kerr et al., 2005). In the present study, composite self-efficacy scores were calculated by adding the subscale scores and dividing the sum by the total number of subscale items (Kerr et al., 2005).

The knowledge scale was also a supplemental scale administered after the conclusion of the main ACCESS study questionnaire (Appendix 1 [SQ2]). The 10 knowledge true/false items were taken from a study in HIV-negative individuals (Halpern, Metzger, Berlin, & Ubel, 2001; Koblin et al., 2000) (with permission, Koblin, November 2007), although the scale has knowledge items also pertaining to preventive trials. The scale was kept intact to allow

for comparison to other studies such as ours administering the scale to HIV-negative individuals (Dhalla et al., 2010). The knowledge questions were categorized as correct vs. incorrect/do not know. Corrected item-total correlations for the knowledge items were also calculated.

Outcome variable

Willingness to participate was the outcome variable and was assessed via the question: "If an HIV vaccine study were available, would you be willing to participate in it?" (Appendix 1 [SQ0]). Five possible answers were provided: "definitely not ", "probably not", "don't know", "probably ", and "definitely". The outcome variable was dichotomized into "definitely/probably" vs. "definitely not/probably not". Those who answered "don't know" for WTP were excluded from the analysis.

Statistical Analysis

Data analysis was undertaken using SPSS Version 17.0. Contingency table analysis was used to compare willing with unwilling subjects (Table 1). The t-test was used for normally distributed continuous variables, while the Mann-Whitney test was used for skewed continuous variables. The p-value of self-efficacy ($p \leq 0.07$, 1-tailed test) was the criterion for variable inclusion in a logistic regression model, as self-efficacy was the primary variable that we chose to examine in the present study.

RESULTS

Between June 2007 and May 2008, 85 HIV-positive individuals were recruited for participation in this study. The number of people who were "definitely willing" to participate was 24 (28%), "probably willing" was 22 (26%), "probably not willing" was 15 (18%), and "definitely not willing" was 14 (17%). Ten people (12%) responded "don't know", leaving 75 participants for our analysis. Overall, 54% of individuals were WTP. For the sample analyzed, 57% were male and 48% were of Aboriginal ethnicity, and 65% were on HAART. The follow-up rate in the ACCESS participants was 82% during the period of 2007–2008. This value can be linked to self-efficacy in that these participants could believe that they could follow up in an actual HIV vaccine trial.

HIV treatment optimism

Participants tended to be low in HIV treatment optimism (most values < 3/10). The mean HIV treatment optimism score was 3.9/10. The Mann-Whitney test showed that the HIV treatment optimism sum was not significantly related to WTP ($p = 0.95$). As well, the HIV treatment optimism sum was unrelated to Aboriginal ethnicity ($p = 0.44$) and sex ($p = 0.12$). The correlation between the two HIV treatment optimism items was 0.49.

Self-efficacy

Participants tended to be high in self-efficacy (most values >80/100). The mean self-efficacy score was 79.8/100. In a logistic regression analysis, a 20-unit increase in self-efficacy was significantly and positively associated with WTP (odds ratio [OR] = 1.61, 95% CI = 1.04–2.46, $p<0.05$). The self-efficacy items were highly correlated with each other (range = 0.44 to 0.92) and Cronbach's α was 0.89, indicating high internal consistency. Scores above 0.7 are the usual criteria for adequate internal consistency (Horne et al., 2004). The sum of efficacy expectations items #1 to #4 in our self-efficacy scale yielded a self-efficacy mean value of 85.1 for WTP, and 72.0 for not WTP. These are similar values to the mean values of efficacy expectations in the study by Kerr et al (2005), which showed the mean values to be 87.6 for no HAART discontinuation, and 70.5 for HAART discontinuation.

Knowledge of HIV vaccine trial concepts

Participants tended to be low in this knowledge with a mean knowledge score of 4.1/10. In general, the knowledge items were unrelated to WTP. The sum of the 10 knowledge items was unrelated to WTP in a therapeutic HIV vaccine trial (Table 1). As knowledge items #1 to #4 (Table 2) pertained more specifically to preventive HIV vaccine trials, rather than therapeutic HIV vaccine trials, a separate subanalysis was conducted and showed that the sum of knowledge items #5 to #10 (Table 2) was also unrelated to WTP in a therapeutic HIV vaccine trial.

In light of the STEP study results, we paid particular attention to knowledge item #7, which stated “Once a large-scale HIV vaccine trial begins, we can be sure the vaccine is completely safe” (correct answer = false). This item was responded to correctly by only 35% of participants. The STEP study showed greater HIV acquisition in the group vaccinated with an adenovirus type 5 (Ad5) vaccine, who had pre-existing immunity to Ad5, compared to a placebo amongst uncircumcised men (Gray, Buchbinder, & Duerr, 2010). This result brought into question the issue of safety of the Ad5 vaccine and any future vaccines.

Cronbach’s alpha was 0.64 for the knowledge items, slightly higher than in our study in HIV-negative individuals (alpha = 0.61) (Dhalla et al., 2010). Corrected item-total correlations showed several items below a recognized cut-off of 0.3, indicating low correlation with the overall scale (Table 2) (Field, 2009).

Being on HAART treatment was not significantly related to WTP in a therapeutic HIV vaccine trial ($p = 0.60$) or to HIV treatment optimism (Mann-Whitney = 0.25). As well, removing the variable on daily crack use from the analysis did not result in a significant change in the relationship between self-efficacy and WTP.

DISCUSSION

To our knowledge, this is among the first therapeutic phase 3 HIV VPS conducted to determine factors associated with WTP in a hypothetical HIV vaccine trial in IDU. Willingness to participate was found to be 54%. A 20-unit increase in self-efficacy was significantly and positively related to WTP (OR = 1.61, 95% CI = 1.04–2.46, $p<0.05$). HIV treatment optimism, and the knowledge sum were unrelated to WTP. These results are similar to our recent VPS in HIV-negative individuals (Dhalla et al., 2010).

We were unable to identify a previous study examining the relationship between HIV treatment optimism and WTP in an HIV vaccine trial, in HIV-positive individuals. However, in a previous study in a Swedish general population, it was found that optimism surrounding an HIV vaccine developed in the next 5 years was positively related to the belief that treatment with HAART reduced infectivity (Herlitz & Steel, 2001). Further studies could be developed to discover the important relationship specifically between vaccine optimism and WTP, as well as the longitudinal relationship between optimism and sexual behavior.

Given previous findings (Kerr et al., 2005), it is reasonable that self-efficacy may factor into decisions such as WTP. Therefore, from our study, high self-efficacy scores may be useful in the enrolment of individuals into a phase 3 therapeutic HIV vaccine trial. However, as there was a lack of data at lower values of self-efficacy, the relationship between self-efficacy and WTP at lower levels of self-efficacy was inconclusive. Cognitive-behavioral interventions could be used to increase self-efficacy, potentially increasing WTP (Barclay et al., 2007). For example, it could be explained to participants that as they are able to follow-up in the ACCESS study, they would in effect be capable of following up in an actual HIV vaccine trial.

Knowledge item #7 (see Table 2), which assessed HIV vaccine safety (Koblin et al., 2000) could also be asked more specifically with respect to the STEP study results (von Bubnoff & Jeffreys, 2009). A recent study by Newman et al. (2008) in Toronto, Canada, found that concerns about vaccine safety were associated with uncertainty in WTP with respect to the phase 2B STEP study, though the respondents in Toronto were mainly gay men.

The knowledge scale in our study had a Cronbach's $\alpha = 0.64$, indicating the scale could be further refined, or other more reliable knowledge scales could be used (Smit, Middelkoop, Myer, Seedat, Bekker, & Stein, 2006). In previous studies by Koblin et al. who developed the knowledge scale used in the present study, internal consistency was not reported (Koblin et al., 2000). Knowledge in relation to WTP in IDU has yielded contradictory results in separate studies also using Koblin's scale (Halpern et al., 2001; Koblin et al., 2000). Other studies have used various knowledge scales in IDU (Harrison, Vlahov, Jones, Charron, & Clements, 1995) and other populations (Smit, Middelkoop, Myer, Seedat, Bekker, & Stein, 2006; Starace, Wagner, Luzi, Cafaro, Gallo, & Rezza, 2006). Koblin et al. (1998) developed another similar scale than used in the present study, although the scale consisted of more items. The original purpose of the knowledge scales was to ensure that participants understood all the relevant study information, and that their consent was truly informed.

A large percentage (65%) of the ACCESS cohort claimed they were on HAART treatment, but in our analysis, being on treatment did not affect their WTP. Treatment with HAART is not without complications such as toxicities and necessity for long-term adherence (Thompson et al., 2010). Given this, potential participants may be duly concerned about the short-term and long-term side effects of adding another medical intervention in the form of an HIV therapeutic vaccine.

In reference to WTP, it should be noted that the progression to development of AIDS may potentially be a concern to these HIV-positive individuals, but this may be offset by the fact that many participants were already on HAART. The discouraging results of the STEP study (von Bubnoff & Jeffreys, 2009) may also negatively affect WTP, although the STEP study was in HIV-negative individuals. Only 35% of individuals were aware that there may be issues surrounding vaccine safety in general, and this suggests that individuals should be educated prior to conducting a therapeutic HIV vaccine trial in this case.

Previous studies have examined HIV vaccine acceptability (Newman & Logie, 2010). However, the concept of vaccine acceptability refers to taking a proven vaccine, while WTP in the present instance refers to participation in an HIV vaccine trial that utilizes an unproven vaccine (therefore WTP may be lower). Determinants of participation including self-efficacy and altruism may differ depending on whether one is examining vaccine acceptability versus WTP in a vaccine trial.

Limitations

There were several limitations in our study. The ACCESS cohort is a non-random sample and only a small subsample of the cohort was included in this particular study. These issues could affect generalizability and increase the likelihood of a Type 2 error. Another issue is that the study could not examine changes in cognitive factors over time. Furthermore, oral interviews might have resulted in socially desirable reporting. Another limitation of our study was that the order of scale administration was not varied between participants. Furthermore, treatment optimism may also not necessarily be a proxy for vaccine optimism. In addition, there were only two items in the treatment optimism scale, and more items would be required to improve scale reliability. As well, it is possible that the answers on knowledge were not based on true understanding of vaccine trial concepts but on rote recall. Another limitation of the study was that some of the items on the knowledge scale were not

applicable to therapeutic HIV vaccine trials. The psychometrics of Koblin's scale (2000) were also not strong (alpha = 0.64). It should also be kept in mind that trials at specific sites depend on local cultural and social environments (Lau, Stansbury, Gust, & Kafaar, 2009).

CONCLUSIONS

This study addresses gaps in knowledge regarding cognitive factors and WTP in therapeutic HIV vaccine trials. In this study, HIV treatment optimism and knowledge of vaccine trial concepts were unrelated to WTP in a therapeutic HIV vaccine trial. At higher values, self-efficacy may be useful in increasing WTP in a therapeutic HIV vaccine trial. The self-efficacy scale that we have developed may be validated to determine the relationship to WTP in other populations and settings. A prediction model could be developed to quantify the contribution of self-efficacy to variations in WTP. To build on a recent study which examined factors associated with non-enrolment in the phase 2B STEP study (Newman et al., 2008), quantitative (e.g., Likert-type scales) and qualitative (e.g., focus groups) research in IDU could further examine WTP in an HIV vaccine trial, as well as knowledge and beliefs surrounding vaccine trial concepts in IDU. The knowledge scale used in the present study could be further refined for future HIV vaccine trials.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Factors associated with willingness to participate in an HIV vaccine trial among HIV-positive injection drug users (n=75)

Variable	WTP (n=46) n (%)	not WTP (n=29) n (%)	p-value*
Sociodemographics			
Age mean (median) (IQR) **	42.3 years (43.7) (35.6–48.0)	41.7 years (43.1) (36.9–46.9)	0.76 * (t-test)
Female (reference) Male	19 (41) 27 (59)	13 (45) 16 (55)	0.76
Aboriginal ethnicity ***	20 (43)	16 (55)	0.32
Education ≥ high school	24 (52)	13 (45)	0.54
Employment	9 (20)	4 (14)	0.76 ¥
Unstable Housing †	37 (80)	21 (72)	0.42
Drug use & risk variables			
Borrowed needles †	2 (4)	1 (3)	1.00 ¥
Lent needles †	1 (2)	0	1.00 ¥
Injection heroin ≥daily ‡	9 (20)	7 (24)	0.64
Injection cocaine ≥ daily ‡	5 (11)	2 (7)	0.70 ¥
Smoking crack ≥ daily ‡	25 (54)	9 (31)	0.05
Sex trade involvement †	4 (9)	5 (17)	0.30 ¥
Incarceration †	7 (15)	2 (7)	0.47 ¥
Health Service and Utilization			
Attended NEP (ever vs. never)	34 (74)	16 (55)	0.09
NEP ≥ 1/week	17 (37)	10 (34)	0.83
Injecting in Insite (ever vs. never	34 (74)	19 (66)	0.44
Injecting in Insite †	24 (52)	13 (45)	0.54
Drug / alcohol treatment †	23 (50)	15 (52)	0.88
Psychosocial Variables			
Depression (≥ 16) § (n = 62)	26 (67) (n=39)	14 (61) (n=23)	0.65
Cognitive Factors			
Treatment optimism			
By taking HIV medicines, an HIV+ person reduces the chance of infecting someone with HIV through sharing needles ■			0.73
By taking HIV medicines, an HIV+ person reduces the chance of infecting someone with HIV through unprotected sex ■			0.74
Treatment optimism sum			0.95
Knowledge Questions Correct vs. Incorrect / Don't know (Question)			

Variable	**WTP (n=46) n (%)**	**not WTP (n=29) n (%)**	**p-value***
1	12 (26)	10 (34)	0.44
2	11 (24)	8 (28)	0.72
3	16 (33)	13 (45)	0.38
4	24 (52)	16 (55)	0.80
5	4 (8)	9 (31)	0.03¥
6	25 (51)	12 (41)	0.28
7	13 (27)	13 (45)	0.14
8	17 (35)	13 (45)	0.50
9	18 (39)	13 (45)	0.63
10	39 (85)	19 (66)	0.05
Knowledge sum (items 1–10)			0.41 (t-test)
HAART treatment	29 (63)	20 (69)	0.60

Notes: NEP, needle-exchange program; HAART, highly active antiretroviral therapy.

*Two-tailed probability.

**IQR, Interquartile range

***First Nations (native), Metis, or Inuit.

†Activities in the last 6 months.

‡Current activities.

¥Fisher's exact test.

§Center for Epidemiologic Studies Depression Scale (CES-D) (20 item 4-point scale) standard cut-off score of ≥ 16.

▪5-point optimism scale ranging from "strongly disagree" to "strongly agree".

Table 2

Corrected item-total correlations of knowledge scale (n = 75)

Knowledge item	Corrected item-total correlation
1. An HIV vaccine could weaken the immune system's ability to fight off HIV infection	0.05
2. Only vaccines that are known to be at least 50% effective at preventing HIV will be tested	0.29
3. The vaccine will have no effect on a participant's HIV test results	0.49
4. If people test HIV-positive after the vaccine, they may really be infected with HIV, or they may just be having a reaction to the vaccine	0.19
5. People in these studies will receive health care for any medical problems they have	0.14
6. People in a vaccine study will know whether or not they got the placebo because only the vaccine will cause side effects	0.48
7. Once a large-scale HIV vaccine trial begins, we can be sure the vaccine is completely safe	0.30
8. People in these studies are guaranteed to be in any future vaccine studies	0.43
9. The study nurse will decide who gets the real vaccine and who gets placebo	0.49
10. Some participants will get the real vaccine and some will get a placebo	0.22