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Hepatitis C vaccine clinical trials among people who use drugs: potential for participation and involvement in recruitment

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Abstract

Candidate prophylactic HCV vaccines are approaching phase III clinical trial readiness, yet little is known about the potential for participation among target groups or innovative ways to promote enrollment within 'hard-to-reach' populations. This study describes HCV vaccine trial participation willingness among a high-risk sample of people who use drugs and their willingness to assist researchers by promoting the trial among peers. Willingness to participate in and encourage peers' participation in an HCV vaccine trial was assessed among injection and non-injection drug users enrolled in a cohort study in Kentucky using interviewer-administered questionnaires (n=165 and 415, respectively, with willingness to participate assessed among HCV-seronegative participants only). Generalized linear mixed models were used to determine correlates to being "very likely" to participate or encourage participation in a trial. Most reported being likely to participate or encourage participation in a vaccine trial (63% and 87%, respectively). Men were significantly less likely to report willingness to encourage others' participation, while willingness to encourage was higher among HCV-seropositive participants. Unemployment, lesser education, receipt of financial support from more peers, and nonmedical prescription drug use were positively associated with willingness to participate, as were heroin and methamphetamine use. Differential enrollment in HCV vaccine clinical trials by socioeconomic status may occur, underscoring ethical considerations and need for avoiding coercion. Notably, the data suggest that a peer-driven approach to promoting trial participation among people who use drugs could be feasible in this population and that HCV-seropositive individuals and women could be especially instrumental in these efforts.

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Statement of Interests

The authors declare no conflicts of interest.

Keywords

clinical trial; drug users; hepatitis C; vaccine; injection drug use; social network

Over 450,000 people worldwide die annually from liver disease caused by hepatitis C virus (HCV) (1). Mortality resulting from HCV in the United States (US) now exceeds that of HIV (2). Transmission persists in populations at risk for parenteral exposure to the virus, particularly via injection drug use (IDU) (3). There is evidence of rising incidence among young people who inject drugs (PWID) in the US (4, 5), where 50 to 80% of PWID are infected with HCV (6). Given the high prevalence and infectiousness of HCV via parenteral transmission (7), behavioral interventions to reduce HCV transmission should be supplemented by biomedical approaches to prevention, potentially including prophylactic vaccination (8, 9).

HCV vaccination among PWID could be a cost-effective strategy for decreasing future HCV-related healthcare burden (9–11). Several candidate prophylactic HCV vaccines are nearing readiness for phase III trials (12–16) and research supports the feasibility of a large, multi-center HCV vaccine trial among PWID (17). PWID (3), as well as those sharing straws for snorting (18, 19) are at risk for HCV acquisition and could be an appropriate study population for trials; however, recruitment may be challenging (20). Given the importance of involving at-risk populations in HCV vaccine trials, identification of factors associated with willingness to participate (WTP) is vital, as is research investigating novel approaches to recruitment.

Few studies have examined WTP among HCV-seronegative PWID. Extant research indicates that trial-related characteristics (e.g., safety, privacy, efficacy, trial duration, compensation, vaccine administration method), as well as altruism, peer support, mistrust, confidentiality concerns, and comprehension of the concept of clinical trials, vaccines, and/or HCV may affect WTP (21–25). In addition, two qualitative studies reported financial compensation as a key motivator for trial participation, along with altruistic motives and positive peer communication and support (23, 24). Despite evidence that peer communication and support can play a role in promoting participation in HCV and HIV clinical trial research (20, 23, 26), no study to date has explored feasibility of involving peer-promotion in HCV trial recruitment among drug users.

The purpose of this study was to examine drug users' willingness to participate in and encourage their drug-using peers to participate in a clinical trial for a prophylactic HCV vaccine in the context of participants' injecting networks. This study was conducted in rural Appalachian Kentucky, a region with high prevalence of HCV among PWID (27, 28) in the state reporting the highest number of acute HCV infections in the United States (29). The incidence rate among PWID in this region (approximately 14 per 100 person-years) (30) is near the primary infection rate estimated in a recent study to be necessary to adequately power a trial evaluating efficacy of a highly efficacious vaccine designed to prevent chronic HCV (31). In an economically deprived area with limited healthcare access, under-resourced social service structure (32–34), and prohibition of needle/syringe provision (NSP) (35, 36), the future HCV-related healthcare burden is likely staggering. Thus, the region would

greatly benefit from an efficacious vaccine and present a prime population for HCV vaccine research.

Materials and methods

Sample

The data used for this analysis were collected during the 24-month assessment of the longitudinal Social Networks among Appalachian People study (described in detail elsewhere (37)). Participants (n=503) were recruited using respondent-driven sampling and, to be eligible for participation, were required to be 18 or older, reside in Appalachian Kentucky, and to have used prescription opioids, heroin, crack/cocaine, or methamphetamine "to get high" in the prior 30 days. Questionnaires and HCV testing were administered by trained, community-based staff approximately every 6 months and the follow-up rate at the time of data collection for the present analysis exceeded 90%. Participants who tested antibody-positive in a previous follow-up assessment were not re-tested at subsequent visits. Participants were tested using the OraQuick (Bethlehem, PA) (38) Rapid-HCV test and were provided with post-test counseling tailored to their study result.

Following their 24-month interview, participants (n=433) were invited to complete an additional interviewer-administered questionnaire that examined their attitudes toward HIV and HCV vaccines and clinical trial participation. All invited participants provided informed, written consent to participate and were compensated \$35. The University's Institutional Review Board approved the protocol.

HCV Vaccine Clinical Trial Participation—Preceding the questions about HCV vaccine clinical trial participation, participants were read the following script: "Hepatitis C is a virus that can be transmitted from person to person through sharing drug equipment such as syringes, cookers, cottons, and rinse water. Scientists are working on developing a vaccine that would prevent people from getting hepatitis C. It would not cure hepatitis C, it would only stop people from getting it. "Then, willingness to participate in a clinical trial for a prophylactic HCV vaccine was assessed with the following: "Before the hepatitis C vaccine can be approved for use for everyone, researchers must study the vaccine in clinical trials. In a clinical trial, researchers give volunteers an experimental vaccine to study the effects of the vaccine. If there was a clinical trial on hepatitis C vaccines in this community, how likely would you be to volunteer to be in it?", followed by a 4-point Likert scale ranging from 'very unlikely' to 'very likely'. Participants were also given the option to indicate that the question did not apply to them because they already were infected with HCV. Participants, including those with HCV, were then asked, "How likely would you be to encourage the people you use drugs with to be in a clinical trial for a vaccine against hepatitis C?", with responses arranged on the same 4-point Likert scale described above.

Demographic and Behavioral Characteristics—Participants also provided demographic data, including age, gender, race, marital status, education, employment, total monthly income, health insurance status, self-reported health, and recent (past 30 day) incarceration. Income was recoded into quartiles and treated as ordinal in analysis due to

positive skew of the continuous distribution. Behavioral data collected from participants included recent (past 6-month) alcohol and illicit drug use (substances listed in Tables 1 and 2), injection drug use, use of an unclean needle, having gave/loaned/sold a used needle to someone, and unprotected sex with PWID.

Network Characteristics—The questionnaire also elicited network data (described in detail elsewhere (39)). Briefly, each participant, or 'ego', gave the first name and last initial and demographic information (e.g., age and gender) of up to eight individuals, or 'alters', from/with whom they had received social support, used drugs (excluding alcohol and marijuana), and engaged in sex during the past 6 months. Of note, none of the participants named more than seven drug or sex network members and only one named eight social support network members; therefore, it is unlikely that limiting participants to eight named partners per network restricted data on network size. Respondents were then asked with whom of the individuals they listed had they shared drugs (frequency on 5-point Likert scale), shared injection equipment (sum of two 5-point Likert scales on which participants rated the frequency of needle and cooker sharing), discussed risk reduction (i.e. bleaching and/or not sharing injection equipment), or injected drugs. To construct the "injection network" (i.e. comprised of relationships in which individuals injected together), alters' names and demographic information were cross-referenced against that of study participants, with the assistance of community-based staff. UCINET (40) was used for network analysis and NetDraw (41) was used for network visualization.

Statistical Analyses

Evidence from research on vaccine uptake has demonstrated that intent is an important predictor of vaccine uptake (42–44). However, meta-analyses have found that the average correlation between intention and behavior is often only moderate (45–47). Given the debatable association between intent and behavior in similar vaccine research (48) and the desire to provide insight on behavior, a conservative dichotomization scheme was chosen (0=Very unlikely/Unlikely/Likely; 1=Very likely) in order to provide a more conservative estimate of future clinical trial participation. This coding scheme also addressed challenges posed by skewness in the response distributions. Hereafter, being 'very likely' to participate in a clinical trial is referred to as "willing to participate" (WTP) and being 'very likely' to encourage trial participation to drug using partners is referred to as "willing to encourage participation" (WEP). Given that the target population for HCV vaccine trials will be HCV seronegative PWID, WTP was assessed among HCV seronegative participants only and results specific to PWID are presented in the text. Aggregated data involving those who have and have not recently engaged in injection drug use were also analyzed, given that most had a history of injection drug use and relapse to injection is common among those who have ever injected (49, 50).

Evidence suggests that these participants are nested in a dense risk network (39); therefore, accounting for autocorrelation among participants' responses was required in analysis. Generalized linear mixed models, estimated using the PROC GLIMMIX (51) procedure (SAS software, v9.3) with a random effect for subject and Laplace approximation (52), were used for analyses. To account for possible biases presented by the use of respondent-driven

sampling (53) to recruit the original cohort, all analyses were weighted using individualized weights based on individual network size computed using RDSAT 7.1 (Ithaca, NY) (54). Odds ratios (ORs) and 95% confidence intervals (CIs) were reported. All variables that were significant (p -value <0.05) in univariate analyses were evaluated in multivariate analysis. Collinearity in multivariate models was assessed using the %COLLIN_2011 macro (55). Condition indexes of greater than 30 and corresponding variance decomposition proportions of greater than 0.5 were considered indicative of collinearity (56). Collinearity was not present in either multivariate model.

Results

Descriptive demographic and behavioral characteristics of the sample ($n=433$) are described in detail elsewhere (57). Most respondents were White (94%), male (55%), and unmarried (74%). The median age was 34 years (range: 21–68). Most (76%) reported injecting drugs in their lifetime, and 34% ($n=146$) reported recent injection (past 6 months). Among recent injectors, 38% had shared injection equipment and a sizeable proportion had engaged in receptive and/or distributive needle sharing in the past 6 months (23% and 11%, respectively).

Attitudes toward clinical trial participation for an HCV vaccine

Of the 433 participants, 266 (61%) were HCV-seropositive, and when queried about their willingness to participate in an HCV vaccine clinical trial, 158 reported that the question was not applicable because they were already infected with HCV (including two that were seronegative). Among the remaining participants ($n=165$), 44% of the total sample (72/165) and 44% (33/75) of participants who had ever injected drugs reported that they would be 'very likely' to participate in a trial, and an additional 19% and 21%, respectively, indicated that they would be 'likely'. Overall, 37% indicated that they would be 'unlikely' (18%) or 'very unlikely' (19%) to participate in an HCV vaccine clinical trial.

Of the respondents who answered the question regarding WEP ($n=415$, including 314 who had ever injected and 252 HCV-seropositive participants), the overwhelming majority were either 'very likely' (48%) or 'likely' (39%) to encourage their drug-using peers to participate in an HCV vaccine clinical trial. In the overall sample, few indicated that they were 'unlikely' (7%) or 'very unlikely' (6%) to do so. Of the 161 participants who answered the WEP and WTP questions, 23% ($n=15$) of the 66 people who were WEP were *not* WTP, and of the people who were WTP ($n=71$), just 72% were WEP.

Many of the highly connected individuals in the injection network (i.e. in which ties represent injecting together) were not WTP or WEP in an HCV vaccine trial. Of the 47 injection network ties in which participants were willing to encourage trial participation, 17 (36%) would involve encouragement of an HCV-seropositive person. The serostatuses of the remaining 30 potential recipients of encouragement were unknown (i.e. they were not participants in the study). Of the 340 'isolates' (i.e., participants reporting no injection partners), slightly fewer than half (47%) were WEP, and of the HCV-seronegative isolates ($n=155$), 46% were WTP.

Correlates to WTP and WEP in an HCV vaccine clinical trial

Univariate analyses (Table 1) revealed that participants who were HCV-seropositive were significantly more likely to indicate WEP than those who were seronegative. Most demographic characteristics (e.g., age, race, education) were not associated with WEP; however, men were significantly less likely to indicate WEP, as were those with higher income. With the exception of heroin and methamphetamine use, behavioral characteristics were not associated with WEP. Participants who had used heroin and/or methamphetamine were more likely to report WEP, as were those who reported receipt of financial support from more network partners. When variables significant in univariate analysis were entered into a multivariate model (Table 2), all with the exception of heroin and methamphetamine use remained significantly associated with WEP.

Among HCV-seronegative participants (n=165), lesser education, unemployment, receipt of financial support from more network members, and nonmedical use of prescription drugs were positively associated with WTP (Table 3). Other demographic and behavioral characteristics were not associated with WTP, although the negative association between male gender and WTP neared statistical significance (p-value=0.064). In a multivariate model (Table 4) including only variables that were significant in univariate analysis, unemployment remained significantly associated with WEP.

Discussion

In this sample of drug users, 63% of HCV-seronegative participants indicated that they would be very likely or likely to participate in a clinical trial for a prophylactic HCV vaccine, and 87% of the overall sample was either very likely or likely to encourage their peers to participate in HCV vaccine clinical trial research. This proportion reporting WTP is somewhat lower than that reported by other researchers, although comparisons are difficult given differences in survey instrumentation. In a study of young HCV-negative PWID from San Francisco, 88% of participants reported on a 4-point Likert scale item that they would be definitely (44%) or probably (44%) willing to participate in an HCV vaccine trial (21). In a study of 113 Australian PWID, 74% indicated in response to an open-ended question that were willing to participate in an HCV vaccine trial (22).

Participants who were unemployed were significantly more likely to report willingness to participate in an HCV vaccine clinical trial. These findings are important given that differential enrollment by socioeconomic status could bias trial outcomes if behavioral or other clinically-relevant characteristics differ by socioeconomic status. Interestingly, characteristics traditionally related to unemployment, such as income and education, were not associated with WTP. Of note, the income measure used in this study includes income from *all* sources, including that made through illegal activities such as selling drugs; therefore, income in this study may not be as closely related to employment status as it would be in other populations. Education was associated with WTP in univariate analysis, but not after controlling for employment, drug use, and receipt of financial support from network members. Speculatively, unemployment may have emerged as having a stronger association with WTP than related socioeconomic indicators due to its relationship with other relevant factors, such as time availability and lack of access to private insurance;

however, further research is needed to explore these possibilities. Previous research has indicated that financial incentives are likely to be key motivators of HCV vaccine trial participation among PWID (22–24). Thus, as similar research has suggested (58), socioeconomic status of prospective participants must be taken into account when considering the use of monetary incentives during a clinical trial, as large incentives may induce coercion. Ensuring participants' comprehension of trial concepts is critical to the ethical conduct of HCV vaccine clinical trials, and research has indicated that provision of plain language information coupled with brief oral discussion can significantly enhance comprehension of trial concepts (59).

An additional criterion for the ethical conduct of clinical trials is that participants have adequate access to resources promoting HCV prevention, such as substance abuse counseling, opiate substitution treatment (OST) and NSPs. Although Eastern Kentucky currently has clinics offering OST, particularly buprenorphine substitution (60), many opioid users in the region are uninsured or under-insured and the majority are unlikely to have the resources to pay for OST independently. In addition, Kentucky is one of 17 U.S. states with no NSPs (61), as such programs are currently proscribed by state law (35). Thus, for the purposes of both research ethics and analysis of comparative efficacy, establishment of prevention opportunities must be integrated into the design and implementation of prophylactic HCV vaccine trials in Central Appalachia and other similarly underserved regions.

Beyond the considerations of socioeconomic status, men were significantly less likely to indicate they would encourage trial participation among peers, but consistent with previous research (21), there were no gender differences with regard to WTP in a vaccine trial. Interestingly, similar research in this setting revealed that men were somewhat less willing to encourage HIV vaccination among peers but more likely to receive encouragement to get vaccinated (37). Together, these findings highlight the instrumental role that women may play in disseminating positive vaccine messages among their drug-using peers. However, more research is needed to explore reasons for reluctance among men to encourage trial participation among peers and to examine individuals' receptivity to peer promotion of trial participation.

Participants who were HCV-seropositive were more than two times as likely to encourage HCV vaccine trial participation compared to participants who were HCV-seronegative. This finding indicates that HCV-seropositive individuals could play an important role in facilitating recruitment, particularly if they encourage trial participation in serodiscordant relationships involving risk behavior. However, many HCV-seropositive participants who indicated WEP were connected to other HCV-seropositive individuals in the injection network. In fact, the network data revealed that at least one in three potential 'encouragements' of trial participation in the injection network would be directed to an HCV-seropositive person. Thus, while network-based promotion may be a feasible strategy, efficiency should be evaluated as it may result in increased screening of HCV-seropositive individuals depending on the distribution of HCV in the network and the pattern of communication. Coupling a peer-driven approach with trial promotion by community

organizations engaging HCV seronegative PWID or practitioners aware of clients' HCV serostatuses may be the most efficient approach.

The findings from this study should be generalized with caution and considered in light of study limitations, including reliance on self-reported behavioral data, focus on intent, and absence of measures to assess the influence of factors such as trial duration, side effects, and other trial-related characteristics. Though not ideal for assessment of theoretical constructs such as intent, one-item measures were used in an effort to minimize respondent-burden which is already elevated due to the network inventory and subsequent network member-specific questions. Furthermore, predictive validity of the intent measure can only be assessed in the context of an available clinical trial (i.e., assessing intent, then offering opportunity to enroll and examining correspondence). Of note, this study was conducted in a rural population that, despite its elevated HCV burden, has been significantly underrepresented in similar research to date. The findings based on this sample, comprised predominately of white, nonmedical prescription drug users, may not be generalizable to urban drug using populations with different demographic, behavioral, and network characteristics. In this study, most participants who had recently (past 6 months) engaged in injection drug use were HCV seropositive, leaving only 17 HCV seronegative PWID for inclusion in the WTP analysis and precluding our ability to evaluate correlates of WTP specifically among PWID. However, the aggregated analyses including those who had not injected in the past 6 months remain valuable given that most had a history of injection and could be prone to re-initiation of injection and HCV acquisition. Also, this study did not assess straw sharing, a behavior that should be examined in future research given its association with HCV transmission (18, 19). In addition, participants were asked only about their WEP among drug-using peers in general and not on a partner-by-partner basis. Given previous research that suggests selectivity in vaccine communication among social, sexual and drug network members (37), future studies should examine not only *if* participants will encourage trial participation but *to whom*. Nevertheless, it is notable that indication of strong willingness to encourage trial participation among peers was present in nearly half the sample.

Despite evidence that peer communication and support can play a role in promoting participation in HCV clinical trial research (20, 23), no study to date has explored feasibility of involving peer-promotion in trial recruitment among drug users. This study's findings suggest that a peer-driven approach to recruitment for a prophylactic HCV vaccine trial could be possible to implement in this population and has potential to reach a large number of individuals in the community at risk for acquiring HCV. However, several notable findings emerged. This study revealed that selecting "peer promoters" based on their centrality in the local injection network, in terms of their number of contacts, may not be the most efficient approach; many participants with multiple partners in the risk network reported being *unlikely* to encourage trial participation among their peers. Moreover, many of the partners of those who were central in the injection network were already HCV positive and would not benefit from a prophylactic vaccine. In this setting, women and HCV-seropositive individuals would be more appropriate promoters, as they indicated the most willingness to encourage others to enroll in a trial. Moreover, HCV-seropositive

individuals are likely connected to those who are at high risk for incident infection. This study also revealed that individuals of lower socioeconomic status may be more willing to participate in clinical trials, indicating that drug users of higher socioeconomic status may be the hardest to reach in this 'hard to reach' population. This finding underscores the need for more formative research into trial logistics, incentive structure, and messaging that could promote enrollment across the socioeconomic spectrum. Overall, these findings indicate that while a network-based approach may be an effective strategy for trial recruitment and vaccine promotion, the strategy should be coupled with other approaches such as social marketing or public endorsement by community leaders. Finally, safeguards to prevent the coercion of prospective low-income individuals along with the provision of established HCV preventive services for enrolled study participants are crucial factors to consider in the design of vaccine trial research in this and similar at-risk populations.

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Abbreviations

HCV	hepatitis C virus
HIV	human immunodeficiency virus
IDU	injection drug use
PWID	people who inject drugs
WEP	willingness to encourage participation in an HCV vaccine clinical trial
WTP	willingness to participate in an HCV vaccine clinical trial

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Table 1

Univariate correlates to being 'very likely' to encourage drug-using partners to participate in a clinical trial for an HCV vaccine (n=415)^a

Characteristic ^b	Willingness to encourage trial participation - n (%)		OR (95% CI)	p-value
	Not very likely ^c (n=216)	Very likely (n=199)		
<i>Demographic and Serostatus</i>				
Male – n(%)	149 (69.0)	79 (39.7)	0.16 (0.08 – 0.34)	<0.001 **
White – n(%)	199 (92.1)	190 (95.5)	2.52 (0.80 – 8.00)	0.116
Age – mean (SD)	35.8 (8.8)	34.7 (8.2)	0.97 (0.95 – 1.00)	0.088
Total Monthly Income				0.049 *
First quartile (\$0 – \$200)	51 (23.7)	65 (32.7)	2.82 (1.32 – 6.02)	
Second quartile (\$201 – \$698)	46 (21.4)	51 (25.6)	2.14 (0.98 – 4.66)	
Third quartile (\$699 – \$1100)	55 (25.6)	42 (21.1)	1.48 (0.69 – 3.15)	
Fourth quartile (> \$1101)	63 (29.3)	41 (20.6)	Reference	
Education (years) – mean (SD)	11.22 (1.97)	11.24 (1.81)	1.03 (0.90 – 1.19)	0.646
Married – n(%)	54 (25.0)	55 (27.6)	1.24 (0.69 – 2.24)	0.470
Uninsured – n(%)	135 (62.5)	140 (70.4)	1.50 (0.86 – 2.62)	0.154
Unemployed – n(%)	82 (38.0)	82 (41.2)	1.00 (0.59 – 1.70)	0.993
Self-report of being in good health – n(%)	132 (61.1)	168 (84.4)	5.49 (2.69 – 11.23)	<0.001 **
Incarcerated (past 30 days) – n(%)	56 (25.9)	59 (29.7)	2.11 (1.00 – 4.47)	0.050
HCV seropositive – n(%)	121 (56.0)	131 (65.8)	2.21 (1.27 – 3.83)	0.005 **
<i>Substance use in past 6 months</i>				
Alcohol – n(%)	92 (42.6)	82 (41.2)	1.03 (0.61 – 1.74)	0.921
Alcohol to intoxication – n(%)	68 (31.5)	51 (25.6)	0.58 (0.33 – 1.01)	0.055
Nonmedical use of prescription drugs – n(%)	186 (86.1)	166 (83.4)	0.86 (0.42 – 1.76)	0.678
Heroin – n(%)	6 (2.8)	16 (8.0)	4.25 (1.13 – 15.94)	0.032 *
Methamphetamine – n(%)	13 (6.0)	22 (11.1)	2.89 (1.05 – 8.00)	0.041 *
Cocaine – n(%)	24 (11.1)	27 (13.6)	1.20 (0.52 – 2.79)	0.666
Crack – n(%)	5 (2.3)	9 (4.5)	3.15 (0.66 – 15.09)	0.152
<i>Risk behavior^d</i>				
Injected drugs – n(%)	70 (32.4)	70 (35.2)	1.14 (0.66 – 1.96)	0.642
Injected with unclean needle – n(%)	13 (6.0)	20 (10.1)	1.75 (0.67 – 4.57)	0.252
Distributed unclean needle ^e – n(%)	7 (3.2)	9 (4.5)	1.01 (0.27 – 3.77)	0.993
Shared injection equipment ^f – n(%)	24 (11.1)	29 (14.6)	1.22 (0.56 – 2.65)	0.619
Bleached needles – n(%)	15 (6.9)	18 (9.1)	1.30 (0.52 – 3.22)	0.576
Unprotected sex with PWID – n(%)	36 (16.7)	45 (22.6)	1.80 (0.95 – 3.42)	0.073
Snorted drugs (past 30 days) – n(%)	105 (48.6)	77 (38.7)	0.67 (0.39 – 1.17)	0.158
<i>Network characteristics (n=356)^g</i>				
Number of injection partners – mean (SD)	0.28 (0.84)	0.17 (0.65)	0.84 (0.59 – 1.21)	0.356

Characteristic ^b	Willingness to encourage trial participation - n (%)			p-value
	Not very likely ^c (n=216)	Very likely (n=199)	OR (95% CI)	
Number of people in personal network who inject – mean (SD)	0.58 (1.05)	0.58 (1.13)	1.05 (0.82 – 1.35)	0.695
Number of people to whom participant talks about injection-related risk reduction – mean (SD)	0.26 (0.78)	0.21 (0.69)	0.87 (0.59 – 1.28)	0.482
Frequency of sharing injection equipment with all network members – mean (SD)	0.59 (2.94)	0.38 (1.85)	0.91 (0.78 – 1.05)	0.179
Number of people with whom participant uses drugs – mean (SD)	1.46 (1.68)	1.24 (1.66)	0.94 (0.79 – 1.12)	0.501
Frequency of drug sharing with all network members – mean (SD)	3.83 (4.52)	3.16 (4.60)	0.97 (0.91 – 1.03)	0.354
Number of network members providing social support – mean (SD)	1.74 (1.23)	1.62 (1.22)	0.91 (0.72 – 1.16)	0.451
Number of network members providing financial support – mean (SD)	0.58 (0.69)	1.05 (0.97)	2.56 (1.62 – 4.04)	<0.001**

PWID: person who injects drugs; OR: odds ratio; CI: confidence interval; SD: standard deviation

* p-value <0.05;

** p-value <0.01

^a Does not include those who reported that the question was not applicable (n=18).

^b All categorical variables (indicted with a 'n(%)') were dichotomous.

^c Includes responses "very unlikely", "unlikely", and "likely"

^d The recall period for risk behaviors listed was 6 months with the exception of snorting, which was assessed based on the past 30 days

^e Sold, loaned, or gave needle to someone after using it

^f Cookers, cottons, and/or rinse water

^g 59 participants reported no network members

Table 2

Multivariate correlates to being 'very likely' to encourage drug-using partners to participate in a clinical trial for an HCV vaccine (n=356)^a

Characteristic ^b	AOR (95% CI)	p-value
<i>Demographic</i>		
Male	0.18 (0.08 – 0.37)	<0.001*
Self-report of being in good health	3.73 (1.70 – 8.16)	0.001*
HCV seropositive	2.52 (1.29 – 4.92)	0.007*
Total Monthly Income		0.034*
First quartile (\$0 – \$200)	3.77 (1.51 – 9.40)	
Second quartile (\$201 – \$698)	2.74 (1.08 – 6.97)	
Third quartile (\$699 – \$1100)	2.66 (1.04 – 6.81)	
Fourth quartile (> \$1101)	Reference	
<i>Substance use in past 6 months</i>		
Heroin	3.63 (0.80 – 16.50)	0.095
Methamphetamine	1.93 (0.57 – 6.49)	0.288
<i>Network characteristics</i>		
Number of network members providing financial support	1.62 (1.05 – 2.49)	0.031*

AOR: adjusted odds ratio; CI: confidence interval

* p-value <0.05

^a Does not include those who reported that the question was not applicable (n=18) or those who reported no network members (n=59)

^b All variables were dichotomous with the exception of the continuous variable, "Number of network members providing financial support".

Table 3Univariate correlates to being 'very likely' to participate in a clinical trial for an HCV vaccine (n=165)^a

Characteristic ^b	Willingness to participate in HCV Vaccine trial			p-value
	Not very likely ^c (n=93)	Very likely (n=72)	OR (95% CI)	
<i>Demographic</i>				
Male – n(%)	55 (59.1)	30 (41.7)	0.42 (0.17 – 1.05)	0.064
White – n(%)	87 (93.6)	69 (95.8)	2.06 (0.28 – 15.23)	0.479
Age – mean (SD)	36.6 (9.4)	37.0 (9.8)	1.01 (0.97 – 1.06)	0.516
Total monthly income				0.133
First quartile (\$0 – \$200)	22 (23.6)	18 (25.0)	3.49 (1.02 – 11.90)	
Second quartile (\$201 – \$698)	23 (24.7)	18 (25.0)	2.88 (0.88 – 9.43)	
Third quartile (\$699 – \$1100)	19 (20.4)	23 (31.9)	3.96 (1.12 – 13.99)	
Fourth quartile (\$1101)	29 (31.2)	13 (18.1)	Reference	
Education (years) – mean (SD)	11.7 (1.7)	11.0 (2.1)	0.78 (0.61 – 0.99)	0.044*
Married – n(%)	28 (30.1)	29 (40.3)	1.89 (0.77 – 4.62)	0.162
Uninsured – n(%)	60 (64.5)	42 (58.3)	0.67 (0.28 – 1.57)	0.354
Unemployed – n(%)	21 (22.6)	29 (40.3)	3.78 (1.51 – 9.45)	0.004**
Self-report of being in good health – n(%)	59 (63.4)	51 (70.8)	1.07 (0.46 – 2.48)	0.884
Incarcerated (past 30 days) – n(%)	6 (6.5)	5 (6.9)	0.61 (0.11 – 3.41)	0.570
<i>Substance use in past 6 months</i>				
Alcohol – n(%)	41 (44.1)	33 (45.8)	1.20 (0.53 – 2.70)	0.664
Alcohol to intoxication – n(%)	32 (34.4)	20 (27.8)	0.93 (0.37 – 2.33)	0.881
Nonmedical use of prescription drugs – n(%)	74 (79.6)	66 (91.7)	4.11 (1.24 – 13.69)	0.021
Heroin – n(%)	1 (1.1)	4 (5.6)	3.44 (0.30 – 39.85)	0.322
Methamphetamine – n(%)	6 (6.5)	7 (9.7)	2.23 (0.44 – 11.21)	0.331
Cocaine – n(%)	8 (8.6)	8 (11.1)	1.39 (0.30 – 6.46)	0.674
Crack – n(%)	4 (4.3)	1 (1.4)	0.14 (0.00 – 5.90)	0.306
<i>Risk behavior^d</i>				
Injected drugs – n(%)	8 (8.6)	9 (12.5)	1.65 (0.43 – 6.32)	0.464
Injected with unclean needle – n(%)	2 (2.2)	2 (2.8)	0.63 (0.02 – 18.96)	0.793
Distributed unclean needle ^e – n(%)	1 (1.1)	0 (0.0)	---	---
Shared injection equipment ^f – n(%)	3 (3.2)	2 (2.8)	0.36 (0.02 – 7.87)	0.513
Bleached needles – n(%)	3 (3.2)	1 (1.4)	0.35 (0.02 – 7.37)	0.501
Unprotected sex with PWID – n(%)	8 (8.6)	5 (6.9)	0.49 (0.10 – 2.33)	0.371
Snorted drugs (past 30 days) – n(%)	53 (57.0)	38 (52.8)	0.67 (0.30 – 1.51)	0.337
<i>Network characteristics (n=145)^g</i>				
Number of injection partners – mean (SD)	0.11 (0.52)	0.15 (0.81)	1.18 (0.69 – 2.01)	0.539
Number of people in personal network who inject – mean (SD)	0.29 (0.80)	0.29 (0.91)	1.04 (0.67 – 1.60)	0.878
Number of people to whom participant talks about injection-related risk reduction – mean (SD)	0.27 (0.94)	0.16 (0.55)	0.73 (0.38 – 1.37)	0.325

Characteristic ^b	Willingness to participate in HCV Vaccine trial			p-value
	Not very likely ^c (n=93)	Very likely (n=72)	OR (95% CI)	
Frequency of sharing injection equipment with all network members – mean (SD)	0.14 (0.83)	0.35 (2.16)	1.01 (0.70 – 1.47)	0.954
Number of people with whom participant uses drugs – mean (SD)	1.46 (1.79)	1.10 (1.31)	0.87 (0.66 – 1.15)	0.334
Total frequency of drug sharing with all partners – mean (SD)	3.94 (5.19)	2.71 (3.28)	0.94 (0.84 – 1.04)	0.234
Number of network members providing social support – mean (SD)	1.75 (1.32)	1.85 (1.32)	1.05 (0.76 – 1.46)	0.768
Number of network members providing financial support – mean (SD)	0.59 (0.73)	0.95 (1.02)	1.75 (1.01 – 3.03)	0.047*

PWID: person who injects drugs; OR: odds ratio; CI: confidence interval; SD: standard deviation

* p-value <0.05;

** p-value <0.01

^a Does not include 266 participants who were already HCV positive (confirmed using OraQuick Rapid HCV tests) and two additional participants who were prompted to skip WTP questions when they self-reported being HCV positive although confirmatory testing had not yet been performed

^b All categorical variables (indicated with a 'n(%)') were dichotomous.

^c Includes responses "very unlikely", "unlikely", and "likely"

^d The recall period for risk behaviors listed was 6 months with the exception of snorting, which was assessed based on the past 30 days

^e Sold, loaned, or gave needle to someone after using it

^f Cookers, cottons, and/or rinse water

^g 20 participants reported no network members

Table 4Multivariate correlates to being 'very likely' to participate in a clinical trial for an HCV vaccine (n=145)^a

Characteristic ^b	AOR (95% CI)	p-value
<i>Demographic</i>		
Education (years)	0.85 (0.66 – 1.09)	0.189
Unemployed	4.52 (1.59 – 12.86)	0.005*
<i>Substance use in past 6 months</i>		
Nonmedical use of prescription drugs	3.97 (0.96 – 16.49)	0.058
<i>Network characteristics</i>		
Number of network members providing financial support	1.68 (0.95 – 2.96)	0.074

AOR: adjusted odds ratio; CI: confidence interval

* p-value <0.05

^a Does not include those who reported no network members (n=20), those who were already HCV positive (confirmed using OraQuick Rapid HCV tests, n=266), and two additional participants who were prompted to skip WTP questions when they self-reported being HCV positive although confirmatory testing had not yet been performed

^b All variables were dichotomous with the exception of the continuous variable, "Number of network members providing financial support".