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Increased hepatitis C virus vaccine clinical trial literacy following a brief intervention among people who inject drugs

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Abstract

Background and Aims—While people who inject drugs are at high risk of hepatitis C virus (HCV) infection and will be the target population for future HCV vaccine trials, little is known about clinical trial literacy (CTL) in this group. We assessed the impact of a brief intervention (BI) designed to improve HCV vaccine CTL among people who inject drugs in Sydney, Australia.

Design and Methods—People who inject drugs enrolled in a community-based prospective observational study between November 2008 and September 2010 (n = 102) completed a CTL assessment followed immediately by the BI. Post-test assessment was conducted at 24 weeks.

Results—The median age of the sample was 27 years, 73% were male and 60% had 10 or less years of schooling. The median time since first injection was five years and 20% reported daily or more frequent injecting. The mean number of correct responses increased from 5.3 to 6.3/10 (t = −4.2; 101df, $P < 0.001$) 24 weeks post-intervention. Statistically significant differences were observed for three knowledge items with higher proportions of participants correctly answering questions related to randomisation ($P = 0.002$), blinding ($P = 0.005$) and vaccine-induced seropositivity ($P = 0.003$) post-intervention.

Discussion and Conclusions—A significant increase in HCV vaccine CTL was observed, suggesting that new and relatively novel concepts can be learned and recalled in this group. These findings support the feasibility of future trials among this population.

Keywords

hepatitis C virus; injecting drug use; clinical trial literacy; brief intervention; vaccine preparedness study

Introduction

An effective preventive vaccine has the potential to eradicate the infectious disease it targets [1]. Although the development of a vaccine against the hepatitis C virus (HCV) faces many challenges, including the significant viral diversity of HCV, the virus's capacity to avoid various immune responses and limited animal models of infection, several candidates are currently in clinical assessment [2–5] and the field has expressed cautious optimism [6–8]. Recent developments indicate that while sterilising immunity is unlikely, progression to chronic disease may be reduced, particularly in combination with antiviral treatment [6].

The prevalence of HCV infection among people who inject drugs (PWID) is unacceptably high, with at least 50% prevalence reported in a range of settings [9] and incidence rates up to 45 per 100 person-years documented [10]. As the key target group, effective engagement of HCV antibody (anti-HCV) negative PWID will be required to evaluate preventive candidate HCV vaccines [11]. Feasibility or 'vaccine preparedness studies' (VPS) provide a way to assess the knowledge and attitudes of PWID prior to the implementation of efficacy trials. In order to ensure ethical informed consent, how best to communicate the potential risks and benefits of trial participation to this group will also require specific consideration [12,13].

Issues related to the ethical enrolment of PWID in future vaccine trials also include the potential impact of drug intoxication, drug withdrawal and impaired cognitive function resulting from drug use [14,15]. While it has been noted that obtaining consent from potential participants in extreme states of intoxication and withdrawal should be avoided, evidence to support the long-term impact of drug-related impaired cognitive functioning on understanding and capacity to provide consent is lacking [16–18]. Further, while poor educational attainment is common among drug users [19], a factor found to be associated with poorer understanding of consent processes in a systematic review [20], evidence suggests that this group has the capacity to comprehend informed consent processes [21] and that knowledge improves overtime [22] and following educational interventions [23,24].

Efforts to improve understanding of HIV vaccine trial concepts among key risk groups including PWID have been successful [24–27]. We are not aware however, of attempts to improve HCV clinical trial literacy (CTL) among PWID, and while there is overlap between HIV and HCV vaccine development, candidate HCV vaccines trials are likely to face unique challenges [11]. Some HCV candidate vaccines currently in development aim to prevent chronic, rather than primary infection, a complicated concept which highlights the importance of HCV vaccine CTL. As part of a program of HCV VPS [11,13,28] we assessed the impact of a brief intervention (BI) designed to improve understanding of key HCV vaccine trial concepts on CTL among PWID, the first study of its kind.

Methods

Study design and setting

The Hepatitis C Incidence and Transmission Study-community (HITS-c) is a community-based prospective observational study. Field sites in six Sydney neighbourhoods (Australia) were selected for recruitment following ten months of ethnographic fieldwork, which

included mapping, observation and engagement with communities of interest to determine potential eligibility and interest in the study [13]. PWID were recruited through fieldwork contacts, street outreach and snowball sampling based on drug use and social networks [13,29]. Field staff spent time in areas known to be frequented by local PWID, including coffee shops and train stations, as well as in parks and public spaces. Behavioural data and sera were collected by research assistants with experience working with the target population and trained in venepuncture and pre- and post-test counselling. Data from participants enrolled between November 2008 and September 2010 were included in the current analyses.

Participants

Screening involved completion of a brief demographic and risk behaviour interview and serological testing. Eligibility criteria included: (i) age 16 years or older; (ii) injecting drug use in the previous 12 months; (iii) confirmed anti-HCV negative serostatus. All PWID received appropriate pre- and post-test counselling. At enrolment, eligible PWID completed an extensive interviewer-administered assessment of lifetime and recent drug use and injecting risk behaviour, history of opioid substitution therapy and incarceration, and provided written informed consent.

Measures and brief intervention

The pre-test assessment of HCV vaccine CTL was conducted at participants' first quarterly HITS-c follow-up visit. Post-test knowledge was assessed 24 weeks later. The development of the survey instrument was informed by focus groups with a range of key stakeholders including PWID [28]. Ten true and false questions adapted from published reports of HIV and HCV vaccine trial knowledge [30–33] assessed understanding of key clinical trial and HCV vaccine trial concepts (see Table 1). The focus throughout the study, including the CTL assessment, was on a hypothetical candidate vaccine designed to prevent HCV infection. The distinction between a vaccine designed to prevent primary infection and one designed to prevent chronic infection following exposure was not made in the study materials. Indeed both types of candidate are considered prophylactic in that they aim to prevent the significant mortality and morbidity associated with chronic infection and both will require anti-HCV negative PWID for efficacy trials.

Immediately following the pre-test assessment, all participants received a BI comprising a plain language double-sided A4-sized paper handout summarising HCV transmission and risk factors, principles and purpose of immunisation, key clinical trial concepts (comparison, placebo, randomisation, blinding, side-effects, follow-up) and HCV vaccine trial concepts specifically (safety, efficacy, potential birth defects and vaccine-induced seropositivity) and a 10–15 minute discussion with a Research Assistant. Following the BI, any incorrect answers in the pre-test knowledge assessment were reviewed. The content of the BI was reviewed by Hepatitis New South Wales and The Australian Injecting & Illicit Drug Users League.

Participants were remunerated AU\$30 for the completion of each assessment. The study protocol was approved by the University of New South Wales Human Research Ethics Committee.

Statistical analysis

Data were analysed using Stata 12.0 [34]. Means were calculated for normally distributed continuous data, and medians and corresponding interquartile ranges (IQR; 25th – 75th percentiles) for non-normally distributed data. Categorical data were presented as proportions. CTL was determined by the number of correct responses to the true and false

questions. Participants could also respond “unsure” which was coded as incorrect for analytical purposes. Change in the mean number of correctly answered questions was assessed using a paired samples t-test. Additionally, the proportion of participants correctly answering individual knowledge items at each study visit was compared using the McNemar test. Multiple logistic regression was used to assess key demographic and drug use characteristics considered potentially associated with an increase in vaccine trial literacy, including age, gender, education, country of birth, injecting duration and recent injecting frequency.

Results

Of the 110 anti-HCV negative enrolled participants who received the BI following completion of the baseline HCV vaccine CTL assessment, 102 (93%) were followed-up a mean of 181.8 days (SD 56.3) post-intervention. Participants lost to follow-up were significantly younger than those retained (mean age 22.4 vs. 27.5 years, $P = 0.02$) but there were no differences between the groups with respect to gender, educational attainment, country of birth, time since first injection, frequency of injecting and baseline CTL.

The median age of the 102 participants was 27 years (IQR 23–31 years), 73% were male and a majority were Australian born (Table 2). The prevalence of other demographic characteristics, injecting risk behaviours and history of opioid substitution therapy engagement are also reported in Table 2. Three-quarters (73%) self-reported having been immunised against a vaccine-preventable disease (such as tetanus, rubella, hepatitis A or B), while less than half (39%) had serological evidence of hepatitis B vaccine-induced immunity (anti-HBs 10 IU/ml and anti-HBc negative) at study entry.

Impact of a brief intervention on clinical trial literacy

A statistically significant increase in HCV vaccine CTL was observed among participants at 24 weeks post-intervention ($t = -4.2$; 101df, $P < 0.001$) with the mean number of correct responses increasing from 5.3/10 (SD 2.1) to 6.3/10 (SD 2.2) (Table 2). Further, statistically significant increases in the proportion of participants correctly answering specific questions post-intervention were observed for three of the ten individual items. Importantly, these included items about randomisation, blinding and vaccine-induced seropositivity. Questions about the potentially long duration of follow-up and potential sides effects, including treatment of these, were answered correctly by the majority of participants at each visit, as was the question regarding the need to be anti-HCV negative for enrolment into a prevention trial. The question relating to trial efficacy was answered correctly by only 55% of participants post-intervention, while questions about trial safety and potential birth defects in pregnant women were answered incorrectly by the majority of participants at both visits (Table 2).

Associations with increased clinical trial literacy

Overall, 39% of participants correctly answered two or more additional questions post-intervention. Associations with an increased score of this magnitude were assessed using multiple logistic regression where all variables of interest were included in the final model, however, there were no statistically significant differences observed in terms of age, gender, education, country of birth, injecting duration and recent injecting frequency (data not shown).

Discussion

The current study is the first to demonstrate an increase in HCV vaccine CTL among PWID, the key population at risk of HCV, following a BI designed to improve understanding of key HCV vaccine trial concepts. Statistically significant differences were observed for three of ten knowledge items 24 weeks post-intervention. Improvement was not observed for all concepts however, with three out of four participants incorrectly indicating that candidate vaccines would be “completely safe” and just under half incorrectly indicating that only vaccines known to be at least 50% effective would be tested in a trial. However, results are encouraging given that the areas where the greatest improvements were observed were those where literacy had been poor prior to the BI.

Misconceptions and misunderstandings in relation to safety and efficacy are consistent with results from studies of HIV vaccine CTL interventions [25,27], and previous work that indicates that drug users both over- and under-estimate the potential risks and benefits of hypothetical clinical trials [19]. The concept of “therapeutic misestimation” [35] may explain these findings – participants may presume that safety is guaranteed and therefore investigators will not assess safety as part of a trial. An individual’s perception of acceptable vaccine efficacy is likely to be influenced by their perceived HCV risk. For example, a 50% efficacious candidate may be acceptable to those who consider themselves at high risk of HCV but not to individuals who consider themselves at low or negligible risk. Our findings suggest that safety and efficacy will be important components of future educational efforts.

Consistent with our data, a cross-sectional survey of HCV vaccine trial literacy among PWID in San Francisco found that approximately half correctly answered questions regarding randomisation and blinding, with a greater proportion correctly answering the item about treatment of side-effects [33]. Strengths of our larger study were the delivery and assessment of the impact of a BI designed to improve HCV vaccine CTL and the prospective measurement of HCV vaccine CTL over a relatively long follow-up period.

Previous work suggests that PWID comprehend HIV vaccine trial informed consent processes [21] and reports from HIV VPS suggest that understanding of vaccine trial concepts increases over time and with repeated educational efforts among participants including PWID [23,24,31,32,36]. Results from the current study support these findings, with significant improvements in HCV vaccine CTL observed 24 weeks post-intervention, suggesting that new and relatively novel concepts may be retained over a reasonable period by PWID.

Age, gender, country of birth, education and injecting risk behaviour were unrelated to the intervention outcome. In contrast, a systematic review of interventions designed to improve understanding of informed consent found lower education to be associated with poorer understanding, although the authors found inconsistent effects in relation to age, gender and minority group status [20]. Approaches designed to improve clinical trial literacy in other contexts have included “corrected feedback” [37] and peer-based interventions designed to increase screening rates for HIV trials [38]. A key recommendation of the systematic review was that ‘one-on-one’ approaches are likely to be most beneficial to ensure information provision is tailored to the individual [20]. Initiatives of this nature warrant further investigation in the context of future HCV VPS.

Our study has several limitations. While we used multiple recruitment sites and methods to reduce sampling bias and to obtain a diverse sample, the sample was not selected randomly and the degree to which results are generalisable to the broader population of PWID is unknown. Given the relatively small sample size it was not possible to randomise participants to a control condition and the lack of power may also have resulted in an

inability to identify statistically significant associations with clinical trial literacy. Although knowledge was measured both prior to and following the administration of the brief intervention, our study design does not permit us to measure the impact on internal validity – it is possible that alternative explanations, such as ongoing or incidental contact with study staff, or exposure to trial concepts via other sources during the follow-up period, may account for the increase in clinical trial literacy observed, although given the specific nature of the questions this is unlikely. Further, the use of true and false questions potentially overestimated the number of correct responses [39] and may have been measuring recall rather than understanding. Finally, although the ten true and false questions were not validated, they were adapted from published reports of HCV and HIV vaccine CTL [30–33].

To our knowledge, this is the first study to examine the impact of a brief intervention designed to improve HCV vaccine clinical trial literacy among PWID. Our findings suggest that the ethical implementation of future HCV vaccine trials is feasible in the group at greatest risk. With a promising prophylactic candidate in Phase I/II trials [20], our results are particularly timely and encouraging. Findings have the potential to inform future educational efforts to develop clinical trial literacy in this population, increasing confidence in ethical informed consent processes. However, further research into strategies that improve understanding of the important concepts of safety and efficacy is warranted. Finally, the level of CTL required to support ethical informed consent in this context remains unknown [41].

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Table 1

Characteristics of HITS-c participants at study entry, n=102

	N=102	%
Gender		
Male	74	73
Female	28	27
Median age, years (IQR)	27	(IQR 23–31)
Age		
26 years	45	44
27 years	57	56
Education		
10 years	61	60
11 years	41	40
Country of birth		
Australia	78	76
Other ^a	24	24
Ethnicity		
Caucasian Australian	69	68
Asian	20	20
Other CALD [*]	13	13
Employed full-time		
No	86	84
Yes	16	16
Prison, ever		
No	56	55
Yes	46	45
OST ^b , ever		
No	52	51
Yes	50	49
OST, current		
No	63	62
Yes	39	38
Median time since first injection, years (IQR)	5	(IQR 2–9)
Time since first injection		
4 years	45	44
5 years	57	56
Frequency of injecting, last month		
No IDU last month	26	25
< Daily	56	55
Daily	20	20
Main drug injected, last month		
No IDU last month	26	25

	N=102	%
Heroin	39	38
Any meth	28	27
Other ²	9	9
Receptive syringe sharing ³ , ever		
No	76	75
Yes	26	25
Receptive syringe sharing, last month		
No IDU last month	26	25
No	71	70
Yes	5	5
HBV vaccine-induced immune, serology (n=97) [†]		
No	59	61
Yes	38	39
Ever been immunised [∞] , self report		
Don't know	18	18
No	10	10
Yes	74	73

[¶]Other countries included New Zealand (n=3), Vietnam (n=2), Laos (n=2), Cambodia, Thailand, Taiwan, South Korea, Philippines, Fiji, Chile, Peru, England, Germany, Italy, Portugal, Qatar, Iraq, Macedonia, Bosnia and Croatia

* Culturally and linguistically diverse (CALD) refers to all other ethnic groups other than the English-speaking Anglo-Saxon majority in Australia

¹; ²Other drugs included cocaine, methadone, Buprenorphine and steroids;

³ Having used a needle and syringe previously used by someone else, even it was cleaned;

[†] n=5 HBcAb pos excluded;

[∞] Against vaccine-preventable diseases such as hepatitis A virus, hepatitis B virus, tetanus, rubella, human papillomavirus (HPV) and/or influenza. Opioid substitution therapy

Table 2

Impact of brief intervention on clinical trial literacy among HITS-c participants, n=102

	% correct pre- intervention	% correct post- intervention	<i>P</i>
A preventative hepatitis C vaccine trial would only enrol people who are not infected with hepatitis C (T)	65	67	0.864
In a hepatitis C vaccine trial, the participants would be randomly assigned to get the actual vaccine OR a 'placebo' (an inactive substance) (T)	49	74	0.002
In a hepatitis C vaccine trial, neither the research staff nor the participants would know who gets the actual vaccine or the 'placebo' vaccine until the end of the trial (T)	53	71	0.005
Participants in a hepatitis C vaccine trial would be treated for side effects or health problems they might experience during the study, that are related to the vaccine (T)	78	80	0.839
Only vaccines that are known to be at least 50% effective at preventing hepatitis C will be tested (T)	46	53	0.360
Once a large-scale hepatitis C vaccine trial begins, we can be sure the vaccine is completely safe (F)	25	25	1.000
Being in a vaccine trial that assesses safety and efficacy can involve being followed-up and attending study visits for one, two or even three years (T)	80	89	0.093
A hepatitis C vaccine could cause minor side effects that may last a few days (T)	66	71	0.410
If people test hepatitis C positive after the vaccine they may just be having a reaction to the vaccine (T)	36	57	0.003
A hepatitis C vaccine could cause birth defects if a woman was pregnant while participating in a hepatitis C vaccine trial (T)	36	46	0.133
Total mean score out of 10 (SD)	5.3 (2.1)	6.3 (2.2)	0.000

HIITS-c, Hepatitis C Incidence and Transmission Study-community.