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Adherence to Hepatitis B Virus Vaccination At Syringe Exchange Sites

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ABSTRACT *Injection drug users (IDUs) are at high risk for hepatitis B virus (HBV); however, they often do not receive preventive vaccination. IDUs who use mobile health care services linked to a syringe exchange program in New Haven were routinely screened for HBV, hepatitis C virus, and syphilis. Individuals without prior exposure to HBV were offered three-part vaccination series. Of the 212 IDUs screened for HBV infection, 134 (63%) were eligible (negative for HBV surface and core antibodies) for vaccination and 10 (4.7%) had evidence of chronic HBV infection. Compared to those with previous exposure to HBV, vaccine-eligible patients were significantly more likely to be younger and use heroin and less likely to be black, homeless, daily injectors, and cocaine users. Of the 134 vaccine-eligible subjects, 103 (77%) and 89 (66%) completed two and three vaccinations, respectively. Correlates of completing all three vaccinations included older age (OR = 1.06, 95% CI = 1.04–1.07), injecting daily (OR = 2.12, 95% CI = 1.36–6.73), and being homeless (OR = 1.98, 95% CI = 1.14–12.27). These results suggest that IDUs remain at high risk for acquiring HBV infection. Programs that link health care to a syringe exchange program are effective ways to provide preventive health care services to IDUs, particularly HBV vaccination. Trust engendered by and mutual respect afforded by such programs result in repeated encounters by active IDUs over time.*

KEYWORDS *Access to health care, Adherence, Financial incentives, Hepatitis B virus, Injection drug users, Mobile health care, Prevention, Syringe exchange programs, Vaccination.*

INTRODUCTION

Hepatitis B virus (HBV) infection and its complications remain important public health problems in the United States.[1–3] A comprehensive immunization strategy to eliminate HBV transmission began nearly two decades ago and included testing of pregnant women to prevent perinatal HBV transmission, comprehensive vaccination of infants and adolescents, and vaccination of high-risk groups.[4,5] With the exception of those with occupational risk, successful immunization programs for other high-risk groups of adults and adolescents have had less than optimal results. This has been true among injection drug users (IDUs), men who have sex with men, individuals with multiple sexual partners or sexually transmitted diseases, and correctional inmates.[6] Indeed, these high-risk groups still account for 75% of all new

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cases of HBV each year.[7] Moreover, over two thirds of these individuals have had a missed opportunity for HBV vaccination.[4]

Injection drug users are at particularly high risk for HBV infection through shared use of injection equipment and unprotected sexual contact. Despite the availability of a safe and effective HBV vaccine, there are multiple problems in vaccinating IDUs in the United States, including negative attitudes towards IDUs in primary care settings, the need to reach IDUs before they are exposed to HBV, availability of resources to pay for vaccination,[8] and logistical difficulties in completing the three-part vaccination series.[2,9,10]

Syringe exchange programs (SEPs) have increasingly provided opportunities to interact with IDUs on a routine basis. IDUs using SEPs have a large number of unmet medical and psychiatric needs.[11] Some SEPs have incorporated enhanced services that include provision of or linkage to drug treatment,[12–14] onsite health care,[15,16] diagnosis and treatment of sexually transmitted diseases,[17] and provision of directly administered antiretroviral therapy for treatment of HIV.[18–19] Unfortunately, IDUs in SEP settings are less likely to receive preventive health care services such as screening for tuberculosis, viral hepatitis, and sexually transmitted diseases when compared to their counterparts in methadone maintenance treatment programs.[20] During the past 5 years, a HBV screening and vaccination program was added to the services provided by a community-based SEP in New Haven, CT. We report on an evaluation of the need and the effectiveness of this program among IDUs attending the SEP. We therefore examined our clinical data from an SEP-based health service program in New Haven, Connecticut, for HBV screening and vaccination completion rates.

METHODS

Definitions

All data were collected on IDUs who were routinely screened for viral hepatitis from January 1, 1998, through December 31, 2001, on the Community Health Care Van (CHCV). Follow-up vaccination information was gathered through the end of 2002. On the basis of HBV screening information provided by the Connecticut Department of Public Health, subjects were classified into three distinct groups: (1) vaccine-eligible—susceptible to HBV, evidenced by a negative HBV surface antigen (HBsAg), surface antibody (anti-HBs), and core antibody (anti-HBc); (2) HBV-exposed—evidence of prior exposure to HBV infection, evidenced by a positive HBsAg or anti-HBc and a negative anti-HBs; and (3) previously vaccinated—laboratory evidence of prior vaccination demonstrated by a positive anti-HBs and a negative HBsAg and anti-HBc. Vaccination completion was defined as having received all three HBV vaccinations within a twelve-month period.

Setting

New Haven (census approximately 123,000) is an urban city with a high prevalence of substance abuse,[21] homelessness,[22] poverty,[23] and HIV/AIDS.[24] The CHCV has traveled to four New Haven neighborhoods in tandem with the New Haven SEP since January 1993.[25] The CHCV is a 36-foot mobile health program that provides acute episodic treatment and preventive health care proximate to SEP sites. Use of the SEP or active drug use is not a requirement for CHCV use. The details of the program have been described elsewhere.[15,17] All CHCV services are provided free of

charge. Injection drug users who request health care services are offered screening for a number of preventable or treatable conditions, including HBV infection. Screening for HBV or other conditions is not a requirement for CHCV services. Patients are simultaneously offered testing for hepatitis C virus and syphilis and asked to return 1 week later to obtain results. All vaccine-eligible subjects were offered a standard three-part vaccination over 6 months (vaccinations at months 0, 1, and 6) as part of routine care (Engerix B®, Smith-Kline Beecham, Philadelphia, PA, USA) and not enrolled as part of a prospective clinical trial. At the time of the first vaccination, patients are provided with a wallet-sized schedule of dates to return for the two subsequent vaccinations. Scheduled follow-up appointments and reminders are provided by phone, post cards, and primarily through outreach efforts. No monetary incentives are provided. Demographic and drug use characteristics, laboratory results, and vaccination information are available from routine intake information obtained from all CHCV clients and stored in an electronic database. CHCV data are not linked to the SEP for confidentiality purposes. All subjects identified with active HBV infection (HBsAg positive) were referred to available health care in the community.

Analysis

Bivariate analyses were conducted to examine the associations with lack of exposure to HBV infection. Student's *t* tests, chi square tests, and Fisher's exact tests for expected cell sizes less than five were used to compare proportions where appropriate. Multiple logistic regression analysis was used to determine correlates of completing all three HBV vaccinations within a twelve-month period. All statistical analyses were conducted using SAS® version 12 (SAS Institute Inc., Cary, North Carolina). The Yale University School of Medicine's institutional review board approved the research.

RESULTS

During the 4-year study period, 212 IDUs were screened for viral hepatitis. Among these, 134 (63%) were eligible for vaccination. Only 79% of IDUs were regular clients of the SEP; the remainder reported being secondary exchangers or had acquired their syringes from a pharmacy. The patients screened for HBV were demographically similar to SEP clients with the exception of younger age. SEP clients have a mean age of 41.2 years and are comprised of 26% women, 56% Blacks, and 26% Hispanics. Previous HBV exposure was evident in 78 individuals; 10 (4.7%) of all IDUs screened had active HBV (positive HBsAg) and 68 (32%) had evidence of previous exposure to HBV with immunity (either positive anti-HBs or anti-HBc). Only six patients (2.8%) had evidence of prior HBV vaccination by serology. Baseline information on all IDUs who were screened for viral hepatitis and offered HBV vaccination is provided in Table 1. Comparisons between IDUs who were previously exposed to HBV and those who were eligible for HBV vaccination indicate that vaccine-eligible patients were more likely to be younger and white, and use only heroin; they were less likely to be homeless, be black, use cocaine, and inject daily. In this sample, cocaine use was associated with daily injection and black race was associated with homelessness (data not shown). Of the 134 vaccine-eligible IDUs, only 8 (6%) either refused vaccination or did not return for their hepatitis screening results; 103 (77%) patients completed two vaccinations and 89 (66%) completed all three vaccinations (Figure). Reasons for refusal included believing that there was

TABLE 1. Characteristics of injection drug users screened for viral hepatitis

Characteristic	Screened IDUs [N = 212 (%)]	Vaccine eligible [N = 134 (%)]	*P* value*
Age (years)			
Mean	38.1	35.8	<.001
Interquartile range	26.4–49.7	24.6–48.1	.06
Gender			
Male	146 (69)	99 (74)	
Female	66 (31)	35 (26)	
Race			
Black	117 (55)	66 (49)	.02
Hispanic	61 (29)	38 (29)	Not significant
White	34 (16)	30 (22)	<.001
SEP client	167 (79)	96 (72)	.13
Homeless	76 (36)	31 (23)	<.001
Health insurance	131 (62)	64 (48)	.01
Injects daily	151 (71)	87 (65)	.01
Drug injected			
Heroin only	57 (27)	48 (36)	<.001
Cocaine only	36 (17)	12 (9)	<.001
Heroin and cocaine	119 (56)	74 (55)	Not significant
HCV antibody positive	165 (78)	95 (71)	Not significant
HBsAg positive	10 (4.7)	Not applicable	

HCV, hepatitis C virus; HBsAg, hepatitis B virus surface antigen.
*Chi square or Student's *t* test for immune versus nonimmune status for hepatitis B virus (HBV).

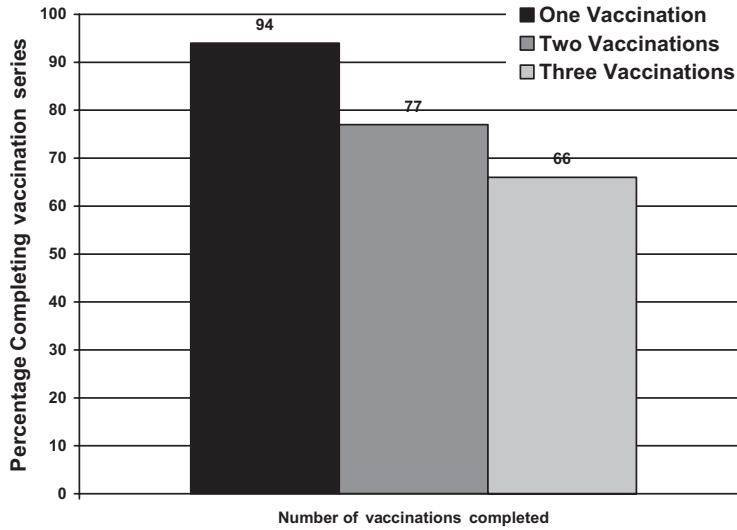

FIGURE. Completion rates of hepatitis B virus (HBV) vaccination series (N = 134).

TABLE 2. Multiple logistic regression analysis of correlates of completing three vaccinations

Characteristic	Odds ratio	95% confidence interval
Age (per year increase)	1.06	1.04–1.07
Injects daily	2.12	1.36–6.73
Homeless	1.99	1.14–12.27

Model includes all variables in Table 1 with $P < .10$.

no need to be vaccinated (n = 4), being too busy (n =2), and wanting to receive vaccination from their primary provider (n = 2). The correlates of completing all three vaccinations in the multiple logistic regression analysis (see Table 2) include older age (6% increased likelihood for each year older), injecting drugs daily (OR = 2.12), and being homeless (OR = 1.99).

DISCUSSION

Four important lessons about IDUs in the setting of an SEP were learned from this study: (1) HBV screening and vaccination is feasible; (2) the majority was eligible for vaccination against HBV; (3) the majority willingly accepted vaccination; and (4) completion of HBV vaccination was high in light of no monetary incentives.

One of the key policy issues regarding SEPs has been their ability to provide more than sterile injecting equipment in exchange for contaminated ones. This includes using SEPs as an entry to drug treatment[14] and health care.[25] Prevention of HBV among IDUs is an important component of health care for this population, and this research suggests that both HBV screening and vaccination are feasible when healthcare is provided onsite at an SEP. The rate of HBV vaccine acceptance (94%) in this study is comparable to acceptance of and return for tuberculin skin test readings (93%)[26] with monetary incentives and compares favorably to acceptance of the one-time influenza (86%) and pneumococcal (70%) vaccination provided at an SEP in New York.[27]

Most IDUs in New Haven using SEP-linked health services were eligible for HBV vaccination. Serologic examination demonstrated that relatively few of these IDUs had vaccination serology compatible with prior HBV vaccination. These findings contrast to other settings where IDUs screened for HBV had higher rates of previous exposure[28–31] or previous vaccination.[20] In the past decade, the prevalence of prior HBV exposure among clients of methadone maintenance programs was 20%–52%.[32,33] This rate is similar to our findings (37%) among active drug injectors in New Haven.

Only 2.8% of these subjects had serological evidence of prior HBV vaccination. Possible explanations for low vaccination among this group include enrolment of older IDUs, recent initiation of drug injection behavior, many immunocompromised individuals, and possible risk reduction practices through the use of the SEP. Routine HBV vaccination at entry to school and at birth has been recommended only for the past one to two decades. For this population whose mean age approaches 40 years, the benefit of early vaccination has not yet been realized, and this emphasizes the importance of vaccinating high-risk individuals irrespective of age. Though not discernible from our data, this population recruited at SEP sites may be more recent initiatives to IDU and therefore had less potential exposure[28]—this would result in fewer individuals with evidence of prior infection.

Immunocompromise can result in decreased efficacy of vaccination.[34] It is unclear from our data how many subjects may have been HIV-infected or who were otherwise immunocompromised from malnutrition. Lastly, the population of IDUs using SEP-based health services may have decreased their risk of HBV exposure by reducing unsafe injection risk behaviors because increased access to uncontaminated injection equipment. Information regarding duration of SEP use was not available to confirm this supposition. Irrespective of the reason, many IDUs in this sample were vaccine-eligible and would have remained at risk of HBV infection if they had not been vaccinated.

To date, there is only one comparable study of HBV vaccination among SEP clients. Of the 97 persons attending an SEP in Anchorage, Alaska, only 74 (76%) of SEP subjects were willing to participate in a HBV screening and vaccination program. This is lower than the 94% acceptance by our subjects. Only 36 (49%) of their subjects were eligible for vaccination. Of these, 30 (83%) received all three vaccinations using monetary incentives—a completion rate that exceeded our rate of 66% using no monetary incentives. The authors of the Alaska study suggest convenient location, and financial incentives explain the high rate of vaccination completion.[35] Carefully controlled randomized trials using monetary incentives to assess HBV vaccination strategies among this population are needed.

In this study, the population of IDUs with prior exposure to HBV tended to include individuals who were injecting daily, of older age, homeless, cocaine users, and black race. In our analysis, it was shown that cocaine use was a surrogate of daily injection and likely explains the higher prior HBV exposure among this group due to repeated use of possibly contaminated injection equipment. Not surprisingly, older drug users are likely to have had longer duration of previous HBV exposure resulting from repeated unprotected sexual and drug use events, a finding that is similar to that of previous studies.[28–30] Despite these findings, it remains of great interest that most IDUs in this study needed vaccination to prevent HBV infection.

Unlike other studies of HBV vaccination among IDUs, two thirds of this SEP-based population adhered to all three HBV vaccinations and over three-quarters completed two vaccinations. This occurred without the use of financial incentives. Our study documented that increased age was correlated with completing the three-part vaccination. Young injectors have previously complied poorly with preventive health behaviors. A study of young IDUs in San Francisco found that only 10% completed the hepatitis B series.[36,37] This poor vaccination completion rate among younger IDUs is even more critical given that the highest incidence rate for HBV infection in the United States is among IDUs aged 15–29 years.[28] Although vaccination in young IDUs is generally suboptimal, at least one study found that many youth are interested in vaccination[38] and another found that 75% of young IDUs completed two vaccinations and 47% completed all three.[39] This higher completion rate was obtained using financial incentives and rigorous outreach.

Although all substance users may not complete all three vaccines, protective levels of antibody may develop after one (30–50%) or two (89%) vaccinations.[40,41] Additionally, the high rates of completion of two vaccinations within 1 month support the use of an accelerated HBV vaccination schedule (immunizations at 0, 7 and 21 days) for IDUs as recommended in 2000.[42] The high rate of completion of two doses, coupled with known benefit from one to two doses of vaccine,[41,42] may suggest that accelerated, high dose vaccination (months 0, 1, and 2) schedules[43] may greatly benefit this population. Accelerated vaccination, however, may not be as

efficacious as standard schedules; at least one study with a 2-month accelerated vaccination (months 0, 1, and 2) schedule found lower rates of seroconversion in response to vaccination, especially in older patients.[44] However, these data are biased because 21.6% of patients who completed vaccination did not show up for their post vaccine assessments to ascertain immune status. Nonetheless, patients who visit SEP-linked sites and obtain either an accelerated vaccination schedule or even a reduced number of vaccinations still stand to benefit patients clinically.

In this study, it is not surprising that older IDUs who inject daily were more likely to complete the HBV series compared with younger IDUs. The reasons for this finding are several-fold. First, SEPs are likely to provide repeated services for older drug users who inject daily.[45–49] This is true for New Haven as well.[21] Second, when SEPs are conveniently located within the neighborhood where IDUs obtain and use illicit drugs, daily drug users are likely to use the SEP repeatedly to obtain clean injecting equipment[50,51] and also access the adjacent CHCV and its outreach services. Third, the user-friendly and nonjudgmental approach used at SEPs allows IDUs to interact with a linked health system they trust that is provided on their own turf. Trust in the health care system, in a study of acceptance of antiretroviral therapy among HIV positive prisoners, was one of the most influential factors associated with initiating HIV medications[52] and participating in clinical trials.[53]

It is unclear why homeless subjects were more likely to complete the vaccination schedule compared to other IDUs. One explanation is that SEPs and the CHCV frequent areas where the homeless tend to congregate, and this provides more opportunities for clients to access both SEP and CHCV services. Additionally, many homeless individuals lack health insurance. Without health insurance, the homeless may not have had any other source of traditional health care and therefore only managed to meet their own health care needs through repeated interactions with the CHCV clinical team. Finally, the SEP and the CHCV provide a nonjudgmental atmosphere where clients feel welcome regardless of housing status. This is reflected by the strong relationships that have developed between the CHCV outreach team and homeless shelters in New Haven.

Some SEPs have noted a greater difficulty in providing continuity of care and noted that vaccination completion rates were higher where clients had continuing relationships with services and where staff training and confidence was better.[23] The SEP-based health care provided by the CHCV is a unique model that offers primary care services and linkage to drug treatment for substance users and community members alike. This comprehensive approach toward health care in a nonjudgmental setting may have improved outcomes compared to other sites whose services may not have evolved to this level of comprehensiveness.

The vaccination completion rate at the SEP site in this study is better[39,54] or comparable[35,55] to that of some studies that link vaccination to other settings, including methadone maintenance programs. A Dutch study screened 1,068 drug users (number of IDUs not differentiated) and found 740 (69%) drug users to be eligible for vaccination. Of these, 615 (83%) obtained two vaccinations, and 430 (58%) completed all three vaccinations. Of these drug users, 494 were screened from methadone clinics, of which 359 were eligible for vaccination; 303 (84%) completed two vaccines and 214 (59%) completed all three.[56] Another study using methadone-maintained substance users in New York City demonstrated that 37 of 43 (86%) patients completed all three vaccinations in 6 months.[55] One might expect a near-perfect vaccination completion rate at an MMTP where daily structure and reminders are available. Our study suggests that SEPs may also provide adequate

structure, social support, and sufficient interaction to implement preventive health care services for IDUs.

This study is not without limitations. First, it is impossible to generalize these findings to all IDUs within a community. It is likely that the individuals who sought health services linked to an SEP were more highly motivated to complete vaccination. Second, data from the CHCV are not linked to the SEP database. We therefore cannot determine if our sample is a probability sample representative of the SEP program. We do know, however, that 21% of subjects had never used the SEP directly (secondary exchangers) and that they felt less stigmatized using the mobile health van to receive preventive health services. This pattern suggests the possibility of destigmatizing SEPs by incorporating them into existing health care services that focus on the health care needs of vulnerable populations. Notwithstanding these limitations, SEP-based health services may play an important role in the prevention of HBV and other health care initiatives.

CONCLUSIONS

Screening for HBV and subsequent vaccination is feasible in the setting of an SEP where onsite healthcare services are provided. Unlike previous reports of the prevalence of HBV exposure, most IDUs in New Haven utilizing health services linked to an SEP, are at risk for and unvaccinated against HBV. If offered, HBV vaccination is acceptable to IDUs and the completion of the standard 6-month vaccination schedule is high without the use of financial incentives. Syringe exchange programs, therefore, are important sites to integrate preventive health care services and interface regularly with IDUs. The provision of health care at SEP sites is one of the important public health interventions that can positively affect the health of IDUs who otherwise do not use traditional sources of clinical and preventive care.

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