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HEPATITIS B VIRUS PREVALENCE AND VACCINATION RATES AMONG HISPANIC INJECTION DRUG USERS PARTICIPATING IN A VACCINATION CAMPAIGN

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Injection drug users are at high risk for hepatitis B virus infections. Nevertheless, few concerted efforts have been made to provide injectors with access to an available, safe, and effective vaccine. A campaign to screen and vaccinate injectors was conducted at syringe exchange programs in Chicago, Illinois, and Hartford and Bridgeport, Connecticut. Injectors with no evidence of past hepatitis B infection were eligible for vaccination. Eligible injectors were offered the three doses of vaccine and questioned about their past and current drug use, their sociodemographics, their understanding of hepatitis infections, and their motivation for participating in the study. Disease prevalence, vaccination rates, and the answers to study questions were analyzed comparing the sample of Hispanic to non-Hispanic injectors. We screened 1970 injectors, 860 of whom were eligible for vaccination. Of those, 591 received at least one dose of the vaccine. Hispanics comprised 30.9% of those screened, 24.9% of those eligible, and 25.2% of those receiving at least one dose. Hispanics were more likely than non-Hispanic Whites or non-Hispanic Blacks to have already been infected with hepatitis B—55.6% for Hispanics versus 46.5% for non-Hispanics. Although it is impossible to generalize from our study population to Hispanic injectors as a whole, it seems apparent that if greater efforts are made to promote hepatitis B vaccination among Hispanics, high rates of vaccination can be achieved.

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INTRODUCTION

Hepatitis B virus (HBV) is a vaccine-preventable infection, and national immunization efforts have significantly decreased the HBV incidence rate (Wasley, Miller, & Finelli, 2006). Nevertheless, certain groups appear to lag in the efforts to reach the goal of universal vaccination. Among these groups are injection drug users (IDUs), the risk group with the highest incidence rate. Given that Hispanics in the U.S. have generally lower than average rates for many vaccinations (Darling, Barker, Shefer, & Chu, 2005; Larson, 2003; Lees, Wortley, & Coughlin, 2005; Winston, Wortley, & Lees, 2006), it is particularly pertinent to explore the extent of HBV infection and vaccination among Hispanic IDUs.

HBV was shown to be the major etiologic agent of serum hepatitis in the late 1960s. A percentage of those infected with HBV, ranging from 20% of those infected as young children to 5% of those infected as adults, go on to develop chronic infection (Nelson & Masters Williams, 2007). Population-based surveys of the United States from the 1990s indicated that the prevalence of HBV infection was slightly higher than 5% (McQuillan et al., 1999). Surveillance of infections has detected more than 525,000 acute infections since record keeping began in 1966. At present, the incidence of acute HBV infection in the United States population as a whole is highest in non-Hispanic blacks (2.9 per 100,000) and lowest in Hispanics (1.0 per 100,000) despite lower than average rates of immunization (Wasley et al., 2006). The discovery of HBV led to an increase in the number of reported HBV incident infections, but also to the implementation of steps to reduce transmission. Since the mid-1980s the incidence of acute HBV infections in the United States has declined from a high of 26,654 cases in 1985 to 6,212 cases in 2004 (Wasley et al., 2006). Screening of the blood supply to prevent HBV transmission through transfusions and blood products began in 1973. The first effective vaccine became available in 1982, and vaccine efficacy has continued to improve, especially with the introduction of safe, reliable vaccines based on recombinant DNA technology (André, 1989). An aggressive campaign to provide children and adolescents universal immunization against HBV was begun in the 1990's. By 2004, greater than 92% of children, ages 19-35 months, had been fully vaccinated, receiving the established three-dose vaccine regimen (Centers for Disease Control and Prevention [CDC], 2005). Despite the implementation of an effective universal vaccination campaign targeting infants and children, only 35% of adults report having been vaccinated (Centers for Disease Control and Prevention [CDC], 2006). The United States lacks an aggressive campaign to vaccinate high-risk adults, which has left gaps in protecting the adult population. The most recent recommendations from the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices recognize the gap but provides no resources to close it, stating only: "In

other primary care and specialty medical settings in which adults at risk for HBV infection receive care, health-care providers should inform all patients about the health benefits of vaccination, including risks for HBV infection and persons for whom vaccination is recommended, and vaccinate adults who report risks for HBV infection and any adults requesting protection from HBV infection...us[ing] available reimbursement mechanisms to remove financial barriers to hepatitis B vaccination” (Mast et al., 2006). The major group at risk due to the lack of aggressive adult vaccination is IDUs.

Injection drug use has long been recognized as a major risk factor for HBV infection (Levine, Vlahov, & Nelson, 1994; Muraskin, 1988). Prevalence rates range from 40% to 90% among IDU populations surveyed (Levine et al., 1994; Murrill et al., 2002). In 2004, 16% of acute infections were in individuals who reported injection drug use (Wasley et al., 2006). This percentage has been constant for many years (Goldstein et al., 2002). Making matters worse, vaccination rates among IDUs are consistently lower than for adults in general. Less than one in four IDUs surveyed reported having been offered vaccination and even fewer had been immunized, as measured serologically (Carey et al., 2005; Heimer et al., 2002; Kuo, Sherman, Thomas, & Strathdee, 2004; Lum et al., 2003; Maqbool, 1998; Seal & Edlin, 2000; Thiede, Hagan, & Murrill, 2000). Calls by medical professionals and government agencies to enhance vaccination rates for IDUs have been plentiful but have not translated into increased vaccine coverage among IDUs (Academy for Educational Development, 2002; Kuo et al., 2004; Mast et al., 2005; Quaglio, Lugoboni, Mezzelani, Des Jarlais, & Lechi, 2005; Rich et al., 2003).

Building on preliminary work from many quarters, we developed an approach to increase vaccination rates among IDUs. First, in order to provide vaccine through venues acceptable to IDUs, we identified syringe exchange programs (SEPs) as existing health promotion programs that interact with and are comfortable providing a range of medical services to IDUs (Bluthenthal, 1998; Grau, Arevalo, Catchpool, & Heimer, 2002; Heimer, 1998; McGregor, Marks, Hayward, Bell, & Slack, 2003; Paone, Clark, Shi, Purchase, & Des Jarlais, 1999). Second, reimbursing participants for getting vaccination has been shown to be an effective strategy, increasing participation rates by three- to ten-fold (Des Jarlais et al., 2001; Seal & Edlin, 2000; Trubatch, Fisher, Cagle, & Fenaughty, 2000). Finally, we chose to compare the standard three-dose schedule (at 0, 1, and 6 months) to an accelerated schedule that administered the final dose after 2 months. In this report, we explore the prevalence of HBV and prior vaccination rates among Hispanic IDUs, as well as the rates at which HBV-susceptible Hispanic IDUs agreed to participate and completed the vaccine series offered by our program.

METHODS

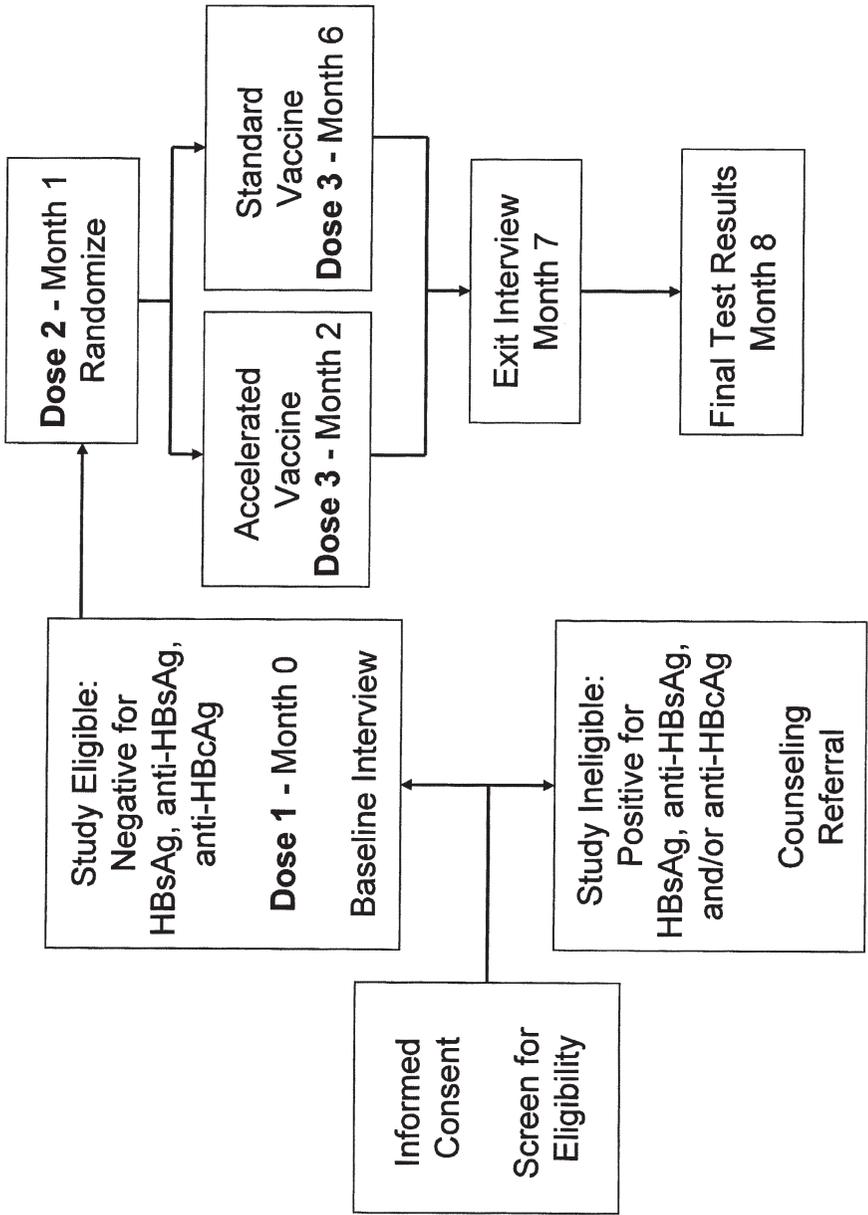
The HBV Vaccination through Syringe Exchange Program Study (HVS) was designed as a randomized controlled trial to compare two schedules for vaccine administration (Figure 1). The campaign was conducted at syringe exchange program locations in Hartford, Connecticut and Chicago, Illinois between October 2003 and March 2006 and in Bridgeport, Connecticut between December 2004 and March 2006. Results of the trial comparing the two arms will be presented elsewhere.

Individuals were introduced to the study by syringe exchange program staff, fellow injectors, and other individuals in the community, as well as through posters displayed on the exchange vans or pamphlets distributed by the exchanges. Participation in HVS was open to all individuals 18 or older who presented evidence of recent injection stigmata. The details of the study were described to eligible participants who were free to consent or decline to participate. Spanish speaking staff were available in each city to assure that individuals who spoke Spanish could be properly informed and consented. The study protocols, along with English and Spanish informed consent documents and HIPAA notification forms, were approved by institutional review boards at all participating research organizations (Yale University, the Hispanic Health Council, DePaul University, and Case Western Reserve University). Participation was anonymous in that no names were collected; each consenting participant provided enough self-identifying data (initials, date of birth, and sex) to allow the generation of a unique identification code to permit longitudinal tracking. Anonymity was further protected by obtaining a Certificate of Confidentiality from NIH to prevent anyone from obtaining identification codes and using them to name participants.

Once consented, individuals provided a blood sample for serological testing marked with the unique participant identifier that was then used throughout the study for tracking the delivery of test results and progress in getting vaccinated. Individuals were instructed to return in two weeks to obtain their test results and receive the first dose of vaccine if testing found them susceptible, i.e., negative for three markers: hepatitis B surface antigen (HBsAg), antibody to hepatitis B surface antigen (anti-HBsAg), and antibody to hepatitis B core antigen (anti-HBcAg). Testing in Illinois was performed by a commercial laboratory; testing in Connecticut was performed in the state-certified AIDS Core Laboratory at the Yale School of Medicine.

Upon return, individuals were informed of their HBV status and its meaning. Those with active infection (anyone testing positive for HBsAg) were referred to syringe exchange staff for assistance in accessing medical care. Those susceptible to HBV infection were administered the first dose of Twinrix® vaccine (SmithKline Beecham, Philadelphia, PA) at this visit and were interviewed. The vaccine, a sterile bivalent biological containing recombinant HBsAg and inactivated hepatitis

FIGURE 1
VACCINATION OF INJECTORS AT SYRINGE EXCHANGE PROGRAMS



A virus, provides safe and effective protection against both hepatitis A and B virus infections. The vaccines were provided free of charge to the study by local and state health departments. Interviews used a forced-choice questionnaire that elicited sociodemographic information, drug use history and practices, medical status, and reasons for getting vaccinated. All participants were instructed to return in one month for their second vaccine shot and interview.

Individuals who returned received the second dose were randomized using a block randomization procedure to one of two dosing schedules, either the standard 0, 1, and 6 month dosing schedule or an accelerated 0, 1, and 2 month schedule. On the basis of the randomization, individuals were instructed to return either one or five months later for their final dose of the vaccine. Individuals who returned for the final dose were asked to give blood and instructed to return seven months after their initial dose to give a final blood sample. These blood samples were used to determine the rate of successful immunization, which is defined as a titer of anti-HBsAg in excess of 0.01 international units international units per ml (10 mIU/ml) of serum in the absence of anti-HBcAg.

Individuals were reimbursed for their participation in the study. These payments varied by site based on what was locally considered to be a fair and reasonable payment for participation in a research study. Chicago paid \$10 for all but the exit visit where they were paid \$20; the Connecticut sites paid \$15 across the board.

Data collected at screening was limited to demographic data (age, sex, race/ethnicity), city of recruitment, and SEP customer status. A more expansive interview was conducted with those receiving the first dose of vaccine. The set of variables was expanded to include more sociodemographic data, data on health service utilization, drug use history and behaviors, sexual risk, hepatitis knowledge, and motivations for vaccination. Motivation was assessed using first a battery of 21 questions assessing hepatitis threat expectancy and vulnerability, self-efficacy, and social norms posed as statements with potential answers on a five-point Likert scale ranging from “disagree strongly” to “agree strongly” and second a set of four questions directly asking about reasons for participating, with potential answers on five-point scale ranging from “not at all important” to “it was the only reason I decided to participate”. The responses to the forced-choice questions were analyzed using SPSS (version 12). Bivariate analyses to detect significant difference between Hispanics and other study participants for each outcome of interest (rate of prior vaccination, prevalence at baseline, rate of completing vaccine series, and rate of successful immunization among those completing vaccine series) employed chi-square tests for categorical variables and one-way ANOVAs for continuous ones. Multivariate analyses were conducted for those outcomes for which Hispanics differed significantly from the other study participants to identify correlated variables.

RESULTS

A total of 1964 active injection drug users completed screening, 1333 in Chicago, 478 in Hartford, and 153 in Bridgeport. Demographic details culled from the limited range of questions asked at screening are presented in Table 1. Individuals who reported themselves of Hispanic ethnicity comprised 202 individuals in Chicago, 304 in Hartford, and 99 in Bridgeport. The higher percentage of Hispanics in the two Connecticut cities is consistent with the population that uses the syringe exchange programs in these three cities as well as the population of the neighborhoods served by these programs (data not shown). Of the 1,964 individuals screened, 1,108 were excluded from vaccination—949 (49.5%) were already infected with HBV, 45 (4.1%) individuals did not provide enough blood for the serological panel, and 114 (5.8%) had already been vaccinated. The last numbers affirm the failure to include IDUs in vaccination campaigns despite the long-standing availability of HBV vaccines. The remaining 860 participants (43.8%) were eligible to be vaccinated.

Of the 1964 IDUs screened, 605 individuals reported their ethnicity as Hispanic. Of these, 322 (53.2%) were positive for the presence of anti-HBcAg, with or without the presence of anti-HBsAg, serological evidence that they had already been infected with HBV (Table 2). This was significantly higher than the anti-HbcAg prevalence of 38.4% among non-Hispanic Whites and 51.4% among non-Hispanic Blacks ($p < 0.001$). Despite the fact that older IDUs in the overall sample were more likely to have been positive for anti-HBcAg ($p < 0.001$), the Hispanic IDUs were on average

TABLE 1
CHARACTERISTICS OF INDIVIDUALS SCREENED FOR HEPATITIS B INFECTION
AND ELIGIBILITY FOR VACCINATION

		Number	Percent
Total		1964	
Sex	Male	1425	72.6
	Female	527	26.8
	Missing	12	0.6
Race/ethnicity	Non-Hispanic White	432	22.0
	Non-Hispanic Black	883	45.0
	Hispanic	605	30.8
	Other/Missing	44	2.2
City	Chicago	1333	67.9
	Hartford	478	24.3
	Bridgeport	153	7.8
Age	<30	304	15.5
	30-39	586	29.8
	40-49	704	35.8
	≥50	370	18.8
Syringe exchange	Customer	1375	70.0
	Non-customer	399	20.3
	Not reported	190	9.7

younger, having a mean age of 36.9 years compared to 40.4 years for the sample as a whole ($p < 0.001$). Hispanics who presented for screening were also more likely than non-Hispanics to have already been vaccinated (Table 2). Hispanics were also more likely than non-Hispanics to be male, younger, and from Hartford (Table 3). In multivariate analysis, however, none of these covariates except residing in Hartford was correlated with the higher baseline prevalence and none were associated with the higher baseline vaccination rates found in Hispanics.

Of the 860 individuals who screened susceptible to HBV, 595 (69.2%) returned for test results and received their first dose of vaccine. Of the 214 Hispanics who were susceptible to HBV infection, 149 (69.6%) returned for the first vaccine dose. Hispanics were no more or less likely than non-Hispanics Whites (61.3%) or Blacks (76.4%) to return to obtain their test results ($p = 0.87$). The reported motivations among Hispanics for participating in the study were no more or less likely to be pecuniary. Over 98% of participants, regardless of ethnicity, reported that they chose to be vaccinated because of the health benefits rather than for the reimbursement offered by the study.

Hispanics were assigned randomly to the standard and accelerated vaccine schedules at proportions equal to non-Hispanics (56.7% assigned to the accelerated arm). Of the individuals who received the first vaccine dose, the percentage of Hispanics receiving the second dose (107 of 149, 71.8%) was lower than for non-Hispanics (353 of 446, 79.1%), but the difference was not significant (Table 2). Of the individuals who received the first vaccine dose, the percentage of Hispanics receiving all three doses (78 of 149, 52.3%) was lower than for non-Hispanics (269 of 446, 60.3%), but again the difference did not achieve statistical significance ($p = 0.090$). Within each arm of the study (standard versus accelerated dosing) there were no significant differences in retention rates as a function of ethnicity.

TABLE 2
HBV PREVALENCE AND VACCINATION STATUS OF HISPANIC VERSUS NON-HISPANIC IDUs

	Hispanic	Non-Hispanic	p Value
Individuals screened	605	1359	--
Already infected (% of Screened)	322 (53.2%)	627 (46.1%)	<0.01
Already vaccinated	48 (7.9%)	66 (4.9%)	<0.01
Eligible for vaccination	214 (35.4%)	646 (47.5%)	<0.001
Returned for first dose (% of eligible)	149 (69.6%)	446 (69.0%)	0.870
Returned for second dose (% of first dose)	107 (71.8%)	353 (79.1%)	0.065
Returned for third dose (% of first dose)	78 (52.3%)	269 (60.3%)	0.085
Returned for follow-up (% of third dose)	48 (61.5%)	188 (69.9%)	0.161

TABLE 3
POTENTIAL CO-VARIATES OF HIGHER HBV PREVALENCE AMONG HISPANIC IDUs

	Hispanic IDUs (n = 605)		Non-Hispanic IDUs (n = 1359)		p value
Sex					
Female	113	(18.7%)	414	(30.5%)	<0.0001
Male	492	(81.3%)	933	(68.7%)	
Missing	0	(0%)	12	(0.8%)	
Age					
<30	117	(19.3%)	187	(13.8%)	<0.0001
30-39	256	(42.3%)	330	(24.3%)	
≥40	232	(38.4%)	842	(62.9%)	
City					
Chicago	201	(33.2%)	1132	(83.3%)	<0.0001
Hartford	305	(50.4%)	173	(12.7%)	
Bridgeport	99	(16.4%)	54	(4.0%)	
SEP Customer					
Yes	413	(68.2%)	962	(70.4%)	0.31
No/Not reported	192	(31.8%)	397	(29.6%)	

Although ethnicity did not predict completing the vaccine series, there are others factors might influence completing a vaccine series that requires three visits over several months. Studies have shown that homelessness among drug users limits their utilization of health care and prevention services (Singer, Himmelgreen, Weeks, Radda, & Martinez, 1997). We tested this hypothesis in our study, but self-reported homelessness was not associated with failure to complete the vaccine series, although residing in a shelter was found to be significant ($p < 0.05$).

Overall, 210 of 236 (89.0%) people who received all three doses and who returned for an exit serology seven months after receiving the first dose exceeded the 10 MIU/ml level of anti-HBsAg that indicates successful immunization. Another 12 (6.1%) people had indeterminate serology indicative of partial protection. Among those receiving all three doses, ethnicity did not predict immunization failure, indicating that completion of the vaccine series was as reliable in protecting Hispanic IDUs from HBV infection as it was in protecting non-Hispanics.

DISCUSSION

The health disparities experienced by all IDUs are exemplified by the high prevalence of HBV infection and the low level of vaccine protection found at entry into our study; while more than one-third of adults in the U.S. population report being vaccinated, less than one quarter of IDUs do, and the actual immunization rates among IDUs are lower still. In the current study, only one in seventeen IDUs presenting for screening had been immunized prior to participating in this study.

This low rate persists despite repeated calls in the public health domain to vaccinate this high-risk population.

The HBV prevalence among Hispanics at screening was higher than among non-Hispanics, but so too was the rate at which they had already been vaccinated when they presented for screening. However, the latter rate was only 7.9%, which left more than four Hispanic IDUs susceptible to HBV infection for every one that had been vaccinated. Among Hispanics, the rate of completing the three-dose vaccine series was slightly, but not significantly, lower. It is interesting to note that this rate is lower even though Hispanics were more likely to have participated in research projects prior to entering this study. The pattern may be explained by the injection patterns among Puerto Rican drug injectors who comprise a high percentage of the Hispanic participants at all sites. It has been found that Puerto Rican IDUs inject more frequently, have less stable residence arrangements, and have lower levels of income (Singer, 1999; Singer & Jia, 1993). Consistent with this is the finding that reliance on a shelter for housing was predictive of failing to complete the vaccine series, even though for this study population self-reported homelessness was not.

Nevertheless, for those who complete the series, ethnicity had no impact of the success of immunization. Therefore, if efforts to increase the retention of Hispanic IDUs in vaccination campaigns can succeed, increased protection of Hispanic IDUs against HBV infection is possible. These efforts will need to appreciate the difficulties encountered by Hispanic IDUs that include the day-to-day demands of securing money and drugs and immediate threats of withdrawal and arrest (Singer, 2006). These can result in a reduced likelihood that they will return for a series of appointments, such as those needed to receive three doses of HBV vaccine.

A major limitation of this study is that the sample is non-representative. It was not our intention to obtain a representative sample of IDUs since our primary goal was to see if a vaccination campaign could attract large numbers of IDUs through low cost, word-of-mouth promotion in communities of IDUs served by syringe exchange programs. It is possible that many IDUs who already knew that they had already been infected or vaccinated might have chosen not to appear for screening. However, many studies have found that IDUs are unlikely to properly report their hepatitis status (Best et al., 1999; Heimer et al., 2002; Kuo et al., 2004). Furthermore, all individuals who passed the initial screening criterion of being an active injector were compensated for their time, so there was no incentive for individuals, regardless of HBV infection status, to eschew screening. Nevertheless, we cannot and do not claim that the rates we observed for previous infection (prevalence) and previous vaccination represent the rates in the populations from which the samples were drawn.

A second limitation is that Hispanics were not recruited in equal number at all three sites. Again, the goal of the campaign was to recruit from the several communities, and the ethnic composition of these communities varies. Our recruitment appears to mirror the ethnic composition of IDUs in the three cities that were part of our study and are comparable to samples accrued in prior studies (Heimer et al., 2002). Another limitation is the small amount of data on individuals collected at screening. Again, this was intentional since our primary aim was to determine the feasibility of using SEPs as sites to enroll IDUs into vaccination campaigns and to maximize the number of individuals screened. The respondent burden at screening was high due to informed consent and phlebotomy procedures, so we kept data collection to a minimum. However, this meant that we have very limited information on individuals who were eligible for vaccination but did not return for their test results and dose one of the vaccine. As a result, it is impossible to assess factors associated with failure to return and use this information to increase the likelihood of return.

One possible approach to increase vaccine coverage, and among Hispanics in particular, is to give the first dose at screening. We observed that the rate of return among susceptible individuals was greater between doses one and two than between screening and dose one even though the period between events was half as long between screening and dose one than between doses one and two. Initiating the vaccine series at screening might have increased the chance that individuals return for follow-up doses.

In conclusion, the vaccination campaign conducted at SEPs revealed a major health disparity faced by Hispanic injectors – pre-existing high prevalence of HBV infection. We further found that the HBV vaccination campaigns at the three syringe exchange programs could begin to overcome this disparity by succeeding in protecting about half the IDUs eligible without differences between Hispanics and non-Hispanics within each arm of the study. Although Hispanics had the lowest rate of completing the series of the three major ethnic groups, the rate of completion was significantly higher than the pre-campaign background rate, an important step in reducing the risks for HBV infection in IDUs. Furthermore, the results have implications for getting Hispanic drug users access to HBV vaccination, most notably the need to work in conjunction with social service agencies, especially homeless shelters, that serve Hispanic IDUs. For the study population as a whole, significant differences in vaccine completion rates between individuals enrolled in the two arms – standard and accelerated – did exist, and these differences will be presented in detail elsewhere.

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