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Variations in Hepatitis B Vaccine Series Completion by Setting Among Adults at Risk in West Virginia

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Abstract

Introduction: West Virginia leads the nation with the highest rate of acute hepatitis B. From 2013 to 2015, the West Virginia hepatitis B Vaccination Pilot Project distributed more than 10,000 doses of hepatitis B vaccine to at-risk adults through local health department clinics and through outreach to correctional facilities and substance use treatment centers. This study aims to determine which setting type is associated with the greatest likelihood of at-risk adults receiving all 3 or at least 2 doses of hepatitis B vaccine.

Methods: Data for this retrospective cohort study were accessed, extracted, and analyzed in 2019 from Pilot Project participant forms initially completed from 2013 to 2015. Odds of receiving all 3 or at least 2 doses were calculated using bivariate, multivariable, and mixed-effects regression models.

Results: Data were available for 1,201 participants. In multivariable logistic regression, participants vaccinated at substance use treatment centers (AOR=1.37, 95% CI=1.01, 1.86) and local health department family planning clinics (AOR=3.74, 95% CI=1.98, 7.06) were more likely to receive the 3-dose series versus those vaccinated at local health department sexually transmitted disease clinics. Participants vaccinated through substance use treatment centers (AOR=1.79, 95% CI=1.31, 2.44), correctional facilities (AOR=3.34, 95% CI=2.09, 5.34), and local health department family planning clinics (AOR=3.97, 95% CI=1.72, 9.16) were more likely to receive at least 2 doses.

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SUPPLEMENTAL MATERIAL

Supplemental materials associated with this article can be found in the online version at <https://doi.org/10.1016/j.amepre.2020.05.022>.

Conclusions: Hepatitis B vaccination delivered at local health department family planning clinics, substance use treatment centers, or correctional facilities may increase vaccine dose completion in West Virginia.

INTRODUCTION

West Virginia (WV) has been disproportionately affected by the opioid crisis, resulting in increased rates of acute hepatitis B virus (HBV) infection.^{1–3} For more than a decade, WV's rate of acute HBV infection has been the highest in the U.S.^{1,2} In 2017, WV's rate was 11.7 per 100,000, almost 12 times higher than the national rate.^{1,2} This increase in acute HBV infections largely is due to substance misuse, including injection drug use.^{2,3}

From 2012 to 2015, the Centers for Disease Control and Prevention (CDC) funded a vaccine pilot program in 14 state and local health departments, including WV, to reduce the number of new HBV infections in at-risk adults.⁴ Adults were vaccinated in settings where universal vaccination is recommended and in specific settings where those with risk factors were typically seen or who were living in communities with an increased incidence of acute HBV infection.^{4,5} As part of the national pilot program, the WV Hepatitis B Vaccination Pilot Program (WV Pilot Project) distributed more than 10,000 doses of HBV vaccine to the 18 counties with higher rates of acute HBV.⁶ Eighteen WV local health departments (LHDs) vaccinated at-risk adults in their own sexually transmitted disease (STD), family planning, vaccine, and other clinics, as well as through expanded outreach to correctional facilities and substance use treatment centers through vaccine delivery partnerships.

The objectives of this study are to determine which setting type is associated with the greatest likelihood of receiving all 3 doses (primary objective) or at least 2 doses (secondary objective) of the 3-dose HBV vaccine series among WV Pilot Project participants vaccinated through WV LHDs. Receipt of at least 2 doses of vaccine is the secondary objective for 2 reasons. First, some protective antibody response is conferred from receipt of just 2 doses of the standard 3-dose series, with approximately 75% of healthy adults achieving HBV antibodies ≥ 10 mIU/mL after receiving 2 doses.^{5,7,8} Second, in 2017, the U.S. Food and Drug Administration approved a new 2-dose HBV vaccine, Heplisav-B, that can be completed in just 4 weeks compared with the minimum of 16 weeks needed to complete the traditional 3-dose series.^{9,10} Therefore, understanding which sites are associated with completion of at least 2 doses of HBV vaccine has implications for future vaccination efforts using either the traditional 3-dose series or the new 2-dose Heplisav-B vaccine.

METHODS

Study Sample

De-identified data for this retrospective cohort study were accessed in 2019 from LHDs that participated in the WV Pilot Project and extracted from available participant forms previously completed from January 2013 through September 2015. This study was approved by the West Virginia University IRB.

The LHDs that received HBV vaccine through the WV Pilot Project were contacted and invited to participate in the study. Vaccine recipients were eligible for inclusion in the study if they received at least 1 dose of vaccine through the WV Pilot Project through an LHD, had not previously started the HBV vaccine series elsewhere, were negative for all HBV lab markers if tested, were not vaccinated at multiple settings, and had available data for both the main exposure variables and vaccine doses administered. A flow chart detailing inclusion criteria for the final sample selection can be found in Figure 1. The 3 participating clinics serving people with HIV were not included in this study.

Measures

The outcome for the primary objective, completion of the 3-dose HBV vaccine series, was defined as a vaccine recipient having received all 3 doses at the appropriate dosing interval with 4 weeks between doses 1 and 2, 8 weeks between doses 2 and 3, and a minimum of 16 weeks between doses 1 and 3.^{11,12} Noncompletion for the primary outcome was defined as receiving 1 or 2 doses. The outcome for the secondary objective was defined as receiving 2 doses of the 3-dose HBV vaccine series; noncompletion was defined as receiving only 1 dose.

The primary exposure variable, setting type, was restricted to the options available to LHDs on the participant form. These included STD and other clinics located at an LHD and LHD outreach to correctional facilities and substance use treatment centers. LHD other clinics included participants vaccinated at any on-site LHD clinic other than the STD clinic. A separate LHD family planning clinic category was derived from the other clinics category owing to the number of participants who were vaccinated at this setting. To receive the HBV vaccine through the WV Pilot Project, participants vaccinated through other clinics, including family planning, were required to have a risk factor; however, people could state they did not wish to answer the risk factor information but would still like to be vaccinated against HBV. Because of differences among LHDs in coding for correctional facilities and substance use centers, the 2 categories were standardized according to the following criteria: settings that included regional jails, drug courts, and day report centers were coded as correctional facility, and inpatient and outpatient drug treatment facilities, methadone, and buprenorphine clinics were coded as substance use treatment center. Additional exposure variables included vaccine recipient sex, age, and race. Age was categorized as 18–29, 30–39, 40–49, and 50 years. Race was categorized as African American or white/other/missing, given most participants identifying as white.

Statistical Analysis

Analyses were completed in 2019. SAS, version 9.4 was used for all analyses with a set to 0.05. Missing data were treated with pair wise deletion. Frequencies and percentages were calculated for all exposure variables and both the primary and secondary outcomes. Chi-square tests were used to assess significant relationships between the exposure variables and the outcomes. Unadjusted ORs with accompanying 95% CIs were calculated using bivariate logistic regressions with logit link and standard selection. Multivariable logistic regressions were used to calculate the AORs with accompanying 95% CIs for the main exposure variable and primary and secondary outcomes controlling for sex, age, and race. Mixed-

effects generalized linear regression models (GLIMMIX) were used to account for the random effects of participants nested within LHDs. Exposure variables from the bivariate and multivariable models were included in the GLIMMIX models.

In this study, ORs are reported in lieu of RRs because of the convergence problems when estimating RR with the complex mixed-effects models. To assess for the possibility of the ORs overestimating the strength of association, a sensitivity analysis was conducted using unadjusted and adjusted RRs and accompanying 95% CIs using generalized linear (GENMOD) models.

RESULTS

Eighteen LHDs received vaccine from 2012 to 2015 through the WV Pilot Project, of which 10 LHDs, representing counties from across the state, had participant forms available in 2019 for inclusion in the study. A total of 1,428 at-risk adults received at least 1 dose of HBV vaccine through the WV Pilot Project. Of the 1,428 participants, 227 were excluded from the analysis, including 191 that started the series at a location other than the LHD or were fully immunized per immunization records, 24 that had laboratory results consistent with past or present HBV infection, and 12 that were vaccinated at multiple sites or their forms could not be located. Overall, 1,201 participants met the inclusion criteria and were included in the analyses, with the number of study-eligible participants vaccinated through each LHD ranging from 26 to 441 (Figure 1 and Appendix Table 1, available online).

A description of the number of participants vaccinated through each of the 10 LHDs by setting type can be found in Appendix Table 1, available online. Nine LHDs vaccinated participants through their on-site STD clinics, 8 vaccinated participants in other on-site LHD clinics, and 2 vaccinated women through on-site LHD family planning clinics. Half of the LHDs vaccinated participants through partnerships with local substance use treatment centers, and 6 collaborated with local correctional facilities.

Most of the participants were vaccinated through LHD STD clinics (46%) or LHD outreach to substance use treatment centers (27.6%) (Table 1). More than half were male (54.5%) and most self-identified their race as white (85%). Approximately three quarters of participants were aged 18–39 years, with almost equal numbers in the 18–29 years (37%) and 30–39 years (36.7%) age groups.

Of the study participants, 36% received all 3 doses of the HBV vaccine series and 64.4% received at least 2 doses (Appendix Table 2, available online). Although most were vaccinated at LHD STD clinics (46%), the highest percentage of 3-dose completion occurred among those vaccinated at LHD family planning clinics (63.3%) and through LHD outreach to substance use treatment centers (41.6%). Additionally, the highest percentage of those receiving at least 2 doses were documented at LHD family planning clinics (85.7%), correctional facilities (80.9%), and substance use treatment centers (72%).

For the primary objective, participants vaccinated at substance use treatment centers (OR=1.34, 95% CI=1.02, 1.78) and LHD family planning clinics (OR=3.25, 95% CI=1.77, 5.97) were significantly more likely to complete the 3-dose HBV vaccine series than those

vaccinated at LHD STD clinics (Table 2). Participants vaccinated through other LHD clinics (OR=0.53, 95% CI=0.34, 0.82) were significantly less likely to receive 3 doses. Women (OR=1.43, 95% CI=1.13, 1.81) and participants aged 30–39 years (OR=1.34, 95% CI=1.01, 1.78), 40–49 years (OR=2.13, 95% CI=1.48, 3.08), and 50 years (OR=2.21, 95% CI=1.50, 3.24) were all significantly more likely to complete the 3-dose series.

For the secondary objective, participants vaccinated at substance use treatment centers (OR=1.90, 95% CI=1.42, 2.55), correctional facilities (OR=3.12, 95% CI=1.98, 4.91), and LHD family planning clinics (OR=4.43, 95% CI=1.96, 10.04) were all significantly more likely to receive at least 2 doses of HBV vaccine than those vaccinated at LHD STD clinics. Again, women (OR=1.37, 95% CI=1.08, 1.75) were significantly more likely to receive at least 2 doses, whereas participants self-identifying as African American (OR=0.82, 95% CI=0.69, 0.98) were less likely to receive at least 2 doses.

In the multivariable logistic regression model, after controlling for sex, age, and race, participants vaccinated at substance use treatment centers (AOR=1.37, 95% CI=1.01, 1.86) and LHD family planning clinics (AOR=3.74, 95% CI=1.98, 7.06) were more likely to complete the 3-dose series, whereas those vaccinated at other LHD clinics (AOR=0.38, 95% CI=0.23, 0.61) were significantly less likely to complete the 3-dose series (Table 3). In this model, older age remained significantly associated with 3-dose completion.

For the secondary outcome, participants vaccinated through substance use treatment centers (AOR=1.79, 95% CI=1.31, 2.44), correctional facilities (AOR=3.34, 95% CI=2.09, 5.34), and LHD family planning clinics (AOR=3.97, 95% CI=1.72, 9.16) were significantly more likely to receive at least 2 doses. Once again, women (AOR=1.44, 95% CI=1.11, 1.86) and participants aged 50 years (AOR=1.83, 95% CI=1.20, 2.78) were also more likely to receive at least 2 doses in the full model.

In the mixed-effects model, after controlling for the LHD as a random effect and sex, age, and race as fixed effects, participants vaccinated at substance use treatment centers (AOR=1.73, 95% CI=1.20, 2.50) and LHD family planning clinics (AOR=3.51, 95% CI=1.63, 7.56) were significantly more likely to receive 3 doses than those vaccinated at LHD STD clinics (Appendix Table 3, available online). In this model, older age remained significantly associated with 3-dose completion.

For the secondary objective, participants vaccinated at substance use treatment centers (AOR=2.12, 95% CI=1.46, 3.09), correctional facilities (AOR=2.94, 95% CI=1.74, 4.96), and LHD family planning clinics (AOR=4.88, 95% CI=1.87, 12.72) were significantly more likely to receive at least 2 doses of HBV vaccine. Women (AOR=1.51, 95% CI=1.11, 2.06) and participants aged 50 years (AOR=1.88, 95% CI=1.18, 3.01) were also significantly more likely to receive at least 2 doses.

Unadjusted and adjusted RR estimates were compared with the calculated OR. In general, the OR closely approximated the RR. Given that ORs and RRs gave similar results that remained significant across both estimates, ORs were deemed an acceptable measure of association for this retrospective cohort study.

DISCUSSION

This is the first study to evaluate the impact of setting on completion of the HBV vaccine series among at-risk individuals vaccinated through WV LHDs, either at their own clinics or through expanded vaccine delivery partnerships in locations serving at-risk adults. In this study, LHD family planning clinics and LHD outreach to substance use treatment centers were associated with increased odds of receiving all 3 doses and at least 2 doses of HBV vaccine compared with LHD STD clinics. Additionally, participants vaccinated through LHD outreach to correctional facilities were more likely to receive at least 2 doses. Differences in receiving either 2 or 3 doses between sites most likely reflect the vaccine delivery setting and the potential for continued future interactions with participants. People attending LHD STD clinics may only have a single visit, whereas women attending a family planning clinic are likely to return at least once a year or more often. Substance use treatment centers and correctional facilities are also settings where clients are likely to have sustained interactions with program staff.

Both in WV and nationally, the greatest number of participants were reached through STD clinics, but the proportion of participants receiving all 3 doses were low.⁴ Although STD clinics provide a way to initiate the HBV vaccine series in many at-risk adults, series completion remains a challenge in this setting. The use of electronic medical records and immunization information systems can potentially generate automatic reminders and flag client charts, so staff can contact individuals for return visits to complete the vaccine series in the future.

In 2016, the 3 most common risk factors among people with acute HBV infection in WV were injection drug use, street drug use, and incarceration.¹³ The percentage of participants receiving at least 2 doses through LHD outreach at correctional facilities including drug court (81%) and substance use treatment centers (72%) indicates that ongoing LHD partnerships with these settings might facilitate their ability to reach more at-risk individuals who need HBV vaccination owing to a history of substance misuse or injection drug use. Harm reduction programs across the state also provide another venue to reach these high-risk individuals. LHDs manage most harm reduction programs in WV; the first LHD syringe services program opened in late 2015, and as of 2020, a total of 16 LHDs offer harm reduction services including testing for injection drug use–related infections and HBV vaccination.¹⁴ Given the risk factors for acute HBV infection in WV, targeting HBV vaccination efforts through substance use treatment centers, correctional facilities, and harm reduction programs, in conjunction with the potential use of the new 2-dose HepB vaccine, would provide protection to a greater number of those with the highest risk of HBV in a shorter period.

A notable finding of this study is that women were significantly more likely to receive all 3 and just 2 doses than men. This, in combination with the increased odds of completion among family planning clinic participants, has important implications for preventing new HBV infections in women of reproductive age. A recent study using national data from Quest Laboratories found a significant increase in the number of reproductive age women in WV testing positive for anti-HBc, a marker of past or current HBV infection.¹⁵ Although the

odds of completing the series were highest among LHD family planning clinic participants, the number of women reached was relatively small compared with other settings. Future vaccination efforts should include screening LHD family planning participants for HBV risk factors. Women with risk factors, or those requesting STD screening as part of their family planning appointment, should be offered testing and vaccination.

Overall, completion of the second and third doses were higher in WV than for other participants in the CDC Pilot Program. In WV, of those who received the first dose, 59% received the second dose, and 32% received all 3 doses.⁴ Completion of the second and third doses for the 6 primarily urban CDC Pilot Program awardees with available data were 40% and 22%, respectively.⁴ The success of the WV Pilot Project may be due in part to the important role LHDs play in rural communities where healthcare access is limited. However, given limited staff and associated vaccine and program costs, the WV LHDs were unable to sustain the WV Pilot Project activities after its conclusion in 2015. Expansion of Medicaid through the Affordable Care Act, along with the increased ability of LHDs to bill for services, may allow for provision of testing and HBV vaccination without additional cost to the client or LHDs in WV.

Limitations

Both a strength and a limitation of this study is the inclusion of participant-level data from 10 of the 18 LHDs participating in the WV Pilot Project. The 10 LHDs included counties from across the state, thus increasing the generalizability of findings; however, despite broad geographic representation, data were only available for 56% of the participating LHDs. Another potential limitation of this study is that data were not collected for research purposes, and the quality of the data varied among LHDs. To help overcome this limitation, settings where vaccines were administered were standardized across the LHDs, but there is still potential for misclassification bias.

CONCLUSIONS

The WV Pilot Project provided more than 10,000 doses of HBV vaccine to adults considered at risk of HBV infection. Targeting vaccine delivery in settings outside of LHD STD clinics may increase vaccine dose completion in WV, thus resulting in more at-risk adults protected against HBV infection. Given that substance misuse and incarceration are the most common risk factors among people with acute HBV infection in WV, future LHD HBV vaccine interventions should prioritize testing and vaccinating in settings serving high-risk adults, including substance use treatment centers, correctional facilities, and harm reduction programs.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Flow chart of sample selection process.

Setting Type and Demographics of WV Pilot Project Participants and Primary and Secondary Outcomes

Table 1.

Variable	All subjects <i>n</i> (%)	Primary outcome		Secondary outcome	
		Received 3 doses ^a		Received at least 2 doses ^a	
		Yes	No	Yes	No
<i>n</i>	1,201	432 (36.0)	769 (64.0)	773 (64.4)	428 (35.6)
Setting type					
LHD—STD clinic	546 (46.0)	189 (34.6)	357 (65.4)	314 (57.5)	232 (42.5)
LHD outreach to substance use treatment center	332 (27.6)	138 (41.6)	194 (58.4)	239 (72.0)	93 (28.0)
LHD outreach to correctional facility	141 (11.7)	45 (31.9)	96 (68.1)	114 (80.9)	27 (19.1)
LHD—other clinic ^c	133 (11.1)	29 (21.8)	104 (78.2)	64 (48.1)	69 (51.9)
LHD—family planning clinic	49 (4.1)	31 (63.3)	18 (36.7)	42 (85.7)	7 (14.3)
Sex					
Male	655 (54.5)	211 (32.2)	444 (67.8)	400 (61.1)	255 (38.9)
Female	546 (45.5)	221 (40.5)	325 (59.5)	373 (68.3)	173 (31.7)
Age, years					
18–29	443 (37.0)	128 (28.9)	315 (71.1)	267 (60.3)	176 (39.7)
30–39	439 (36.7)	155 (35.3)	284 (64.7)	292 (66.5)	147 (33.5)
40–49	168 (14.1)	78 (46.4)	90 (53.6)	113 (67.3)	55 (32.7)
50	146 (12.1)	69 (47.3)	77 (52.7)	97 (66.4)	49 (33.6)
Race					
White, missing, and other	1,093 (91.0)	396 (36.2)	697 (63.8)	715 (65.4)	378 (34.6)
African American	108 (9.0)	36 (33.3)	72 (66.7)	58 (53.7)	50 (46.3)

Note: Boldface indicates statistical significance ($p < 0.05$).

^a Outcome variables are reported as the percentage relative to the row attribute.

^b *p*-value for chi-square test statistic.

^c Includes participants vaccinated in LHD clinics other than STD and family planning.

LHD, local health department; STD, sexually transmitted disease; WV, West Virginia.

Table 2.

Unadjusted ORs for Exposure Variables and Primary and Secondary Objectives

Variable	Primary objective		Secondary objective	
	Received 3 doses OR (95% CI)	p-value	Received at least 2 doses OR (95% CI)	p-value
Setting type				
LHD—STD clinic	1		1	
LHD outreach to substance use treatment center	1.34 (1.02, 1.78)	0.039	1.90 (1.42, 2.55)	<0.001
LHD outreach to correctional facility	0.89 (0.60, 1.32)	0.547	3.12 (1.98, 4.91)	<0.001
LHD—other clinic ^a	0.53 (0.34, 0.82)	0.005	0.69 (0.47, 1.00)	0.05
LHD—family planning clinic	3.25 (1.77, 5.97)	<0.001	4.43 (1.96, 10.04)	<0.001
Sex				
Male	1		1	
Female	1.43 (1.13, 1.81)	0.003	1.37 (1.08, 1.75)	0.009
Age, years				
18–29	1		1	
30–39	1.34 (1.01, 1.78)	0.042	1.31 (1.00, 1.72)	0.055
40–49	2.13 (1.48, 3.08)	<0.001	1.35 (0.93, 1.97)	0.112
50	2.21 (1.50, 3.24)	<0.001	1.31 (0.88, 1.93)	0.184
Race				
White, missing, and other	1		1	
African American	0.88 (0.58, 1.34)	0.549	0.61 (0.41, 0.91)	0.016

Note: Boldface indicates statistical significance ($p < 0.05$).^aIncludes participants vaccinated in LHD clinics other than STD and family planning.

LHD, local health department; STD, sexually transmitted disease.

Table 3.

AORs for Exposure Variables and Primary and Secondary Objectives

Variable	Primary outcome		Secondary outcome	
	AOR (95% CI)	p-value	Received at least 2 doses AOR (95% CI)	p-value
Setting type				
LHD—STD clinic	1		1	
LHD outreach to substance use treatment center	1.37 (1.01, 1.86)	0.041	1.79 (1.31, 2.44)	<0.001
LHD outreach to correctional facility	0.91 (0.60, 1.39)	0.6622	3.34 (2.09, 5.34)	<0.001
LHD—other clinic ^a	0.38 (0.23, 0.61)	<0.001	0.58 (0.39, 0.87)	0.008
LHD—family planning clinic	3.74 (1.98, 7.06)	<0.001	3.97 (1.72, 9.16)	0.001
Sex				
Male	1		1	
Female	1.28 (0.98, 1.66)	0.069	1.44 (1.11, 1.86)	0.006
Age, years				
18–29	1		1	
30–39	1.40 (1.04, 1.89)	0.027	1.21 (0.91, 1.62)	0.196
40–49	2.57 (1.76, 3.77)	<0.001	1.39 (0.94, 2.05)	0.102
50	3.38 (2.23, 5.13)	<0.001	1.83 (1.20, 2.78)	0.005
Race				
White, missing, and other	1		1	
African American	0.92 (0.59, 1.44)	0.729	0.78 (0.52, 1.19)	0.254

Note: Boldface indicates statistical significance ($p < 0.05$).^aIncludes participants vaccinated in LHD clinics other than STD and family planning.

LHD, local health department; STD, sexually transmitted disease.