



# Acceptability and Feasibility of Home-Based Hepatitis B Screening Among Haitian Immigrants

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Accepted: 15 February 2021 / Published online: 9 March 2021

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## Abstract

Hepatitis B (HBV) is endemic in Haiti, therefore Haitian immigrants should be screened to identify and link affected individuals to care. Current screening approaches are ineffective. We assessed the acceptability and feasibility of home-based screening among Haitian immigrants using community health workers (CHWs). We recruited participants exiting a pragmatic trial evaluating strategies to improve care delivery (NCT02970136). Participants completed an acceptability questionnaire. Blood drawn by CHWs at participants' homes or community sites was tested for hepatitis B surface antigen, hepatitis B surface antibody and hepatitis B core antibody. Of 60 participants, 59 found screening acceptable; 53 had blood drawn. Of those, 45.3% had HBV previously, 49.1% remained susceptible and 5.7% were vaccinated. Respondents cited various reasons community members might find screening unacceptable. The high prior HBV rate highlights the need for effective outreach programs. Home-based HBV screening was both acceptable and feasible among Haitian immigrants.

**Keywords** Hepatitis B · Racial disparities · Hepatocellular carcinoma · Haitian immigrants · Liver cancer · Community health workers

## Introduction

Chronic infection with hepatitis B virus (HBV) causes more cases of hepatocellular carcinoma (HCC) than all other causes combined [1, 2]. In the United States (US), nearly two million people are chronically infected with HBV [3, 4]. Immigrant and minority populations are disproportionately affected [4–7]. However, fewer than 30% are aware of their chronic HBV infection [8, 9] Persons

with undiagnosed HBV are not afforded the opportunity to receive antiviral treatment, which mitigates HCC risk. They do not receive appropriate HCC screening and thus present with more advanced cancer which has negative survival implications. Furthermore, infected individuals who have not been screened and diagnosed can unknowingly transmit infection to others. To address these gaps in care, in 2017 the US Department of Health and Human Services (HHS) published the Viral Hepatitis Action Plan [10] which aims to increase the number of persons aware of their HBV infection to 66%. To accomplish this goal, HBV screening must be more widely disseminated.

There are multilevel barriers to screening at-risk persons for HBV. The Centers for Disease Control and Prevention (CDC) [11] and the World Health Organization (WHO) [12] recommend screening in persons born in regions with intermediate seroprevalence, defined as  $\geq 2\%$  hepatitis B surface antigen (HbSAg) seroprevalence. Guidelines also recommend screening other high-risk groups including persons who inject drugs (PWID), men having sex with men (MSM), incarcerated persons, healthcare workers, sex workers, and family members of HBV-infected persons. However, over 40% of primary care providers in a large safety-net healthcare system reported they were unfamiliar with screening guidelines [13]. Physicians are

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more likely to screen persons with behavioral risk factors, but less likely to screen based on birthplace alone [14]. Physician-reported barriers to HBV screening include lack of education among healthcare workers, time constraints, limited expertise in the screening of immigrants and limited patient education [14–16].

Community-engagement and educational efforts have been successful in large communities of immigrants from HBV-endemic regions. Programs like Hep B Free [17, 18], Hep Free NYC [19], and BFreeNYC [20] were generally targeted to Asian immigrants given their disproportionate HBV and HCC risk. Subsequently, HCC incidence declined among Asians in the US, while rising in other races [21]. Smaller-scale educational efforts linked with screening have been successful in African immigrant communities [22–24]. Like many African immigrants, Caribbean immigrants from countries such as Belize, Colombia, Haiti, Jamaica, and the Dominican Republic are also at high risk for HBV infection and its sequelae [23, 25] However, there is no contemporary data about programs targeting Caribbean immigrants to the US [26]. It is unclear whether approaches successful in one immigrant community, e.g. Asian or African immigrants, can be generalized to other communities, as inter- and intra-racial ethnic differences influence health education and behaviors [27].

One particularly high-risk group are Haitians. Previous reports estimated the seroprevalence of chronic HBV in Haiti at 13.5% [28]. Although the US is generally considered to have a low chronic HBV prevalence, 0.27% [28], certain states, like Florida, have a higher disease burden reflecting immigration patterns [29, 30]. South Florida is also home to the largest enclave of Haitian immigrants in the US. In an analysis of HCC patients treated in our center, we noted that Blacks with HBV were less likely to receive HBV treatment prior to HCC diagnosis or HCC screening, compared to other races [31]. Blacks had the lowest overall survival. Stratified by birthplace, Haitian Blacks had the worst survival when compared to other Blacks. We subsequently conducted focus groups in Haitian and US-born Blacks to characterize ethnic differences in perceptions of and barriers to HBV and HCC screening [32]. Focus group participants indicated that lack of awareness, fear, stigma and financial constraints were the greatest barriers to HBV screening. They suggested that community-based screening might circumvent these barriers. Incorporating this feedback, we designed this study to assess the acceptability and feasibility of community-based HBV screening performed by community-health workers (CHWs).

## Methods

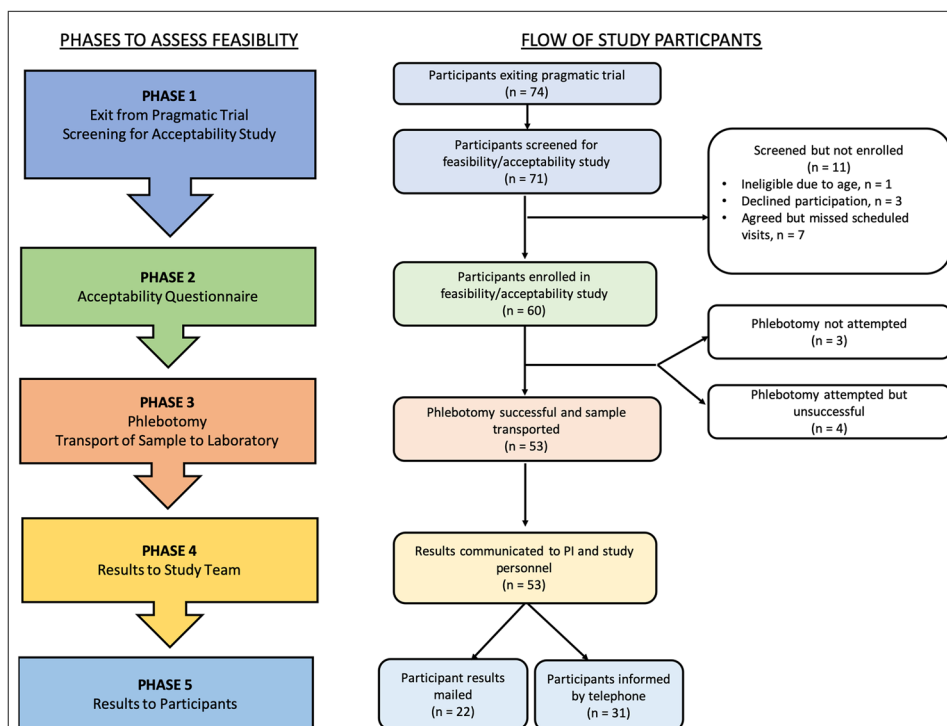
### Participant Recruitment

Study participants were recruited from an ongoing randomized pragmatic comparative effectiveness trial (NCT02970136) that is assessing a variety of strategies to improve delivery of preventive health services to medically underserved immigrant communities. These include screening for human immunodeficiency virus (HIV), hepatitis C virus (HCV), colorectal cancer and cervical cancer (in females). Inclusion and exclusion criteria for the parent trial have been previously described [33]. For the parent trial, participants aged 50–64 years are recruited from three South Florida communities: Hialeah, Little Haiti and Southern Dade County via convenience sampling at community-based locations such as churches, botanicas, markets, and health clinics as well as via the social networks of community partners. After randomization, participants receive CHW-delivered home-based screening versus CHW navigation to primary care clinics. Participants are enrolled for six months and have an average of 2–3 contacts with the CHW. Over the first three years of the parent study, we have enrolled 731 persons. At six months, we have retained 578 persons, e.g. 24% attrition rate. While some of the preventive testing in that study involves fingerstick (HCV), none involved phlebotomy which is needed for HBV. For this supplementary study, we added an additional component focused on screening for Hepatitis B among Haitian participants (given high HBV seroprevalence in Haiti) [28]. To increase efficiency and maximize cost-effectiveness, we conducted this additional assessment when participants were exiting from the parent study. We approached all potential participants for this supplemental study, regardless of whether they had completed screening activities from the parent study. Participants had the option to complete study procedures at their home or a mutually convenient location. We excluded participants with known chronic HBV.

### Measures

Feasibility was measured by participant completion of all study procedures. For this measure, we conceptualized the study as having five phases: (1) exit from the parent study and screening for the pilot study, (2) completion of the acceptability questionnaire, (3) phlebotomy/transport of blood from the community to the University of Miami Core Laboratory, (4) resulting of blood tests, and (5) dissemination of results to participants Fig. 1. Feasibility was determined by calculating the completion rate for each

**Fig. 1** Phases to assess feasibility. The flow of study participants is color-coded to correspond with each respective feasibility phase



study phase. We also assessed feasibility qualitatively by recording technical difficulties and adverse events.

Acceptability was assessed using two approaches. One was the proportion of participants who agreed to be screened. The other was a questionnaire developed by the principal investigator (PDJ) and informed by cognitive debriefing with three Haitian personnel representative of the intended study population from Sylvester Comprehensive Cancer Center's Behavior and Community Shared Resource. The questionnaire was further refined after debriefing and the final version was approved through a process of expert consensus (PDJ, EK, OC). Supplementary Fig. S1. The questionnaire contains four questions and combines closed and open-ended questions to maximally elicit participant perceptions of acceptability. The questionnaire was translated into Haitian Creole by American Translators Association-certified translators.

## Conceptual Framework

Additional analyses were guided by the RE-AIM framework [34, 35] for dimensions of Reach and Effectiveness. Indicators of Reach included recruitment rate, participation rate, and participant characteristics, specifically representativeness of the study population to the wider community. Indicators of Effectiveness include the screening rate and results relative to our hypothesis. Based on an estimate published in 2016 [28], we hypothesized that the prevalence of active

HBV in our sample would approximate 10%. Based on a cross-sectional serosurvey of pregnant women in Haiti [36], we hypothesized that the prevalence of prior HBV infection among participants would approximate 35%. We evaluated other Effectiveness indicators by assessing for potentially negative outcomes such as worsened quality of life or increased anxiety.

## Study Procedures and Data Collection

After obtaining informed consent, CHWs administered the acceptability questionnaire. The last question assessed willingness to have blood drawn. In those who agreed, blood was drawn by the CHW, a certified phlebotomist. Using aseptic technique, 3–5 mL of blood was collected. After coagulating for 10 min, blood was centrifuged for 10–20 min using a Cole-Parmer® FS-3500 Portable Centrifuge (Vernon Hills, IL, USA). Samples were transported to the UM Core Laboratory for processing. All samples were tested for hepatitis B surface antigen (HbSAg) using Elecsys® HbSAg II immunoassay, hepatitis B surface antibody (HbSAb) using Elecsys® Anti-HBs II immunoassay by Roche Diagnostics (Pleasanton, CA, USA) and total hepatitis B core antibody (HbCAb) using the VITROS® Anti-Hbc immunoassay by Ortho-Clinical Diagnostics (Raritan, NJ, USA). Results were securely faxed to the PI, who interpreted and communicated results to CHWs. At enrollment, we ascertained participants' preferred method for results. Participants who preferred telephone calls were called by the CHW. Others were mailed

a standard form letter with results and guidance tailored to their HBV serostatus via USPS Certified Mail. (Supplementary Fig S2) Participants received a \$10 cash incentive. This was in addition to the \$25 incentive they received for being in the parent study.

## Analysis

For continuous variables, we report mean and standard deviation. We used Student's *t*-tests to evaluate differences. Categorical variables are presented as counts and percentages. We used Pearson's chi-square test to examine associations between baseline characteristics, randomization arm, and gender. Fisher's exact test was utilized when chi-square assumptions of cell counts were violated. In above analyses, *p*-values  $\leq 0.05$  were statistically significant. Data was analyzed using Statistical Analysis System (SAS) University Edition 3.8 (Cary, NC).

## Ethical Approvals

This study was approved by the Institutional Review Board at the University of Miami Miller School of Medicine. It was also presented for input and feedback to UM's Sylvester Comprehensive Cancer Center (SCCC) Community Advisory Board.

## Results

### Baseline Characteristics

We screened 71 persons and enrolled 60 participants in this supplemental study. Most assessments were done at the participant's home but 9 chose to complete study procedures at the Center for Haitian Studies, Health and Human Services (CHS) a longstanding community partner of SCCC. Median age was  $59.5 \pm 4.1$  years and 75% of the sample was female. Further, 74% had not completed high school and 50% were unemployed. Mean number of years living in the US was  $18.1 \pm 13.8$  and 97% indicated that Haitian Creole was their preferred language. There were no significant differences in gender or age when comparing those who enrolled in the study to those who did not enroll. See Table 1 for details.

### Feasibility of Home-Based HBV Screening

In Phase 1, 74 participants exited the parent study and 71 participants, 95.9%, were screened for the pilot study. See Fig. 1. Of 71 persons screened, 60 participants enrolled in the pilot study, an enrollment rate of 84.5%. Phase 2 evaluated feasibility of assessing acceptability; 100%

completed the acceptability questionnaire and 98.3% indicated that proposed screening procedures were acceptable.

There were minor technical challenges in Phase 3. The phlebotomy failure rate was 5.4%. Per initial standard operating procedures (SOP), CHWs transported the portable centrifuge to each participant's home with plans to centrifuge blood there. However, an interim feasibility assessment conducted after the first three study visits revealed that some homes were poorly equipped for centrifugation due to lack of appropriate outlets, electricity and/or crowded living conditions. Additionally, CHWs reported discomfort spending 10–20 additional minutes in participants' homes solely for centrifugation since all other study procedures were complete. After consultation with laboratory personnel, we ascertained that centrifugation could be delayed (30 min) without adversely affecting test performance. Ultimately, we housed the portable centrifuge at CHS. From the participants' homes, CHWs transported blood to CHS for centrifugation prior to delivery to the UM Core Laboratory.

All assays were performed in each participant undergoing phlebotomy. All results were interpretable. Results were securely faxed to the PI without incident in Phase 4 and disseminated to participants in Phase 5. Thirty-one participants requested telephone calls and CHWs informed each of their results by telephone. Letters were mailed to the 22 participants requesting results by mail. There were no reports of increased anxiety due to study procedures or notification of HBV serostatus.

### Acceptability of Home-Based HBV Screening:

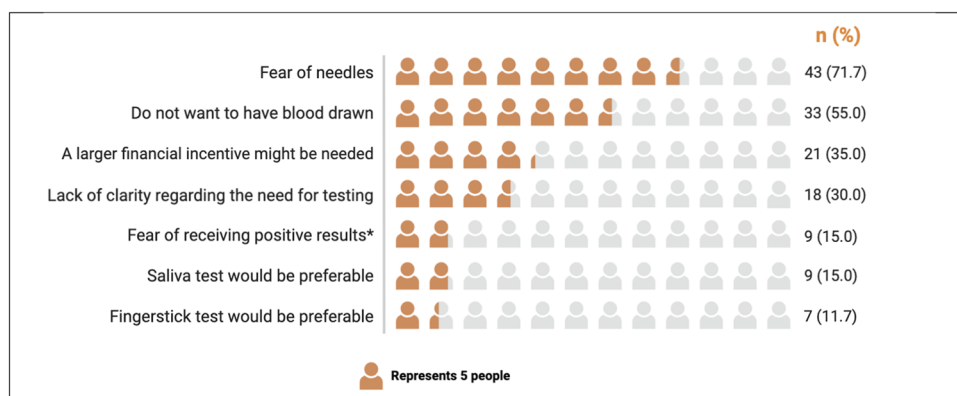
Fifty-seven participants, or 95% of the sample who agreed to enroll in the study also agreed to have blood drawn for HBV screening. Of the three who declined, one noted they were afraid of needles. However, they stated that a fingerstick and/or a saliva test would increase their willingness to complete HBV screening. The other two who declined cited prior HBV screening as the reason. We then asked participants to indicate why other community members might be uncomfortable with CHW-delivered HBV screening. Participants selected all applicable responses and provided open-ended responses. While 98% indicated that community-based screening was acceptable, fear of needles and the desire to avoid blood draws were the top reasons participants thought other community members might find community-based HBV screening unacceptable. Additionally, 30% indicated that lack of clarity regarding the rationale for screening might limit acceptability among community members. More men, 60%, chose this response compared to women, 20%, *p* 0.007. In open-ended responses, 15% of participants suggested that fear of receiving positive results might discourage community members from screening. Only

**Table 1** Demographic Characteristics of Participants, Overall and Stratified by Gender

Variable	Overall (n=60)	Male (n=15)	Female (n=45)	p-value
Age, years Mean (Standard Deviation)	58.5 (4.1)	58.5 (3.8)	58.5 (4.2)	0.97
Years since immigration to the United States Mean (Standard Deviation)	18.1 (13.8)	24 (15.2)	15.7 (12.7)	0.05
Preferred Language, n (%)				0.56
English	2 (3.3)	0	2 (4.4)	
Haitian Creole	58 (96.7)	15 (100)	43 (95.6)	
Employment Status, n (%)				0.21
Employed for wages	30 (50)	10 (66.7)	20 (44.4)	
Out of work for over 1 year	17 (28.3)	2 (13.3)	15 (33.3)	
Out of work for less than 1 year	4 (6.7)	0	4 (8.9)	
Homemaker	1 (1.7)	0	1 (2.2)	
Retired	3 (5)	2 (13.3)	1 (2.2)	
Unable to work	5 (8.3)	1 (6.7)	4 (8.9)	
Highest grade completed, n (%)				0.26
Never attended school/kindergarten	1 (1.7)	0	1 (2.2)	
Grades 1–8	24 (40)	8 (53.3)	16 (35.6)	
Grades 9–11	19 (31.7)	3 (20)	16 (35.6)	
Grade 12/ GED	10 (16.7)	1 (6.7)	9 (20)	
Some college or technical school	1 (1.7)	1 (6.7)	0	
College graduate	2 (3.3)	1 (6.7)	1 (2.2)	
Graduate school	3 (5)	1 (6.7)	2 (4.4)	
Randomization arm in pragmatic trial, n (%)				0.29
CHW Screening	35 (58.3)	7 (46.7)	28 (62.2)	
CHW Navigation	25 (41.7)	8 (53.3)	17 (37.8)	
Completed HCV Screening, n (%)	56 (93.3)	14 (93.3)	42 (93.3)	1
HCV antibody reactive, n (%)	2 (3.64)	1 (7.1)	1 (2.4)	0.45
Completed HIV Screening, n (%)	40 (75.5)	10 (76.9)	30 (75)	1

CHWCommunity Health Worker, GEDGeneral Education Development, HCVHepatitis C, HIVHuman Immunodeficiency Virus

**Fig. 2** Top reasons community members might find HBV screening unacceptable. The asterisk denotes the top open-ended response regarding acceptability



one participant suggested that concerns about confidentiality might cause others to avoid community-based HBV screening. See Fig. 2 for participant responses.

**Prevalence of Prior HBV Infection**

Although 57 participants agreed to phlebotomy, attempts were unsuccessful in 3 participants. One participant agreed to phlebotomy at a later date but was not scheduled despite



repeated attempts. Fifty-three participants were screened using hepatitis B surface antigen, hepatitis B surface antibody and total hepatitis B core antibody and 24 participants, 45.3% of the sample, had evidence of prior HBV infection. Of those with prior infection, 83% were immune while 17% were not. The prevalence of prior HBV was higher among men, 64.3%, vs women, 38.5% However, sample size constraints limited statistical power to detect differences. Three participants, 5.7%, had immunity to HBV through vaccination. Twenty-six participants, 49.1%, had no serological evidence of prior infection or vaccination and were therefore vulnerable to infection. See Fig. 3. See Supplementary Table S1 for baseline characteristics of the sample stratified by HBV serostatus.

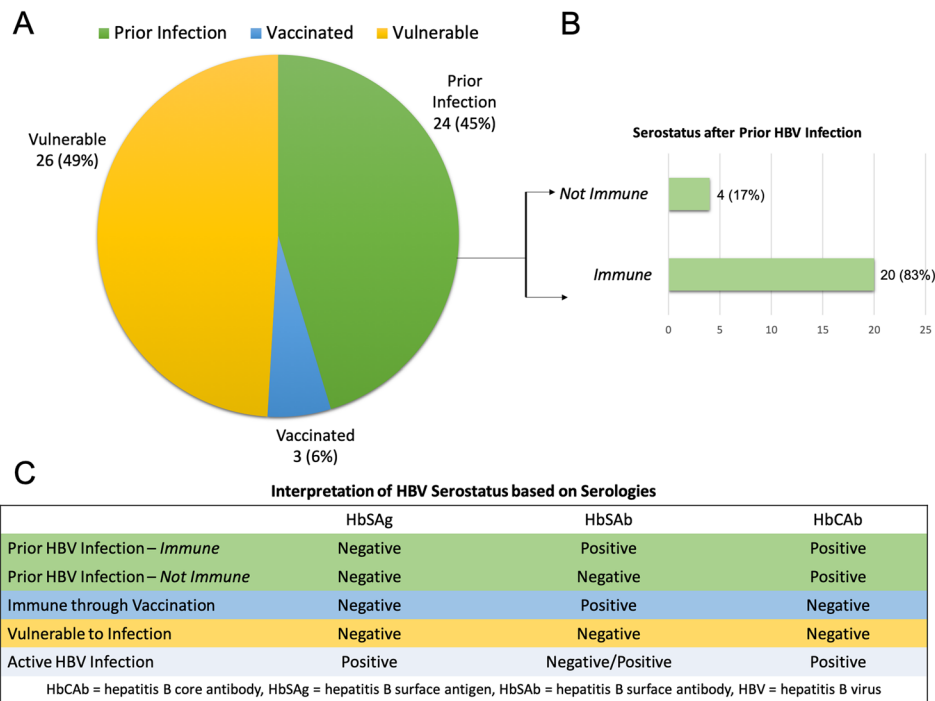
### Discussion

Our study demonstrates that CHW-performed home-based HBV screening was feasible among Haitian immigrants living in South Florida. The completion rate for each phase exceeded 95%, including dissemination of results. Due to our strong relationship with CHS, we overcame the only logistical challenge, which was related to where samples would be centrifuged. Ultimately a centralized location for centrifugation increased CHW comfort with study procedures and improved efficiency. Our study was also acceptable for the population as 95% of participants agreed to be screened.

We also found that the prevalence of prior HBV infection in our sample was 45%. However, no participants had active HBV. Prevalence data for HBV among Haitian immigrants in the US is limited; the most recent report is from 1985 [26]. Based on an estimate from 2016 by Schweitzer et al.[28], we hypothesized that our sample’s prevalence of active HBV would approximate 10%. Schweitzer’s estimate, 13.5%, was based on two studies published in 1989 and 1992 [37–39] with combined sample size of 155. More recent studies suggest lower HBV prevalence, ranging from 2.5% in one study of approximately 1300 samples [36] to 5% in a study testing over 7,000 samples [40]. The largest serosurvey conducted to date among blood donors in Haiti, n = 198,758, estimated the prevalence of active HBV at 3.8% [41]. However, this study’s unit of analysis was the sample, not the individual. Because each individual can donate multiple samples, we cannot accurately determine the direction of bias. Furthermore, this serosurvey encompassed the catastrophic 2010 earthquake and included external donations, which also influenced estimates. Regardless, HBV accounted for 37–46% of transfusion-transmissible infections during this timeframe, 2005–2014, highlighting the significant disease burden [41].

Even with conservative estimates, HBV rates in Haiti are higher than neighboring nations [37, 42] and seroprevalence is intermediate. Thus, Haitian immigrants should receive HBV screening. Although we did not find any cases of active HBV, our finding that 45% had prior infection is of concern. Informed by prior studies from Haiti [36], we expected the prevalence of prior HBV to be 35% or lower. Our findings

**Fig. 3** **a** illustrates the number and percentage of screened participants with prior infection, immunity to HBV through vaccination, and vulnerability to HBV. **b** shows the number and percent of those with immune vs. non-immune status in previously infected participants. **c** shows how serostatus is interpreted based on HbSAg, HbSAb and HbCAb results



highlight the need for targeted HBV screening programs in this community. Yet despite clear guidelines [11] recommending screening in persons born where HBV endemicity is intermediate, only 3.3% of our sample reported previous screening. Furthermore, only 5.7% of this high-risk sample had been previously vaccinated while 49.1% had not been vaccinated, and thus remained vulnerable.

Although we found high acceptability, participants clearly indicated that a point of care (POC) test that was blood-based via fingerstick or saliva-based would increase acceptability. Prior reports on POC assays have shown 99% sensitivity and specificity that exceeded 95% [43, 44]. While such tests are currently commercially available in other countries, no POC assays have been approved by the Food and Drug Administration (FDA) [45]. Another advantage of POC testing is cost. Prior studies suggest phlebotomy is five times more expensive than POC testing [46]. While POC test costs range from \$0.30 to \$2.00 USD, in our study we were charged \$11.26 to run HbSAg alone which includes laboratory but not personnel costs. While a POC HBV testing would enhance the feasibility and cost of community-based HBV screening, such testing remains inaccessible in the US.

One caveat of our findings is that participants were already enrolled in a study requiring engagement with most participants already having had 2–3 prior visits over the six months with the Haitian CHW. Therefore, our sample might more readily agree to phlebotomy due to the CHW-participant relationship forged of the parent study, suggesting that having a health care worker who is trusted also helps maximize completion rates. We acknowledge that the small sample size of our study is a limitation. Additionally, our study was comprised mostly of women, reflective of enrollment of the parent study at the time that the supplemental study was conducted. This, and small sample size, limited our ability to characterize gender differences in HBV serostatus. Furthermore, generalizability to the larger Haitian immigrant community in other parts of the US may also be limited, thus larger subsequent studies with greater gender and geographic diversity may be needed.

## Conclusion

Worldwide, chronic HBV is the leading cause of HCC. The HHS Viral Hepatitis Action Plan [10] aims to reduce health disparities, reduce deaths, and improve the health in people living with viral hepatitis. However, there are substantial barriers to HBV screening on the patient, provider, health system and community levels. Our study found that that using CHWs to conduct HBV screening was both feasible and acceptable to Haitian immigrants, a community disproportionately affected by HBV. These findings suggest that

such community-based screening in vulnerable communities may help address existing gaps in HBV screening.

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s10903-021-01165-z>.

**Acknowledgements** The authors acknowledge members of the Behavioral and Community-Based Research Shared Resource for assisting with study recruitment and procedures. We also acknowledge our participants as well as staff at the Center for Haitian Studies, Health and Human Services. The salary for PDJ was partially supported by a Diversity Supplement awarded by the National Institutes of Health (NIH) National Institute on Minority Health and Health Disparities U01MD010614-01S1. Also, OC and EK receive partial salary support through U01MD010614. Patient incentives were also made possible through this grant. The NIH was not involved in study design or in the collection, analysis or interpretation of data. Further, the NIH did not contribute to the writing of this manuscript or decision to submit for publication.

## Declarations

**Conflict of Interest** None.

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