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BRIEF REPORT

Enhancing Hepatitis B Virus Vaccine Uptake and Immunity Through Long-Acting Antiretroviral Therapy Programmatic Synergy in the US South

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We leveraged a long-acting antiretroviral therapy program infrastructure in the US South to vaccinate 32 of 39 (82%) eligible persons with HIV against hepatitis B virus. Novel interprofessional programmatic synergy may facilitate hepatitis B virus vaccine uptake in a population uniquely at risk in the era of 2-drug and injectable antiretroviral therapy.

Keywords. hepatitis B virus vaccination; interprofessional team-based HIV care; long-acting injectable antiretroviral therapy; persons with HIV; synergistic programming.

As compared with the general population, persons with HIV (PWH) are at increased risk of HBV acquisition and progression to chronic infection [1, 2]. Up to 10% of PWH have HBV coinfection, in whom HBV-associated liver disease can be accelerated, leading to higher rates of cirrhosis, hepatocellular carcinoma, and liver-related deaths [1]. HBV is preventable by vaccination, which is universally recommended for PWH without evidence of prior infection or immunity [3]. However, despite widespread availability, HBV vaccination uptake remains low: 10% to 28% of eligible patients in HIV care have completed a 3-dose series [4, 5]. Furthermore, PWH vs the general population have lower response rates following standard HBV vaccine series (18%–71% vs 90%–95%) [6, 7], and vaccine-induced immunity wanes more rapidly [8–10].

Cabotegravir/rilpivirine (CAB/RPV) is the first and only long-acting injectable (LAI) antiretroviral therapy (ART) approved for use as a complete HIV-1 treatment regimen [11]. This novel treatment strategy offers clinical, psychosocial, and public health benefits for PWH and those at risk [12–14]. However, emerging data reveal that switching to 2-drug ART without HBV activity may increase the risk of HBV infection and/or reactivation in those with native susceptibility, waned vaccine-induced immunity, and/or isolated core antibody (cAb) positivity [15–18]. It is therefore critical to assess HBV immunity among PWH who are interested in using LAI-CAB/RPV and to vaccinate nonimmune persons to minimize HBV coinfection burden [3, 11].

We describe and evaluate the integration of an HBV vaccine initiative into a long-acting ART program at the largest Ryan White–funded clinic in the southeastern United States.

METHODS

The Grady Ponce de Leon Center serves >6000 PWH in metropolitan Atlanta, a population with disproportionate social determinants of health. We implemented a long-acting ART program in April 2021, for which additional details on development, staffing, and workflow have been published [19, 20]. In brief, providers referred patients who were interested in using LAI-CAB/RPV to a centralized interprofessional team (clinician, pharmacy, nursing, program management, patient navigation) who verified clinical and programmatic eligibility and coordinated medication authorization and injection administration, adherence, tolerability, and virologic monitoring for eligible patients [19, 20]. LAI-CAB/RPV was primarily prescribed on-label until 2023 when we adapted our protocol to offer LAI-CAB/RPV ± lenacapavir (collectively referred to as LAI-ART henceforth) to individuals with HIV-1 viremia and/or persistent difficulty taking oral ART.

Herein, we performed a retrospective analysis of data collected among PWH who initiated LAI-ART from 14 April 2021 to 4 March 2024, with follow-up assessed through 30 September 2024. We report the outcomes of integrating HBV immunity assessment and vaccination into the long-acting ART program infrastructure and patient HBV status, including serologic data, vaccination status, postvaccination results, and HBV incidence at end of follow-up. Integrating the HBV prevention initiative was facilitated by leveraging existing long-acting ART programmatic resources, including our interprofessional team (details previously published [19, 20]) and our customized electronic medical record–integrated population health database (adapted from the Grady HIV prevention program in collaboration with its medical leadership [21]). This database includes

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Table 1. Baseline HBV Status by Serologic Data and Immunization History Among Persons With HIV Initiating Long-Acting Injectable CAB/RPV ± Lenacapavir at a Ryan White–Funded Clinic in Atlanta, Georgia Informing HBV Vaccination Plans

	Patients, No. (%)					
HBV Serology[a]	Total (n = 109)	HBV Vaccination Previously Documented	Needing Updated Serologies[b] (n = 47)	Results of Updated Serologies	No. of Patients Needing HBV Vaccine[c] (n = 39)	Follow-up Status of Patients Prioritized for HBV Vaccine Based on Integrated Program Initiative
Vaccine immunity: sAb^+	51 (47)	51/51	21/51	20 sAb^+; 1 sAb^-	1	1 completed vax, follow-up sAb^+
Natural immunity: sAb^+/cAb^+	18 (17)	NA	16/18	14 sAb^+/cAb^+; 2 sAb^-	2	1 completed vax, follow-up sAb^-, revax 1 vax series ongoing
Isolated cAb^+	4 (4)	2/4	2/4	2 cAb^+	4	2 completed vax, follow-up sAb^+ 1 completed vax, follow-up sAb pending 1 vax series pending CD4 ≥200 cells/mm^3
HBV susceptible: $sAb^-/cAb^-/sAg^-$	29 (27)	20/29	3/29	3 sAb^+: vax completed prior to program entry	26	12 completed vax, follow-up sAb^+ 1 completed vax, follow-up sAb pending 7 vax series ongoing 5 vax series pending CD4 ≥200 cells/mm^3 1 incident HBV infection[d]
HBV sAb indeterminant	4 (4)	4/4	2/4	2 sAb indeterminant	4	2 completed vax, follow-up sAb^+ 1 completed vax, follow-up sAb pending 1 vax series ongoing
Serologies unknown	3 (3)	2/3	3/3	1 sAb^+; 2 $sAb^-/cAb^-/sAg^-$	2	2 completed vax, follow-up sAb^+

Abbreviations: ART, antiretroviral therapy; cAb, core antibody; CAB/RPV, cabotegravir/rilpivirine; HBV, hepatitis B virus; sAb, surface antibody; sAg, surface antigen; vax, vaccination.

[a]Classification at long-acting injectable ART initiation. Only qualitative HBV sAb was available for testing in this clinical setting (institutional positivity threshold, ≥12 mIU/mL).

[b]Either due to HBV serologies last obtained ≥5 years or not yet repeated after a completed HBV vaccination series prior to program entry. Updated HBV serology results were then used to determine the next HBV step for patients, as shown in the final column.

[c]Total number incorporates number of patients in need of vaccination based on original and updated HBV serologies.

[d]Occurred in a patient who initiated long-acting injectable CAB/RPV plus lenacapavir in the setting of a CD4 count and percentage of 15 cells/mm^3 and 1% with an HIV-1 RNA of 2.7 log and severe malabsorption from *Cryptosporidium*. At the end of study follow-up, HIV-1 RNA was not detected, and the CD4 count and percentage were 156 cells/mm^3 and 8%.

clinical and care coordination metrics to facilitate interprofessional team–based care of patients referred and enrolled into the program and serves as a registry to support real-time centralized monitoring and tracking of relevant data among patients using LAI-ART [21, 22].

For patients initiating LAI-ART, an HIV-trained advanced practice provider (E. O.) led the process of assessing HBV status and formulating an appropriate HBV care plan. HBV status was assessed by using immunization history and serologic data (ie, surface antibody [sAb], cAb, surface antigen [sAg]). If HBV serologies were measured ≥5 years ago or were not repeated after completion of an HBV vaccine series prior to program entry, they were updated to assess for incident exposure and/or waned immunity. PWH who were nonimmune to HBV ($sAb^-/cAb^-/sAg^-$ or isolated cAb^+) were prioritized for vaccination if their CD4 count was ≥200 cells/mm^3; those with CD4 levels <200 cells/mm^3 were deferred pending soon institutional availability of the more effective adjuvant vs the currently available recombinant HBV vaccine [23]. A 3-dose series of Recombivax HB was administered intramuscularly at 0, 1 or 2, and 6 months; administration of the second HBV vaccine dose at 1 or 2 months was determined by the patient's 4- or 8-week LAI-ART dosing schedule so they could be synchronized. Each HBV vaccine dose was 40 mcg/1 mL (for patients ≥18 years old) or 10 mcg/1 mL (<18 years old, n = 1). The full vaccine series vs single-dose boosting was administered, regardless of PWH having evidence of waned vaccine-induced immunity or isolated cAb^+ given the unavailability of quantitative sAb monitoring. A qualitative sAb was measured 4 to 8 weeks after vaccine series completion to evaluate the serologic response (institutional positivity threshold, ≥12 mIU/mL).

HBV care plans were operationalized via the electronic medical record–integrated population health registry, which facilitated interprofessional collaboration, including communication with nursing staff who provided HBV vaccine education and administration and obtained laboratory results for serologic monitoring. To minimize visit burden and maximize vaccine uptake and completion, these activities were synchronized with the patient's LAI-ART visit schedule every 4 or 8 weeks.

Patient Consent

The Emory University institutional review board approved a waiver of informed consent and Health Insurance Portability and Accountability Act authorization for this study.

RESULTS

A total of 115 PWH initiated LAI-ART, including 5 with lenacapavir augmentation. Among 109 (95%) who persisted on LAI-ART, the median age was 35 years (IQR, 28–47) at the time of initiation, and 90% identified as Black, 28% as cisgender

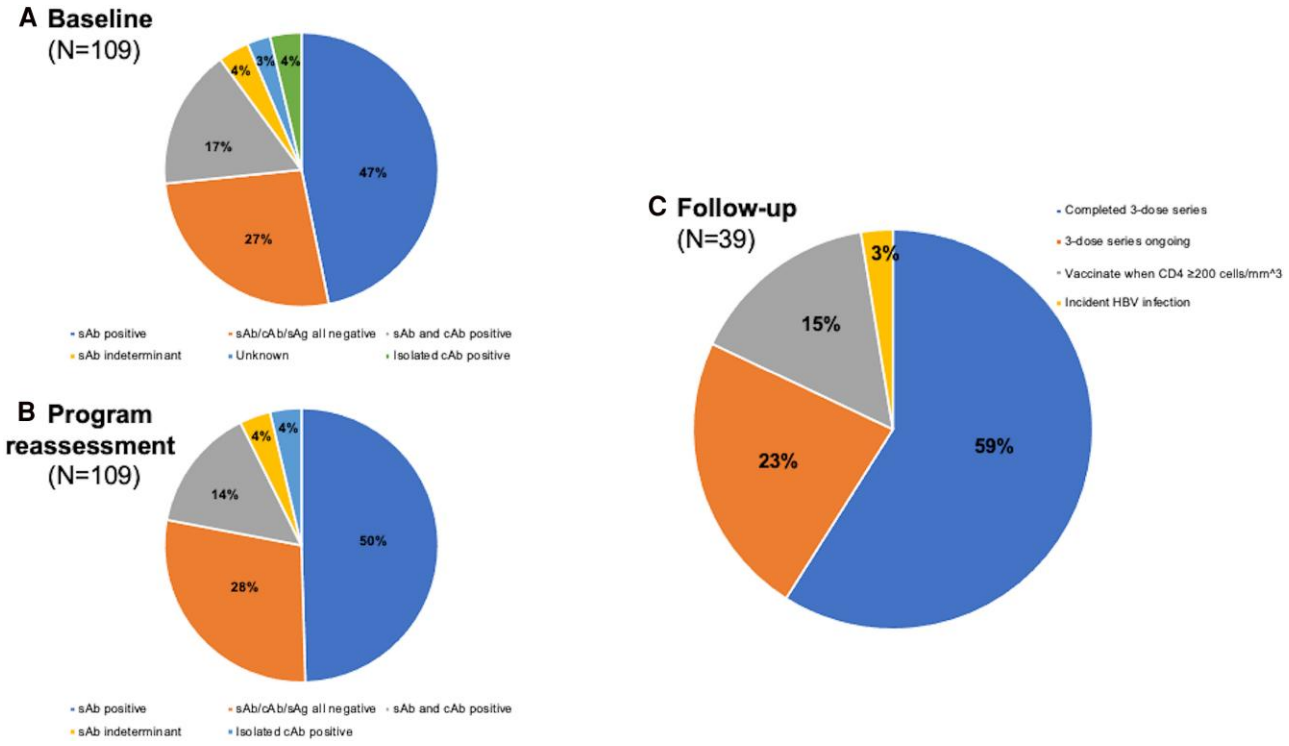

Figure 1. *A*, Baseline hepatitis B virus (HBV) immunity assessment upon referral is shown among 109 persons with HIV who initiated long-acting injectable antiretroviral therapy from 2021 to 2024 at a Ryan White–funded clinic in Atlanta, Georgia. *B*, Slight shifts in HBV categorization occurred after reassessment for those with HBV serologies that were measured ≥5 years since program entry or were not repeated after HBV vaccination prior to program enrollment. *C*, Among 39 individuals identified as HBV susceptible upon initiation of long-acting injectable antiretroviral therapy, 32 (82%) completed or initiated a vaccination series by end of follow-up (30 September 2024). cAb, core antibody; sAb, surface antibody; sAg, surface antigen.

women, and 8% as transgender women. The median CD4 count and percentage were 494 cells/mm^3 (IQR, 282–753) and 28% (IQR, 19%–37%). Table 1 summarizes HBV status upon initiation, program reassessment, and end of follow-up.

Of 109 PWH upon LAI-ART initiation, 51 (47%) had evidence of HBV vaccine-induced immunity (sAb$^+$); 18 (17%) had natural immunity (sAb$^+$/cAb$^+$); 4 (4%) had isolated cAb$^+$; 29 (27%) had no evidence of HBV infection or immunity (sAb$^-$/cAb$^-$/sAg$^-$) and were presumed HBV naive; 4 (4%) had indeterminant sAb; and 3 (3%) had unknown serologies (Figure 1*A*). Of 29 PWH presumed to be HBV naive, 20 (69%) had documented previous HBV vaccination.

Of 109 PWH, 47 (43%) required updated HBV serologies because prior studies were not conducted within 5 years or since vaccination. Upon reassessment, 9 of 47 (19%) PWH changed HBV status: 4 who gained vaccine-induced immunity, 3 who lost prior immunity (1 from vaccine, 2 from infection), and 2 who shifted from unknown to presumed HBV naive (Figure 1*B*). Thirty-nine total PWH were identified as needing HBV vaccination, including 5 newly identified based on updated serologies (Table 1).

Among the 39 PWH at end of follow-up, 23 (59%) completed the 3-dose series; 9 (23%) have the series ongoing; 6 (15%) are awaiting vaccination pending CD4 ≥200 cells/mm^3; and 1 developed incident HBV (Figure 1C, Table 1). Of 20 PWH who completed the series and had postvaccination serologies measured, 19 (95%) developed an sAb$^+$ response; the nonresponder, with a CD4 count and percentage of 316 cells/mm^3 and 13% at LAI-ART initiation, will require reimmunization.

DISCUSSION

In a southern Ryan White–funded clinic, we leveraged a long-acting ART program infrastructure to initiate or complete an HBV vaccination series in 32 of 39 (82%) eligible PWH. More than one-third of PWH initiating LAI-ART were identified as HBV susceptible and prioritized for vaccination, resulting in a 95% serologic response rate among those who completed the series and had serologic follow-up. This has a local impact given that 6.6% of PWH had an active HBV diagnosis or a positive HBV sAg or DNA result documented at their most frequent place of HIV care in the past 2 years (Georgia Medical Monitoring Project, 2023 cycle, unpublished data) [24]. This study highlights the pragmatic success of optimizing HIV–viral hepatitis outcomes through synergized interprofessional programming, thus offering a potential framework

for integrating other primary care health initiatives, and it illuminates key areas where additional data are needed to guide HBV prevention efforts in PWH.

PWH vs people without HIV have lower serologic response rates from initial HBV vaccination and limited durability of vaccine-induced seroprotection [25–27]. Waning immunity may occur as early as months to a few years after vaccine series completion, as influenced by HIV duration, CD4 trajectory, and virologic control at the time of vaccination [26]. Of 47 PWH initiating LAI-ART in our program, 9 shifted HBV categories after serologic reassessment, resulting in several newly identified as HBV naive and needing vaccination. In the era of increasing use of 2-drug ART for HIV treatment and non–tenofovir-based preexposure prophylaxis for HIV prevention, we must remain vigilant about HBV reactivation or acquisition risk and implement upstream preventive measures [28, 29]. Additional data are needed on HBV vaccine immunogenicity and durability to inform serologic reassessment intervals in PWH who have prior immunity, especially given novel vaccine adjuvants and dosing strategies [23, 30].

By integrating HBV immunity assessment into a long-acting ART program, we facilitated vaccine uptake in >80% of PWH identified as HBV susceptible over a nearly 3-year period, a rate significantly higher than previous reports [4, 5]. Key facilitators included leveraging the dedicated personnel, resources, and workflow of our long-acting ART program and streamlining HBV processes, which at times entailed adapting national clinical guidelines to implement HBV prevention approaches in a real-world setting and institutional framework. This included employing flexibility in the HBV vaccine dosing and serologic reassessment schedule to synchronize with LAI-ART visits; administering complete vaccine series for HBV-nonimmune PWH instead of single-dose boosting followed by quantitative sAb assessment; and awaiting soon availability of a more effective HBV vaccine for use in PWH with lower CD4 counts who have variable responses to recombinant vaccine [27]. Specifically, our health care system currently offers qualitative but not quantitative sAb testing and HepB-alum but not yet the HepB-CpG adjuvant vaccine, a novel 2-dose series administered 1 month apart with superior efficacy in PWH [23, 31]. Once available, HepB-CpG use will further optimize HBV prevention efforts and clinical outcomes in our clinic population.

In conclusion, integrating HBV prevention efforts into long-acting ART programming supports several goals of the Viral Hepatitis National Strategic Plan and may serve as a platform to implement and scale novel HBV vaccine strategies and improve vaccine-induced HBV immunity in PWH [32]. This approach carries promise in developing interprofessional models of syndemic care as part of long-acting ART programs, including testing and treatment of hepatitis C virus and sexually transmitted infections, additional vaccine preventive measures (eg, mpox, COVID-19, influenza), and substance use disorders and social determinants of health evaluation and intervention [33, 34].

Notes

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Author contributions. E. O., J. A. C., and L. F. C. designed the study. E. O. led the initiative with the support of V. R., E. A., L. N.-C., and B. L. S. and clinical oversight provided by J. A. C. and L. F. C. M. L., L. N.-C., B. L. S., J. A. C., and L. F. C. collaborated on the development of the electronic medical record–integrated population health registry, and M. L. was primarily responsible for building the database with iterative input and guidance from L. F. C. All authors contributed to data collection. Data analysis was led by E. O., W. S. A., J. A. C., and L. F. C. E. O. and L. F. C. drafted the initial manuscript, prepared the table and figure, and iteratively revised the manuscript. Critical revisions were additionally provided by B. L. S., W. S. A., M. L., and J. A. C. All authors reviewed and approved the final manuscript.

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