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BRIEF REPORT

Early Experience and Effectiveness of Long-Acting Injectable Cabotegravir and Rilpivirine in a South Side Chicago HIV Clinic

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We describe referrals and uptake of long-acting injectable cabotegravir/rilpivirine at an academic clinic in Chicago. In a pharmacy-led model, 118 (18%) people with HIV were referred and 78 (12%) initiated long-acting injectable cabotegravir/rilpivirine from 1 January 2021 to 31 May 2023. Implementation, especially for people with HIV who were not virally suppressed, requires further support for patients, providers, and clinic systems.

Keywords. cabotegravir; injectable; long-acting; people with HIV; rilpivirine.

In 2021, the Centers for Disease Control and Prevention estimated that 34% of people with HIV (PWH) in the United States have not achieved sustained virologic suppression (VS) [1]. Adherence and persistence during oral antiretroviral therapy (ART) remain a challenge for a significant number of PWH [2]. Poor adherence to oral ART is fueled by a complex interplay of individual, psychosocial, and structural factors. Prior research has indicated that factors such as mental illness, HIV-related stigma, substance use, housing and/or food insecurity, restricted access to care or insurance issues, and medical mistrust can all affect ART adherence and VS [3–9]. Long-acting injectable cabotegravir/rilpivirine (LAI-CAB/RPV) is a promising option to overcome some of these barriers and address challenges associated with daily oral ART adherence [10].

Early implementation studies conducted in various health care settings have confirmed the effectiveness of LAI-CAB/RPV [11–18] and have consistently reported a high level of patient satisfaction [14, 16, 19, 20]. However, implementation barriers at multiple levels have curbed the public health impact of this new ART formulation, especially among vulnerable populations facing adherence challenges and HIV outcome disparities. Common provider and clinic challenges include concerns about virologic failure, hesitancy to prescribe to patients with adherence challenges, difficulties with insurance coverage, and lack of resources to track injections [21–23]. Addressing these barriers is critical to improving access to LAI-CAB/RPV.

In this study, we present our experience in implementing LAI-CAB/RPV within a Ryan White–funded academic clinic in an Ending the HIV Epidemic (EHE) priority jurisdiction, primarily serving a Black population on the South Side of Chicago. The study objectives were the following: (1) to describe the characteristics of PWH who were referred for LAI-CAB/RPV initiation, (2) to compare the characteristics of referred PWH who initiated LAI-CAB/RPV treatment with those who did not, and (3) to evaluate treatment outcomes among PWH who started LAI-CAB/RPV.

METHODS

The University of Chicago HIV clinic is a single-center facility on Chicago's South Side, serving predominantly Black PWH. We included people with HIV-1 aged ≥18 years with at least 1 HIV-related clinic visit and 2 HIV viral load measurements from 1 January 2021 to 31 May 2023. PWH were considered eligible to receive LAI-CAB/RPV injections if their most recent HIV viral load measurement was <50 copies/mL and they had no resistance-associated mutations to cabotegravir or rilpivirine and/or no history of treatment failure to nonnucleoside reverse transcriptase inhibitors or integrase strand transfer inhibitors. The pharmacy-led model used to deliver LAI-CAB/RPV within the clinic is described in the supplementary information. Participants referred for LAI-CAB/RPV were identified by the pharmacy tracking system, and treatment initiation was defined as having received at least 1 LAI-CAB/RPV injection within the period. An automated data extraction process was used to collect basic characteristics from the electronic medical record, such as age, sex, race and ethnicity, zip code, primary insurance, date of follow-up visits, and all HIV-1 viral load and CD4 measurements over the study period. We used patient zip code and the 2022 American Community Survey

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to determine the percentage of patients below the federal poverty level [24]. We performed manual electronic medical record abstraction to collect the following information at the time of referral: housing status, employment status, date of HIV diagnosis, active substance use, mental illness, medications, HBV status, HIV genotype history, and reasons for noninitiation of LAI-CAB/RPV. For patients who started LAI-CAB/RPV, we recorded dates of injections, use of an oral lead-in, and reasons for treatment discontinuation. Virologic failure with LAI-CAB/RPV was defined as 2 consecutive HIV-1 viral load measurements >200 copies/mL. An injection was considered on time if it was given within 7 days before or after the planned injection date. Descriptive statistics were used to summarize the characteristics of PWH referred for LAI-CAB/RPV: proportions for categorical variables and median, IQR, and range of continuous variables. Characteristics of patients who initiated LAI-CAB/RPV were compared with those who did not via a Wilcoxon rank sum test for continuous variables and a chi-square or Fisher exact test for categorical variables. A multivariable logistic regression model was used to evaluate the

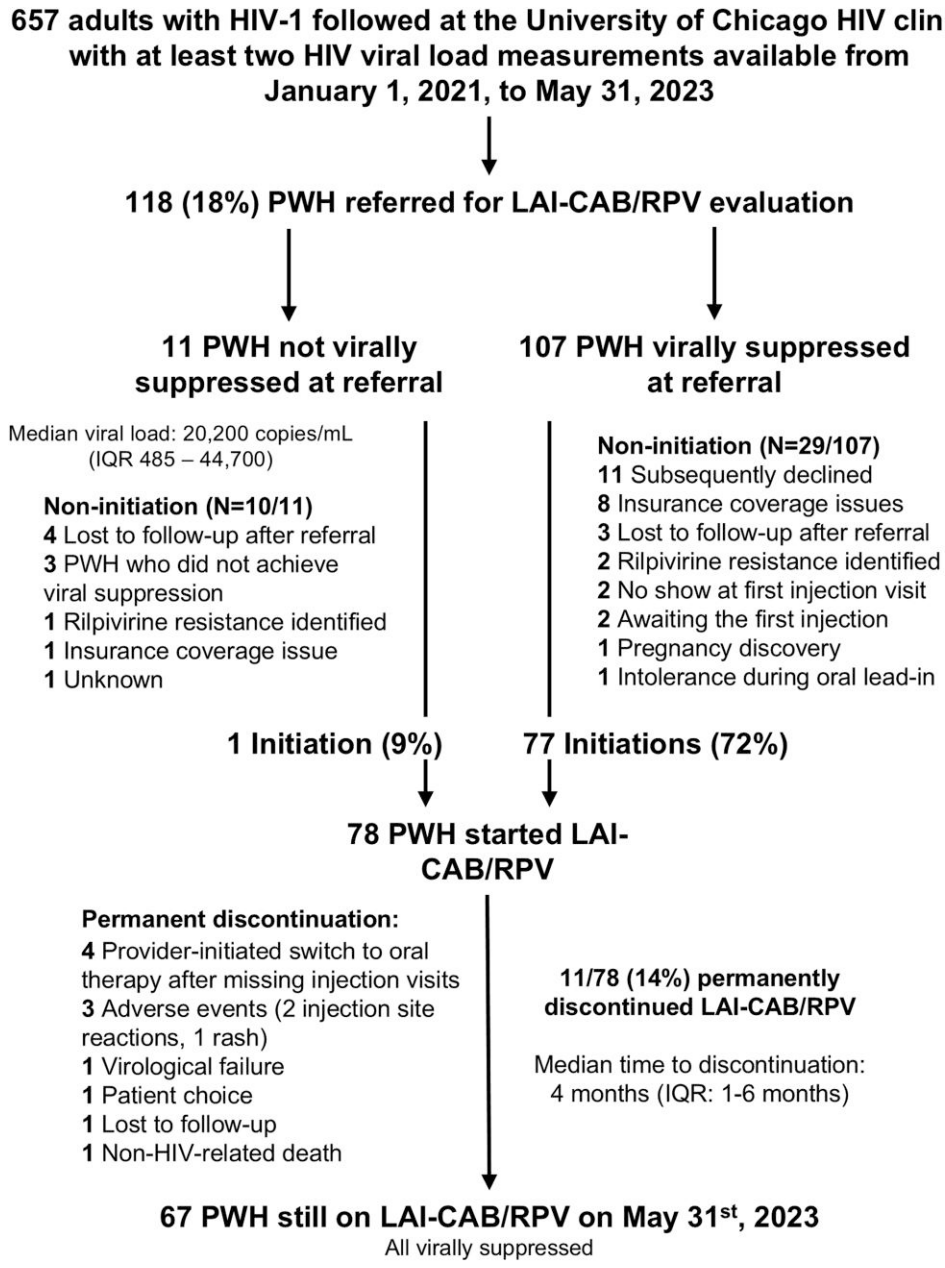

Figure 1. Flowchart of PWH at the University of Chicago, including those referred and initiating LAI-CAB/RPV. Abbreviations: LAI-CAB/RPV, long-acting injectable cabotegravir/rilpivirine; PWH, people with HIV.

factors associated with LAI-CAB/RPV initiation. Covariates identified as possible factors in the bivariate logistic regression models ($P < .10$) were retained for the multivariable model. Statistical significance was considered if $P < .05$. Statistical analyses were performed with SAS version 9.4 (SAS Institute). This project received a formal Determination of Quality Improvement status according to the University of Chicago Medicine institutional policy. As such, this initiative was not human subjects research and was not reviewed by the institutional review board.

RESULTS

From 1 January 2021 to 31 May 2023, 657 PWH had 1 clinic visit and ≥2 viral load measurements: 118 PWH (18%) were referred for LAI-CAB/RPV evaluation, 78 (12%) initiated the treatment, and 67 (10%) were still undergoing treatment on 31 May 2023 (Figure 1). Of the 118 PWH referred for evaluation, the median age was 35 years (IQR, 30–49), with 85% identifying as Black, 64% as cisgender male, 31% as cisgender female, and 5% as transgender or nonbinary. Gay, bisexual, and other men who have sex with men accounted for 56% of referred patients. Among the referred PWH, 64% had comorbidities, 69% were taking 1 or more chronic medications other than oral ART, and 36% had a body mass index >30 kg/m^2. The majority (64%) were insured under Medicaid and 27% had nonpermanent housing. Mental illness or active substance use affected 33% and 8%, respectively. Upon referral, 78 PWH (66%) had at least 1 HIV genotype available in the electronic medical record, and 11 were non-VS (9%). Characteristics of referred PWH are detailed in Table 1.

Of the 118 PWH referred for LAI-CAB/RPV evaluation, 78 (66%) started the treatment. Of PWH who initiated, 26 (33%) had no HIV genotype available, and 14 (18%) had achieved VS for <6 months when they initiated LAI-CAB/RPV. The median time between referral and first injection was 1 month (IQR, 0–2; range, 0–11). Figure 1 presents reasons for noninitiation of LAI-CAB/RPV, categorized by VS status. In bivariate analysis, LAI-CAB/RPV initiations were significantly lower in non-VS cases (odds ratio [OR], 0.04; 95% CI, .005–.32; $P < .001$). A trend was also observed for an association with CD4 counts <200/mm^3 (OR, 0.31; 95% CI, .08–1.16; $P = .08$). Patients with other comorbidities, excluding psychiatric or cardiovascular, were more likely to initiate LAI-CAB/RPV (OR, 3.17; 95% CI, 1.19–8.49; $P = .02$; Table 2). In multivariate analysis, the only independent factor associated with treatment initiation was VS at the time of referral (OR, 0.04; 95% CI, .003–.49; $P = .01$).

Table 1. Baseline Characteristics of PWH Referred for LAI-CAB/RPV

	PWH, No. (%) or Median (IQR)		
	Referred for LAI-CAB/RPV (n = 118)	Started LAI-CAB/RPV (n = 78)	Did Not Start LAI-CAB/RPV (n = 40)
Sex			
Male	79 (67.0)	51 (65.4)	28 (70.0)
Female	39 (33.1)	27 (34.6)	12 (30.0)
Gender			
Cisgender male	76 (64.4)	49 (62.8)	27 (67.5)
Cisgender female	36 (30.5)	25 (32.1)	11 (27.5)
Transgender/nonbinary	6 (5.1)	4 (5.1)	2 (5.0)
Race and ethnicity			
Black	100 (84.8)	65 (83.3)	35 (87.5)
Hispanic	4 (3.4)	3 (3.9)	1 (2.5)
White	8 (6.8)	6 (7.7)	2 (5.0)
Asian	1 (0.9)	1 (1.3)	0
Missing data, unknown, patient declined	5 (4.3)	3 (3.9)	2 (5.0)
Age at time of referral, y	35 (30–49)	35 (30–49)	32.5 (27.5–45.5)
Age categories, y			
21–34	58 (49.2)	34 (43.6)	24 (60.0)
35–49	31 (26.3)	25 (32.1)	6 (15.0)
≥50	29 (24.6)	19 (24.4)	10 (25.0)
Housing			
Permanent	86 (72.9)	55 (70.5)	31 (77.5)
Temporary	8 (6.8)	6 (7.7)	2 (5.0)
Unstable	5 (4.2)	5 (6.4)	0 (0.0)
Homeless	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	19 (16.1)	12 (15.4)	7 (17.5)

Table 1. Continued

	PWH, No. (%) or Median (IQR)		
	Referred for LAI-CAB/RPV (n = 118)	Started LAI-CAB/RPV (n = 78)	Did Not Start LAI-CAB/RPV (n = 40)
Families below the federal poverty line by zip code of residence, % (missing, n = 2)[a]	19.2 (13.8–24.7)	19.2 (15.3–24.7)	18.6 (12.2–25.2)
Employment status			
Employed	75 (63.6)	52 (66.7)	23 (57.5)
Unemployed	13 (11.0)	7 (9.0)	6 (15.0)
Retired	7 (5.9)	5 (6.4)	2 (5.0)
Student	0 (0.0)	0 (0.0)	0 (0.0)
Disability	11 (9.3)	8 (10.3)	3 (7.5)
Unknown	12 (10.2)	6 (7.7)	6 (15.4)
Primary insurance[a]			
Medicare	2 (1.7)	1 (1.3)	1 (2.5)
Medicaid	75 (63.6)	49 (62.8)	26 (65.0)
Private	41 (34.8)	28 (35.9)	13 (32.5)
Medical comorbidities			
Cardiovascular diseases[b]	48 (40.7)	34 (43.6)	14 (35.0)
Other active comorbidities[c]	34 (28.8)	28 (35.9)	6 (15.0)
Psychiatric comorbidities[d]	38 (32.2)	26 (30.0)	12 (33.3)
Any comorbidity[e]	75 (63.6)	54 (69.2)	21 (52.5)
Body mass index >30 kg/m^2	44 (37.3)	32 (40.5)	12 (30.7)
Other chronic medication			
At least 1 other chronic medication	81 (68.6)	54 (69.2)	27 (67.5)
At least 1 other oral drug	77 (65.3)	50 (64.9)	27 (67.5)
No. of oral drugs	2 (1–3)	2 (1–4)	2 (1–3)
At least 1 injectable drug	12 (10.2)	10 (12.8)	2 (5.0)
Current ART regimen			
2 NRTIs + second-generation INSTI	79 (67.0)	50 (64.1)	29 (72.5)
2 NRTIs + first-generation INSTI	13 (11.0)	12 (15.4)	1 (2.5)
2 NRTIs + NNRTI	10 (8.5)	7 (9.0)	3 (7.5)
2 NRTIs + PI	6 (5.1)	3 (3.9)	3 (7.5)
Dual regimen	7 (5.9)	5 (6.4)	2 (5.0)
Multiclass regimen	2 (1.7)	1 (1.3)	1 (2.5)
Missing (n = 1)	…	…	…
Active substance use			
At least 1 substance	9 (7.6)	5 (6.4)	4 (10.0)
Alcohol	7 (6.0)	4 (5.1)	3 (7.5)
Stimulants	3 (2.6)	2 (2.6)	1 (2.5)
Opioids, hallucinogens, other	0 (0.0)	0 (0.0)	0 (0.0)
Intravenous drugs	0 (0.0)	0 (0.0)	0 (0.0)
Time from HIV diagnosis, y (missing, n = 3)	8 (3–15)	7.5 (3–15.5)	8 (3–14)
Mode of HIV acquisition[f]			
GBMSM	67 (56.8)	42 (53.9)	25 (62.5)
Heterosexual transmission	48 (0.6.)	34 (43.6)	14 (35.0)
People injecting drugs	5 (4.2)	5 (6. 4)	0 (0.0)
Perinatal transmission	4 (3.4)	1 (1.3)	3 (7.5)
Other	2 (1.7)	1 (1.3)	1 (2.5)
Unknown	2 (1.7)	2 (5.0)	0 (0.0)
No. of follow-up visits during the study prior to referral	2 (1–4)	2 (1–4)	2 (1–4)
Referral period			
1 Jan 2021–31 Jan 2022	25 (21.2)	17 (21.8)	8 (20.0)
1 Feb 2022–31 May 2023	93 (78.8)	61 (78.2)	32 (80.0)
HIV resistance test available			
At time of HIV diagnosis	61 (51.7)	42 (53.8)	19 (47.52)
At referral	26 (22.2)	14 (18.0)	12 (30.0)
Neither	40 (33.9)	26 (33.3)	14 (35.0)
Time from the most recent HIV resistance test to the date of referral, mo	53.5 (10–79)	54 (20–82)	40.5 (0–75)

Table 1. Continued

	PWH, No. (%) or Median (IQR)		
	Referred for LAI-CAB/RPV (n = 118)	Started LAI-CAB/RPV (n = 78)	Did Not Start LAI-CAB/RPV (n = 40)
Non-VS at the time of referral: HIV-1 viral load measurements >50 copies/mL	11 (9.3)	1 (1.3)	10 (25.0)
CD4 count/mm^3			
Over the study period	595 (440–822)	620 (488–844)	510 (360–799)
<200	10 (8.5)	4 (5.1)	6 (15.4)
HBV status			
Susceptible: CoreAb−, SAg−, SAb−	25 (21.2)	16 (20.5)	9 (22.5)
Isolated core antibody: CoreAb+, SAg−, SAb−	3 (2.5)	2 (2.6)	1 (2.5)
Resolved infection: CoreAb+, SAg−, SAb+	14 (11.9)	10 (12.8)	4 (10.0)
Vaccinated: CoreAb−, SAg−, SAb+	67 (56.8)	44 (56.4)	23 (57.0)
Acute or chronic infection: SAg+	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	9 (7.6)	6 (7.7)	3 (7.5)

Abbreviations: ART, antiretroviral therapy; CoreAb, core antibodies; GBMSM, gay, bisexual, and other men who have sex with men; HBV, hepatitis B virus; INSTI, integrase inhibitor; LAI-CAB/RPV, long-acting injectable cabotegravir/rilpivirine; NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, nonnucleoside reverse transcriptase inhibitor; PWH, people with HIV; PI, protease inhibitor; SAb, surface antibodies; SAg, surface antigen; VS, viral suppression.

[a]First zip code and insurance information available during the study period.

[b]Cardiovascular comorbidities include diabetes, hypertension, dyslipidemia, coronary artery disease, congestive heart failure, peripheral artery disease, and stroke.

[c]Cancer, chronic infection diseases other than HIV, connective tissue disease, chronic kidney disease (estimated glomerular filtration rate <60 mL/min), chronic obstructive pulmonary disease, liver disease, and inflammatory disease.

[d]Anxiety disorders, depression or bipolar disorder, posttraumatic stress disorder, schizophrenia or psychosis, and other psychiatric disorders.

[e]Presence of any comorbidity noted in this section.

[f]Several categories can apply for 1 patient.

Table 2. Factors Associated With LAI-CAB/RPV Initiation Among PWH Referred

	PWH, No. (%)					
	Referred for LAI-CAB/RPV (n = 118)	Started LAI-CAB/RPV (n = 78)	OR (95% CI)	*P* Value	Adjusted OR (95% CI)	*P* Value
VS						
Yes	107	77 (72.0)	1 [Reference]		1 [Reference]	
No	11	1 (9.0)	0.04 (.005–.32)	.002	0.04 (.003–.49)	.01
Age categories, y						
21–34	58	34 (58.6)	1 [Reference]		1 [Reference]	
35–49	31	25 (80.7)	2.94 (1.05–8.26)	.04	2.47 (.77–7.90)	.30
≥50	29	19 (65.5)	1.34 (.54–3.39)	.53	0.75 (.26–2.17)	.59
Other comorbidities[a]						
No	84	50 (59.5)	1 [Reference]		1 [Reference]	
Yes	34	28 (82.4)	3.17 (1.19–8.49)	.02	2.50 (.84–7.41)	.13
CD4 <200/mm^3						
No	108	74 (68.5)	1 [Reference]		1 [Reference]	
Yes	10	4 (40.0)	0.31 (.08–1.16)	.08	1.43 (.13–16.32)	.77

Abbreviations: LAI-CAB/RPV, long-acting injectable cabotegravir/rilpivirine; OR, odds ratio; PWH, people with HIV; VS viral suppression

[a]Noncardiovascular and nonpsychiatric comorbidities, including cancer, chronic infection diseases other than HIV, connective tissue disease, chronic kidney diseases (estimated glomerular filtration rate <60 mL/min), chronic obstructive pulmonary disease, liver disease, and inflammatory disease.

The 78 PWH who initiated LAI-CAB/RPV were followed for a median 8 months (IQR, 5–12). Patients received a median 6 injections, ranging from 1 to 12. An oral lead-in phase preceded the first injection for 23 patients (29%). The majority, 73 patients (94%), began with injections administered every 2 months, while 5 patients (6%) started with monthly injections. Of the 456 injections, 426 (93%) were on time, 22 (5%) occurred 1 to 4 weeks late, and 8 (2%) occurred >4 weeks late. Most patients had on-time injection attendance (71%), with 18 (23%) late for 1 injection and 4 (5%) late for ≥2 injections. Among those who initiated LAI-CAB/RPV, 67 (86%) were still undergoing treatment as of 31 May 2023, all of whom maintained VS. Eleven patients (14%) permanently discontinued the treatment after a median 4 months (IQR, 1–6). Missed injections and adverse events accounted for two-thirds of discontinuations. Providers initiated all discontinuations related to

missed injections (Figure 1). Only 1 patient was lost to follow-up after initiation. Primary insurance and benefit plan were not associated with treatment discontinuations (Supplementary Table 1). Among the 8 patients with VS who discontinued injections, all maintained VS after transitioning to oral ART. One PWH undergoing hemodialysis experienced virologic failure after receiving 5 on-time LAI-CAB/RPV injections; HIV genotype revealed resistance-associated mutation to integrase strand transfer inhibitor (E138A, G140S, Q148S) and nonnucleoside reverse transcriptase inhibitor (K101E, N348I).

DISCUSSION

In this study, we present our initial experience implementing pharmacy-led delivery of LAI-CAB/RPV in a Ryan White–funded academic clinic serving primarily Black PWH. When compared with other clinics in the United States, some had more referrals and higher uptake than our program [25] while others reported lower uptake [26–28]. We faced challenges in initiating LAI-CAB/RPV for PWH who were non-VS at the time of referral and required oral ART. Although about 15% of the patients at our clinic are non-VS, they accounted for only 8% of referrals and 2% of initiations. Clinic policy as well as provider hesitancy may explain the low number of referrals in this group [22].

We identified barriers to LAI-CAB/RPV initiation among referred patients that were similar to those reported in previous research [25]. One-quarter of noninitiations were due to patients losing interest in LAI-CAB/RPV. Insurance issues were the second-leading cause of noninitiation, resulting in treatment delays for some patients. We also experienced a high proportion of treatment discontinuation at 14%. This discontinuation was twice as high as that reported at 48 weeks in the FLAIR and ATLAS-2M studies [29, 30]. Outside of adverse events, most treatment discontinuations were provider initiated due to missed injection visits, highlighting the importance of addressing barriers to adherence with the injection visit schedule [31]. Consistent with other real-world cohorts [11–13, 32], confirmed virologic failure was a rare event, with only 1 case occurring in our cohort.

Our cohort's primary strength is the high representation of Black and cisgender women starting LAI-CAB/RPV in an EHE priority jurisdiction. This study offers valuable insights into reach and effectiveness outcomes in populations usually underrepresented in cohorts of PWH. Our findings provide additional evidence for the feasibility of introducing LAI-CAB/RPV to populations facing social and economic challenges, as well as high rates of comorbidities. However, low uptake among patients who were non-VS highlights the need for our care model to evolve toward greater flexibility in treatment indications and delivery methods, as well as enhanced support to promote retention. Solutions such as a low-barrier clinic offering same-day services, extended operating hours, reduced-cost or free services, and on-site support could all improve access of LAI-CAB/RPV in our patient population [12, 13, 33].

Our study has several limitations, notably its retrospective single-center design in an academic setting. Our LAI-CAB/RPV delivery model is contingent upon various local factors, including programs, providers, and policies, which may limit the generalizability of our findings to other settings. Early adopters of LAI-CAB/RPV may also be more motivated to initiate and persist with injections, which could limit the applicability of our findings to late adopters. Despite these limitations, our experience offers valuable insights into the implementation of LAI-CAB/RPV in priority populations beyond the context of clinical trials.

CONCLUSIONS

Our results showed the feasibility of implementing a pharmacy-led LAI-CAB/RPV program at an urban clinic for PWH in Chicago. Our program, consisting of mostly Black PWH in a priority EHE jurisdiction, saw 118 referrals and 78 LAI-CAB/RPV starts, with 86% remaining on the treatment at the end of the study. However, few persons who were non-VS were referred or started LAI-CAB/RPV. This disparity highlights the need for additional interventions to support PWH with adherence challenges to oral ART, including resources for providers and the clinic system to initiate LAI-CAB/RPV in those without VS.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

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Author contributions. M. C. M., P. D., K. S., A. H., and J. S. implemented LAI-CAB/RPV at the University of Chicago adult clinic serving PWH. G. L., M. C. M., K. A. C., and J. A. S. designed the study. G. L., C. K., A. D., and S. P. collected the data. G. L., M. C. M., and E. E. F. designed and conducted the analysis. G. L., M. C. M., E. E. F., and C. K. reviewed the analysis and validated the final results. G. L. wrote the first draft of the report. All authors critically reviewed and approved the manuscript.

Data availability statement. Anonymized data and study documents can be requested by email to geoffroy.liegeon@aphp.fr. The authors will evaluate each proposal.

Disclaimer. ViiV Healthcare, the manufacturer of LAI-CAB/RPV, was not involved in the research.

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Potential conflicts of interest. G. L. has participated in advisory boards for ViiV Healthcare. M. C. M. has served on an advisory board for

Gilead Sciences. K. A. C. has been a medical advisory board member for Gilead Sciences and a workshop participant for Janssen. K. S. joined ViiV Healthcare in 2024 after the completion of this research. All other authors report no potential conflicts.

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