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BRIEF REPORT

Low Uptake of Long-Acting Injectables in the First 2.5 Years Following Approval Among a Cohort of People Living With HIV

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Human immunodeficiency virus (HIV) continues to persist as an issue of public health concern with more than a million people living with HIV (PLWH) in the United States [1]. One of the pillars of the "Ending the HIV Epidemic" (EHE) initiative is to implement treatment as prevention strategies to lower viral load and prevent new transmissions among PLWH [2]. Although current antiretroviral (ARV) regimens are highly tolerable and efficacious, a relatively high proportion of PLWH lack durable viral suppression (VS) [3–7]. Potential reasons for the low proportion of those with VS include barriers to adherence to oral ARV regimens. Previous studies have found that stigma, substance use disorders, and mental health comorbidities pose barriers to adherence to oral ARV regimens [8–10].

One alternative to oral ARV is long-acting injectable (LAI) ARV, which is a combination regimen of cabotegravir and rilpivirine [11]. In 2021, the Food and Drug Administration (FDA) approved LAI for the management of HIV-1 [12]. This regimen provides a less frequent dosing alternative to those with barriers to adherence for the daily oral ARV that may also address some privacy concerns stemming from storing oral ART at home or receiving oral medications by mail [13, 14]. Despite these advancements, it is currently unclear whether there has been a strong uptake of LAI in urban regions with higher HIV prevalence such as Washington, DC. Some barriers to implementation include the need for viral suppression before starting treatment, cost and insurance approval, and logistics of acquiring and distributing the medication [15]. One study found that less than one-third of clinical encounters had discussions surrounding LAI, suggesting these discussions are not prioritized during appointments [16]. Medical mistrust and concerns surrounding safety and effectiveness of the injections have also been found to be potential barriers [17, 18]. If implemented effectively, LAI ARVs could significantly contribute toward the EHE benchmarks of increasing national VS rates and ultimately assist in ending the HIV epidemic. The objective of this analysis was to evaluate use of LAI ARV in a large observational urban cohort of individuals living with HIV of people receiving HIV care in Washington, DC.

METHODS

We evaluated uptake of LAI among participants in the DC Cohort. The DC Cohort is a longitudinal cohort of consenting PLWH receiving HIV care in Washington, DC. Enrollment began in 2011 and is ongoing. Participants are recruited across 14 sites in Washington, DC, and data are extracted from the electronic health record (EHR). Data on HIV laboratory values, medications, procedures, healthcare encounters, and medications are collected and stored in a secure database, which is updated daily. The DC Cohort study is approved by the George Washington University institutional review board (IRB #: 071029) and the methods have been described previously [19]. The DC Cohort includes both hospital clinics (an ambulatory center in/at a hospital) and community clinics. Among active DC Cohort participants, we examined eligibility for LAI using the eligibility criteria from the medication package insert based on our study index date of 31 December 2020 [20]. Participants with missing eligibility criteria were excluded from the analysis. A detailed list of LAI criteria definitions can be found in the Supplementary material.

Among those who were eligible, HIV care providers identified participants who were on an LAI regimen using deidentified DC Cohort participant identification numbers. Given the various avenues in which LAI is reported in the EHR, this provider-identified list of participants on LAI was used to ensure accuracy. Any LAI regimen started between 31 December 2020 and 1 July 2023 was considered for analysis. Demographics, mode of HIV transmission, insurance, employment, and housing status were all collected from the EHR. Clinic type (i.e., hospital, community) and whether the clinic receives Ryan White funding, are available from DC Cohort records.

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We used χ^2 tests for categorical variables and 2-sided Wilcoxon rank-sum tests for continuous variables to analyze statistically significant differences between the those who began LAI versus those on oral ARV. Finally, we used a line graph to examine LAI uptake over calendar time and compared it with the number of participants who did not begin LAI but switched to a new oral ARV prescription over time.

RESULTS

We found that 1469 active participants in the DC Cohort (28.6%) were eligible for initiation of LAI. Most were non-Hispanic Black (1089 [74.1%]), male (1017 [69.2%]), and received HIV care at a community site (1084 [73.8%]). The median age was 59 (interquartile range: 49–66) and the most common mode of HIV transmission male to male sexual contact (554 [37.7%]). We found that 23 (1.6%) of these participants had begun LAI 31 December 2020. Of these 23 participants, the earliest start date for LAI was May 2022. Among the total individuals who began LAI, the median age was 50 (interquartile range: 41–59) and the most common mode of HIV transmission was male to male sexual contact (12 [52.2%]). Most were non-Hispanic Black (18 [78.3%]), male (15 [65.2%]), and received HIV care at a hospital site (14 [60.9%]). Among participants who began LAI, 69.6% had public insurance, whereas 26.1% had private insurance. None of the individuals who began LAI was uninsured. In our study, 65.2% of participants on LAI and 80.0% of participants who were not on LAI attended a clinic with Ryan White funding. However, none of the individuals on LAI ART had Ryan White/AIDS Drug Assistance Program (ADAP) as their payer of record. Those that started LAI were significantly different by age and type of HIV care site ($P = .004$; $P = .0001$). Specifically, those who started LAI were significantly younger and more likely to receive care at a hospital site than those who did not start LAI (median age: 50 vs 59; % hospital site: 60.9% vs 25.7%) (Table 1). When visually comparing initiation of LAI to initiation of new oral regimen, the switches to new oral regimen remained constant over time, whereas the initiation of LAI began increasing in late 2022 and peaked in the spring of 2023 (Figure 1).

DISCUSSION

We found that among PLWH in the DC Cohort eligible for LAI per initial labeling, there was very low uptake of LAI. Those who began LAI were significantly younger and more likely to receive HIV care from a hospital site compared with those who did not start LAI. This age discrepancy is concerning given that tenofovir/nucleoside reverse transcriptase inhibitor–sparing regimens, such as cabotegravir/rilpivirine, may benefit older PLWH with reduced renal function or osteoporosis/osteopenia [21]. Providers have previously described younger PLWH and people who do not take other pills as more appropriate candidates for LAI [22]. Older age has also been associated with increased ARV adherence, which also may explain why this population has not been targeted for LAI [23, 24]. Although not an absolute necessity, LAI may be especially beneficial to older PLWH; therefore, it is important that providers are made aware of these gaps to ensure older patients are not being overlooked for LAI initiation.

The differences in LAI uptake at hospital versus community sites may be elucidating an underlying difference in access to care at different HIV care sites. Insurance coverage for LAI is limited and insurers may institute cost-containment conditions, including requirements for prior authorization, patient cost sharing, step therapy, and formulary exclusions that can further impede LAI prescribing [25]. The only option for many PLWH to access treatment is through the Ryan White HIV/AIDS program [26]. One study found that financial coverage for LAI and staffing challenges caused barriers to LAI administration at Ryan White–funded HIV clinics [27]. Financial and administrative barriers to care between different HIV care site types may explain this discrepancy.

Given the benefits of LAI and its potential contribution to the EHE initiative, the low uptake of LAI in our cohort is concerning. It is possible our study population is reluctant to begin LAI, potentially because of concerns with privacy during scheduled LAI administration days, fear of injections, or satisfaction with their oral regimen. However, this is unlikely as a previous study found that 57% of patients were likely to accept an LAI regimen and this acceptance increased substantially with at least 1 month between injections, which is the current standard of care. That study also found no significant predictors of LAI acceptance [28]. Follow-up studies should be conducted to better understand patient perspectives that may be contributing to low uptake.

It is possible that the strict eligibility criteria for LAI initiation is also creating barriers. Previously, it has been found that resistance to rilpivirine, strict VS criteria, and hepatitis B coinfection were limitations to uptake [27, 29, 30]. A previous study in California found that of 15 patients who initiated LAI with a detectable viral load, 12 achieved VS [31]. Additionally, LAI ARV may benefit patients who have detectable viremia and high rates of unstable housing, mental illness, and substance use. A cohort study conducted at an urban academic safety net HIV clinic showed that LAI-ARV was successful in achieving virologic suppression among PLWH, including those with viremia and challenges to adherence [32]. A qualitative study conducted in women across 6 states in the United States also found that women living with HIV preferred LAI ARV over daily pills [33]. Thus, expanding LAI ARV access to patients who face significant health disparities and barriers to treatment should be considered [34, 35]. Future clinical trials should be performed to establish long-term safety and efficacy of LAI in

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Table 1. Frequency Counts and Prevalence Estimates of Demographic Characteristics for DC Cohort Participants Eligible for LAI, Stratified by LAI Uptake

Demographic	Eligible For LAI (N = 1469)	Started on LAI (N = 23)	Not on LAI (N = 1446)	P[f]
Age, median (IQR)	59 (49, 66)	50 (41, 59)	59 (50, 66)	.004
Gender, N (%)	…	…	…	.93
Male	1017 (69.23)	15 (65.22)	1002 (69.29)	…
Female	415 (28.25)	7 (30.43)	408 (28.22)	…
Transgender	36 (2.45)	1 (4.35)	35 (2.42)	…
Unknown	1 (0.07)	0 (0.00)	1 (0.07)	…
Race/ethnicity, N (%)	…	…	…	.91
Non-Hispanic Black	1089 (74.13)	18 (78.26)	1071 (74.07)	…
Non-Hispanic White	181 (12.32)	3 (13.04)	178 (12.31)	…
Hispanic	140 (9.53)	2 (8.70)	138 (9.54)	…
Other[a]	17 (1.16)	0 (0.00)	17 (1.18)	…
Unknown	42 (2.86)	1 (5.00)	42 (2.90)	…
Mode of HIV Transmission, N (%)	…	…	…	.58
Sex among male-to-male sexual contact	554 (37.71)	12 (52.17)	542 (37.48)	…
Heterosexual contact	516 (35.13)	5 (21.74)	511 (35.34)	…
Injection drug use	71 (4.83)	1 (4.35)	70 (4.84)	…
Other[b]	22 (1.50)	0 (0.00)	22 (1.52)	…
Unknown	306 (20.83)	5 (21.74)	301 (20.82)	…
Site Type, N (%)	…	…	…	.0001
Hospital	385 (26.21)	14 (60.87)	371 (25.66)	…
Community	1084 (73.79)	9 (39.13)	1075 (74.34)	…
Patient attends clinic that is a Ryan White program participant, N (%)	1172 (79.8)	15 (65.2)	1157 (80.0)	.08
Nadir CD4 (cells/μL), median (IQR)	343 (192, 524)	374 (240, 666)	342 (192, 522)	.37
Years since HIV diagnosis, Median (IQR)	16 (11, 24)	16 (9, 23)	16 (11, 24)	.32
Insurance, N (%)	…	…	…	.75
Private insurance	306 (22.04)	6 (26.09)	300 (20.75)	…
Public insurance[c]	1018 (68.2)	16 (69.57)	1002 (69.29)	…
Other[d]	39 (2.6)	0 (0.00)	39 (2.70)	…
Unknown	106 (7.21)	1 (4.35)	105 (7.26)	…
Employment, N (%)	…	…	…	.61
Employed	402 (27.37)	8 (34.78)	394 (27.25)	…
Unemployed/disabled	413 (28.11)	5 (21.74)	408 (28.22)	…
Other[e]	60 (4.08)	0 (0.00)	60 (4.15)	…
Unknown	594 (40.44)	10 (43.48)	584 (40.39)	…
Housing, N (%)	…	…	…	.94
Permanent/stable	1224 (83.32)	20 (86.96)	1204 (83.26)	…
Homeless/unstable housing	130 (8.85)	2 (8.70)	128 (8.85)	…
Other	4 (0.27)	0 (0.00)	4 (0.28)	…
Unknown	111 (7.56)	1 (4.35)	110 (7.61)	…

[a]Asian, Native Hawaiian/Pacific Islander, American Indian/Alaskan Native, Multiracial, Other.

[b]Perinatal, transfusion, other modes of transmission.

[c]Medicare, Medicaid, DC Alliance, Ryan White Funding.

[d]Clinical study, insurance terminated, self-pay/fee for service, other insurance.

[e]Retired, student, other employment.

[f]Chi-square tests were used for categorical variables and Wilcoxon rank-sum test was used for continuous variables.

PLWH without VS to address whether the VS criterion is required. In parallel with efforts to increase access to LAI for those already eligible by current FDA label criteria, review of the criteria themselves may lead to future changes that allow additional PLWH to access LAI.

Our study has several limitations. First of all, we only had 23 participants uptake LAI in our dataset and may have been underpowered to detect significant associations. Furthermore, we evaluated LAI uptake as of 1 July 2023. However, uptake across PLWH may have improved since this time, especially as more time passes and providers prescribe to individuals who do not meet the initial packaging indications. In addition, our data came from the EHR and did not include thorough information on stigma and other social determinants of health, which may play a role in LAI uptake. Our dataset included participants eligible for LAI with information on all eligibility criteria; we will examine uptake of LAI among all DC Cohort participants in future work.

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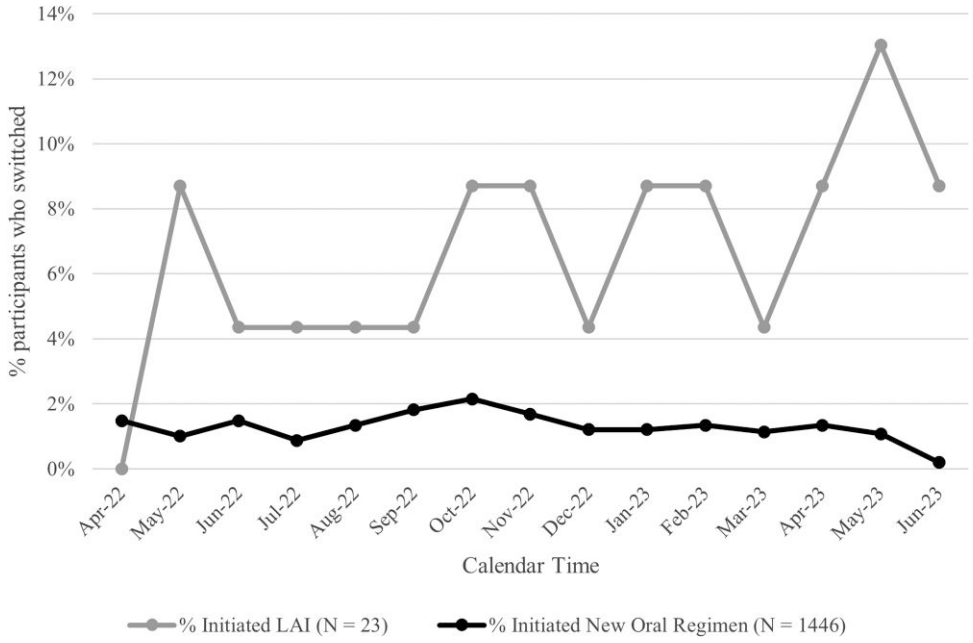

Figure 1. Comparison of the timeline of LAI initiation compared to initiation of a new oral regimen.

In summary, LAI ARV regimens provide an effective alternative to maintaining long-term VS for those who may find it difficult to adhere to oral ARVs [13, 36, 37]. We found that younger PLWH and participants receiving care at a hospital-based clinics were more likely to have initiated LAI. These differences may be due to discrepancies in which patients are being offered LAI, which clinics have the resources to support the regimen and/or administrative logistics. Successful implementation of LAI will depend substantially on coordinating stakeholder engagement and fostering partnerships, especially for implementation within communities that have faced systemic racism and prior negative healthcare experiences [29]. As we strive to meet benchmarks for the EHE initiative, it is imperative we take on the implementation challenges of LAI and seek to increase access for patients who would benefit from this innovative ARV regimen.

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.

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