Likelihood of Trying Long-Acting Injectable Antiretroviral Therapy Among Women With HIV in Nine Sites Across the United States

To the Editors:

INTRODUCTION

Long-acting injectable antiretroviral therapy (LAI ART), in the formulation of cabotegravir/rilpivirine (LA-CAB/RPV), has been approved as monthly (2021) and every 2-month (2022) regimens by the US Food and Drug Administration for virally suppressed individuals.[1] LAI ART has the potential to address adherence-related challenges faced by people on daily oral ART, including pill burden, daily pill-taking challenges, stigma, and confidentiality. LAI ART may be particularly beneficial for women living with HIV (WLWH), who have worse care continuum outcomes than men,[2] including lower rates of testing, care linkage and retention, and viral suppression.[3,4] Women face numerous gender-specific barriers to daily oral ART adherence. For example, caregiving responsibilities can complicate the scheduling of medical visits and may cause women to forget to take oral ART;[5] heightened HIV stigma and gender-based violence may discourage women from keeping and taking oral HIV medication at home.[6] In addition, viral suppression is lower among women who are younger,[7] live in the southern United States,[8] and who use illicit substances.[9]

LAI ART may help address some of these structural and interpersonal barriers to adherence, but whether WLWH switch to LAI will in large part be determined by their individual perceptions and preferences. While clinical trial participants reported high acceptability of LAI ART (97% preferred it to oral ART),[10] women constituted only 8%–33% of Phase II/III trial participants,[11–14] and the trials excluded pregnant people and those whose HIV viral load was not suppressed.[15,16] Research has demonstrated disconnections between LAI ART acceptability in clinical trials and "real-world" interest and uptake: despite its established efficacy,[12,13] as of December 2023, only 26,000 of the estimated 1.2 million people living with HIV in the United States[17,18] were receiving LAI ART in the formulation of cabotegravir/rilpivirine.[19] Some studies examined individuals' LAI ART interest in "real-world" settings, although much of this research was conducted before the availability of LAI ART, making responses hypothetical.[15,20,21] Women constituted a minority of clinical trial participants, yet have a variety of experiences and preferences, which uniquely impact ART adherence[11–14]; despite this, no studies to date have focused exclusively on women. Qualitative research conducted among WLWH suggests heterogeneity in women's interest in LAI ART, including which populations could most benefit: these included younger people, women with child-rearing and caretaking responsibilities, and women who use substances.[22] Thus, a more comprehensive understanding of the profiles of WLWH who are interested in LAI ART can help researchers and practitioners tailor programming, messaging, and clinical guidelines.

METHODS

Data were collected from women with HIV enrolled in the Multicenter AIDS Cohort Study (MACS)/Women's Interagency HIV Study Combined Cohort Study (MWCCS).[23] MWCCS is the longest-running HIV-focused cohort study in the United States and has been collecting data among women since

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1993; it collects biomedical, clinical, and psychosocial/behavioral outcomes. Women in this study were recruited from 9 geographically diverse MWCCS sites: Atlanta, GA; Birmingham, AL/Jackson, MS; Bronx, NY; Brooklyn, NY; Washington DC; San Francisco, CA; Chicago, IL; Chapel Hill, NC; and Miami, FL. From October 2020 to September 2021, a computerized survey was administered to 1078 WLWH as part of data collection wave V101. None had participated in LAI ART clinical trials.

Before completing questions on LAI ART, all participants were provided a standardized description of LAI ART, including information on clinical effectiveness, route and frequency of administration, and the side effect of injection site pain. Participants then responded to the question "How likely are you to try monthly shots for HIV treatment instead of daily pills?" using a 5-point Likert scale. For analysis, we collapsed responses into 2 categories: "definitely" or "probably" were likely to try LAI ART versus "not sure," "definitely not," and "probably not."

Independent variables included age, educational attainment, race/ethnicity, study site, and income above $12,000/yr. Participants reported any past year illicit substance use (heroin, crack/cocaine, or other), which was combined into a single dichotomous indicator; cannabis was excluded due to its varied legal status. Participants self-reported their years living with HIV and oral ART adherence, with "adherent" defined as taking oral ART ≥95% of the time, a standard measure within MWCCS.[23] HIV viral load (copies/mL) at the most recent study visit was also included.

Variables significant at $P = 0.05$ in the bivariate analyses were included in the final models, along with sociodemographic indicators. Adjusted logistic regression models examined associations of sociodemographic and behavioral factors with women's likelihood of trying LAI ART.

RESULTS

Descriptive statistics of all variables are presented in Table 1. Among 1078 women, with the mean age of 54.2 years, 73% identified as Black, 32% had less than a high school education, and 11% reported past-year illicit substance use. Nearly three-quarters (72%) had an undetectable viral load and 88% reported taking oral ART ≥95% of the time. Fewer than half of women (43%) reported they were "probably" (22%) or "definitely" (20%) likely to try LAI ART; 24.0% said that they definitely were not likely, 12.4% probably were not likely, and 21% were unsure.

In the adjusted model (Table 1), women reported being less likely to try LAI ART if they were older [adjusted odds ratio (aOR) = 0.98 per year (95% confidence interval: 0.96 to 0.99)] and reported taking oral ART ≥95% of the time [aOR = 0.67 (0.45 to 0.99)]. Women with past-year illicit substance use [aOR = 1.66 (1.07 to 2.56)] were more likely to try LAI ART, as were women from all other study sites compared with Miami, FL (aOR range: 2.04–4.51). There were no significant differences by race/ethnicity or educational attainment. Our findings did not change in a sensitivity analysis that used an ordinal logistic regression model with the uncategorized 5-point Likert scale.

CONCLUSIONS

Our study builds upon, and extends, prior research by identifying significant differences in women's likelihood to try LAI ART by age, substance use history, self-reported ART adherence, and geographic region.[15,20] Owing to the dearth of women included in clinical trials, additional research is needed to better understand their varying perspectives, which can inform the tailoring of interventions, messaging, and outreach. For example, WLWH in Miami, FL, merit further consideration to explore whether potential regional cultural barriers and variations in clinical culture may contribute to a lower interest in LAI compared with other sites, even after controlling for sociodemographic factors. In addition, while our analyses included those who were undecided about their likelihood of trying LAI ART with those who were definitely or probably unwilling to try it, this undecided group may have had distinct characteristics which are worth exploring. The study findings demonstrate the need to develop programs and interventions that increase WLWH's awareness and understanding of LAI ART and that facilitate individual choice between LAI and oral ART.[24]

Our results showed that individuals who reported past-year substance use were significantly more likely to try LAI ART. This higher likelihood is essential given historically lower levels of viral suppression among this subgroup. However, women who use illicit substances may not be offered LAI ART by providers under current guidelines, further widening disparities in HIV outcomes; there is a need to ensure that women who want LAI ART are eligible to receive it and get the necessary support to ensure continued adherence. In addition, women who reported taking oral ART ≥95% of the time were less likely to be interested in LAI ART. This finding parallels research on contraception choices, including that women who were satisfied with their current method of birth control had lower intention to switch modalities.[25] While our research did not identify significant differences by race/ethnicity, this has been documented for contraception modalities[26–29] and merits further consideration.

Ongoing clinical trials and "real-world" studies involving people who are nonadherent to oral ART (i.e. who are not virally suppressed) have demonstrated the benefits of initiating LAI ART for this subgroup.[30–32] Given that, additional attention is needed to understand which factors medical providers, who are gatekeepers to medication, will consider when deciding who should be offered LAI ART. In addition, research on other medications suggests that initial enthusiasm for LAI ART may not lead to use, as social and structural barriers may limit availability or prevent access.[33] Indeed, LAI ART may present novel barriers to adherence that are not present in oral ART use: this includes a lack of information about use during pregnancy and the postpartum period (as pregnant women were excluded from clinical trials), the more frequent clinical visits required to receive injections, and higher medical mistrust of injection-based medications. Future research should explore these potential barriers

TABLE 1. Factors Associated With Willingness to try LAI ART (n = 1078 Women Living With HIV)

Variable	No. (%)	Would Probably/Definitely Try LAI ART: OR (95% CI)	*P*
Would probably/definitely try LAI ART			
No	614 (57.2)		
Yes	459 (42.8)		
Total	1073 (100.0)		
Age (continuous)			
≤35	19 (1.8)		
>35–≤45	169 (15.7)		
>45–≤55	381 (35.3)		
>55–≤65	424 (39.3)		
>65–≤75	76 (7.1)		
>75–≤100	9 (0.8)		
Total	1078 (100.0)	0.98 [0.96, 0.99]	0.005
Education			
<HS	342 (31.7)	Ref	
HS	341 (31.6)	1.32 [0.95, 1.83]	0.10
>HS	395 (36.6)	1.04 [0.76, 1.43]	0.80
Total	1078 (100.0)		
Race/ethnicity			
Non-Hispanic White	105 (9.7)	Ref	
Hispanic	138 (12.8)	1.02 [0.57, 1.82]	0.94
Non-Hispanic Black	783 (72.6)	1.01 [0.63, 1.60]	0.97
Other	52 (4.8)	1.12 [0.55, 2.29]	0.76
Total	1078 (100.0)		
Income >$12,000/yr*			
No	435 (41.7)		
Yes	609 (58.3)		
Total	1044 (100.00)		
Site			
Bronx	150 (13.9)	3.36 [1.63, 6.91]	0.00
Brooklyn	187 (17.4)	3.456 [1.73, 6.87]	0.00
Washington DC	128 (11.9)	2.34 [1.13, 4.83]	0.02
San Francisco	114 (10.6)	2.55 [1.21, 5.41]	0.01
Chicago Cook County	150 (13.9)	2.04 [1.01, 4.12]	0.05
Chapel Hill	95 (8.8)	2.47 [1.17, 5.21]	0.02
Atlanta	127 (11.8)	4.51 [2.18, 9.33]	0.00
Jackson	65 (6.0)	2.91 [1.32, 6.43]	0.01
Miami	62 (5.8)	Ref	
Total	1078 (100.0)		
Illicit substance use (excluding cannabis) in the past year?			
No	928 (89.2)	Ref	
Yes	112 (10.8)	1.656 [1.07, 2.56]	0.02
Total	1040 (100.0)		
Median years living with HIV*	16.3 (SD 8.2)		
Taking ART ≥95% of the time			
No	120 (11.7)	Ref	
Yes	907 (88.3)	0.67 [0.45, 0.99]	0.047
Total	1027 (100.0)		
Viral suppression*			
No	381 (27.6)		
Yes	999 (72.39)		
Total	1380 (100.0)		

*Not significant at $P < 0.05$ in bivariate analyses, so not included in the final model.
CI, confidence interval; HS, high school; OR, odds ratio.

to implementation, particularly among marginalized subgroups of WLWH with historically lower adherence and high levels of stigma.[34] Research and programming must also address identified clinic-level barriers to LAI ART scale up to ensure that it is readily accessible to all who are interested.[35]

LAI ART has the potential to address numerous adherence-related obstacles that women face with oral ART. Providing tailored support to those likely to try LAI ART can significantly contribute to viral suppression among women, a key, and often underrepresented, demographic. By providing WLWH with the option to take ART less frequently, and in a private clinical location, LAI ART has the potential to facilitate greater adherence and improve women's overall quality of life.

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