

SHORT REPORT

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Patient and clinic staff perspectives on the implementation of a long-acting injectable antiretroviral therapy program in an urban safety-net health system

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Abstract

Background Long-acting injectable cabotegravir plus rilpivirine (LAI CAB/RPV) has several potential benefits over daily oral formulations for HIV treatment, including the potential to facilitate long-term adherence and reduce pill fatigue. We aimed to assess facilitators of and barriers to LAI CAB/RPV implementation and delivery through the perspectives of physicians and clinical staff, and the experiences of LAI CAB/RPV use among people living with HIV (PLWH) at a Ryan-White supported safety-net clinic in North Texas.

Methods We conducted semi-structured interviews with recruited clinic staff (physicians, nurses, and support staff) involved with LAI CAB/RPV implementation and PLWH who switched to LAI CAB/RPV and consented to participate in individual interviews. Data were collected from July to October 2023. Our interview guide was informed by the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM), and Proctor Implementation Outcomes frameworks. Qualitative data were analyzed using a rapid qualitative analysis approach to summarize key themes.

Results We recruited and interviewed 15 PLWH who transitioned to LAI CAB/RPV and 11 clinic staff serving these patients. PLWH conveyed that emotional and informational support from family or a trusted clinician influenced their decision to switch to LAI CAB/RPV. PLWH also reported that injectable treatment was more effective, convenient, and acceptable than oral antiretroviral therapy. Clinic staff and physicians reported that staff training, pharmacist-led medication switches, flexible appointments, refrigeration space and designated room for injection delivery facilitated implementation. Clinic staff cited medication costs, understaffing, insurance prior authorization requirements, and lack of medication access through state drug assistance programs as critical barriers.

Conclusions Our study offers insights into real-world experiences with LAI usage from the patient perspective and identifies potential strategies to promote LAI CAB/RPV uptake. The barriers to and facilitators of LAI CAB/RPV program implementation reported by clinic staff in our study may be useful for informing strategies to optimize LAI CAB/RPV programs.

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Keywords HIV/AIDS, Long-acting injectable antiretroviral therapy, Implementation science, Injectable cabotegravir/Rilpivirine

Contributions to the literature:

- Prior studies have identified potential barriers to LAI CAB/RPV implementation, but none addressed multi-level factors that may impact LAI CAB/RPV sustainment.
- We evaluated LAI-CAB/RPV implementation and assessed the experiences of LAI CAB/RPV use among PLWH who switched to injectable therapy.
- Patients, physicians and clinical staff endorsed LAI CAB/RPV use, but several barriers were reported including medication costs, understaffing, prior authorization requirements, and lack of medication access through state drug assistance programs.
- Our findings address multi-level factors that may impact LAI CAB/RPV implementation and sustainment which may inform the development of strategies to facilitate scale-up of LAI CAB/RPV, particularly in safety-net settings.

Background

In January 2021, the US Federal Drug Administration approved a combination of long-acting injectable cabotegravir plus rilpivirine (LAI CAB/RPV) as the first complete LAI therapy for maintenance of HIV treatment in virally suppressed patients [1–3]. LAI CAB/RPV was initially approved for monthly administration with an oral CAB/RPV lead-in [2, 4, 5] but subsequently updated to make the oral CAB/RPV lead-in optional [4, 6]. The regimen is delivered either monthly or bimonthly through two intramuscular injections. LAI CAB/RPV has the potential to facilitate adherence by alleviating the pill fatigue associated with oral antiretroviral therapy (ART), reducing stigma, and increasing privacy for people living with HIV (PLWH) [7, 8].

Prior studies [7, 9–18] have identified potential barriers to LAI CAB/RPV implementation, including workflow changes [10, 12], provider concerns about potential drug resistance [11–14, 18], and administrative difficulties with medication approval and billing [7, 9, 12, 18]. Nevertheless, these studies have certain limitations. First, sustainability on LAI CAB/RPV implementation has not been addressed in published studies [7, 9–13, 17]. Thus, it is unclear how multi-level factors to initial implementation may impact the long-term sustainability of LAI CAB/RPV delivery. Furthermore, several studies [7, 15–17, 19, 20] only assessed implementation anecdotally

without reporting data on implementation outcomes. Similarly, studies [9, 10, 12, 13] that used determinant frameworks were mainly focused on understanding contextual factors that influence implementation outcomes before or during the early stages of implementation. A few studies were also conducted before FDA approval or prior to implementing LAI CAB/RPV in real-world settings [10, 13, 14]. Finally, patient preferences of LAI CAB/RPV were primarily studied in the context of clinical trials [21–23] or included PLWH who had not received LAI CAB/RPV [10, 12–14, 24–40].

Our health system recently implemented an LAI CAB/RPV program, which presented an opportunity to address these limitations and extend prior research by evaluating the implementation process. Our goal was to gain insight into how LAI CAB/RPV was implemented, what worked well, and what could be improved for scale-up and sustainable provision of LAI CAB/RPV in health systems. Therefore, we aimed to (1) explore the experiences of LAI CAB/RPV use among PLWH who switched to injectable therapy and (2) assess facilitators and barriers to implementing an LAI CAB/RPV service delivery program from the perspective of clinic staff involved in that delivery at a Ryan-White funded HIV Clinic in an *Ending the HIV Epidemic in the U.S.* (EHE) jurisdiction.

Methods

Study design and setting

We used the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) [41] and Proctor et al. implementation outcomes frameworks [42] to guide our qualitative evaluation of factors influencing LAI CAB/RPV implementation and sustainability. Specifically, we assessed all five constructs from RE-AIM and the acceptability construct from the Proctor et al. framework (Table 1). The North Texas Regional Institutional Review Board approved this study (IRB approval 2023-023). We followed the Consolidated Criteria for Reporting Qualitative Studies (COREQ) guidelines [43] [Additional file 1].

Our study was conducted at JPS Health Network (JPS), a large urban safety-net health system in Tarrant County, North Texas, which has over 2 million residents [44]. Tarrant County is an HIV hotspot [45] and a priority jurisdiction for ongoing EHE initiatives [46]. The JPS Healing Wings Clinic, a Ryan White-funded HIV clinic that serves uninsured or underinsured PLWH, began implementing LAI CAB/RPV for HIV treatment in

Table 1 Implementation outcomes and their description

Implementation outcome measure	Description	Framework used	Participant type
1. Acceptability	Acceptability is the perception of patients and clinic staff that LAI CAB/RPV treatment is agreeable, relevant, suitable, and satisfactory.	PROCTOR	PLWH
2. Reach ^a	Reach is the extent to which LAI CAB/RPV is received by its target group. Qualitatively, the reach dimension involves understanding why people accept or decline participation. Are we reaching those who would benefit most from LAI CAB/RPV treatment?	RE-AIM	PLWH, physicians
3. Effectiveness ^a	Effectiveness is the influence or impact of LAI CAB/RPV on important patient outcomes, including potential negative effects, quality of life, & economic outcomes.	RE-AIM	PLWH, physicians, clinic staff
4. Adoption ^a	Adoption refers to understanding why different clinic staff/key agents within an organization choose to adopt LAI CAB/RPV or not in general practices, namely facilitators and barriers.	RE-AIM	Physicians, clinic staff
5. Implementation ^a	Implementation refers to the extent to which LAI CAB/RPV was delivered with fidelity and to understanding adaptations made to deliver injectable treatment, implementation strategies used, and cost.	RE-AIM	Physicians, clinic staff
6. Maintenance ^a	Maintenance explores sustainability problems, i.e., reasons why patients/clinic staff may continue or discontinue LAI CAB/RPV use or delivery in the long term.	RE-AIM	PLWH, physicians, clinic staff

^a Qualitative description of RE-AIM Constructs [72]

August 2021. *Supplementary Text 1* and *Supplementary Table 1* provide additional details of the study setting, the JPS LAI CAB/RPV program, and a description of the patient population that switched to injectable therapy since program inception.

Study recruitment

Study participants were recruited between July and October 2023 until information saturation was reached and no new relevant knowledge was obtained from new participants [47].

Eligible patients were English-speaking adults living with HIV who received care at JPS Healing Wings Clinic, switched to LAI CAB/RPV after meeting clinical criteria for switching, and provided a valid phone number. The clinic pharmacist initially invited potentially eligible PLWH to the study. The research team then contacted these PLWH by phone to verify interest. PLWH interested in the study received a one-time web link via text message to complete an informed consent and a screening questionnaire to verify eligibility. PLWH were sent up to three text message reminders for their scheduled interview. PLWH who completed the interview were offered a \$25 Walmart gift card as compensation for their time.

We used purposive sampling to recruit stakeholders from the Healing Wings Clinic. Eligible clinic staff included clinicians, front-line staff, and administrators with direct or supportive roles in LAI CAB/RPV implementation. The research team sent a recruitment invitation email to eligible participants, which included a one-time web link to complete an informed consent.

Once the consent process was completed, participants were scheduled for an interview. We sent a recruitment reminder to clinic staff who had not responded after two weeks. The clinic staff were not offered any compensation.

Data collection and analysis

We invited 33 PLWH and 26 clinic staff. In total, 15 PLWH and 11 clinic staff participated in the study. PLWH were predominantly male (67%), racial-ethnic minorities (67%), and had a median age of 40 years (interquartile range: 33–52). Clinic staff were primarily female (73%) and included two HIV physicians, three nurses, and six support staff.

The research team followed a pre-interview script and semi-structured interview guides informed by RE-AIM [41] and Proctor et al. [42] constructs (see *Table 1, Supplementary Text 2*). For PLWH, the interview guide (*Supplementary Text 3*) explored perceptions of and experiences with LAI CAB/RPV and the degree of acceptability of the treatment. We used probing questions to elicit feedback on their experiences with LAI CAB/RPV. The interview guide for physicians and clinic staff (*Supplementary Text 4, 5*) included questions that elicited feedback on implementation lessons learned, clinic adaptations to enable program delivery, LAI CAB/RPV adoption among physicians, and factors impacting LAI CAB/RPV implementation and sustainability.

All participants completed a 20–30-minute interview via Zoom [48]. We used video conferencing instead of in-person interviews to save time and travel expenses,

provide flexibility and allow participants to be more comfortable in familiar settings [49–51]. Interviews were audio-recorded and transcribed verbatim by research staff using *NVivo 12* software (Lumivero; Denver, CO).

We used a rapid deductive analysis approach [52–55] to generate a summary for each interview transcript and identify themes, using summary template which included pre-specified domains based on the RE-AIM and Proctor et al. constructs. Two Ph.D researchers (MA and ET) independently coded each interview to identify blocks of text representing constructs from the RE-AIM and Proctor et al. frameworks. Data were aggregated across participants. MA and ET discussed the data, resolved discrepancies, and agreed on the emergent themes. We did not seek feedback or share transcripts with participants.

Results

Table 2 summarizes representative quotes organized by RE-AIM and Proctor et al. constructs.

Acceptability

Overall, LAI CAB/RPV users expressed a high level of satisfaction with injectable treatment and found it to be more convenient and flexible than oral ART. They also confirmed that injectable therapy offered several advantages over daily dosing of oral ART, including reduced pill burden, decreased anxiety and fear of missing treatment doses, and fewer refills. These benefits motivated the patients to switch to injectable treatment. Participants perceived injection-site pain and soreness as the most common side effects experienced with injectable treatment use; however, this was predominantly at the first injection.

Reach

We evaluated how PLWH learned about LAI and identified key attributes HIV physicians seek in LAI CAB/RPV recipients. The majority of LAI CAB/RPV users heard about injectable treatment through their HIV physician. Several PLWH reported hearing about LAI CAB/RPV through TV commercials or social media before discussing it with their HIV physician. Most PLWH endorsed having social support (emotional and informational) from a family member or a trusted clinician as an enabling factor that influenced the decision to switch to LAI CAB/RPV. Physician interviewees stated that they followed national guidelines for patient selection, but a key patient characteristic that guided their referral was patient adherence to general care and lab visits.

Effectiveness

Effectiveness examined the impact of LAI CAB/RPV on important patient outcomes, including potential adverse

effects, quality of life, and economic outcomes. PLWH expressed satisfaction with switching to LAI CAB/RPV, as it alleviated the daily pill burden and minimized the psychosocial impact associated with daily oral therapy. PLWH emphasized that injectable treatment provided a feeling of freedom, empowerment, and normalcy in contrast with previously feeling chained to a pill bottle. Some PLWH expressed the benefit of being able to travel for leisure or work. Patient-reported challenges with injectable treatment, as expressed by PLWH, included headaches, diarrhea, and weight gain. PLWH also expressed fear of losing health insurance or covered co-pays, challenges with getting injectable treatment funded by their insurance, and long waiting periods for prior authorization approval. Some users expressed being initially scared and wary of LAI since it was a new medication. Despite these challenges, users expressed that injectable treatment met and exceeded their expectations.

Clinic staff reported varying opinions regarding the potential effectiveness of LAI CAB/RPV on patient outcomes and healthcare practitioners' satisfaction with LAI CAB/RPV. In general, clinic staff perceived injectable therapy as a positive intervention and described its implementation as going well for their patients. Both physicians and some staff perceived reduced pill burden, improved adherence, and greater convenience as the most common benefits reported by their patients. Based on feedback from their patients, clinic staff and physicians cited injection site soreness, insurance costs and prior authorization as common challenges of injectable use.

Adoption

We assessed reasons for and intention to adopt LAI CAB/RPV among clinic staff. Some clinic staff and physicians' decision to adopt LAI CAB/RPV was attributed to their involvement in implementation and having many patients who were potential candidates for injectable therapy. Common concerns clinic stakeholders mentioned included rapid growth, understaffing, and changes in billing requirements for injectable therapy. One physician cited concern for unknown potential long-term effects of LAI CAB/RPV.

Implementation

Key implementation findings are summarized in *Supplementary Table 2*. Physicians perceived a positive overall experience with implementation. Clinic staff with a role in implementation also described their experience positively. Several staff perceived themselves as not having a high level of involvement in implementation. Both physicians and staff perceived that injection-related visits increased the nurses' workload. One of the most

Table 2 Representative quotes organized within RE-AIM and Proctor et al. constructs as reported by PLWH, physicians, and clinic staff during interviews

Construct	PLWH Quotes	Physician and Clinic Staff Quotes
Acceptability	<p>"... I was tired of taking so many pills. On top of HIV, I have high blood pressure and other things. So I was just tired. I wanted something different. And that's why I decided to get the shot." (Female, 52 years, Hispanic).</p> <p>"... They hurt really. This time they hurt this time really bad. I don't know if he just stuck me really good or I don't know. I usually have a high pain tolerance for it, but they're in my right and left hip. And I will have a hard time walking today and yesterday." (Female, 44 years, Non-Hispanic).</p> <p>"Just because remembering to take a pill almost every day seemed impossible. So it seemed like it'd be just a better idea to come to the doctor every two months to get a shot versus remembering to take a pill every day." (Male, 26 years, Non-Hispanic Black).</p>	N/A
Reach	<p>"I have been seeing it on the commercials and TV. And then when I be... on on YouTube. You know your commercials come on YouTube as well. And I've been hearing about it for like... before I got into it... for like a few months..." (Male, 62 years, Non-Hispanic Black).</p> <p>"So my family was just very excited, very, very happy for me. They were thrilled from a distance. To know that I would just have one less thing to have to worry about in my life on a regular basis." (Male, 40 years, Non-Hispanic White).</p> <p>I heard about it through Healing Wings [clinic] because I've been going there forever and they said I would be a good candidate. So I said, Well, let's do it. I'm wanting to try it. It's better than taking meds every day. So I got started." (Female, 57, Non-Hispanic White)</p>	<p>"... I like to know that they've been consistently making their appointments because I feel like that's really important as far as them coming in to get their injections." (PID 2, Physician).</p> <p>"Well, one going by, the guidelines being at least being undetectable for at least six months or more. And really, at that point, it's more on I know they've been compliant with care as far as showing up the lab results and office visits, both telehealth and in person. Plus overall compliance with their general care. Like any kind of screenings, things of that nature and kind of referrals." (PID 13, Physician)</p>
Effectiveness	<p>"... There'd be some times where if I was traveling, I'd always try my best to pack it. But it gets lost. Something gets damaged. It's a fear, right? And then if the virus becomes now resistant because you've missed a few medications, it's just it is a fear that always looms over me every time... And now that fear is gone because I get my injection." (Male, 26 years, Non-Hispanic White).</p> <p>"It's just a feeling of, I don't know, more freedom. Feeling better? I don't know. It kinda makes you feel better about yourself, if that makes any type of sense. Like living a normal... more of a normal life. Not feeling like a... and it's weird to say, but not feeling like a sickly person, which I'm not sick, but I am sick." (Female, 57, Non-Hispanic White)</p> <p>"I'm glad that I'm not taking the med and I'm on the injectable because it has allowed me to regain my life back, my freedom. I'm not chained up to a pill bottle every night, you know. And it becomes a toll on somebody sometimes when you're constantly having to think, I need to take this pill to stay alive..." (Male, 40 years, Hispanic).</p> <p>"... I was hoping that it would be a success. And it has been. My expectations were exceeded. I was, I was worried at first. Would there be, you know, a day or two or three of side effects or was because it's a very potent injection. But I haven't had you know, all those worries are gone." (Male, 53 years, Non-Hispanic White).</p>	<p>"There was a patient on my caseload that was receiving Cabenuva. He was set to graduate from case management, and he said it was life-changing for him. It completely was a game changer because he no longer had to take medications. He didn't have to set daily reminders on his phone. He didn't have to send out backup reminders to help him remember to take his medicines. He was busy with work and lots of other things." (PID 11, Clinic staff).</p> <p>"It's more the compliments I get or the positive feedback I get is from the convenience aspect. One less pill. They don't have to take medicines every day..." (PID 2, Physician)</p>

Table 2 (continued)

Construct	PLWH Quotes	Physician and Clinic Staff Quotes
Adoption	N/A	<p>"As we grow in our Cabenuva patients. I think we now have over 60 of them and we're constantly getting more and more patients. So maybe one nurse specifically for the Cabenuva program, which would be amazing..." (PID 23, Clinic staff). "Again, just positive. You know, it seems like it's what's best for the patient. It would be nice if I keep hearing that, you know, more and more of the plans are starting to approve the medication. And so it would be good if eventually that we move to almost exclusively go on that route." (PID 21, Clinic staff): "...it's a new territory, it's an injectable, I haven't really you know been practicing with this, you know, until this wonderful invention. And you always got to be concerned with long term side effects that we will pick up in the future. Or could there be resistance that comes down ten years down the line, etc" (PID 2, Physician).</p>
Implementation	N/A	<p>"I know it is challenging. It's very expensive. Our pharmacist handles all that for us. But I know it takes a significant amount of time to get all the prior authorizations done, so would speak better on that" (PID 21, Clinic staff). "Well, specifically for our population is has got to be affordable. You know, and we can say that about any med in this world at this point. But this is a new medication. It needs to be placed on THMP [Texas HIV medication program] formulary. It needs to be accessible to a wider range of patients outside of just insurance patients" (PID 2, Physician). "But it would be nice, you know, for patients who are medically eligible to not have to jump through the financial eligibility hoops, insurance coverage, hoops." (PID 4, Clinic staff). "... Um, it[s] [implementation] been very favorable. Um, I have definitely the resources and the specified area needed to give the medications. We have a designated room that we give it in." (PID 24, Clinic Staff). "...For the most part, from my standpoint, it's been very easy. I'll give all the credit to Dr. X for kind of developing the infrastructure there. So from a provider standpoint, it's been very easy, smooth, really no hiccups from our standpoint." (PID 2, Physician). "... Well, we are very lucky because we have doctor X. So like as far as determining insurance issues and things for people, I mean, she's doing all of that. I mean, I kind of know the guidelines to some extent, but everything gets sent to her. So she's been amazing for acquiring it for our patients. ... (PID 13, Physician)</p>

frequently cited barriers to implementation was the time the clinical pharmacist spent obtaining and tracking insurance authorizations. Clinic staff felt this was an administrative burden that made implementation challenging and caused significant delays in initiating patients.

Another challenge commonly cited by clinic staff and physicians was the affordability of LAI CAB/RPV and its exclusion from the Texas AIDS Drug Assistance Program (ADAP) formulary. Some staff also mentioned limited medication access for uninsured and low-income patients due to lack of drug coverage from ADAP. Despite challenges, clinic staff and physicians identified key facilitators: staff training, pharmacist-led switches, flexible appointments, refrigeration space, and a designated injection room. Physicians and clinic staff attributed implementation success to the clinical pharmacist managing medication switches and patient education. Some clinic staff noted that retraining nurses on injection delivery, offering flexible appointments, and providing refrigeration space and a designated injection room supported implementation.

Maintenance

PLWH and clinic staff were asked about the sustainability of injectable treatment, the integration of LAI CAB/RPV into clinic operations, and willingness to continue using injectable therapy long-term. Maintenance themes are summarized in Table 3. On an individual level, PLWH declared a desire to continue using LAI but mentioned that financial barriers related to insurance and co-pay could threaten their treatment maintenance. PLWH suggested several strategies for sustaining LAI use in the future, including expanding LAI CAB/RPV access to more patients, increasing timing between shots to a bi-annual schedule, and offering at-home injectable kits, different formulations of LAI CAB/RPV, and alternative anatomic sites for injections (e.g., thigh or arm).

Clinic staff perceived that the LAI CAB/RPV program was well-integrated into clinic operations but felt that more physician involvement could increase the number of patients initiated. One physician stated that seeing real-life data may have encouraged speaking with patients a bit earlier. At the institutional or health system level, clinic staff suggested the following to improve and expand LAI CAB/RPV implementation success: insurance reform, including standardizing eligibility requirements across insurance carriers; expanding clinical eligibility; patient education; staff training; and provision of dedicated staffing to manage injection appointments and insurance pre-approvals.

Discussion

Our study provides insights into experiences with LAI CAB/RPV use among PLWH and experiences with LAI CAB/RPV implementation among physicians and clinic staff. Our findings suggest high acceptability of LAI CAB/RPV among PLWH, physicians, and clinic staff. Participants expressed a strong desire to expand access to LAI CAB/RPV. PLWH generally perceived LAI CAB/RPV to have many benefits over oral ART and endorsed improved mental well-being and decreased anxiety. PLWH shared that emotional and informational support from family or a trusted clinician influenced their decision to switch to LAI CAB/RPV. Staff training, refrigeration space, designated injection room, pharmacist-led medication switches and flexible appointments facilitated implementation, but injection site soreness, medication cost, insurance, and medication access barriers were reported as implementation challenges.

Several limitations to our study should be acknowledged. Our findings may generalize to settings with similar populations and clinic structures but may not generalize to all healthcare settings. As with all qualitative interviews, social desirability bias is a possibility. The responses from our interviews may not represent the full scope of perspectives if participation was associated with certain perspectives. For example, a considerable number of PLWH and clinic staff were non-responsive to our invitation or declined to participate in an interview. We speculate that use of electronic consent during recruitment may have impacted PLWH enrollment [56]. In addition, we could not recruit and interview any patients who stopped using LAI CAB/RPV, which may over-represent positive perspectives. Nevertheless, available evidence suggests that few patients have discontinued LAI CAB/RPV in early studies [7, 16, 22, 57]. We also did not share transcripts or invite feedback on our findings, which could have been a valuable approach to validating interview data and improving data quality.

PLWH and clinic staff endorsed LAI CAB/RPV as highly acceptable and beneficial compared with daily oral medication, which is consistent with previous reports [13, 14, 22, 25, 28, 30, 32, 33, 35, 36, 38–40, 58–62]. Despite high acceptability, lack of ADAP coverage for injectable therapy was a commonly cited barrier in our study, which is consistent with other research on LAI CAB/RPV implementation [7, 9]. Currently, LAI CAB/RPV is covered as a medical benefit under Texas Medicaid and several commercial plans, but is not covered under the state's ADAP [63, 64], which raises concerns about worsening disparities in LAI CAB/RPV access [9]. Rapid inclusion of LAI CAB/RPV on government-based insurance formularies may facilitate access to LAI therapy, particularly in safety-net settings [16].

Table 3 Participant recommendations to sustain and expand injectable treatment potential for success

PLWH (n = 15)	Physician (n = 2)	Clinic Staff (n = 9)
<ul style="list-style-type: none"> Remove financial barriers related to insurance and copays 	<ul style="list-style-type: none"> Provision of real-life data to overcome practice inertia 	<ul style="list-style-type: none"> Insurance reform <ul style="list-style-type: none"> Standardize eligibility requirements for injectable treatment across insurance carriers
<ul style="list-style-type: none"> Increase access to more patients 	<ul style="list-style-type: none"> Increase patient eligibility and reach 	<ul style="list-style-type: none"> Expand clinical eligibility and reach <ul style="list-style-type: none"> Street medicine integration Include patients in case management and adherence counseling Include the uninsured Patient advertising
<ul style="list-style-type: none"> Offer at-home injectable kits 	<ul style="list-style-type: none"> Patient education 	<ul style="list-style-type: none"> Patient education to create awareness and available coverage Expand staff training and additional physicians should be trained and involved
<ul style="list-style-type: none"> Increase timing between shots to bi-annual 	<ul style="list-style-type: none"> Staffing: Consistent trained nurse staff/no attrition 	<ul style="list-style-type: none"> Create an autonomous clinic for injectable treatment
<ul style="list-style-type: none"> Include other anatomic sites for injections 		<ul style="list-style-type: none"> More stakeholder ownership <ul style="list-style-type: none"> Designate clinic staff to partake in program ownership Have dedicated staff to manage prior authorizations and the PAP process Dedicated staff to manage injection appointments
<ul style="list-style-type: none"> Other formulations of LAI CAB/RPV 		<ul style="list-style-type: none"> Provide case management and support services, especially for medically fragile patients. E.g., patient navigation Provide a compassionate environment and care

PAPatient assistance program, LAI CAB/RPVLong-acting injectable cabotegravir plus rilpivirine

Fear of losing prescription drug coverage for treatment was a key patient concern for maintaining LAI CAB/RPV, and participants strongly desired expanded medication access for LAI CAB/RPV. Clinic staff and PLWH also reported facing challenges in obtaining pharmacy benefits and prior approvals from payers, as well as significant delays in initiating injectable treatment, which is consistent with reports from early adopters in the southern US [7] but not the western US [19]. Notably, more than half of the Ryan White clients across the country live at or below 100% of the federal poverty line and have no insurance coverage [65]. Equitable access to LAI CAB/RPV may thus be limited without financial assistance. Standardization of insurance coverage policies and authorization criteria for LAI CAB/RPV approval among insurance vendors and removal of payer restrictions are needed to promote equitable access and increase injectable therapy utilization.

Several key implementation lessons emerged from this study, some of which are consistent with recent publications [9, 12] on LAI CAB/RPV implementation. First, from the patient perspective, having social support (emotional and informational) from family members or a trusted physician was an enabling factor that influenced the decision to switch and facilitated reach. Therefore, engaging trusted healthcare practitioners to facilitate

access by providing informational support may be a strategy to promote injectable therapy uptake among PLWH [11–14]. Second, at the practice-level, managing prior authorizations can be an administrative burden for clinic staff [9, 12]. Simplifying the prior authorization process, promoting automation, or providing centralized technical assistance for billing questions may alleviate this burden [9, 66]. Flexible appointments [9, 12, 16], nurse retraining, dedicated refrigeration and injection delivery space, and physician referrals to a clinical pharmacist eligibility assessment, patient education, medication switches facilitated implementation [67]. A centralized referral approach to a pharmacist-led LAI CAB/RPV service can streamline medication switches, ease physician burden, improve patient experience and promote team-based care [67, 68]. However, this approach may be impractical in clinics without an embedded clinical pharmacist. Finally, participants suggested several measures to promote the sustainability of injectable therapy, including offering at-home injectable kits [69].

Conclusions

Our study provides insights into the real-world experiences of LAI CAB/RPV implementation and use, and identifies potential strategies to facilitate sustainable uptake in clinical settings. Our data suggest that trusted

healthcare practitioners can be crucial in promoting LAI CAB/RPV by providing informational support to PLWH. Ensuring durable drug coverage may also be a key consideration in settings where LAI CAB/RPV is implemented. Nevertheless, clinic settings may lack dedicated personnel to manage complicated insurance requirements and administrative burdens. This issue will become more critical when LAI CAB/RPV eligibility expands to include viremic patients [20, 70, 71]. Lastly, high drug and co-pay costs remain significant obstacles to equitable access to LAI CAB/RPV. Addressing these crucial barriers can help support sustainable implementation and ensure fair access to LAI CAB/RPV.

Abbreviations

ART	Antiretroviral Therapy
ADAP	AIDS Drug Assistance Program
COREQ	Consolidated Criteria for Reporting Qualitative Studies
EHE	Ending the HIV Epidemic
FDA	Federal Drug Administration
IRB	Institutional Review Board
JPS	JPS Health Network
LAI CAB/RPV	Long-acting Injectable Cabotegravir plus Rilpivirine
PLWH	People Living with HIV
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
US	United States

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

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Authors' contributions

AMA developed the initial study concept, oversaw the management of the study, and drafted the manuscript. RO and all other authors contributed to the protocol development and project design. AMA, KC, CT, EF, and MP conducted recruitment and data collection. ET and AMA conducted data coding and analysis. RO and all other authors contributed to the critical revision of the manuscript and approval of the article.

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Availability of data and materials

To minimize the risk of participant identification, full transcripts of the interviews are not publicly available.

Declarations

Ethics approval and consent to participate

All procedures for this study were approved by the North Texas Institutional Review Board [IRB approval 2023-023]. All participants signed an informed consent prior to participation.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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