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Authors

McCrimmon, Tara
Collins, Lauren
Perez-Brumer, Amaya
et al.

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Long-Acting Injectable Antiretrovirals for HIV Treatment: A Multi-Site Qualitative Study of Clinic-Level Barriers to Implementation in the United States

Tara McCrimmon, MPH, MIA,[1] Lauren F. Collins, MD, MSc,[2] Amaya Perez-Brumer, PhD, MSc,[3] Angela R. Bazzi, PhD,[4] Victoria A. Shaffer, PhD,[5] Deanna Kerrigan, PhD, MPH,[6] Maria L. Alcaide, MD,[7] and Morgan M. Philbin, PhD, MHS[8]

Abstract

Long-acting injectable antiretroviral therapy (LAI ART) has the potential to address adherence obstacles associated with daily oral ART, leading to enhanced treatment uptake, adherence, and viral suppression among people living with HIV (PLWH). Yet, its potential may be limited due to ongoing disparities in availability and accessibility. We need a better understanding of the organizational context surrounding the implementation of LAI ART, and to inform its widespread rollout, we conducted 38 in-depth interviews with medical and social service providers who offer HIV care at private and hospital-based clinics across six US cities. Our findings highlight real-world implementation barriers outside of clinical trial settings. Providers described ongoing and anticipated barriers across three stages of LAI ART implementation: (1) Patient enrollment (challenges registering patients and limited insurance coverage), (2) medication delivery (insufficient personnel and resources), and (3) leadership and management (lack of interprofessional coordination and a lack of programming guidelines). Providers described how these barriers would have a disproportionate impact on under-resourced clinics, potentially exacerbating existing disparities in LAI ART access and adherence. Our findings suggest strategies that clinic leadership, policymakers, and other stakeholders can pursue to promote rapid and equitable LAI ART implementation in clinics across the United States. Resource and staffing investments could support clinics to begin, sustain, and scale up LAI ART delivery; additionally, the establishment of guidelines and tools could facilitate wider adoption of LAI ART across clinical settings. These efforts are crucial to promote resourced, standardized, and equitable implementation of LAI ART and maximize its potential to help end the HIV epidemic.

Keywords: HIV treatment, long-acting injectable ART, implementation science, clinic-level barriers, qualitative

[1]Department of Sociomedical Sciences, Columbia University Mailman School of Public Health, New York, New York, USA.
[2]Department of Medicine, Emory University School of Medicine, Atlanta, Georgia, USA.
[3]Dalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada.
[4]Herbert Wertheim School of Public Health and Human Longevity Science, University of California San Diego, La Jolla, California, USA.
[5]Department of Psychological Sciences, University of Missouri, Columbia, Missouri, USA.
[6]Department of Prevention and Community Health, Milken Institute School of Public Health, George Washington University, Washington, District of Columbia, USA.
[7]Department of Medicine, University of Miami Miller School of Medicine, Miami, Florida, USA.
[8]Division of Vulnerable Populations, Department of Medicine, University of California San Francisco, San Francisco, California, USA.

Introduction

As of 2021, only 66% of the 1.2 million people living with HIV (PLWH) in the United States were virally suppressed.[1] Long-acting injectable antiretroviral therapy (LAI ART) may help mitigate many well-documented barriers to oral ART adherence, including pill fatigue, stigma, and the daily reminder of one's HIV status.[2–6] LAI ART clinical trial data demonstrate high tolerability, acceptability, and preference over oral ART;[7] this is also supported by research from nontrial settings in the United States and globally.[8–10] The US Food and Drug Administration (FDA) approved an injectable formulation of ART (intramuscular long-acting cabotegravir and rilpivirine, LA-CAB/RPV; brand name Cabenuva) for monthly administration (January 2021) and bimonthly administration (February 2022).[11] However, despite over 2 years of availability, LAI ART uptake remains low, with only 15,000 individuals in the United States receiving LA-CAB/RPV as of December 2022.[12]

The integration of new biomedical technologies into health care settings is often constrained by organizational limitations and regulations, particularly when the route of administration differs from previous options. First-line HIV medication has previously only existed in oral form; intramuscular injection may necessitate additional clinical and operational infrastructure to facilitate its delivery, potentially restricting its availability, provision, and uptake. The field of implementation science emphasizes the importance of organizational context, which can impact whether a clinic decides to adopt an intervention or new medication (e.g., LAI ART), and how an intervention is incorporated into existing systems, practice patterns, and ultimately offered and delivered.

Determinant frameworks such as the widely used Consolidated Framework for Implementation Research (CFIR)[13,14] provide structures for understanding the factors that affect the successful implementation of evidence-based practices, and can guide the selection of strategies to enhance uptake.[15] Prior research[16–18] has identified clinic-based factors that shape implementation of new health care technologies, practices, or guidelines: these include regulatory and legislative standards, access to financial and other resources, infrastructure and workflow structure, leadership, communication, organizational culture, and social and clinical norms. An understanding of these determinants can then inform the selection of implementation strategies to facilitate the uptake of new practices, including new medications.[19–21]

Existing research on LAI ART has focused primarily on people's perceptions and interest before availability, making respondents' perspectives hypothetical. Most of these studies have assessed either patients' or physicians' anticipations regarding LAI ART, and data from other multi-disciplinary health care team members are lacking. Existing research has identified anticipated organization-level challenges with LAI ART medication procurement,[9,22] supply chain,[2] and readily accessible cold storage.[5,22–24] Anticipated workflow challenges include having private space to administer injections,[22,23] adequately trained staff to support programming at all levels (e.g., clinical eligibility assessment, drug approval and procurement, delivery of injections, patient tracking and monitoring), and protocols to manage patient and program challenges as they arise (i.e., complications from injections, toxicity, approvals, missed visits).[2,5,23,24]

Anticipated challenges have also included costs to patients and clinics regarding LAI ART medications and their delivery.[22,23] Most existing studies were conducted in a single clinic or city, rather than across states that vary by health policies and payment structures (e.g., Medicaid expansion and AIDS Drug Assistance Programs or ADAP). Recent publications drawing on the experiences of individual clinics with LAI ART have begun to address this gap,[25–27] but additional research is needed.

This study seeks to fill these gaps by characterizing barriers to LAI ART implementation post-FDA approval. We therefore interviewed HIV medical and social service providers across six US cities to understand clinics' approaches to LAI ART implementation and to examine factors that influence their delivery of LAI ART to their PLWH clients.

Methods

Participant recruitment and eligibility

Recruitment occurred from September 2021 to March 2022. We selected six cities due to their geographic variation and high HIV burden: Atlanta, GA, Birmingham, AL, Brooklyn, NY, Jackson, MS, Miami, FL, and Pittsburgh, PA. We used purposive sampling to ensure recruitment from a range of settings, including academic medical centers, private clinics, and publicly funded (e.g., Ryan White) clinics. Key contacts at each site helped identify potential medical and service providers (physicians, nurses, pharmacists, social workers, etc.) based on their experience or interest in LAI ART. Study investigators approached potential participants by email, which included a brief description of the research study. Participants provided verbal informed consent and interviews were conducted over Zoom. All study procedures were approved by the Institutional Review Board at Columbia University.

Data collection

Interview questions were developed through formative work by the study team.[3,28–30] Providers were asked to describe their actual or planned experiences with LAI ART in their clinic (Table 1). Interviews were conducted by three MPH- and PhD-level research associates, and lasted 45–60 min. Participants received a $75 gift card. Interviews were digitally recorded and professionally transcribed.

Data analysis

As described above, since prior research has focused on individual attitudes toward LAI ART, we limited our application of the CFIR to its inner and outer setting domains—the structures and processes within clinics that deliver LAI ART and the organizational or regulatory contexts in which they function. Our study follows others that have used implementation science frameworks,[31] and the CFIR's inner and outer domain settings,[32] to focus on the health care system context in which an evidence-based intervention was implemented.

Research associates read the same four transcripts to identify an initial set of inductive codes for analysis; these codes were supplemented by deductive codes based on existing literature and CFIR domains. The initial set of codes

Table 1. Mapping of Interview Data onto Consolidated Framework for Implementation Research Constructs

CFIR domain	*CFIR construct (CFIR 2.0)*	*Inductively identified code*	*Sample interview questions*
Inner setting	Structural characteristics	Clinic structures	Is there any challenge that is unique to your city, or neighborhoods within the city, which affects how patients access the clinic or their adherence to oral ART?
	Available resources	Clinical scale-up	What changes would your clinic have to make to begin giving LAI ART every 4 to 8 weeks?
			How do you plan to track LAI ART administration to patients, and what support do you provide to ensure patients come to receive their injections?
	Culture	Clinic culture	What are some challenges to providing LAI ART at your clinic?
	Organizational leadership	Rollout guidelines and leadership	Who is responsible for making decisions about introducing LAI within the clinic?
Outer setting	Partnerships and connections	Interagency collaboration	Does your clinic provide any wraparound service to meet your patients' needs?
	Financing, policies, and law	Health insurance	Have your patients experienced any challenge regarding insurance coverage for HIV medications?

CFIR, Consolidated Framework for Implementation Research; LAI ART, long-acting injectable antiretroviral therapy.

were applied and refined across seven transcripts. The research associates proposed updates and refinements to the initial codebook and used updated codebooks in each subsequent meeting to achieve consensus on coded transcripts.

Once a final coding framework was established, two researchers coded all transcripts using Dedoose software. Coded data were analyzed using a thematic analysis approach;[33,34] we were guided by CFIR's inner and outer context-related domains and their underlying constructs to select codes for inclusion in the thematic analysis. This included applying CFIR constructs to identify codes related to health insurance, clinical scale-up, clinic- or state-level guidelines and leadership related to LAI ART, interagency collaboration, pharmacies, and the clinic culture, as relevant (Table 1). Coded excerpts were reviewed by the analysis team, and findings were organized into broader themes.

Results

Of the 38 medical and social service providers interviewed (Table 2), nearly half ($n=17$) worked in clinics where LAI ART was fully available at the time of interview; six were in clinics with small-scale pilot studies; and 15 worked in clinics where LAI ART was not yet available. Providers were primarily physicians ($n=18$), but included nurse practitioners ($n=3$), other nursing positions ($n=4$), pharmacists ($n=2$), patient navigators or case managers ($n=6$), and other clinic or program coordinators or other supervisory positions ($n=5$). Providers described multiple existing and anticipated challenges at three stages of LAI ART implementation: (1) Patient enrollment in LAI ART, (2) delivery of LAI ART medication, and (3) leadership and management of LAI ART programming.

Patient enrollment in LAI ART

Providers identified multiple insurance and regulatory hurdles to procuring LAI ART for individual patients and the amount of time associated with these processes. Further, at the time of the interviews (until March 2022), a month-long oral lead-in was required to assess tolerance to LAI ART before the first injection,[11] which presented additional challenges. Financial concerns were paramount; providers described LAI ART's maintenance dose list price as "astronomical" and "prohibitively costly"—it was $6,429.34 per initial or 8-week dose and $4,286.23 per monthly dose for LA-CAB/RPV at the

Table 2. Sociodemographic Characteristics of Provider Interview Participants

Site, n *(%)*	N = *38*
Atlanta, GA	12 (31.58)
Miami, FL	8 (21.05)
Brooklyn, NY	7 (18.42)
Pittsburgh, PA	5 (13.16)
Jackson, MS	4 (10.53)
Birmingham, AL	2 (5.26)
Gender	
Female	29 (76.32)
Male	9 (23.68)
Race	
White/Caucasian	15 (39.47)
Black	11 (28.95)
Asian	4 (10.53)
Other	8 (21.05)
Hispanic/Latinx/Latine	9 (23.68)
Professional role	
Physician	18 (47.37)
Nurse practitioner	3 (7.89)
RN, LPN or other nurse	4 (10.53)
Pharmacist or pharmacy related	2 (5.26)
Patient navigator/case manager	6 (15.79)
Clinic/community coordination (coordinators, supervisors)	5 (13.16)
Years providing HIV care	
0 to 5	12 (31.58)
6 to 10	9 (23.68)
11 to 20	9 (23.68)
21+	8 (21.05)

LPN, licensed practical nurse; RN, registered nurse.

time of this publication.[35] Cost was a magnified barrier for clinics whose patients came primarily from underserved communities. Some staff felt that funding for LAI ART programs could be better allocated to support oral ART:

> *We are a clinic for under or uninsured patients, you want the most bang for your buck, right? So how can you justify spending 3 times the amount of money? For each regimen we give to a patient we could have provided [oral] ART to 3 or 4 different people. (Physician #1, Atlanta, GA)*

Providers also worried about clinical costs related to LAI ART reimbursement, including spillover costs to the clinic due to the additional appointments and staffing that LAI ART requires.

Several providers reported uncertainty and initial confusion regarding how to classify LAI ART for billing and reimbursement, specifically as a pharmaceutical versus a medical benefit. This was particularly salient for clinics with limited experience delivering other periodical injectable medications (e.g., injectable birth control) since LAI ART visits required new billing and reimbursement protocols and clarifications for administrative staff:

> *A lot of this just falls between insurances being able to talk to doctors' offices. How is this administered? Is it a pharmacy or medical benefit? (Pharmacist, Jackson, MS)*

In addition to confusion, this also created additional staff burden to explain to other clinic personnel how to categorize this for insurance.

> *Initially, I [had] to explain that there is a new way to treat HIV. It is an injection. Don't write down that the patient is follow-up because he is not follow-up… unfortunately everything now is money and billing. (Physician #1, Miami, FL)*

These sentiments reflect a widespread perception that insurance and administrative considerations shaped how clinics planned for and integrated LAI ART into their practice. These processes were not only administratively complex but also time-consuming, especially for already overburdened clinics. Multiple providers described experiencing challenges with the LAI ART patient enrollment process, referring to it as a ''nightmare'' and describing lengthy delays in obtaining the month-long oral lead-in medications:

> *Going back and forth trying to figure out where this medication is has been exhausting… You tell patients, 'Yes, we can start you on this injection', and just getting the [oral lead-in] pills is taking more than a month. (Medication Access Coordinator, Atlanta, GA)*

While providers across sites noted that patients without commercial insurance faced more barriers to obtaining LAI ART, those in Atlanta, Georgia, noted a particular challenge. At the time of interview, Georgia's ADAP did not include LAI ART on their formulary, yet having ADAP coverage made a patient ineligible for the pharmaceutical company's patient assistance program. This rendered the most marginalized patients ineligible for this novel treatment option. Georgia-based providers also noted that it took 10 months from LAI ART's initial approval for it to be covered under the state's Medicaid program.

> *Unfortunately, the only successes we have had have been patients with private insurance or Medicare…which is the huge frustration and is perpetuating inequity in HIV care in terms of access to ART and clinical outcomes. (Physician #2, Atlanta, GA)*

Several providers emphasized the connection between insurance-based access issues and broader health care equity concerns. Those narratives specifically highlighted how LAI ART implementation could potentially worsen existing inequalities.

> *My concern would be that we don't create a multi-tiered or a two-tiered system, where some people don't ever get these drugs when they deserve them and would benefit from them. (NP, Pittsburgh, PA)*

Delivery of LAI ART medications

Providers identified challenges with maintaining adequate personnel and resources for delivery of LAI ART to clients. Providers reported that the frequency of clinic visits for patients on oral ART varied from monthly to every 6 months, depending on recency of HIV infection, comorbidities, and degree of virologic suppression. The monthly or bimonthly clinic visits required by LAI ART would necessitate hiring additional staff or pulling from the existing pool of staff and reconfiguring their responsibilities:

> *If you get 50 people on injectable ART, it's 50 more nurse visits that take about a half-hour or more, because you've got to document, you've got to give the shot… That's really put a strain on our nurses to have that many more visits coming in… (Physician #1, Pittsburgh, PA)*

In addition to the added visits, providers described the need to ensure services were available when patients could seek care:

> *I have one nurse who's willing to do it [LAI ART], and one pharmacist who's willing to do it, but I can't guarantee that we would have it available every day of the week. So, I haven't really felt comfortable starting it, because with that community health center… flexibility would have to be really important in scheduling. (Physician #2, Pittsburgh, PA)*

This provider highlighted the need to balance staffing constraints with scheduling flexibility for patients, including needing extended hours for patients who faced challenges common to marginalized patient groups such as limited public transportation, constrained childcare options, and inflexible work schedules.[36,37]

Participants emphasized that LAI ART would require not just additional staffing or staff hours but also a reconfiguration of staff roles and responsibilities within health care teams. Specifically, while nurses could delegate some forms of patient care to other members of the health care team (such as certified nursing or medical assistants), many participants noted that nurses may be the only ones with appropriate training to administer LAI ART in its current form (i.e., through intramuscular injection):

> *We don't have a lot of nurses, and most of them are not thrilled at the idea of having another thing. Most of our nursing visits, like our depo injections and things like that, are actually done by medical assistants. But because of the nature of the [LA-CAB/RPV] injections, it would really need to be a nurse doing it. (Physician #2, Pittsburgh, PA)*

Many participants identified the increased staff burden required to verify clinical eligibility to begin LAI ART, and determine whether a patient was ready and interested in LAI

ART. Subsequently, additional efforts were required to track and monitor patients to ensure they remember their injection appointments:

Who is keeping track of the log of patients that need to come for their appointment? Either that becomes a half day for them or a full day of work for them. I think that the way that our clinic is currently functioning, we might not have all the support we need. (Physician #2, Miami, FL)

In addition to tracking, providers also mentioned needing additional resources dedicated to patient education and structural supports, such as childcare and transportation, for the increased number of visits that LAI ART required.

Several participants noted that well-resourced clinics would be better able to handle these workflow and resource challenges. One respondent described having the clinic's staffing needs met as a ''luxury'' that allowed them to implement LAI ART more rapidly and successfully than those who did not. Others described how resource disparities would perpetuate inequities in who was able to access LAI ART.

I do think that this is an operational and staffing hurdle for clinics especially those that are resource constrained and have high patient volumes… because these clinics where the patients may most benefit from LAI. And every diversion of resources to LAI means taking resources away from something else. (Physician #3, Atlanta, GA)

The physician who noted the need for flexible hours and staffing to meet patients' LAI ART needs at a community health center (*#2, Pittsburgh, PA)* also reported working at a tertiary care clinic; she drew a contrast between the two settings based on resource availability:

At the tertiary care clinic it was very smooth. We have a pharmacist who takes care of most of the patient tracking.… And if there's a prior authorization, he gets it through and then is on top of scheduling the follow-up visits. And then we always have nurses, so the patients can come in any day of the week. At the community health center, I have not been able to start long-acting ART. And I don't know when that will be possible. (Physician #2, Pittsburgh, PA)

Leadership and management of LAI ART programming

Participants described the varied pressures that led clinics to adopt LAI ART. Some said that their clinics had introduced LAI ART in response to growing patient interest or requests. Others described their clinic's LAI ART adoption as being driven by physician requests, and still others were waiting for large-scale external outreach efforts from pharmaceutical companies to begin.

At the time of these interviews, there was no standardized national or state protocol to guide LAI ART implementation in clinics, which participants acknowledged would have been beneficial. Only one participant mentioned receiving guidelines from the local Department of Health (New York City). Therefore, planning for LAI ART implementation was frequently clinic specific and organized by staff:

The medical director of the clinic, and then our other physician, took the lead on the physician side…. Then we work with our partners in informatics to build the therapy plan, and the report, and then the special visit type, and then we've got our pharmacy…So there were definitely some steps, and it was an interdisciplinary approach that continues to be doing good stuff. (Physician #1, Pittsburgh, PA)

The composition of these ad hoc committees varied, yet mostly consisted of providers, pharmacists, and administrators. Only one clinic noted including PLWH on these teams, to ensure their perspective was reflected in clinical protocols.

We want to have patients who have [been] administered long acting to tell us what's important, and what has been helpful for them in terms of coming in… We need to build the system that makes this delivery a success rather than just setting it up to fail. (Physician #2, Birmingham, AL)

While these providers were committed to LAI ART implementation and scale-up in their clinics, they did perceive this planning work as an additional burden.

All of us came together more or less motivated by the potential gain and opportunity for offering this new treatment landscape to our patients, which is to say that none of us have protected time to do this work. (Physician #2, Atlanta, GA)

A handful of participants were unsure whether their clinics would ''allow individual providers to just prescribe, or if it will be more centralized in terms of the multi-disciplinary team verifying clinical eligibility.'' (Physician #2, Atlanta, GA). A centralized process would ideally reduce the provider burden during one-on-one interactions of determining patients' clinical eligibility and deciding whether each patient was a good fit for the varied demands of LAI ART.

A few participants also mentioned the desire to develop partnerships with nearby medical organizations to facilitate the implementation of LAI ART. Providers noted this would pool resources to facilitate scale-up, administration, or storage of LAI ART:

But I'm wondering if one way of getting around—doing with whatever staff we already have, would be to combine patients from those two clinics into an injection clinic thing or something like that… right now, we would not be able to take it on all by ourselves. (Physician #2, Miami, FL)

Discussion

Our study, conducted during the initial years of LAI ART availability in the United States, and across geographically diverse sites, offers unique insights into the structural and organization-level factors related to LAI ART implementation and scale-up. Our findings fill a direct gap as research on LAI ART implementation has primarily focused on individual-level drivers and hypothetical acceptability versus experienced or anticipated barriers. The barriers that we identified both parallel and expand on those found in research conducted before LAI ART approval; our findings underscore the pervasive challenges around financial and regulatory hurdles, resources and workflow, and leadership for LAI ART initiatives needed to support successful implementation in clinical settings. Below, we connect our findings to potential implementation strategies for LAI ART programs (Table 3), including methods used to enhance the adoption, implementation, and sustainability of dedicated programs and practices for LAI ART in clinical settings.

HIV medical and social service providers frequently emphasized how their clinic's existing structures and personnel were insufficient for the implementation and scale-up of a treatment option as novel and resource-intensive as LAI

Table 3. Potential Implementation Strategies to Address Organizational Context Barriers Preventing Widespread Access and Uptake of Long-Acting Injectable Antiretroviral Therapy

Identified barrier(s)	*Implementation strategies*
Administrative burdens for LAI ART	Pharmaceutical companies or state/national agencies should provide local or centralized technical assistance for billing questions from providers and pharmacists[a]
Lack of funding for LAI ART	State health agencies and insurance companies should ensure that LAI ART is on formulary lists, adjust incentive structures to ensure access, and make billing processes easier for clinic and pharmacy staff
	Clinics should clearly communicate patient fees, including visit co-pays
Confusion over staff roles related to LAI ART administration	Clinics should revise professional roles and create new clinical teams to clarify responsibilities surrounding LAI ART delivery and patient retention[a]
Lack of standardized protocols; every clinic ''reinventing the wheel'' to develop their own	Health care systems should develop a formal implementation protocol, incorporate LAI ART into electronic health record systems
	Regional collaboratives should identify early adopters of LAI ART and facilitate them sharing their knowledge/experience
Lack of organizational leadership	Clinics and health care systems should recruit, designate, and train individuals to lead or advise on LAI ART efforts at each clinic
	Clinics should identify champions for LAI ART[a] and organize implementation teams among clinicians[a]
	Clinics should leverage or adapt existing clinic advisory boards and workgroups to advise implementation
Concerns regarding inequities	State and national agencies should conduct outreach to under-resourced clinics
	Organizations should develop educational and training materials
	Policymakers and state agencies should advocate for changing LAI ART delivery sites to communities
	Clinics and physicians should utilize tools such as decision aids, which increase patient agency and demand

[a]Indicates that interview participants reported already employing these strategies in their clinics.

ART. This suggests multiple factors are necessary for clinics to reach an inflection point to allow for successful LAI ART implementation, including financial investments in personnel and the technology and resources needed for scale-up. This was particularly salient in under-resourced clinics, whose patient population may most benefit from LAI ART. There was much uncertainty about LAI ART financing, including who would bear the costs of the drug, associated supplies, administration, and additional staffing.

These findings demonstrate that the success of LAI ART, particularly whether it reaches the most marginalized populations, will require strategies that increase LAI ART program infrastructure and financing at federal, state, local, and hospital/clinic levels—this includes private insurance, as well as Medicaid and ADAP. New funding streams to support LAI ART delivery are imperative to cover items such as effort for personnel and technology for monitoring and tracking enrolled patients. Further, existing reimbursement and fee structures should be transparent and comprehensive to ensure coverage of the medication itself, as well as programming for its delivery. Until LAI ART is as financially accessible as oral ART for both clinics and individuals, it will not be a realistic option for many in the United States or globally.

Providers described administrative and delivery systems that were ill-equipped to provide LAI ART. Initiation of LAI ART required clarification on billing codes, reconsideration of staffing, and additional patient monitoring and outreach. To simplify these processes and reduce administrative burden, strategies are needed that support building clinic infrastructure and assembling multi-disciplinary teams to execute LAI ART programming. Electronic medical records should incorporate LAI ART patient tracking and monitoring features to standardize medication delivery. While exact roles and responsibilities of program personnel may vary, clinics should build multi-disciplinary teams of medication access coordinators, pharmacy staff, nursing staff, patient navigators, and physicians, to sustain LAI ART prescription procurement, delivery, storage, and administration, as well as patient tracking and monitoring.

Although LAI ART has been approved since 2021 (monthly) and 2022 (bimonthly), neither national nor regional guideline or protocol exists to provide a roadmap for implementation across varied clinical settings. As a result, our findings suggest that LAI ART is implemented inconsistently among clinics, since each must create its own protocols. Although some context-specific planning is inevitable, this replication of efforts generally drains time and resources. National and state agencies (e.g., health departments) should facilitate the sharing of clinical protocols and experiences with LAI ART implementation through coalitions and partnerships. However, such strategies should avoid a top-down approach to guideline development and should instead facilitate sharing of local experiences and collaborations.

Equity was a consistent challenge across each stage of LAI ART implementation. Our findings raise concerns about geographic disparities in LAI ART access, particularly around Medicaid expansion. Interviewees reported considerable variation in administrative support and leadership, resources, and coverage for LAI ART among state Medicaid and ADAP programs. These shortcomings may further exacerbate disparities in LAI ART access since they may disproportionately impact resource-limited hospitals and clinics that serve patients who are underinsured or uninsured.

Further, the provider-driven process by which LAI ART is being implemented and scaled up heightens the risks of such disparities. Clinics that are understaffed or whose physicians and other providers do not have the time, support, or authority to develop LAI ART programming will likely be later adopters, or offer it to fewer patients. Strategies are needed to ensure equity in LAI ART availability, including targeted outreach, education, and training of staff in under-resourced clinics, as well as targeted financial assistance programs to support implementation and equitable offering of LAI ART in low-resource settings.

In addition, research should explore the possibility of nonclinical settings for LAI ART distribution to reach marginalized populations, for example, recent studies have shown that people with HIV would prefer to receive LAI ART at home.[8] Without these efforts, LAI ART may only reach patients who are already at well-resourced clinics and are more likely to be virally suppressed, limiting the impact of this new technology on the overall trajectory of the HIV epidemic. Future work must also explore how clinics are developing programs and approaches to engage marginalized groups of patients who may not yet be virally suppressed, who can also benefit from this new biomedical technology.[27]

Our findings should be interpreted within the limitations of our study design. Per qualitative standards, we sampled providers who could discuss LAI ART implementation; generalizability was not the goal. Our findings may have been subject to response biases in either direction; providers may have expressed more positive attitudes toward LAI ART than they truly believed in the presence of an interviewer, or used the interviews as an opportunity to express frustrations. Interviews took place during a time period when many clinics were still providing limited services due to the COVID-19 pandemic, which may have influenced participant perceptions of clinic capacity and capabilities. Strengths of our study include its geographic range, and the inclusion of both medical and social service providers. While not a factor in the selection of clinics or providers, the variety in stages of implementation of LAI ART seen among our sample is another strength.

Our findings underscore the importance of research that assesses the unique contexts into which new medications are delivered, as well as the need to develop tailored guidance and protocols on delivery so that new forms of HIV medication are equitable for all PLWH. This is particularly true, given the novel modality of LAI ART.

Other LAI ART formulations (implants, etc.) are in advanced stages of clinical trials, and our findings suggest ways in which these, too, may require reconfiguration of traditional HIV systems and procedures.[4] While we focused on HIV treatment clinics, our findings may also be applicable to the delivery of LAI pre-exposure prophylaxis for HIV prevention, which may face a similar set of implementation and scale-up challenges, despite overall patient and provider enthusiasm.[38,39] Investments that address these organizational context-related barriers and build infrastructure for LAI ART are imperative, given the myriad long-acting forms of ART under study, and should be adaptable to these future formulations.

Authors' Contributions

M.M.P., V.A.S., D.K., and M.L.A. conceptualized the study, designed the methodology, and acquired financing. T.M. and M.M.P. conducted data acquisition. T.M. conducted data analysis under supervision from M.M.P. T.M., M.M.P., L.F.C., A.P., and A.R.B. contributed to writing the original draft of the article. All authors reviewed the article and provided feedback.

Author Disclosure Statement

No competing financial interests exist.

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Address correspondence to:
Morgan M. Philbin, PhD, MHS
Division of Vulnerable Populations
Department of Medicine
University of California San Francisco
UCSF School of Medicine
CVP Box 1339
2540 23rd Street, Room 4212
San Francisco, CA 94143
USA

E-mail: morgan.philbin@ucsf.edu