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Preparing for long-acting injectable antiretroviral therapy for HIV in Los Angeles

Preliminary Findings Report

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Background and Introduction

Daily oral antiretroviral therapy (ART) resulting in virologic suppression has dramatically reduced the morbidity and mortality associated with HIV infection, and the transmission of HIV to sexual partners (1). However, the benefits of ART are not uniformly realized by all people with HIV, as racial/ethnic, sexual, and gender identity minorities lag behind in rates of virologic suppression due to difficulties in accessing health systems (care and medications), challenges with adherence to daily oral ART due to comorbid mental health or substance use disorders, and social, economic, and structural barriers to treatment.

With the imminent regulatory approvals of Long-Acting Injectable (LAI) ART, for the first time, treatment will move beyond daily oral treatment, providing a promising new mechanism for achieving virologic suppression for the most vulnerable populations of people with HIV. Because an LAI regimen does not require adherence to daily pill-taking, LAI ART holds promise to help address HIV care disparities and advance the U.S. goal to End the HIV Epidemic (EHE).

LAI ART is anticipated to achieve regulatory approvals in the United States (US) and be commercially available by late 2020. Regulatory approvals have already been obtained in Canada, and are pending in Europe. The first iteration of LAI ART that will reach the consumer market is based on the use of two antiretroviral medications with long half-lives: cabotegravir, an integrase-strand transferase inhibitor, and rilpivirine, a non-nucleoside reverse transcriptase inhibitor. LAI ART is only approved for use for people with HIV who are suppressed. LAI ART can maintain viral suppression, but it has not been shown to be able to initiate viral suppression.

The combination of LAI cabotegravir and LAI rilpivirine has been demonstrated to be as safe and effective as oral combination ART in maintaining viral suppression in people with HIV. In the ATLAS study, virologic suppression was maintained by 92.5% of participants in the LAI ART arm compared to 95.5% in the oral combination ART arm (2). In the FLAIR study, LAI ART maintained viral suppression in 93.3% of participants in the LAI ART arm compared to 93.6% in the oral combination ART arm (3). In both the ATLAS and FLAIR studies, LAI ART maintained viral suppression at similar rates to oral combination ART, with both outcomes meeting their pre-specified statistical non-inferiority margins (2)(3). Over 98% of participants in both studies preferred the injectable regimen over their previous oral ART regimen. Common side effects in the LAI ART arm were mild and prevalence decreased over time; <1% of participants withdrew from the studies due to side effects.

While maintenance of viral suppression has been proven, the requirement that consumers have already achieved viral suppression on conventional daily oral ART prior to use of LAI ART may pose challenges to those most likely to benefit from LAI ART, such as individuals with adherence issues, substance use, and mental disorders. Thus, although LAI ART has the potential to revolutionize HIV treatment, it also has the potential to widen disparities. Many knowledge gaps remain around how to optimally implement this novel intervention to address these challenges.

LAI ART implementation could also significantly burden healthcare systems. The first iteration of LAI ART will require administration of ART injections at healthcare facilities at monthly intervals. An anticipated early improvement in dosing to every 2 months is likely, a change that will mitigate concerns only slightly at healthcare centers. These requirements increase the number of visits people with HIV have to undertake compared to the current 3-6-month intervals of follow-up using daily oral ART. This will introduce as-yet-unquantified stresses to the healthcare system.

Other critical data gaps around LAI ART include acceptability and willingness of people with HIV to adopt the LAI ART regimen and resistance implications of missed doses (given the prolonged tail-pharmacokinetics and potential for resistance to first-line treatment agents should low antiretroviral levels from a delayed injection result in viral rebound). The particularly worrisome potential of class-level HIV resistance deserves special attention, given these agents are used in initial and salvage treatment in the US and globally.

The Center for HIV Identification, Prevention and Treatment Services (CHIPTS) conducted a formative study to provide the ground work to support successful implementation of LAI ART in Los Angeles County. The aims of this study were to 1) strengthen and develop partnerships and build capacity in partners to support research on implementation of LAI ART as part of a strategy to optimize viral suppression in Los Angeles County; 2) assess the policy, systems, financial, operational and clinical level barriers to and facilitators of the rollout and scale-up of LAI ART in Los Angeles County; and 3) assess the end-user (consumer) perceived barriers to and facilitators of LAI ART use in Los Angeles County. This report summarizes the preliminary study findings and recommendations to inform efforts to prepare for implementation of LAI ART in Los Angeles County. The diverse geography and racial/ethnic profile of Los Angeles County can serve as a microcosm of the larger US epidemic, and lessons learned locally may have national generalizability.

Methods

Consumers, clinical stakeholders and non-clinical stakeholders were enrolled as participants in focus groups in Los Angeles County, California. Consumer participants were recruited using a flyer distributed to agencies that provide HIV-related social and clinical services. The target recruitment population for the consumer participants was adult HIV-positive individuals (i.e., at least 18 years old) who were enrolled in the Los Angeles County Division of HIV and STD Programs (DHSP) Medical Care Coordination (MCC) program. Separately, clinical and non-clinical stakeholders, specifically leaders and key informants from community-based and government organizations such as HIV care service providers, administrators, policy-makers and funders, were identified and invited to participate by email. Interested individuals were enrolled as participants.

Two focus groups and one semi-structured interview session with clinical and non-clinical stakeholders, and two focus groups with consumer participants, were conducted in February 2020 at three sites in Los Angeles County. The interview session was initially scheduled as a focus group but was attended by a lone stakeholder, resulting in a semi-structured interview.

The two consumer focus groups consisted of only consumer participants. The three stakeholder sessions consisted of a non-clinical stakeholder participant, clinical and non-clinical stakeholder participants, and clinical stakeholder participants, respectively.

After providing verbal consent, participants completed a brief socio-demographic questionnaire and were provided with an informational sheet. Participants received a brief overview of LAI ART by a study clinician, including information on efficacy and side effects from the clinical trials. The focus groups were conducted by a trained facilitator using a semi-structured discussion guide and ranged from 50-120 minutes in length. Responses were digitally recorded, transcribed, and stored on a secure server for analysis. The semi-structured guide contained prompts for the following topics: barriers to and facilitators of LAI ART at the consumer level (e.g., adherence, stigma and medical mistrust-related issues) and provider level (e.g., perceived cost, patient volume); overall LAI acceptability; and messaging and recommendations for LAI rollout and implementation. Consumer participants were each compensated \$50 cash for participation. All participants were provided light refreshments during the sessions.

Key clinical and non-clinical stakeholders previously invited by email to participate in the focus groups were asked to provide feedback on a draft of the preliminary findings report. Stakeholder feedback was incorporated into the final version of the report.

Data Analysis

Recordings from the five sessions were transcribed by a certified transcription service. A member of the study team performed quality assurance by comparing transcripts against the audio files. Two team members (study investigators LMB and EDS) performed inductive thematic analysis, reading the transcripts multiple times to identify general themes by looking for patterns, and to generate initial codes. They developed an initial codebook from the transcripts, listing each theme and subthemes with detailed description, inclusion and exclusion criteria, and typical examples. The codebook was further refined through an inductive and reiterative process with the two investigators and two coders (DJ and ERC) that included reliability scoring and discussion of inconsistencies until consensus was reached. Twenty percent of the transcripts were coded and tested for reliability and consensus.

Once an acceptable inter-coder reliability (of Kappa > .80) was reached, the codebook was finalized and the two coders used Dedoose Version 8.3.17 qualitative data management software to code all the transcripts. After all data were coded, the two study investigators and two coders read each coded passage to identify themes representing barriers and facilitators to LAI ART, as well as proposed recommendations, overall and by participant group, in order to develop recommendations and determine next research and implementation steps. The findings and recommendations within this report reflect the preliminary findings and themes gathered during the semi-structured interview and focus groups, and through iterative thematic analysis of the transcripts.

Ethics

All study procedures and documents were approved by the University of California Los Angeles Institutional Review Board.

Preliminary Findings

A total of 18 consumers and 23 clinical and non-clinical stakeholders participated. In the consumer sessions (n = 18), the average age was 52.2; range = 20-69 years, and 39% (n = 7) were Black/African American, 11% (n = 2) White, 44% (n = 8) Hispanic/Latinx, and 6% (n = 1) reported “Other” race. A total of 72% (n = 13) were cisgender males and 28% (n = 5) cisgender females. Sexual orientations of participants were 17% (n=3) bisexual, 61% (n=11) gay or lesbian, and 22% (n=4) straight/heterosexual. A majority of the consumer participants, 61% (n=11), had previously heard of LAI, and 39% (n=7) had not heard of LAI prior to the focus groups. Furthermore, when asked about the likelihood of using LAI, responses varied with 22% (n=4) reporting don’t know/not sure, 22% (n=4) likely, 11% (n=2) not at all likely, and 44% (n=8) very likely.

The average age of the 23 stakeholder participants was 45.65 years, range = 28-75 years. Clinical and non-clinical stakeholders were 17% (n = 4) Asian, 35% (n = 8) Black/African American, 22% White (n = 5), and 26% (n = 6) Hispanic/Latinx, with 26% (n = 6) cisgender female and 74% (n = 17) cisgender male.

The preliminary findings presented below are based on notes made during the semi-structured interview and focus group sessions, review of session audio recordings and transcripts, and preliminary content analysis of session transcripts. Illustrative quotes from consumers, clinical stakeholders, and non-clinical stakeholders are labeled accordingly. Information from the transcripts was used to infer and categorize the quoted speakers from the focus group that included both clinical and non-clinical stakeholders.

Overall Perceptions of LAI ART

Participants were generally enthusiastic about LAI ART and its potential to benefit patient care. Consumer, clinical stakeholder, and non-clinical stakeholder focus groups alike were receptive LAI ART as a “new tool in the toolbox” of HIV treatment options. However, all focus groups expressed significant concerns about barriers to LAI ART implementation and uptake.

Consumer-Level Facilitators of and Barriers to LAI ART Use

Consumer Preferences and Beliefs

All focus groups perceived that some consumers would prefer to use LAI ART, particularly those with pill fatigue, adherence challenges, or anxiety managing their current treatment regimen. Consumer participants expressed interest in LAI ART for their own use or the use of other consumers seeking new options.

"I think that that would be so awesome when that gets approved because for me, I would prefer to do a long acting injectable instead of having to take a pill every day...Being adherent has always been a struggle for me. When I was younger just because of a lot of different reasons. But now in my older age, I am busy, I work a lot. I'm always on the go and sometimes I forget. So I won't have to worry about it." (Consumer)

General beliefs about injections arose as another factor that may impact consumer willingness to use LAI ART, such as the belief among some consumers that injections are more effective or powerful than pill-based treatments.

"In the Black and Brown community it's interesting because while injections are actually more frowned upon I've found in general in the Black community, actually in the Latino community it's like 'give me an injection because somehow it works better and it's going to really make me better. Please give me a shot. It'll take my cold away.' Whatever, right? So an injectable actually might be more accepted in a Latino community." (Clinical stakeholder)

Participants expressed that consumers who are satisfied with their current treatment regimen or fearful of needles or potential side effects of LAI ART may be unwilling to use LAI ART.

"...if it works for anybody else that's good but I like what I'm on now. Because even though you take an injection, you still going to have to deal with that new side effect that's coming from all these different medicines. I don't even want to go through that no more..." (Consumer)

The monthly clinic visits required for LAI ART also emerged as a key factor that may negatively impact consumer willingness to use LAI ART.

"I do see some drawbacks with having to schedule an appointment, go to the appointment, for those that are busy, or those that have other challenges in their life." (Consumer)

Some clinical stakeholder participants perceived patient motivation to use LAI ART as an important factor in determining whether a consumer may be an appropriate candidate for LAI ART.

"I think that the motivation piece is, a patient that is highly motivated, is tantamount to choosing who's best for this." (Clinical stakeholder)

Adherence and Resistance

A key facilitator noted across focus groups was the potential for LAI ART to benefit consumers who have trouble adhering to daily oral ART. Participants expressed that LAI ART may be easier for some consumers to adhere to than daily oral ART due to the reduced treatment frequency and decreased consumer responsibility for treatment management.

“It does become a hassle in remembering to take your meds. Cause there's times that I'm like, "Dang, did I take my meds this morning?" And then sometimes I think I've taken two of them instead of taking the one...So I think that it's going to be very advantageous to cutting down that confusion.” (Consumer)

However, clinical and non-clinical stakeholder participants conveyed concerns about adherence to LAI ART for consumers who experience psychosocial or structural barriers to attending medical appointments, particularly given the lack of flexibility with LAI ART’s treatment interval.

“It's really hard to know whether they're going to come back in, or not. And so I don't want to set them up for failure, or for future resistance, or other issues in the future...the patients I would like to get an injection, so I don't have to worry about their pill adherence, may not be the right people for this medication.” (Clinical stakeholder)

Additionally, fear of resistance as a consequence of non-adherence was identified as a barrier to LAI ART use across focus groups.

“I travel. I might be in different states, different countries in a month. What if something happens and I'm stuck? And I can't get to where I need to be to get my injections? So then that's just like not taking your medicine. So what kind of side effects or resistance am I going to have when I get back? It's like, oh man, you're resistant now and I can't afford to be resistant to anything because I'll die.” (Consumer)

“I think all these concerns bring up this underlying specter resistance. And so if we're missing doses, are we going to start having a lot of resistance.” (Clinical stakeholder)

Treatment Management Burden

Participants perceived that LAI ART may contribute to reduced treatment management burden for consumers, offering consumers relief from pill fatigue, decreased treatment frequency, and decreased responsibility for treatment management. It was noted that some consumers may also experience reduced anxiety using LAI ART as a result of decreased treatment management burden.

“As of right now I'm in a regimen of one pill a day. Sometimes I forgot to...even as one pill, sometimes I forgot to take it. So I think if it will be every month, it will save a lot of time, a lot of worries, a lot of preoccupation.” (Consumer)

However, clinical and non-clinical stakeholder participants perceived the visit frequency required for LAI ART as a significant burden for consumers.

“Because I think that's going to be the big problem...you've been complaining when you have to come in every four months. Now you've got to come in every month. I think this, if we have it every three months, it'd be goldmine. But at once a month, it's going to still be hard for the right patient.” (Clinical stakeholder)

Non-clinical stakeholders also reflected that the decreased treatment control that consumers would experience switching from pills to LAI ART may increase consumer anxiety.

“You relinquish, as a person with HIV you relinquish that control that you would [have] taking your pills...Now you have to go to a place where you have somebody [apply] the medication. You lose some control.” (Non-clinical stakeholder)

Pain and Side Effects

Fear of pain at the injection site and potential side effects were expressed as barriers to LAI ART use across focus groups. Participants commented that some consumers are afraid of needles, and even those who are comfortable with needles may fear the anticipated pain of two high-volume injections in the buttocks.

“I don't like doing shots. I hate to get them when I go to the doctor. And then you tell me I have two of them? One will be enough for me. You talking about two? I'll stick with my pills.” (Consumer)

Consumer participants expressed personal concern about possible short-term side effects and long-term side effects that may be discovered post-implementation of LAI ART.

“...I don't think that I would be happy getting a shot because I know everything has side effects, it doesn't matter if you're taking a Motrin or an Aspirin. It's going to have some side effects.” (Consumer)

Clinical and non-clinical stakeholder participants also noted that the long half-life of an LAI ART dose may make the prospect of experiencing side effects more worrisome for consumers. They believed that some consumers will need to see how early adopters react to LAI ART before feeling comfortable trying it themselves.

“And I think because of the long half-life, that might be a concern because with a pill if you feel like you're having side effects, you can just stop. But with the injectable, I mean you're kind of stuck for at least a month, right? So I could see people being hesitant for that reason.” (Non-clinical stakeholder)

Medical Mistrust/Trust

Medical mistrust was perceived as another possible barrier to LAI ART use, particularly for Black consumers. Consumer and non-clinical stakeholder participants expressed that consumers with medical mistrust may be wary of trying a new treatment, and especially one that requires more reliance on healthcare providers. Participants also made reference to the history of azidothymidine (AZT) use in the Black community as a possible source of hesitancy and mistrust towards LAI ART.

“That is actually a huge thing in the Black community. Mistrust or a lack of trust in the healthcare field...So that could definitely be an issue that could get in the way...”
(Consumer)

“I think most persons would want to see somebody else looked at it before...because remember AZT, because when I hear some of the stories that they told me, they saw their friend dropping and dying and stuff like that. I think a lot of them would be on the sideline trying to see okay, let me see who is going to drop first. It's kind of like see if it works.” (Non-clinical stakeholder)

However, it was noted that medical mistrust may be less of a concern for consumers who will initially be eligible for LAI ART, as this population will already be engaged in routine medical treatment for HIV.

“But if somebody is already positive, they're already taking medications, I just don't see [medical mistrust] as being so much of an issue.” (Non-clinical stakeholder)

Reduced Stigma and Shame

Participants generally felt that the reduction in treatment frequency with LAI ART use may help ease the burden of internalized stigma and shame for consumers. Consumer participants also discussed the reduced risk of others finding out that a consumer is HIV positive when their treatment is administered behind closed doors at a clinic. Though participants primarily discussed the potential for stigma reduction with LAI ART use, it was noted that increased clinic visits may escalate the experience of stigma for consumers who do not want to be seen at HIV-associated locations.

“Some people live with more stigma than we can imagine being HIV positive than others. And then them just sneaking up going to the injection site and nobody don't have to know about what they're doing. It could really save their lives.” (Consumer)

“A lot of patients we find just the daily routine of taking a pill every day is a reminder that they are ill, and I think the injectable has an option to take that stigma away, or at least [take] that personal, internal stigma away from those people living with HIV, who kind of feel that burden.” (Clinical stakeholder)

Psychosocial/Structural/Demographic Factors

Various psychosocial, structural, and demographic factors were identified as potentially impacting use of LAI ART among eligible consumers. Across focus groups, participants expressed that consumers without accessible transportation would have difficulty using LAI ART.

“I think transportation is probably a huge issue for patients. If they're going to have to come in every month, or every two months...making sure that they can get there.”
(Clinical stakeholder)

Participants felt that consumers who are unhoused, use injection drugs, or experience other structural or psychosocial conditions that may make the pill-based regimen challenging could especially benefit from LAI ART, but may have trouble gaining and maintaining access to it.

“I would say target sex workers, target homeless, target injection drug users. I think those are the populations that we always want to target. But in reality, the people that really jump in on these are the ones that have the access to it. And we still haven't figured out how to reach some of them.” (Non-consumer stakeholder)

It was suggested that younger consumers may be good candidates for LAI ART, as they are more prone to forget to take their pills and may be more open to new treatment options than long-standing HIV treatment consumers. Long-term incarcerated consumers were also noted as potential candidates for LAI ART, with the opportunity to receive monthly injections on-site in a jail or prison setting.

“Definitely think younger people are going to be more likely to use the injectable than someone older and a little more comfortable to the routine of using pills as medication.” (Non-clinical stakeholder)

“...people who we know are going to be there longer in jail or in prison, you could start them on long acting injectables before they leave, give them their last dose before they leave and still provide all of those linkage services that it's not like they have to get to them in month one or even month two, and I think that could be really game changing.” (Non-clinical stakeholder)

Eligibility Concerns

Clinical and non-clinical stakeholder participants expressed disappointment that consumers who most need new treatment options, such as those who are non-adherent to current treatment, would not initially be eligible for LAI ART due to lack of viral suppression. For example, they were concerned that many consumers who are homeless or use substances may not be eligible due to adherence issues with daily oral ART. Clinical and non-clinical stakeholder participants also noted that the eligibility requirements eliminate newly diagnosed consumers for whom LAI ART may be the best treatment option. Across focus groups, participants questioned the representation of certain populations in the research studies that determined LAI ART efficacy and eligibility, including treatment naïve consumers, consumers of color, and pregnant consumers.

“It's just going to benefit people who are already doing really well. And when we think about where we need to make advances, that's not the group, right? It's the folks that aren't virally suppressed. It's the folks that are going to have a hard time making it to the doctor's office on a monthly basis.” (Non-clinical stakeholder)

Organization-Level Facilitators of and Barriers to LAI ART Use

Provider/Organization Attitudes

Clinical and non-clinical stakeholder participants felt supportive of LAI ART as a new treatment option and perceived that providers will appreciate having another HIV treatment tool available.

“Well, I think it's a positive contributor to our materials to treat our patients. It's not going to be with every patient, but there will [be] patients that it will be their ideal treatment.”
(Clinical stakeholder)

However, clinical and non-clinical stakeholder participants commented that organizations and providers may be wary of the many implementation needs that would have to be addressed to accommodate LAI ART, particularly given that eligible consumers will already be virally suppressed on an existing regimen.

“But when it's just about supporting choice and acknowledging that people have fatigue that feels really good. But I think for clinic administrators who, they're like, they're getting the same thing. I think it would be a really hard argument with additional cost. And new systems and burdens and asking nurses to do lots of shot teaching potentially and shot administration. I love our clinic administrators but I don't know if they'd go for it.” (Non-clinical stakeholder)

Clinical stakeholders noted the need for clinical guidance on how to best incorporate LAI ART as a treatment option to feel confident offering it.

“And I always think about, how do we offer any new technology, or new treatment options, in medicine? And I think the Community Advisory Board is a good thing, clinic or institutional guidance, or guidelines. Ultimately the DHHS guidelines is, ‘Is this a preferred therapy or not?’ And I think that's a powerful tool to both disseminate the information amongst providers, so we're all using standard quality therapies, and maintaining quality in our prescribing.” (Clinical stakeholder)

Financial Barriers

All focus groups expressed concern about financial barriers to LAI ART use. Consumer participants generally assumed their insurance would cover the cost but noted that cost would be a barrier for many consumers if LAI ART is expensive and/or not covered by insurance.

“I think it's a deal breaker if I can't afford it. I mean, definitely I'm not going to do it, I mean I can't do it, if it's not really in my budget, or my insurance doesn't cover it, or whatever...I mean, that's probably a major consideration.” (Consumer)

Clinical and non-clinical stakeholder participants discussed organization-level barriers around establishing effective and streamlined procedures for prior authorizations and billing. Clinical stakeholders also commented that payment procedures must account for regular changes in consumer insurance coverage and missed LAI ART doses.

“I think the prior authorizations...is where we're going to get crushed on this. And I would assume that, compared to the oral medicines, I would assume it's going to be a more

expensive drug. I don't have any knowledge of that, but I'm assuming that's true. And if it is true, that means a lot of work on our end to do prior authorizations. Is it just a one-time prior authorization, or are there going to be...Is it going to be every month, every three months? When people change insurances, you're going to have to do it again? That's a concern.” (Clinical stakeholder)

Staff Capacity Challenges

Staff capacity emerged as a key organizational barrier to implementation of LAI ART. Clinical and non-clinical stakeholder participants felt concerned about the staffing needed for LAI ART implementation, including responding to increased consumer volume, procuring and monitoring supply, providing treatment education and administration, and managing missed appointments. Anticipated changes to clinic workflow were also perceived as an implementation challenge.

“It's also changing the flow of clinics. Most of our folks, I don't know, at least in our clinics, we're not seeing people monthly unless it's the beginning of their diagnosis. You're talking about an influx actually of new visits potentially. Whether our clinics can handle that, whether we have the staffing...” (Non-clinical stakeholder)

Participants discussed the need for staff education and training to ensure staff are prepared for their roles in LAI ART implementation.

“I want to address something that we haven't addressed and I think it's about the training for the healthcare worker force. I think implementing the program for injectables of HIV clinics has to be very well thought in regard to training and capacity building. Not only from the clinic administrators, but also from the persons dispensing and applying the medications.” (Non-clinical stakeholder)

Physical Infrastructure and Supply Management

Clinical and non-clinical stakeholder participants noted possible physical infrastructure and supply management barriers to LAI ART implementation. They commented on the need for physical space to accommodate increased consumer volume and store LAI ART supply, storage equipment and protocols, and supply procurement procedures. Participants expressed particular concern for clinics without on-site pharmacies regarding their capacity to manage LAI ART supply.

“...there's going to be some logistical issues, too...I mean, how are we getting it? Is it coming from the pharmacy? Do they get it, bring it to the clinic, you inject them? Or does it come straight to the clinic? So your clinic now has to set up to store this. Do we order it ourselves? I mean...Many of us don't have our own pharmacies...” (Clinical stakeholder)

LAI ART Promotion/Marketing Recommendations

Participants generally felt that consumers of LAI ART would be the best people to deliver public promotion of LAI ART. They expressed that medical professionals should deliver the scientific

information, but consumer voices should be at the center of LAI ART promotional campaigns. Participants emphasized that community engagement would be critical for effective message development and implementation, and for establishing buy-in and reducing mistrust of LAI ART among priority populations.

“...the peer to peer strategy. I think [it] is incredibly effective, particularly when using people within a community who are essentially popular, the popular kids. You tell them, ‘Hey, we’ve got this. Could you talk to your friends and stuff about it?’ I think when they’re the ones to push the message, especially for people of color, then it’s a little more digestible.” (Non-clinical stakeholder)

Suggested promotional platforms included TV commercials, billboards, bus stop advertisements, waiting room flyers, community presentations, and social media advertisements, as well as direct outreach programs to reach priority populations who may not have access to mass communication platforms.

“We are talking about people who have no money or anything. We’re talking about homeless and drug users. Outreach programs is the only effective way. They don’t have media, they don’t have access to anything.” (Consumer)

Consumer participants highlighted the value of simple, short messages that promote LAI benefits. Specific messaging suggestions included “imagine not having to take a pill every day,” “simplify your life,” and “now HIV treatment can be even easier.”

“I think it’s nice to have two or three things to position equally the immediate benefits. And you share what is good immediately and you know that, you’re actually not reading many many things, maybe three things...” (Consumer)

LAI ART Implementation Recommendations

Clinical and non-clinical stakeholders recommended that nurses and pharmacists deliver LAI ART treatment

To make best use of staff, clinical and non-clinical stakeholder participants recommended that nurses and pharmacists deliver LAI ART treatment where possible. Participants were uncertain about whether medical assistants would be equipped to deliver LAI ART, particularly with the high likelihood of injection site reactions, and suggested additional training would be needed. It was noted that clinicians may need to be available on-site regardless of who delivers LAI ART in case of severe reactions.

“There’s a much wider group of people who can, I assume can administer, so you have nurses and pharmacists and pharmacy techs even...” (Non-clinical stakeholder)

Participants advocated for LAI treatment education and adherence support

Across all focus groups, participants emphasized the need for treatment education and adherence supports for consumers. Education should include general information about LAI ART, what to expect regarding the injection and potential side effects, the treatment interval, and other factors that may influence a consumer's treatment decision.

"Doctors need to communicate with us on everything whether they're an HIV doctor or not. Primary doctors. It's part of their responsibility." (Consumer)

Adherence supports were also noted as critical facilitators of successful LAI ART implementation. Suggestions included reminders, incentives, and consumer support groups.

"I think one of the easy thing to do is have an app or a program where persons can also go and check in to have kind of [a] support system where they can possibly talk to each other, just to see how somebody else is doing. If they're having any sides, something that they're uncomfortable with that they can share it in that space. That would be a great tool to have. Or maybe we can do the regular old stuff where we have once in a while, like a monthly meeting, where people check in like a support group kind of to help them through the process as well." (Non-clinical stakeholder)

Clinical stakeholder participants also discussed the need for electronic medical record (EMR) modifications to support consumer tracking and reminders.

"...until, I guess, we go to a block chain EMR, there's not really a good ledger in the EMR... We could probably build it, but it'd be something to think about, especially for all of them, because we only have a few EMRs to work with...To build it in a way that it can show up as a do, or as an alert, and a checkbox." (Clinical stakeholder)

Clinical and non-clinical stakeholders emphasized that pilot projects would be critical before a large-scale rollout across the county

Clinical and non-clinical stakeholder participants recommended administering research trial or demonstration projects with key populations in specific settings to inform development of guidelines and standardized procedures for LAI ART implementation in Los Angeles County. CHIPTS plans to conduct implementation research using differentiated care models to help address this identified need.

"But there can be, I think, best practices and guidelines that we should develop, I think, prior to that...This trial, are they looking at real world applications? What are we going to draw from? Not just rolling this out, for patients, just for, in a sense, depending on their desire for adherence, and sticking to the program, too. So we have to study that, too." (Clinical stakeholder)

Participants also mentioned the importance of research projects to study the flexibility of the dosing interval's "window period" and assess long-term effects of LAI ART.

“And also just having a little more information about it...like window periods of how long people could go without it. I don't think there's enough research yet or enough information about long-term effects and all those things about how people will interact with them. And how they could potentially affect their lives.” (Non-clinical stakeholder)

Participants offered innovative strategies to support LAI implementation

Across focus groups, participants recommended innovative strategies to facilitate LAI ART implementation and uptake. Participants discussed ideas of offering LAI ART at delivery locations outside of traditional HIV clinic settings, such as infusion therapy sites or colocated with substance abuse treatment, food bank, pharmacy, and other services for priority populations. Home visits by healthcare providers or nurses were also suggested as a way to mitigate consumer barriers to LAI ART use.

“I think there's a lot of innovative options that we're seeing in all different therapies, and it's going to come down to the different patient groups, and their interests. I think the whole home delivery is one thing. I think pairing it with a support group once a month is another thing. A group clinic. Pairing it with food bank is another. So finding the needs, whether they're psychosocial, or financial, or just mobility, and pairing the needs with the medication delivery.” (Clinical stakeholder)

Participants recommended exploring the possibility of self-injection, looking to home insulin and testosterone injections as models, and noted that this may require assessing alternative anatomic sites other than the buttocks. They advised learning from the implementation of injectable therapies for other conditions as Los Angeles County prepares for the arrival of LAI ART.

“Also, this is not the first time injectable treatment of disease has been introduced to the market. I'm sure diabetes went through the same cycle. At first there were pills or whatever, and then Metformin, and God knows what else. And doctor whatever performed injection. Then it was self... So, they went through a cycle and I'm sure they did a marketing campaign or whatever, however that was introduced to the public, we can replicate that process...” (Consumer)

Discussion: Recommendations

Consumer focus groups and stakeholder sessions provided valuable information on the barriers and facilitators regarding LAI ART implementation. Recommendations were developed by the study team based on the preliminary findings, and expanded to reflect stakeholder feedback on the report. Table 1 succinctly lists the identified barriers and respective recommendations. The team concluded that the formative work suggests that the success of LAI ART implementation will depend largely on extensive preparation to address the potential challenges that could arise, and further taking action to execute recommendations on a community, organizational and policy level.

Develop inter- and intra-agency care coordination and communication, which are key to implementing LAI ART successfully. This includes stakeholder partnership and collaboration across Los Angeles County. Success of this recommendation depends largely on partnership and seamless coordination among HIV service providers and other external partners. All HIV stakeholders need to build relationships and develop partnerships that will support the implementation of LAI ART through development of innovative research ideas and ultimately contributing to Los Angeles County's goal of reaching 90% viral suppression by 2022. A meeting of HIV service organizations and clinical champions facilitated by CHIPTS should be held in early 2021 to set goals and coordinate responses. This meeting will further build on the findings from the *Regional Response to End the HIV Epidemic in California* project, aimed at coordinating efforts among the California counties with the highest HIV burden, including Los Angeles County, to end the HIV epidemic by identifying priority needs, discussing recommendations and developing strategies that can be implemented across the region.

Implement consumer engagement, consumer-centered education, awareness, and support services that are vital to improve consumer willingness to adopt LAI ART and support treatment adherence to LAI ART. HIV service agencies responsible for developing and guiding message content around HIV treatment should engage community stakeholders to ensure the development of appropriate and culturally competent messaging around LAI ART. CHIPTS, Los Angeles County DHSP, and other service organizations at the public and private level can conduct community webinars and develop fact sheets to provide education around LAI ART as a treatment option, including its administration, dosing, side effects and benefits, which could be disseminated at point of care. Furthermore, messaging could involve community informed promotional campaigns, peer-to-peer information sharing, commercials on multimedia platforms and direct outreach presented by members from within the communities to whom the messages are directed. The Los Angeles County Department of Public Health (DPH) and other service organizations should seek community input in the development of community focused multimedia campaigns similar to the GET PrEP LA campaign (<http://getprepla.com/>). Los Angeles County DPH/DHSP can expand education for consumers around LAI treatment and provide consumer support through scaling up and training of peer navigators that will drive awareness of LAI ART as a treatment option and help promote adherence to the new treatment. Los Angeles County DPH/DHSP, as well as non-clinical and clinical stakeholders, can provide support services such as peer support groups to support treatment adherence, and also increase staffing to make reminder calls and track consumers. Los Angeles County's "Testing and Linkage to Care Plus" framework can be updated to include LAI treatment within its ART treatment options and support. Los Angeles County DPH can initiate differentiated program models such as engaging volunteer or paid community health workers to provide health education and consumer support to communities. Federal, state, and private funding agencies can support the education, training, adherence, and messaging development activities.

Address consumer concerns of medical mistrust, loss of personal sense of "treatment control," and stigma. These next steps are important in building the patient-provider relationship and addressing issues that may preclude LAI implementation. Medical mistrust, an issue of great concern to consumers especially in Black communities, can be addressed at the provider and organizational level. Psychosocial training and educational tools could be provided to HIV care

providers to enhance effective consumer communication strategies, allay fears, and build trust between the consumer and health system, trust between the consumer and provider, and confidence in the LAI ART medication. CHIPTS can continue to provide medical mistrust provider education and training specifically highlighting the historical context of racism in healthcare among black communities, detailing experiences of medical mistrust in various disenfranchised communities and discussing solutions to address the issues. Organizations and HIV/AIDS prevention and treatment training centers can either adopt existing curriculum or develop training on medical mistrust that can be offered to providers who are serving diverse populations. In addition, consumers should be equipped with information and engaged in their own healthcare to establish a sense of control and knowledge of the healthcare system and treatment medication. CHIPTS can provide information to assist consumers to address medical mistrust, tackle the fear of loss of control and advocate for their personal health on the consumer level by conducting community webinars and providing fact sheets with helpful communication tips for talking through their concerns with a provider at point of care. In order to address perceived stigma stemming from consumer influx and encounters in waiting rooms during appointments, HIV care clinics can refine their office spaces and appointment procedures. Clinics can also ensure that their office and healthcare delivery spaces are welcoming and inclusive for all. Furthermore, stigma can also be addressed through the aforementioned consumer-centered and culturally sensitive messaging.

Engage vulnerable populations in care from the get-go. It is critical to explore and implement differentiated models of care at the clinic and county level to provide treatment and treatment adherence support to vulnerable populations. In order to address concerns about adherence to LAI ART for consumers who experience structural barriers, leadership from mental health, substance use, jail, and other programs serving vulnerable populations should organize planning meetings to improve care coordination specifically around LAI ART. The Los Angeles County DPH/DHSP can coordinate with the Correctional Health Services (CHS) under the Los Angeles County Sheriff's department to support prison LAI treatment efforts within the Correctional Treatment Center to ensure that there are no lapses in the care continuum for consumers on LAI ART who transition in and out of jails. Also, the Los Angeles County DPH/DHSP and homeless service organizations can work together to support programs that engage displaced individuals into sustained LAI treatment. Providers can adopt treatment support models such as the Direct Observed Therapy (DOT) model to provide medication and supervise adherence to daily oral therapy with the purpose of ensuring consumers achieve viral suppression and eligibility for LAI ART. Street medicine teams in Los Angeles County, such as the University of Southern California (USC) Street Medicine team, can work in partnership with Los Angeles County DHSP to support the application of the DOT model by dispensing daily oral ART and subsequently LAI ART medication to transient populations. Similarly, the Los Angeles Correctional Health Service can adopt this treatment model within correctional institutions to ensure individuals facing adherence barriers to daily oral therapy receive support to become eligible for LAI treatment. Providers should also consider adopting a home visitation model in combination with the DOT model to reach consumers who are unable to commute from their homes to healthcare settings. It is important to note that structural barriers could impact follow-up of individuals within these communities.

Colocate HIV services and activate supplementary delivery sites. These are efficient ways to successfully implement LAI treatment while addressing treatment burden and capacity issues that may serve as LAI treatment barriers. HIV care providers can discover effective ways to partner with other providers to streamline the provision of necessary services, such as coupling LAI treatment with substance use or mental health treatment. For instance, a consumer can combine their LAI ART and medication-assisted treatment for substance use disorder or mental health disorders into a single provider visit. Furthermore, remote sites such as pharmacies, mobile testing vans, clinics and other non-HIV treatment sites with a regular practice model that accommodates monthly visits and high consumer volume can be utilized to deliver LAI treatment. Organizations that support non-hospital, in-office care delivery models, such as the National Infusion Center Association, would also be helpful resources for LAI ART implementation in non-hospital settings. Colocation of services and use of additional sites could significantly reduce monthly visits to a clinic.

Execute the necessary preparatory steps to address barriers pertaining to concerns around staff capacity, increased consumer volume, cost, medication supply chain management, and storage, beginning with conducting a detailed analysis of organizational capabilities. Performing detailed analysis of the best practices for supporting organizational capacity within HIV service delivery organizations will determine the organizational strengths and needs prior to LAI ART implementation. It is important for service organizations, especially HIV care clinics, to set up a plan to analyze and discuss their current financial, physical, and staff capabilities, determine the training and capacity needs of the organization, create a budget to reflect the potential LAI ART-associated costs, and outline the necessary steps needed to increase capacity and funding. A champion at each service organization should be identified to lead a rollout, implementation, and evaluation strategy for LAI ART. Furthermore, in order to address medication procurement issues, clinics could establish and test-run a medication procurement and delivery framework to ensure that processes such as pre-authorizations, payments, and methods of delivery from on-site and offsite pharmacies are systematized. Insurance authorizations can be simplified by implementing a systematic insurance screening process at the clinic to verify insurance coverage such as Medi-Cal. Clinics should set up efficient authorization and payment systems by determining the correct sources and codes, such as the Current Procedural Terminology (CPT) and Healthcare Common Procedural System (HCPS), which are needed to ensure providers get reimbursed for the treatment services provided. These efforts should be backed and monitored by clinic leadership.

Conduct training within HIV care organizations and county stakeholders to address issues such as consumer influx and clinical management education around LAI ART. Clinics would need to set up a consistent program to train current and future clinical staff, such as clinicians, nurses, physician assistants and medical assistants, to administer the LAI medication, and ultimately delegate responsibilities to lessen the expected toll on clinical staff from consumer influx. The Los Angeles County DPH can also partner with experts within the field to provide training around LAI treatment for all clinical and non-clinical staff, frontline workers, and other health professionals across various sites such as Los Angeles County clinics, Ryan White-funded clinics, community based organizations, and HIV service organizations, to handle a broad range of responsibilities, including the integration of clinical, technology and administrative

management of HIV services. It is also important to provide training for prison clinical staff and street outreach teams to administer LAI treatment to consumers, and support training for caseworkers to properly monitor and link transitional consumers to care. Federal, state, and private funding agencies can support the training, education, and integration of care services.

Strengthen care coordination through interconnectivity of Electronic Health Records (EHR) across all LAI ART delivery sites, such as clinics, pharmacies and mobile systems. Coordination of data sharing between EHR systems with the goal of providing updated consumer health information and tracking treatment dosage should be implemented across LAI ART delivery sites. The Los Angeles County DHSP can lead this process facilitated in partnership with EHR and digital health software companies. Such collaboration could lead to the production of advanced and comprehensive health records systems that provide synchronized tracking of consumer health information, including health history around LAI treatment, dosage and safety results. Systems that store and track consumer health information can also be integrated with an electronic notification system that allows for consumers to be reminded of their appointments and available service locations. The success of EHR management will involve the integration of care coordination, data sharing and safety information across all delivery sites, facilitated by leadership at these delivery sites. We acknowledge that there may be feasibility limitations to this approach. However, we challenge health systems and technology infrastructure to consider innovative solutions to address this important need and assist in the evolution of ART paradigms for the most vulnerable populations.

Develop policy to guide success of LAI ART implementation by addressing: access to health insurance coverage, securing pre-approvals of coverage in health insurance policies to ensure affordability of medication, and scaling-up of LAI ART delivery and point of care services.

Changes should be made to bypass any bureaucratic delay and broaden the type of providers and institutions to administer LAI ART medication to consumers by expanding the delivery of the injections to trained pharmacists and clinical staff such as registered nurses. Also, expanding the capabilities of clinical staff to conduct home visits will directly reduce the burden on a lone clinic system or physician. Furthermore, Ryan White HIV/AIDS program legislation should include LAI ART in the AIDS Drug Assistance Program under the Health Resources and Service Administration (HRSA) and expand Program formulary under Part B funding managed by the California Office of AIDS (OA) to provide coverage for low-income people with HIV who do not have insurance coverage. The HRSA AIDS Education and Training Centers program should adopt LAI training under its multidisciplinary education and training programs for healthcare providers treating people with HIV. Furthermore, policies and guidelines governing the overall implementation of LAI ART in the county, clinics, and potential care delivery sites have to be established by leadership of the Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health at the federal level and adopted at the California State, Los Angeles County, and institutional clinic levels to ensure that there is a standard of care followed by all providers.

Measure the process of the rollout. Ensure clinical and implementation research measure outcomes to identify and address challenges with organizational preparedness and eligibility for LAI ART in Los Angeles County. Performing demonstration projects, pilot studies, and/or

scenario-based studies of LAI implementation within different potential LAI delivery sites such as clinics, and further evaluating their LAI implementation strengths and challenges, is fundamental to standardizing systems. CHIPTS could conduct implementation research using differentiated care models to successfully propose LAI treatment as a care option in Los Angeles County. Pilot studies should be conducted in smaller clinic settings servicing diverse populations with a potential for application in larger clinics and hospitals, which will help to identify implementation gaps, needs, and best practices. Within these pilot studies, consumers can provide responses to quantitative surveys that will extend the research findings and offer more information related to the LAI ART implementation process. Future quantitative studies of consumers should be fully representative of Los Angeles County's diverse demographic landscape. Additionally, conducting analyses on other successful injectable treatment models, such as monoclonal antibody injections for plasma and biologics for rheumatoid arthritis, is crucial to identifying strategies and best practices for effective implementation. It will be helpful to conduct further clinical research to explore considerations around LAI ART self-injection, possibly using home insulin, testosterone injections, and Medication Assisted Treatment (MAT) as models. Also, additional research should be done to address potential inclusion of individuals that currently do not qualify for LAI ART treatment, such as those not adherent to daily oral ART. Furthermore, clinical studies should include safety research around administering LAI ART to pregnant women or women of childbearing age, and also explore additional injection sites for individuals with implants or other conditions that may prevent dorsogluteal injections. Stakeholders such as Los Angeles County DPH/DHSP and academic, behavioral, and clinical research centers can lead or support these studies, facilitated by funding through federal, state, and private funding partners.

As a final and important consideration, address LAI treatment rollout in the context of a pandemic. HIV care providers need to be cognizant of the challenges imposed by the COVID-19 pandemic that could further pose a barrier to adopting the key recommendations and delivering LAI ART to individuals. Important safety considerations and innovative approaches to care provision have to be discussed and tested to ensure effective, efficient, and safe provision of LAI treatment. Policies at the organizational level must be implemented to ensure the safety of the consumers and their providers during this period.

Conclusion

Preliminary study findings show that facilitators of LAI ART implementation in Los Angeles County exist, such as high levels of interest and expressed desire for treatment options among potential consumers and service providers, perceived reduction in the frequency and personal responsibility of treatment management for consumers, and perceived reduction in experienced stigma for consumers. Additional LAI ART supporting data, regulatory approvals and the potential for extended dosing interval for LAI ART from 1 month to 2 month intervals are expected, which will help to reduce problems due to consumer visit frequency in clinical care settings for both consumers and clinics, and also allay some anxiety around adherence for consumers who due to travel or work will not be able to access LAI ART care for over the current monthly dosing interval. Simultaneously, major challenges need to be addressed, such as the ability of clinics to handle the potential increased rate of consumer visits, increased

healthcare system contact frequency, and consumer concerns around adherence, psychosocial and structural barriers to treatment, and medical mistrust. In order to be equipped for LAI ART rollout, stakeholders will have to actively take into account operational preparedness, care coordination, staff education, consumer education, adherence support, and funding. HIV care providers will also need to be prepared to address care delivery, treatment support, and implementation challenges in the context of the COVID-19 pandemic. Importantly, partnerships across academic research centers, clinical and non-clinical service providers, consumers, and all stakeholders are vital to the success of LAI rollout in Los Angeles County. Identification of organizational champions invested in the success of this treatment paradigm, and then higher level coordination of such champions across clinical and service organizations, with multidisciplinary support and ongoing iterative research to evaluate various implementation and care delivery strategies in a rigorous way, will all be critical to increasing virologic suppression rates among people with HIV in Los Angeles County.

Table 1. Barriers Limiting Implementation of LAI ART and Recommended Strategies

Barriers Limiting Implementation of LAI ART	Potential Strategies to Address Barriers
<p>Consumer Preferences and Beliefs</p> <p><i>“I think that the motivation piece is, a patient that is highly motivated, is tantamount to choosing who's best for this.”</i> (Clinical Stakeholder)</p> <p><i>“In the black and brown community it's interesting because while injections are actually more frowned upon I've found in general in the black community, actually in the Latino community it's like ‘give me an injection because somehow it works better and it's going to really make me better. Please give me a shot. It'll take my cold away.’ Whatever, right? So an injectable actually might be more accepted in a Latino community.”</i> (Clinical stakeholder)</p>	<p>Develop culturally tailored messaging to educate consumers about LAI ART at point of care through fact sheets, webinars and mass media campaigns.</p>
<p>Monthly Clinic Visits/ Treatment Management Burden</p> <p><i>“I do see some drawbacks with having to schedule an appointment, go to the appointment, for those that are busy, or those that have other challenges in their life.”</i> (Consumer)</p> <p><i>“Because I think that's going to be the big problem...you've been complaining when you have to come in every four months. Now you've got to come in every month. I think this, if we have it every three months, it'd be goldmine. But at once a month, it's going to still be hard for the right patient.”</i> (Clinical stakeholder)</p>	<p>Research other options and healthcare delivery models to support LAI ART delivery such as mobile units, colocation of services, street medical teams, and jail systems, supported by care coordination among stakeholders and an enhanced EHR system.</p> <p>Conduct research to increase the interval between LAI treatment applications and to determine the possibility of self-injection.</p> <p>Provide consumer education to highlight that increased treatment visits are likely to be short, as they only involve injection.</p> <p>Streamline injection scheduling and the ability to reschedule within an allowable time frame.</p> <p>Optimize consumer flow to minimize time spent in the clinic.</p>
<p>Adherence and Resistance Concerns</p> <p><i>“I travel. I might be in different states, different countries in a month. What if something happens and I'm stuck? And I can't get to where I need to be to get my injections? So then that's just like not taking your medicine. So what kind of side effects or resistance am I going to have when I get back? It's like, oh man, you're resistant now and I can't afford to be resistant to anything because I'll die.”</i> (Consumer)</p>	<p>Conduct research to consider increasing the interval between LAI treatment applications and to determine the possibility of self-injection.</p> <p>Implement a coordinated system of clinics where a consumer can receive injections if traveling.</p> <p>Create a back-up system of bioequivalent medication in pill form in case the consumer misses their scheduled injection.</p> <p>Create an electronic reminder system through web or mobile applications for both the consumer and the provider to avoid missed doses.</p>

	<p>Adopt treatment models such as direct observed therapy, home visitation and street medicine programs to provide daily oral ART and supervise treatment adherence to ensure that consumers achieve viral suppression and eligibility for LAI ART.</p>
<p>Loss of Control to Provider</p> <p><i>“You relinquish, as a person with HIV you relinquish that control that you would [have] taking your pills...Now you have to go to a place where you have somebody [apply] the medication. You lose some control.”</i> (Non-clinical stakeholder)</p>	<p>Educate providers and consumers on helpful ways to communicate and address consumer concerns with LAI ART such as loss of control.</p> <p>Create support groups of consumers, as shared experiences are likely to reduce fear of side effects and issues of control.</p>
<p>Pain and Side Effects</p> <p><i>“I don't like doing shots. I hate to get them when I go to the doctor. And then you tell me I have two of them? One will be enough for me. You talking about two? I'll stick with my pills.”</i> (Consumer)</p> <p><i>“...I don't think that I would be happy getting a shot because I know everything has side effects, it doesn't matter if you're taking a Motrin or an Aspirin. It's going to have some side effects.”</i> (Consumer)</p>	<p>Provide symptomatic therapy with ice, NSAIDS or acetaminophen.</p> <p>Educate consumers regarding the rates of side effects and injection site reactions reported in clinical trials. Creating real expectations may minimize complaints of side effects.</p>
<p>Medical Mistrust and Stigma</p> <p><i>“That is actually a huge thing in the black community. Mistrust or a lack of trust in the healthcare field...So that could definitely be an issue that could get in the way...”</i> (Consumer)</p>	<p>Educate providers on how to recognize and communicate with consumers about their concerns around medical mistrust.</p> <p>Promote community buy-in before rollout in a specific community. Community activities could include individual and group educational sessions, webinars, and mass media campaigns.</p> <p>Create peer-groups to help consumers navigate the adjustment from oral to injectable medications.</p> <p>Provide a welcoming clinic environment.</p> <p>Provide services at other delivery sites (e.g., pharmacies) and restructure office spaces to prevent consumers from encountering each other during appointments.</p>
<p>Structural Factors</p> <p><i>“I think transportation is probably a huge issue for patients. If they're going to have to come in every month, or every two months...making sure that they can get there.”</i> (Clinical stakeholder)</p>	<p>Provide incentivized treatment support.</p> <p>Implement colocation of services and additional delivery sites.</p> <p>Implement inter-agency coordination.</p>

<p>Eligibility</p> <p><i>“It’s just going to benefit people who are already doing really well. And when we think about where we need to make advances, that’s not the group, right? It’s the folks that aren’t virally suppressed. It’s the folks that are going to have a hard time making it to the doctor’s office on a monthly basis”</i> (Non-clinical stakeholder)</p>	<p>Develop and conduct new clinical research studies to include those originally excluded from the already presented phase III clinical trials. Specifically recruit individuals with adherence issues, substance use disorders, mental health disorders, young and newly diagnosed people with HIV, and pregnant women.</p>
<p>Staff Capacity/Physical Infrastructure and Supply Management/Logistical Issues</p> <p><i>“I want to address something that we haven’t addressed and I think it’s about the training for the healthcare worker force. I think implementing the program for injectables of HIV clinics has to be very well thought in regard to training and capacity building. Not only from the clinic administrators, but also from the persons dispensing and applying the medications.”</i> (Non-clinical stakeholder)</p>	<p>Perform organizational analyses to determine local and unique needs at each organization.</p> <p>Establish a medication procurement and delivery system.</p> <p>Train HIV care delivery staff around clinical management of LAI ART delivery.</p> <p>Improve education and training for staff around LAI ART administration issues.</p>
<p>Policy Considerations</p> <p><i>“I think it’s a deal breaker if I can’t afford it. I mean, definitely I’m not going to do it, I mean I can’t do it, if it’s not really in my budget, or my insurance doesn’t cover it, or whatever...I mean, that’s probably a major consideration.”</i> (Consumer)</p> <p><i>“I think the prior authorizations...is where we’re going to get crushed on this. And I would assume that, compared to the oral medicines, I would assume it’s going to be a more expensive drug. I don’t have any knowledge of that, but I’m assuming that’s true. And if it is true, that means a lot of work on our end to do prior authorizations. Is it just a one-time prior authorization, or are there going to be...Is it going to be every month, every three months? When people change insurances, you’re going to have to do it again? That’s a concern.”</i> (Clinical stakeholder)</p>	<p>Implement policy changes at the federal, state and local level to establish clinical guidelines for LAI ART delivery.</p> <p>Ensure policies provide for insurance coverage of LAI ART by commercial insurance providers, Ryan White, and ADAP.</p> <p>Streamline prior authorization processes.</p> <p>Implement electronically filled forms in the EHR to aid LAI ART delivery.</p>
<p>Partnership and Coordination</p>	<p>Enhance care coordination and partnership across HIV service organizations.</p> <p>Establish coordinated and secure EHR sharing across various LAI delivery sites.</p>

Research Considerations

“And also just having a little more information about it...like window periods of how long people could go without it. I don't think there's enough research yet or enough information about long-term effects and all those things about how people will interact with them. And how they could potentially affect their lives.” (Non-clinical stakeholder)

Perform pilot and implementation projects of differentiated care models across different delivery sites.

Conduct research to increase the interval between LAI treatment applications and to determine the possibility of self-injection administration.

Develop new clinical research studies to include those originally excluded from the already presented phase III clinical trials. Specifically recruit individuals with adherence issues, substance use disorders, mental health disorders, young and newly diagnosed people with HIV, and pregnant women.

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This report is based on preliminary findings from the study. A manuscript reflecting final findings will be submitted for publication upon completion of the final analysis.