CHAC recommendations following the fall 2023 meeting included:

- CDC and HRSA work with CMS to investigate how to standardize the provision of long-acting injectables across payers for HIV prevention and treatment and to increase access for all populations.
- CDC and HRSA work and partner with IHS to add long-acting injectables to the IHS formulary.
- CDC and HRSA work with the HHS Adolescent and Adult Antiretroviral Treatment Guidelines Committee on two items: 1) evaluating the emergence of new data that will allow people living with HIV to access direct to inject broadly and in settings of non-viral suppression; and 2) reevaluating the long-acting injectable PrEP guidelines to include permissive utilization in unique circumstances.

LAIWG convenings:

- **Synchronous:**
  - February 28
  - March 18, with special guest Jonathan Mermin, MD, MPH
  - March 21

- **Asynchronous:**
  - Online document and article reviews
• CHAC extended the LAIWG in Fall 2023 to allow for further insights into barriers and lived experience for those seeking or utilizing LAI for HIV prevention or treatment.
• Due to challenges facilitating non-clinical external stakeholder input, the decision was made to seek to understand existing literature.
• LAIW reviewed 14 qualitative studies published between 2018-2023 to understand lived experience of >300 people. (See appendix for full details of articles reviewed)
LAI CONSIDERATIONS FOR CHAC

1. Ask the CDC/HRSA to work with partners, such as NIH and Ryan White programs, to request current grantees working in the LAI space to share the current experience including patient feedback and best practices from 2022-present.

2. Ask CDC/HRSA to convene existing advisory boards of people with lived experience to discuss the current barriers to access and uptake of LAI (for HIV treatment and prevention) (for instance in 8/24 Ryan White Conference).

3. Ask CDC/HRSA to partner with CBOs specifically related to populations demonstrating rising risk, such as women and young adults, to increase uptake of LAI.
OVERARCHING “TAKE-AWAYS” FROM ARTICLES REVIEWED

- Lack of awareness re. LAI for both consumers and providers from 2020-2022
- Lack of lived experience in real world settings (e.g., non-randomized control settings) to understand impact of/address access barriers
- Population focused on older white men; need to expand understanding to adolescents, younger adults and women.
- Lack of qualitative studies in the southeast US
- Consistent concerns about the increased burden on number of required visits
- Anxiety and suspicion about the safety of LAI
- Importance of patient-provider communication to identify unique needs/preferences among individuals (e.g., history of injection drug use, currently on other injected treatments)
FLASHBACK: FALL RECOMMENDATION

CDC and HRSA work with CMS to investigate how to standardize the provision of long-acting injectables across payers for HIV prevention and treatment and to increase access for all populations.
LAI CONSIDERATIONS FOR CHAC

#2

• Ask the CDC/HRSA to work with partners (e.g., providers, consumers, pharmacists, insurers) in clinical practice to obtain information on variation of coverage, basis for variation, and optimal mechanism for reimbursement of LAI for best patient access.

• Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under the most optimal benefit and to eliminate cost sharing/co-pays.
FLASHBACK: FALL RECOMMENDATION

CDC and HRSA work with the HHS Adolescent and Adult Antiretroviral Treatment Guidelines Committee on two items: 1) evaluating the emergence of new data that will allow people living with HIV to access direct to inject broadly and in settings of non-viral suppression; and 2) reevaluating the long-acting injectable PrEP guidelines to include permissive utilization in unique circumstances.
• Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to drive study and recommendations related to increasing inter-injection intervals, decrease the burden of additional labs, and allow treatment of viremic patients when clinically appropriate.
• Request CHAC consider modifying scope of LAI WG and extending to include: tracking the emergence of new LAI for other conditions, driving ongoing study to evaluate and eliminate barriers for access to LAI.
SUMMARY OF CONSIDERATIONS

• Ask the CDC/HRSA to work with partners, such as NIH and Ryan White programs, to request current grantees working in the LAI space to share the current state of their learnings from 2022-present.

• Ask CDC/HRSA to convene existing advisory boards of people with lived experience to discuss the current barriers to access and uptake of LAI (for HIV treatment and prevention) (for instance in 8/24 Ryan White Conference).

• Ask CDC/HRSA to partner with CBOs specifically related to populations demonstrating rising risk, such as women, adolescents, and young adults, to increase uptake of LAI.

• Ask the CDC/HRSA to work with partners (e.g., providers, consumers, pharmacists, insurers) in clinical practice to obtain information on variation of coverage, basis for variation, and preferred mechanism for reimbursement of LAI (pharmacy vs. medical benefit) for best patient access.

• Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under exclusively pharmacy or medical benefit and to eliminate cost sharing/co-pays.

• Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to drive study and recommendations related to increasing inter-injection intervals, decrease the burden of additional labs, and allow direct to treat when clinically appropriate.

• Request CHAC consider modifying scope of LAI WG and extending to include: tracking the emergence of new LAI for other conditions, driving ongoing study to evaluate and eliminate barriers for access to LAI.
Antiretroviral Therapy Experience, Satisfaction, and Preferences Among a Diverse Sample of Young Adults Living with HIV

C. K. Campbell, K. Dubé, J. A. Sauceda, S. Ndukwe, P. Saberi

To gain understanding of YLWH’s perceptions, concerns, and interests in long-acting ART (LAART) treatment modalities (e.g., injectables, implants, patch).

Participants were recruited as part of the Youth4Cure (Y4C) study

Eligibility criteria:
1. 18-29 years old living with HIV
2. English-speaking
3. Living in the US
4. Access to mobile telephone &/or computer with internet

Qualitative research (1-1 semi-structured virtual interviews)

Interview topics:
1. Perceptions, motivations, and barriers to participation in HIV cure research
2. Experiences with ART, perceptions of their current treatment, how treatment experiences could be improved

Interview length: 45-60 minutes

Analysis:
1. Framework analysis: Thematic analysis involving interdisciplinary team in coding and developing analytic framework.
2. Author charted data into a framework matrix (sorted data into priori & emergent categories)

Demographics (N=20)
1. Gender: 60% male, 25% female, 15% nonbinary/genderqueer
2. Sexuality: 50% gay, 30% bisexual, 10% heterosexual, 5% queer, 5% pansexual
3. 85% have been living with HIV between 10 months - 8 years (15% diagnosed at birth)
4. 95% self-reported being on ART & had an undetectable viral load

ART experience:
1. Side effects: More than 1/3 of participants reports side effects attributed to ART at some point, but only a few reported mild side-effects at the time of the interview.
2. Adherence: (1) Anxiety related to challenges with adherence and consequence of non-adherence. (2) Treatment fatigue. (3) Most reported rarely/never missing a dose. Some reported taking a daily pill as routine/automatic, but for some when outside of regular routine it was easy to forget

ART Improvements:
1. Injectable: Most were enthusiastic of the possibility of periodic injection. Viewed injectables as potentially making life easier, improve adherence, social benefits (traveling w/out meds), lower risk of disclosure. 3-6 month injection interval would be ideal for some, but others were excited about a once a month option as well. Some expressed a fear of needs, including participants with history of injection drug use.
2. Patch: 10 participants were interested in a potential patch. Similar advantages as injectable, but some concern about patch visibility (fear of stigma).
3. Implants: Least interested in implants. A few liked the idea of having something not visible to others that is changed periodically. Most uncomfortable with the thought of an object in their bodies and fear of complications.
4. Other: Change the daily pills (chewable gummies, smaller pills). Participants diagnosed at birth expressed concern of changes in their current ART regimens.

*Consideration of YLWH preferences and concerns about ART modalities during development has the ability to ensure uptake and acceptance of YLWH
*YLWH ART non-adherence contributed to being out of their routine, forgetting, & treatment fatigue, which was consistent with previous studies
*Perinatally infected persons were less interested in changes to their medication (similar to data on adults) which could be due to less tolerable regimens previously prescribed
*Concerns of short-term side-effects associated with LAI-ART are similar to daily pill, but people would wait until long-term side-effects are more well known for LAI.
*Fear of needles/needle aversion associated with injection drug use another concern for YLWH considering LAI
*
*Preference for less frequent injection (some 1 month, most 3-6 months). Compared to older PLWH, YLWH have less concern over receiving injection – potentially prefer contact with clinical team
*Other modalities (patch, implant) are acceptable and were recognized as modalities for other types of medication

Limitations:
*Small sample size, may not be generalizable

APPENDIX: ARTICLE SUMMARIES
Participants were recruited as part of the Considerations about Long-Acting Injectable therapies in HIV Prevention & Treatment (CLAPT) study. Eligibility: PLWH taking ART or taking PrEP for 6+ months Qualitative (in-depth individual interviews) with PLWH & PrEP users Interview topics: Personal experience taking ART/PrEP Knowledge of new ART treatments/PrEP prevention Willingness to change ART modality Analysis: Interview audio was transcribed and manually coded Cross-cutting thematic analysis

Demographics
(N=28)
15 PLWH (9 M; 6 F; M = 54 years)
13 PrEP users (100% M; M = 42 years)

LA-ART Concerns
(1) Social (daily life w/ART): Most participants had a routine relationship with daily oral regimen
(2) Material (mode of administration): Injectable perceptions based on participants' past experiences (good experience = greater interest; negative experience = more reluctance). More common to have negative injectable experiences. Concerns expressed not being in control when receiving injections.
(3) Experimental (relationships to innovation): Higher skepticism about effectiveness and will "wait and see" approach. Most participants trusted their doctors' referrals and would be open to injectables if recommended.

- ART Concerns

Perceptions of Long-Acting Injectable Antiretroviral Therapy Among People Living with HIV Who Use Drugs and Service Providers: a Qualitative Analysis of the Perspectives of LAI-ART Users

Examining LAI-ART perspectives among PLWH who use drugs and providers who support these populations
Assess LAI-ART ability to mitigate barriers to HIV care among PLWH who use drugs & how location of LAI-ART roll-out may shape access to, and uptake of, this emerging treatment option.

Eligibility
PLWH who use drugs & are ≥18 years old (excluded if only marijuana use self-reported)
Clinical providers & ancillary services (harm reduction/housing outreach workers)
Qualitative Semi-structured interviews with PLWH (~45 mins)
Substance use patterns, experiences with HIV treatment, HIV-related stigma, perceptions of LAI-ART, and implementation considerations (oral lead in was a requirement at time of the interviews)
Focus groups with providers (~60 mins)
Feasibility, acceptability, & implementation considerations for LAI-ART
Analysis Audio recorded, transcribed, & coded & analyzed thematically using NVivo

Demographics
PLWH (n=15)
M=51 years of age (24-68 years; 7 women (transgender-inclusive) & 8 men (transgender-inclusive))
60% used alcohol &/or other drugs daily; 27% used drugs 3-4 times weekly, 13% one or fewer times per week
Providers (n=13)
- Clinicians = 8 (all knew of LAI-ART and had experience with administration)
- Ancillary service providers = 5 (1 of 5 knew of LAI-ART)
- One-site fits all concerns about LAI-ART
- PLWH: A single LAI-ART regimen viewed as a limitation, which was reflective of how they perceived LAI-ART to be as odds with existing ART regimens that participants felt required "trial and error" for their specific treatment
- Providers: Some patients have resistance to a medication in the injection formula Injectable vs. Oral Treatment
- PLWH with experience finding their oral regimen (treatment challenges, disruptions, etc.) they felt their oral regimen was the best, but others expressed difficulty having their oral ART available
- Providers shared for this population it can be extremely difficult to take oral ART and LAI-ART could be a critical solution to HIV management & mental health
- Perceived Risks of LAI-ART
- PLWH felt medication was safe, but worried about how switching may impact viral suppression and overall health
- PLWH did not feel that switching would impact viral suppression or overall health
- Exclusivity and newness created hesitancy that may go away with time
- PLWH & PrEP users had different perceptions about the medication, especially considering competing priorities & barriers
- Uncertainty of side effects and newness created hesitancy that may go away with time
- LAI-ART Implementation Consideration
- Equitable roll-out and offering this as an option to all participants was highlighted, although some participants felt people who have unstable housing and/or drug use should be prioritized (providers echoed this sentiment)
- Community based delivery options, potential for ancillary service providers to receive training and administer injections, at home self injection option

*Experience with oral ART and concerns about HIV health outcomes drive participants' perceptions of LAI-ART
*LAI-ART is a possible mech to address barriers for PLWH who use drugs
*More time on an oral ART regimen made participants more hesitant to change medication compared to participant who experienced frequent disruptions
*Barriers to care were framed around levels of structural concerns (housing, socio-economic, etc.) and not substance use
*Receiving LAI-ART from community settings may be preferred over clinics
*Equitable roll-out of LAI-ART is important

Limitations
Participants were recruited from an HIV clinic and may not reflect perspectives of PLWH who are not engaged in care
Not representative of transgender & gender diverse participants
Not generalizable
Removal of an oral lead as a requirement may have impacted some participants' perspectives
**Perspectives on long-acting injectable HIV antiretroviral therapy at an alternative care site: A qualitative study of PLWH about the injection and whether a more accessible alternative care site would increase their likelihood of adherence**

**Assess attitudes among people with HIV experiencing substance use and/or housing instability**

**L. Fletcher, S. Burrowes, G. Khan, S. Johnsen, S. Kimble, G. Ruiz-Mercado, C. Pierre, M. Draimoni**

Demographics (N=26)
- Gender: 18 M, 8 F
- Race/ethnicity: White (11), Black (11), Latinx (10)
- Time since diagnosis: 3-months-30 years
- Age: 18-34 years old (10), 35-49 years old (10), 50-64 years old (6)

**Eligibility**
- 18+ years old
- English or Spanish speaking
- Have a history of non-adherence to ART
- Qualitative: Semi-structured interviews with PLWH who receive care at Project Trust (PT) or disengaged from HIV care at Boston medical center (BMC)

**Analysis**
- Direct content analysis in core constructs of *PERHIS*
- *Descriptive statistics*
- Analysis: Direct content analysis in core constructs of *PERHIS*
- *1 clinical stakeholder focus group*
- *1 clinical & non-clinical stakeholders focus group*
- *2 consumers focus groups*
- Focus group (4 total)
- Intervention characteristics
- Consolidated Framework for Implementation Research (CFIR)
- *24 clinical/non-clinical stakeholders*
- *18 consumers*
- *Patient needs & resources*
- Address perceived policy, systems, financial, operational, clinical, and consumer-level barriers to and facilitators of rollout and scaleup of LAI ART.
- *Demographics (N=26)*
- *Age: 18-34 years old (10), 35-49 years old (10), 50-64 years old (6)*
- *Gender: 18 M, 8 F*
- *Race/ethnicity: White (11), Black (11), Latinx (10)*

**Themes:**
- Participants are knowledgeable about their HIV care & importance of ART adherence
- Perceived adaptability & complexity:
  - As potential consumers
  - Participants preferred a long-acting injection over a daily pill
  - The potential for drug residence
  - Perceived likelihood of a disruption to clinical workflow and demand by clinic and non-clinic stakeholders.
  - Key features: Needle based injections and potential side effects were identified as barriers across groups.
- Internal setting:
  - Costs was a barrier identified to implementation and financial burden/insurance coverage for consumers
- **Implementation climate:**
  - LAI ART’s ability to address stigma was identified as a key facilitator
  - LAI ART’s ability to address stigma was identified as a key facilitator
  - There is a willingness among clinical, non-clinical stakeholders, and consumers to adopt LAI ART as an HIV treatment option
  - **Limitations**
  - *Themes were based on small sample size of stakeholders and patients*
  - *May not be generalizable and sample was mostly men and white people*
  - *May have been selection bias in recruitment because participants aware of purpose of the study*

**Perspectives on preparing for long-acting injectable therapy for HIV among consumer, clinical and nonclinical stakeholders: A qualitative study exploring the anticipated challenges and opportunities for implementation in Los Angeles County**


Demographics (N=57)
- Gender: 10 M, 47 F
- Race/ethnicity: White (11), Black (11), Latinx (10)
- Time since diagnosis: 3-months-30 years
- Age: 18-34 years old (10), 35-49 years old (10), 50-64 years old (6)

**Eligibility**
- Consumers, clinical stakeholders, and non-clinical stakeholders were invited to participate
- Address perceived policy, systems, financial, operational, clinical, and consumer-level barriers to and facilitators of rollout and scaleup of LAI ART.
- *18 consumers*
- *24 clinical/non-clinical stakeholders*

**Themes:**
- Preparation for engagement, adherence support, education, and training is anticipated to greatly influence the success of LAI ART implementation
- LAI ART’s ability to address stigma was identified as a key facilitator
- There is a willingness among clinical, non-clinical stakeholders, and consumers to adopt LAI ART as an HIV treatment option
- **Limitations**
  - *Themes were based on small sample size of stakeholders and patients*
  - *May not be generalizable and sample was mostly men and white people*
  - *May have been selection bias in recruitment because participants aware of purpose of the study*
Long-Acting Injectable Antiretroviral Treatment Acceptability and Preferences: A Qualitative Study Among US Providers, Adults Living with HIV, and Parents of Youth Living with HIV

J Simoni, K Beima-Sofie, Z Mohamed, J Christodoulou, K Tapia, S Graham, R Ho, A Collier

Assess potential acceptability and identify preferences among potential end users for characteristics of a proposed LAI-ART treatment regimen

Demographics:
- PLWH (n=36)
- Providers (n=7)
- Parents of children living with HIV (n=5)

Eligibility
- PLWH
  - 18+ years old
  - English speaking
  - Living with HIV
  - HIV care providers
  - 18+ years old
  - English speaking
  - HIV Qualitative PWLH & Focus group discussions (FGD): (heterosexual men (n=8), MSM (n=8), women (n=9), people struggling with adherence (n=7), 3 with young adults (n=4)
  - Providers: 1 FGD
  - Parents: In-depth interviews with parents of children living with HIV (n=5)

Analysis: Direct content analysis (Coding, analysis, & data management)

Qualitative:

Initial reactions
- PLWH were generally supportive of LAI ART if it met certain perimeters (less risk of disclosure, normalcy), but for those who had been taking a pill for a long time, they were less interested in changing their routine or if they have to take pills to manage other chronic conditions
- Providers expected patients to be enthusiastic & expected LAI to improve adherence
- Parents had positive reactions, especially if their child already receives regular injections. For parents who were hesitant, they changed their mind considering their child’s future need to manage their own care

Key Factors
- Acceptability most influenced by efficacy and side effects of LAI
- Providers and parents expressed concern over efficacy of LAI compared to oral therapies
- Implicit trust in providers influence medication decisions which was validated by providers

Fear of needles
- PLWH with experience receiving and/or self-administering injections unconcerned of injections, but this was rare and the fear of needles decreased injectables as acceptable treatment option (esp. for parents with children who have a fear of needles)
- Fear of needles was mitigated by possibility for smaller gauge needle &/or lower dose volume
- Injection site, frequency of injections, and clinician vs self-administered vs pharmacist influence PLWH views on acceptability
- Providers expressed concern that self-injections would be too hard for people without secure housing (where would they store medication)
- PLWH, parents, & providers saw benefits in availability for LAI-ART

Barriers to acceptability (listed in order of most mentioned)
- Multiple injections/dose
- Increased cost (if receiving oral ART for free, a copay may deter patients of preferring LAI-ART)
- Shorter intervals between injections (providers concerned of injection schedule being different than recommended routine visits - patients might skip visits)

"All PLWH stressed need for LAI-ART to be an efficacious medication and minimal side-effects for them to be willing to switch from daily oral ART"

"For those struggling with adherence and young adults, if they thought they would have better adherence to injectables compared to a daily pill, they were more interested in injectables"

"Frequency in injection varied, but some were willing to receiving weekly injections making a 1 or 2 month interval acceptable to many"

"Providers were supportive of injectables, but stressed patients must continue to attend regular HIV care appointments"

Limitations
- Sample only included western US residents
- Public health officials, policy makers, insurance companies, or pharmaceutical companies not interviewed
- Self-reported hypotheticals
- Potential group think during FGD
A Qualitative Exploration of Women’s Preferences for Long-Acting Injectable Antiretroviral Therapy Among People Living with HIV (LA-ART)

Demographics (N = 89)
- *Women* (n=88)
- *Men* (n=1)
- *African American* (64%), *White* (9%), *Hispanic* (6%), *Asian* (2%), *Other* (2%)
- *Mean age* 46 years old (SD =12; range: 24-72)
- *73% virally suppressed* (N = 89)
- *Mean years diagnosed with HIV =15 years (range: <1-36 years)
- *LAI might be a better option due to unpredictable living situations and daily life*
- *Women who were currently injecting drugs and had few concerns about LAI*
- *Women who might benefit the most from LAI ART & LAI’s perceived to have ability to improve adherence and reduce treatment fatigue and stigma while increasing privacy*
- *Findings were consistent with other studies (benefits included less adherence burden, more privacy, & potentially more effective & concerns included effectiveness, side-effects, cost, and increased clinic visits)*
- *Participants with suppressed viral loads more focused on maintaining viral suppression compared to participants who struggled with adherence*
- *Women who may benefit the most from LAI ART & LAI structural barriers will need to be addressed for an equitable clinical implementation*
- *Almost all participants wanted more information on LA-ART*
- *Findings were consistent with other studies (benefits included less adherence burden, more privacy, & potentially more effective & concerns included effectiveness, side-effects, cost, and increased clinic visits)*
- *Participants with suppressed viral loads more focused on maintaining viral suppression compared to participants who struggled with adherence*
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AIDS Prevention Education 2023

What's the Benefit? Perceptions and Preferences for Long-Acting Injectable Antiretroviral Therapy Among People Living with HIV

Assessment of LA-ART awareness, perceived benefits and concerns, and preferences among PLWH engaged in routine clinical care in the United States to inform development of tailored decision-making tool for patients and clinicians to engage with when choosing ART options

**Eligibility**
- *Women* (n=89)
- *Age* 50 years old
- *Black* (27%), *White* (22%), *Hispanic* (17%), *Asian* (17%), *Other* (22%)
- *Ever drug use* (55%) and *ever injection drug use* (15%)
- *Black/African American* (76%), *White* (5%), *Hispanic* (5%), *Biracial* (1%), *Other* (6%)
- *Ever used injectable medications (e.g., birth control, flu shots)*
- *Women living with HIV who are interested in learning about LA-ART*
- *Women aged 32+ years older (unclear if eligibility requirement)*
- *Fear of needles would be a hard stop for some women*
- *Most preferred the option for an injection every 2-month over 1-month frequency (few did like idea on monthly frequency)*
- *Can be generalizable to people recently diagnosed and starting oral daily ART*
- *Many participants had lived with HIV for a long period of time which may not be generalizable to people recently diagnosed and starting daily ART*
- *Women who may benefit the most from LA-ART & LAI ART options may be determined by their injection experiences, but ultimately varies woman-to-woman*
- *History of injection influence women’s attitudes toward LAI ART & PrEP*
- *LAI percutaneous needle was perceived to improve adherence and reduce treatment fatigue and stigma while increasing privacy*
- *Perceptions of LAI ART effectiveness*
- *Concerns: Worried it would be less effective (in contract to others who perceived it as more effective), treatment adherence, short term (injection reaction) and long term (injection sites look and feel over time) side-effects in addition to the lack of research on long-term effects, increased clinic visit cost and side effects*
- *History of injection influence women’s attitudes toward LAI ART & PrEP*
- *LAI percutaneous needle was perceived to improve adherence and reduce treatment fatigue and stigma while increasing privacy*
- *Concerns: Worried it would be less effective (in contract to others who perceived it as more effective), treatment adherence, short term (injection reaction) and long term (injection sites look and feel over time) side-effects in addition to the lack of research on long-term effects, increased clinic visit cost and side effects*

**Limitations**
- *Women who were unaware of LAI modalities and had less time to consider what they thought of them*
- *Older cohort of women, yet older women on average have more experience with injectable medications/substance use*
- *Ever drug use (55%) and ever injection drug use (15%)*
- *Women living with HIV who are interested in learning about LA-ART*
- *Women aged 32+ years older (unclear if eligibility requirement)*
- *Fear of needles would be a hard stop for some women*
- *Most preferred the option for an injection every 2-month over 1-month frequency (few did like idea on monthly frequency)*
- *Can be generalizable to people recently diagnosed and starting oral daily ART*
- *Many participants had lived with HIV for a long period of time which may not be generalizable to people recently diagnosed and starting daily ART*
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Drug use was asked about in a hypothetical context at a time when LA-ART was not available as a treatment option
- *Many participants had lived with HIV for a long period of time which may not be generalizable to people recently diagnosed and starting daily ART*

**Findings**
- *Women who were currently injecting drugs and had few concerns about LAI*
- *Women who might benefit the most from LAI ART & LAI’s perceived to have ability to improve adherence and reduce treatment fatigue and stigma while increasing privacy*
- *Findings were consistent with other studies (benefits included less adherence burden, more privacy, & potentially more effective & concerns included effectiveness, side-effects, cost, and increased clinic visits)*
- *Participants with suppressed viral loads more focused on maintaining viral suppression compared to participants who struggled with adherence*
- *Women who may benefit the most from LAI ART & LAI structural barriers will need to be addressed for an equitable clinical implementation*
- *Almost all participants wanted more information on LA-ART*

Demographics (N = 71)
- *Women* (n=71)
- *Mean age* 46 years old (SD =12; range: 24-72)
- *52% had a history of injection drug use (e.g., birth control, flu shots)*
- *Use of injectable medications (e.g., birth control, flu shots)*
- *Race self-reported. Other (1%), white (51%), Black (24%)
- *74% reported living in Spanish speaking clinic*
- *Women diagnosed with HIV =15 years (range: 8-36 years)*
- *Fear of needles would be a hard stop for some women*
- *Most preferred the option for an injection every 2-month over 1-month frequency (few did like idea on monthly frequency)*
- *Can be generalizable to people recently diagnosed and starting oral daily ART*
- *Many participants had lived with HIV for a long period of time which may not be generalizable to people recently diagnosed and starting daily ART*
- *Women who may benefit the most from LAI ART & LAI ART options may be determined by their injection experiences, but ultimately varies woman-to-woman*
- *History of injection influence women’s attitudes toward LAI ART & PrEP*
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- *History of injection influence women’s attitudes toward LAI ART & PrEP*
- *LAI percutaneous needle was perceived to improve adherence and reduce treatment fatigue and stigma while increasing privacy*
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Background - LATTE-2 trial, a phase IIb study assessing the safety, tolerability, and acceptability of LA CAB and RPV for the treatment of HIV. The trial included 309 treatment-naïve HIV-infected participants. All participants were initially provided a three-drug (cabotegravir, abacavir, & lamivudine) oral induction regimen. Those who achieved viral suppression during the induction period were randomized to receive (1) LA injections every 4 weeks, (2) LA injections every 8 weeks, or (3) continue on the daily oral regimen [31].

Sample: 27 trial participants (11 US, 16 Spain), from the LA 4 or 8 week arms, and 12 providers were recruited from LATTE-2; Austin, TX; Long Beach, CA; Ft Lauderdale, FL; and three clinics in Madrid, Spain. Mean age: 37 Spain, 36 US; mostly male; most MSM; 4 participants across the sites received LA injections every 4 weeks while 13 participants received LA injections every 8 weeks. Twelve key informants (2 per site, with 3 sites in each country) were interviewed including study investigators (3 female and 3 male physicians) and staff (2 female nurses and 4 male study coordinators) from the LATTE-2 sites.

There are side effects but they are worth it. "It might be painful, but it's better than pills. -U.S., Male trial participant." LA ART is convenient and confidential "concerns expressed around the # of clinic appointments. "I was a little nervous about seeing the doctor so often. Even my carpool buddy asked a couple of times, 'Wow. You go to the doctor a lot. They draw a lot of blood.' Then, I started saying, 'Well, I just have an appointment for my roofer, and my plumber is going to be coming in a second.' I stopped saying I was going to the doctor so much. -U.S., Male trial participant; Appropriate for every patient and populations for LA ART; Providers were less enthusiastic-desiring to determine on a day to day basis; need for skilled or trained professionals to administer it;

Eval of Phase 3 trial offer an important opportunity to also explore the views of treatment-experienced PLHIV regarding the transition from a daily oral to an injectable ART regimen and to further understand the context of this potentially "game-changing" [23] option prior to its integration into routine care. 53 trial participants in the U.S. and Spain. In the U.S., three urban clinical sites were included: Washington, D.C., Omaha, Nebraska, and San Francisco, California. In Spain, eight sites participated in the study from six locations, including two in Madrid, two in Barcelona, and one each in Santiago de Compostela, Ferrol, Valencia, and Palma de Mallorca. The median age varied by site with participants generally in their 30s in Spain (median 34 years) and in their 40s in the U.S. (median 46.5 years). In both countries, most of the male participants reported being MSM. 38 participants - monthly inj; 15 every 2 month injections; half 26 out of 53 had been receiving for > 6 months.

>108 effects (1 person stopped due to pain) - episodic; concern for clinical efficacy; logistical psychological freedom; "less frequent visits - to lead "normal" lives
Women shared many of the positive perceptions expressed by men but also had unique perspectives, including finding that long-acting antiretroviral therapy addressed the challenge of remembering pills amidst busy day-to-day realities including multiple roles and responsibilities, is less time consuming and creates less stress compared to oral antiretroviral therapy, and is emotionally freeing and empowering. The gendered nature of women’s lives shaped why and how they were satisfied with long-acting antiretroviral therapy.

Of 670 participants (modified intention-to-treat exposed population), 447 (67%) switched to long-acting therapy (274 [61%] of 447 start with injections; 173 [39%] of 447 with oral lead-in) and 223 (33%) continued bictegravir, emtricitabine, and tenofovir alafenamide. 90% (n=382/425) preferred CAB + RPV LA every 2 months, compared with 5% (n=21/425) who preferred oral BIC/FTC/TAF therapy.

Lancet HIV 2023 Ramgopal et al

SOLAR is a randomised, open-label, multicentre, phase 3b, non-inferiority study. The study was done in 118 centres across 14 countries. Participants with HIV-1 RNA less than 50 copies per mL were randomly assigned (2:1), stratified by sex at birth and BMI, to either long-acting cabotegravir (600 mg) plus rilpivirine (900 mg) dosed intramuscularly every 2 months or to continue daily oral bictegravir (50 mg), emtricitabine (200 mg), and tenofovir alafenamide (25 mg).

Participants randomly assigned to long-acting therapy had a choice to receive cabotegravir (30 mg) plus rilpivirine (25 mg) once daily as an optional oral lead-in for approximately 1 month. The primary efficacy endpoint was the proportion of participants with virological non-response (HIV-1 RNA ≥50 copies per mL; the US Food and Drug Administration snapshot algorithm, 4% non-inferiority margin; modified intention-to-treat exposed population) at month 11 (long-acting start with injections) and month 12 (long-acting with oral lead-in group and bictegravir, emtricitabine, and tenofovir alafenamide group). The study is registered with ClinicalTrials.gov, NCT04542070, and is ongoing.

Women preferred the long-acting regimen, with 90% (n=382/425) preferring CAB + RPV LA every 2 months compared with 5% (n=21/425) who preferred oral BIC/FTC/TAF therapy. Treatment satisfaction was greater among participants in the long-acting group compared with those in the bictegravir, emtricitabine, and tenofovir alafenamide group, with larger improvements in satisfaction observed through to month 11–12.

.§ “I don’t have to worry as much about remembering to take HIV medication every day” (324 [85%] of 382),

.§ “It is more convenient for me to receive injections every 2 months” (317 [83%] of 382),

.§ “I do not have to worry about my HIV status every day” (233 [61%] of 382),

.§ “I do not have to worry about others seeing or finding my HIV pill” (227 [59%] of 382);
Patient and Physician Preferences Regarding Long-Acting Pre-Exposure Prophylaxis and Antiretroviral Therapy: A Mixed-Methods Study in Southern California, USA

S Yeager, J Montoya, L Burke, K Chow, D Moore, & S Morris

2022

Adult patients: Understand patient preferences & identify potential advantages & barriers to LA-ART & LA-PrEP

Physicians: Understand physician treatment preferences (i.e., frequency of clinic visits, HIV testing, etc.) for LA-ART & LA-PrEP

Eligibility
Adults taking ART or PrEP
*Age 18+ years old
*Strong/variable adherence to ART or PrEP (ineligible if tested positive for HIV in past 6 months)

Providers
*Age 18+ years old
*Reported at least one patient on ART or providing ongoing care for at least one patient on PrEP

Mixed-methods: Qualitative
*Adult patients - 8 individual interviews (for participants struggling with adherence) and 4 focus groups (participants with strong adherence)
*Topics: Experience with ART/PrEP, LA modality preferences, anticipated advantages & barriers to LA, adherence support strategies

Quantitative: Physician survey
*Topics: Preferred frequency for patient clinic visits & renal functioning testing, anticipated patient treatment barriers, beliefs on improving patient adherence, anticipated adherence to LA

Analysis
Qualitative: Rapid analytic approach
Quantitative: Descriptive analysis

Demographics:
Adult Patients (n=42)
*Demographic info was not collected

Physicians (n=13)
*10/13 provided HIV treatment (ART) and prevention (PrEP) care
*7 had 0-10 years experience; 6 had 10+ years experience
*LA knowledge: 100% aware of injectables, 7 heard of oral agents; 6 heard of subdermal implant

Qualitative (Patients):
*Participant preferences: Oral>injectable>subdermal implant
*Preference given to which ever modality provided the longest duration of coverage, but only 4/42 indicated subdermal implant as a preference (concerns of pain or discomfort)
*More likely to prefer injectable LA over oral LA if receiving hormone therapy injections as part of care

LA ART & PrEP Advantages:
*Convenience, potential to improve adherence, reduce clinic visits & testing
*ART patients - reduce reminders of their HIV status (oral pill is described as a daily reminder of a past mistake or living with chronic disease)

LA ART & PrEP Barriers:
*Potential side effects & efficacy (how to discontinue treatment if side-effects are intolerable?)
*Insurance coverage & medication costs
*Increased clinic visits, questions on who would administer

Adherence Support:
*Text message reminders of injection appts, calendar tracking, smartphone reminders, yearly pillbox

Quantitative (Providers):
*Reduced clinic visits and testing (exception: MSM patients complete HIV testing every 3 months)
*Renal function testing every 3 months
*Preferences of injection/implant admin delivered by: nurse > pharmacist > self-administered > provider
*Insurance & medication costs greatest barrier
*Other barriers: adherence, limited pharmacy medication access, consistent management, side effects, adverse reactions
*Expected adherence to be excellent or good for injectable & implant expected patients attend yearly appointment

Adherence support: Text reminders, calendar tracking, app reminders, phone calls, patient portal messages

Limitations
*Small sample size in southern CA limits generalizability
*No demographic information collected on patient participants
*Focus groups could result in group think
*Self reports of hypothetical treatment preferences not observed behaviors