LONG-ACTING INJECTABLE WORKGROUP

Spring 2024 Report to CHAC

Christopher Gordon
Daniel Driffin
Richard Haverkate
Christine Markham
Wendy Armstrong
Renata Sanders
Jorge Cestou
Shannon Dowler, Chair

OVERVIEW FALL '23 TO SPRING '24 LAIWG ACTIVITIES

- 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

LIVED EXPERIENCE: QUALITATIVE ANALYSES CONSIDERED

- 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.
- 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 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 (eg, 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.

LAIWG CONSIDERATIONS FOR CHAC #3

- 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.

LAIWG CONSIDERATIONS FOR CHAC #4

- 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.

AIDS Care	2022	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: *18-29 years old living with HIV *English-speaking *Living in the US *Access to mobile telephone &/or computer with internet Qualitative research (1-1 semi-structed virtual interviews) <u>Interview topics:</u> *Perceptions, motivations, and barriers to participation in HIV cure research *Experiences with ART, perceptions of their current treatment, how treatment experiences could be improved Interview length: 45-60 minutes Analysis: *Framework analysis: Thematic analysis involving interdisciplinary team in coding and developing analytic framework *Author charted data into a framework matrix (sorted data into priori & emergent categories)	Demographics (N=20) *Gender: 60% male, 25% female, 15% nonbinary/genderqueer *Sexuality: 50% gay, 30% bisexual, 10% heterosexual, 5% queer, 5% pansexual *85% have been living with HIV between 10months-8 years (15% diagnosed at birth) *95% self-reported being on ART & had an undetectable viral load ART experience: *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. *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: *Injectables: 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. *Patch: 10 participants were interested in a potential patch. Similar advantages as injectable, but some concern about patch visibility (fear of stigma). *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. *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 acceptability of YLWH *YLWH ART non-adherence contributed to being out of their routine, forgetting, & treatment fatigue, which was consistent with previous studies *Perinatally infection 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 LAIs. *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

AIDS Care	2020	Perspectives of injectable long acting antiretroviral therapies for HIV treatment or prevention: understanding potential users' ambivalences S.Carillon, L.Gallardo, F.Linard, C.Chakvetadze, J.Viard, A.Cros, J.Molina & L.Slama	Assess potential LA-ART users' perceptions based on their experience with ART (prevention & treatment).	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 *Apprehension: Long history of complex ART regimens made participants skeptical of LA-ART and viewed a change in a regimen they felt comfortable with as a risk to their health *Simplification: Potential to step up daily life by reducing stigma, reduce concern about missing doses/being non-adherent, simplified therapeutic routine (2) Material (mode of administration): Injectable perceptions based on participants paster experiences (good experience = greater interest; negative experience = more reluctance). More common to have negative injectable experiences. Concerns expressed about 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.	*Feelings toward LA-ART are ambivalent and revealed mixed feelings (skepticism, hope, distrust) *PLWH & PrEP have difference context for taking medication which result in different concerns *Medication practices are made according to socio-cultural contexts *Distrust in medicine due to historic mistreatment creates apprehension for innovative treatments, and there was a real concern for loss of autonomy. Participants expressed potential interest once they see LA-ART be successful. *Participant perspectives seemed to be influenced by their history with ART, relationship with HIV, and sociodemographic. Limitations: *Study excluded non-adherent participants. Authors justified this decision due to concerns for resistance developing with patients were are non-adherent or patients who would be ineligible for LA-ART because existing resistance
Journal of Urban Health	2023	Perceptions of Long-Acting Injectable Antiretroviral Therapy Among People Living with HIV Who Use Drugs and Service Providers: a Qualitative Analysis in Rhode Island A.Collins, EC Macon, K.Langdon, R.Joseph, A.Thomas, C.Dogon, C.G. Bechwith	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 <u>Semi-structured interviews with PLWH</u> (~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 as time of the interviews) <u>Focus groups with providers</u> (~60 mins) *Feasibility, acceptability, & implementation considerations for LAI-ART Analysis *Audio recorded, transcribed, & coded & analyzed thematically using NVivo	Demographics <u>PLWH (n=15)</u> *M=51 years of age (24-68 years; 7 women (transgender-inclusive) & 8 men (transgender-inclusive)) *47% white, 20% multi-racial, 13% Black, 13% Indigenous, 13% Hispanic *60% used alcohol &/or other drugs daily; 27% used drugs 3-4X/week, 13% one or fewer times per week <u>Providers (n=13)</u> *Clinicians = 8 (all knew of LAI-ART and had experience with administration) *Ancillary service providers = 5 (1 of 5 knew of LAI-ART) One-size 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 at 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 with 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 *Some concerns focused on if an injection appointment was missed, will this increase risk of adverse HIV outcomes, 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 participant's 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

Harm Reduction Journal	2023	Perspectives on long-acting injectable HIV antiretroviral therapy at an alternative care site: A qualitative study of people with HIV experiencing substance use and/or housing instability L.Fletcher, S.Burrowes, G.Khan, S.Johnson, S.Kimmel, G.Ruiz-Mercado, C.Pierre, M.Drainoni	Assess attitudes among PLWH about the injection, and whether a more accessible alternative care site would increase their likelihood of adherence	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 i-PERIHS	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) Themes: <u>Participants are knowledgeable about their HIV care & importance of ART adherence</u> *Motivated by being undatable & confident discussing lab values *Barriers to adherence related to taking a daily pill included remembering to take it everyday, substance use, housing, non-HIV health issues <u>Participants prefer a long-acting injection over a daily pill</u> *Convenience of a LAI was motivating aspect to switch from current ART regimen and viewed it as less of a burden to day to day life *Not carrying medication with them was another benefit of LAI *An injection was identified as a potentially improving mental health <u>Participants expressed concerns about injection safety & efficacy</u> *Transition period to LAI and potential side-effects were noted as a barrier to LAI *Long-term concerns and the thought of something in your body for extended time was a potential barrier *Participants worked hard to achieve viral suppression, so there were concerns about LAI not working as well <u>Admin logistics of injections</u> *Participants said to be acceptable injection site should not disrupt patients routine *Questions about frequency of appointments and transportation posed barrier *Relationships with care teams determined participants preference of where to receive their injections <u>Participants were confident of their ability to complete oral-lead-in requirement</u> *Being able to receive LAI ART was enough of a motivator for participants to confidently express their ability to complete the oral lead in <u>Concerns about adhering to injections</u> *A barrier to LAI is showing up to a care site for some considering instability of housing and substance use	*Strong interest in LAI ART was expressed by participants in this study and saw the potential an injectable treatment had to address adherence barriers *Barriers to LAI ART, especially vulnerable populations, will persist and need to be addressed to tailor their care and ensure cultural competency in LAI ART implementation Limitations *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
PLOS ONE	2022	Perspectives on preparing for long-acting injectable treatment for HIV among consumer, clinical and nonclinical stakeholders: A qualitative study exploring the anticipated challenges and opportunities for implementation in Los Angeles County O Jolayemi, L Bogart, E Storholm, D Goodman-Meza, E Rosenberg-Carlson, R Cohen, U Kao, S Shoptaw, R Landovitz	Address perceived policy, systems, financial, operational, clinical, and consumer-level barriers to and facilitators of rollout and scaleup of LAI ART, from the perspective of clinical and non-clinical HIV providers, healthcare administrators, and other key stakeholders, as well as potential consumers	Eligibility: Consumers, clinical stakeholders, and non-clinical stakeholders were invited to participate Consolidated Framework for Implementation Research (CFIR) *Barriers and facilitators were addressed in the following contact: Intervention characteristics, outer setting, inner setting, individual characteristics, & implementation process <u>Focus group (4 total)</u> *2 consumers focus groups *1 clinical & non-clinical stakeholders focus group *1 clinical stakeholder focus group <u>1 Semi-structured interview with a clinical stakeholder</u> Analysis *Descriptive statistics *Inductive thematic analysis (dedoose used to code)	Demographics: *18 consumers *24 clinical/non-clinical stakeholders Intervention characteristics <u>Relative advantage</u>: Compared to daily oral ART, injectable ART seen as easier to adhere to, reduce treatment management burden and decrease treatment frequency and responsibility for consumers <u>Perceived adaptability & complexity:</u> Going to clinic monthly for injections was identified as a barrier to willingness to switch to LAI ART. Vulnerable populations may benefit the most from LAI ART but there was concern about non-adherence to injection schedule and the potential for drug residence. Perceived likelihood of a disruption to clinical workflow and demand by clinic and non-clinic stakeholders. <u>Key features:</u> Needle based injections and potential side effects were identified as barriers across groups. <u>Cost</u>: Cost was a barrier identified to implementation and financial burden/insurance coverage for consumers Characterizes of individuals <u>Knowledge & beliefs:</u> All groups expressed support and willingness to adopt LAI ART & providers appreciate an additional HIV treatment method <u>Self-efficacy:</u> Clinical and non-clinical stakeholders were concern about their ability to share efficacy, safety and other questions & concerns of patients Outer setting <u>Patient needs & resources</u>: A key facilitator was ability to address stigma across groups (ease burden of HIV related internalized and social stigma, reduce shame and constant reminder that comes with taking a daily pill, reduce unwanted disclosures). Barriers included increased clinic visits at HIV care locations could cause anxiety and fear of being seen, transportation &/or housing access <u>External policy:</u> Limit access to LAI ART to people who are virally suppressed, which takes it away from populations that struggle with adherence and have the greatest benefits. Clinic & non-clinical participants said they required clear recommendations Inner setting <u>Implementation climate:</u> Organizations admis and providers may be hesitant to complicate workflow, especially for patients who are successful with oral ART <u>Readiness for implementation:</u> Potential barrier if teams do not have effective and clear procedures and adequate training & education <u>Structural characteristics</u>: Staff capacity and physical space was a key barrier identified in implementation Process Planning & engaging: Pre-plan implementation and include community members to better engage patient populations. Community engagement would help facilitate the establishment of trust and buy-in. Advertisements were suggested across platforms (social media, tv, etc.). Planning needs to be done for education and adherence support to be successful as well.	*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 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 *Younger, transgender, and sex worker population was not represented *May not be generalizable because only recruited participants in LA county

AIDS Patient Care & STD	2019	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	Eligibility <u>PWLH</u> *18+ years old *English speaking *Living with HIV <u>HIV care providers</u> *18+ years old *English speaking <u>Qualitative</u> <u>PWLH - 6 Focus group discussions (FGD):</u> (heterosexual men (n=8), MSM (n=8), women (n=9), people struggling with adherence (n=4), 2 with young adults (n=6) <u>Providers:</u> 1 FGD <u>Parents:</u> In-dept interviews with parents of children living with HIV (n=5) (demographic questionnaires completed before interview/focus groups) Analysis: Direct content analysis (Dedoose used for coding, analysis, & data management)	Demographics: PLWH (n=36) Providers (n=7) Parents of children living with HIV (n=5) Qualitative: <u>Initial reactions</u> *PLWH were generally supportive of LAI ART if it met certain perimeters (less risk of disclosure, normalcy), but for those who had been taking pill 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 <u>Key Factors</u> *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 <u>Fear of needles</u> *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) *PLWH with history of injectable drug use were concerned needles could trigger a relapse *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 <u>Barriers to acceptability</u> (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

AIDS Patient Care & STD	2021	A Qualitative Exploration of Women's Interest in Long-Acting Injectable Antiretroviral Therapy Across Six Cities in the Women's Interagency HIV Study: Intersections with Current and Past Injectable Medication and Substance Use M. Philbin, C Parish, S Bergen, D Kerrigan, E Kinnard, S Reed, M Cohen, O Sosanya, A Sheth, A Adimora, J Cocohoba, L Goparaju, M Phil, E Golub, M Fischl, M Alcaide, L Metsch	Gain a better understand how women with a history of injectable medications and substance use perceive LAI-ART	Eligibility *Women living with HIV or at risk for HIV *Used injectable medication &/or history of substance use *Age 32+ years older (unclear if eligibility requirement) Qualitative: In-depth interviews *Women's attitudes & willingness to use LAI-ART/PrEP, experiences with injectable medication, knowledge and attitudes toward injectables, perceived barriers and facilitators Analysis: Thematic content analysis (manually coded)	Demographics (N = 89) *WLWH (n=59) & HIV negative women (n=30) *Age: 32-72 years old (M=51) *Black/African American (76%), White (5%), Hispanic (5%), Biracial (1%), Other (6%) *Ever used any injectable medication (68%) and self-report regular flu shot (72%) *Ever drug use (55%) and ever injection drug use (15%) *50% would prefer LAI PrEP & 56% would prefer LAI ART Qualitative (4 major categories) <u>Women who received episodic injections (e.g., for birth control or physical comorbidities) and had few LAI related concerns</u> *Having experience with shots will make people less afraid of injectable ART/PrEP *HIV therapy was compared to birth control options and had the ability to take away the stress of a daily pill <u>Women who required frequent injections (e.g., diabetes) and would refuse additional injections</u> *Not interested in adding more needles to medication routine - just because shots are tolerated, doesn't make them liked *Fear of needles would be a hard stop for some women <u>Women with a history of injection drug use, some of whom feared LAI might trigger a recurrence, while others had few</u> <u>LAI-related concerns</u> *ongoing recovery from injection drug use makes treatment involving a needle triggering for many, but not all who feel more than comfortable and view an injection as "easy" <u>Women who were currently injecting drugs and had few concerns about LAI</u> *LAI might be a better option due to unpredictable living situations and daily life	*History of injection influence women's attitudes toward LAI ART & PrEP *LAI's perceived to have ability to improve adherence and reduce treatment fatigue and stigma while increasing privacy *Women who may benefit the most from LAI ART & PrEP options may be determined by their injection experiences, but ultimately varies woman to woman Limitations *Some women 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
AIDS Education Prevention	2023	"What is the Benefit?": Perceptions and Preferences for Long-Acting Injectable Antiretroviral Therapy Among People living with HIV H Rodriguez, A Volcan, B Castonguay, J Carda-Auten, C Ruiz, M Peretti, A Suarez, D Kerrigan, D Wohl, C Barrington	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 a shared decision-making tool for patients and clinicians to engage with when choosing among ART options	Eligibility *HIV injection *18+ years old *English or Spanish speaking *Engaged in HIV care at participating clinic Qualitative: Semi-structured interview *Experience living with HIV and receiving HIV care, communication and HIV treatment decision making, perception of LA-ART (monthly or every 2-month dosing of CAB+RPV) Analysis: Narrative & thematic analysis (theory of qualitative data analysis)	Demographics (N=71) *Mean age 46 years old (SD =12; range: 24-72) *Gender: Cismen (55%), ciswomen (27%), transgender women (17%), Non-binary (<1%) *Race self-reported: Other (42%), white (24%), Black (24%) *44% conducted interview in Spanish *Mean years diagnosed with HIV =15 years (range: <1-36 years *73% virally suppressed Qualitative *LA-ART awareness - 54% had not heard of LA-ART & remaining 46% had heard little about it via clinical research or word of mouth. Mix of enthusiasm and caution *Perceived benefits: Reduce adherence stress, more privacy (less involuntary HIV disclosures), & potentially greater effectiveness compared to oral ART, potential to reduce stigma around HIV *Concerns: Worried it would be less effective (in contract to others who perceived it as more effective), treatment resistance, 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 visits and cost burden *Additional information requested from participants to address questions & concerns (how does LA-ART work, how does effectiveness, cost, and side-effects compare to daily oral ART, need more information on injections and potential pain) * Most preferred the option for an injection every 2-months over 1-month frequency (few did like idea on monthly injections to see their provider more often, or because they believed it would be less potent-more gentle than current oral ART) *Required support for attended more frequent clinic visits via earlier appointment reminders, quicker appointments, consistent injection days available so easier to schedule work hours	*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 participant who struggled with adherence highlighted achieving viral suppression as a goal - both perspectives stressed importance of LA-ART effectiveness *Time and financial burden heavily influenced participants willingness to try LA-ART (structural barriers will need to be addressed for an equitable clinical implementation) *Almost all participants wanted more information on LA-ART Limitation *LA-ART 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 oral daily ART

PLOS ONE	2018	Deanna Kerrigan , Andrea Mantsios , Miguel Gorgolas, Maria-Luisa Montes, Federico Pulido, Cynthia Brinson, Jerome deVente, Gary J. Richmond, Sarah W. Beckham , Paige Hammond , David Margolis, Miranda Murray	qualitatively explore the views and experiences of PLHIV and their providers participating in the LATTE-2 trial in the United States and Spain	Background - LATTE-2 trial, a phase IIb study accessing the safety, tolerability, and acceptability of LA CAB and RPV for the treatment of HIV. 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;
AIDS AND BEHAVIOR	2020	Andrea Mantsios, Miranda Murray, Tahilin S. Karver, Wendy Davis, David Margolis, Princy Kumar, Susan Swindells, U. Fritz Bredeek, Miguel García del Toro, Mercedes Garcia Gasalla, Rafael Rubio García, Antonio Antela, Krischan Hudson, Sandy Griffith & Deanna Kerrigan	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. >18 years. 33 PLHIV from Spain and 20 PLHIV from the US; Most male 79%, with 85% and 79% men in the US and Spain, respectively. 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.	* It got better over time - with injection side effects (1 person stopped due to pain) - episodic; *concern for clinical efficacy; *logisitcal psychological freedom; *less frequent visits - to lead "normal" lives

Culture, Health & Sexuality	2020	"I feel empowered": women's perspectives on and experiences with long-acting injectable antiretroviral therapy in the USA and SpainAndrea Mantsiosa Department of Sociology, American University, Washington, DC, USA armantsios@gmail.com , Miranda Murray, Tahilin S. Karver, Wendy Davis, David Margolis, Princy Kumar, Susan Swindells, U. Fritz Bredeek, Miguel García Deltoro, Rafael Rubio García, Antonio Antela, Cindy Garris, Mark Shaefer, Santiago Cenoz Gomis, Miguel Pascual Bernáldez & Deanna Kerrigan; Pages 1066-1078; Cite this article https://doi.org/10.1080/13691058.2020.1752397 CrossMark Logo CrossMark	LATTE-2 and Atlas/Flair study of women	80 people living with HIV participating in Phase 2 and 3 clinical trials of long-acting antiretroviral therapy in the USA and Spain. Fifteen percent (12/80) of trial participants interviewed were women	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.
Lancet HIV	2023	Ramgopal et al	compare long-acting cabotegravir plus rilpivirine every 2 months with continued once-daily bictegravir, emtricitabine, and tenofovir alafenamide for the maintenance of HIV-1 virological suppression in adults living with HIV.	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 group) 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.	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. 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 carry my HIV medication with me" (284 [74%] of 382), § "I do not have to think 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;

2022	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	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): Patient 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, patient portal messages, 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 supports: Text reminders, calendar tracking, app reminders, phone calls, patient portal messages	*Patients were more likely to prefer injectable ART or PrEP if they were currently receiving other injectable treatments, such as hormone therapy (emphasized integrating services to ease burden) *Patients & providers anticipated less clinic visits as a benefit *LA modalities have ability to reduce internalized HIV stigma for PLWH *Insurance coverage was the number one barrier identified by providers & patients *Technology must play a role in supporting LA adherence 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