



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

UCLA Center for HIV Identification, Prevention and Treatment Services RAND Corporation

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- 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
  - The benefits of ART are not uniformly realized by all people with HIV
  - Challenges with adherence to daily oral ART due:
    - Comorbid mental health or substance use disorders
    - Social, economic, and structural barriers to treatment
    - Difficulties in accessing health systems (care and medications)

### Long Acting Injectable ART



- Long-Acting Injectable (LAI) ART provides a promising new mechanism for achieving virologic suppression for the most vulnerable populations of people with HIV
- LAI ART has the potential to help address HIV care disparities and advance the U.S. goal to End the HIV Epidemic (EHE)
- The first 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, Australia, and Switzerland.

## What is LAI ART



- Combination of two antiretroviral medications with long halflives:
  - Cabotegravir, an integrase-strand transferase inhibitor, and
  - Rilpivirine, a non-nucleoside reverse transcriptase inhibitor.
- Given by intramuscular injection at 1- to 2-month intervals
- Phase 3 RCT evidence provided by FLAIR and ATLAS (and ATLAS-2M)

## The Bad (the ugly?)



- Requirement for consumers to 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
  - Such as individuals with adherence issues, substance use, and mental disorders.
- Although LAI 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
  - 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
- Resistance implications of missed doses
  - System wide solutions will be needed for people who fall out of care



# NIMH - EtHE Supplement Study





- Center for HIV Intervention, 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:
  - 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;
  - 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
  - assess the end-user (consumer) perceived barriers to and facilitators of LAI ART use in Los Angeles County.

## **EtHE Study continued**



- Series of focus groups (and one semi-structured interview session)
  - Two focus groups with consumer participants
  - Two focus groups and one semi-structured interview session with clinical and non-clinical stakeholders

• February 2020 in diverse locations in Los Angeles, California



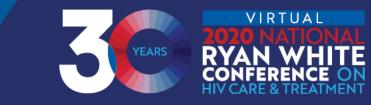


- Overall LAI ART acceptability
- Barriers to and facilitators of LAI ART:
  - Consumer-level (e.g., adherence, stigma and medical mistrust)
  - Clinic-level (e.g., perceived cost, patient volume)
- Messaging and implementation recommendations for LAI ART rollout



# Results

### **Participant Characteristics**



#### Consumers (n=18)

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	Cisgender Male Gay/Lesbian	Cisgender Male Bisexual	Cisgender Female Straight/ Heterosexual	Cisgender Female Bisexual	14	. (
Black/African American	2 (11%)	-	4 (22%)	1 (6%)	Black/African American	
Hispanic/Latinx	6 (33%)	2 (11%)	-	-	Hispanic/Latin x	
White, Non- Hispanic/Latinx	2 (11%)	-	-	-	White, Non- Hispanic/Latin x	
Other: Afro Latino	1 (6%)	-	-	-	^ Asian	
4						-

#### Other Stakeholders (n=23) 14 clinical; 9 non-clinical

	Cisgender Male	Cisgender Female
Black/African American	7 (30%)	1 (4%)
Hispanic/Latin x	3 (13%)	-
White, Non- Hispanic/Latin x	2 (9%)	3 (13%)
Asian	3 (13%)	1 (4%)
More than One Race	2 (9%)	1 (4%)

## LAI ART Acceptability



- Participants were generally enthusiastic about LAI ART and its potential to benefit patient care
  - Consumers felt it would be a good option for them and/or other consumers
  - Stakeholders felt it would be a useful "new tool in the toolbox" of treatment options
- Participants were disappointed LAI ART will not be available to virally unsuppressed consumers who could benefit most from new options
- Participants expressed significant concerns about barriers to LAI ART implementation and uptake

### Key Consumer-Level Facilitators and Barriers

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Option for consumers who have trouble adhering to daily oral ART

Reduced treatment management burden

Reduced internal and external experiences of stigma

Adherence/resistance concerns with increased required appointments

Pain and side effects

Medical mistrust

### Key Clinic-Level Facilitators and Barriers



- High provider support/willingness to implement LAI ART
- Several anticipated barriers:
  - New financial procedures
  - Staff capacity challenges
  - Need for staff training/education
  - New physical infrastructure and supply management requirements

*"I think it's going to be a huge paradigm shift for every clinic..." (focus group participant)* 

### Recommendations for LAI ART Rollout



### Implementation

- Nurse/pharmacist delivery
- Treatment education and adherence support
- Further research and pilot/demonstration projects
- Exploring innovative strategies
  - Alternative delivery locations
  - Alternative anatomic sites
  - Self-injection
  - Learning from implementation of other injectable therapies

VIRTUAL

## **Preliminary Reports**



### New Reports from CHIPTS Ending the HIV Epidemic Supplement Projects



Regional Response to HIV Eradication Efforts in California Counties



Use of Technology-Based PrEP to Improve Uptake, Adherence, and Persistence



Preparing for Long-Acting Injectable Treatment for HIV in Los Angeles

https://chipts.ucla.edu/news/new-chipts-ehe-supplement-project-reports/

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