

## Long-Acting Injectable ARV to Advance Health Equity: US Clinic Perspectives on Barriers, Needed Support, and Program Goals for Implementation

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# Long-Acting Injectables: "Gamechangers" & "Revolutionary"

X Medical Xpress

New HIV treatment shot given only to 'game changer'

The Food and Drug Administration has approved S suppress HIV for patients who suffered drug resista

Dec 30, 2022

INSIDE DEVELOPMENT | GLOBAL HEALTH

'Revolutionary' HIV prevention jab set to expand choices for consumers

By Andrew Green // 01 March 2023



PT Pharmacy Times

Long-Acting HIV Regimen May Prove Revolutionary

FDA approval of 2-drug injectable Cabenuva is a game changer in maintaining viral suppression in patients.

May 24, 2021



NEWS | 05 August 2022 | Correction 16 August 2022

Long-lasting HIV prevention drug could be game changer – but who will pay?

Understanding the HIV epidemic HIV programming News and blogs

Long-acting injectable PrEP: is it

There are some new developments for PrEP that might change the way you take it in the future

a game changer for HIV

prevention?

Sex and relationships HIV an

#### Limited Uptake of Injectable Treatment

#### A Tale of 2 clinics

#### California Clinic

- UC San Diego Owen Clinic
- Ryan White-funded HIV primary care clinic
- Implementing iCAB/RPV April 2021-June 2022 (14 months)
- ~Half of those who expressed interest in iCAB/RPV initiated

#### Georgia Clinic

- Ryan White-funded clinic serving >6000 PWH in metropolitan Atlanta, Georgia
- Implementing iCAB/RPV April 2021-December 2021 (9 months)
- ~A quarter of those who expressed interest in iCAB/RPV initiated within 12 months



# Can these interventions be implemented in ways that decrease disparities in health outcomes?

HIV TREATMENT AND MEDICAL CARE > FEATURES

## Can Long-Acting ART Be an Equitable Care Option for Black Women?



#### Not a Panacea for Inequities in Access

Alongside the excitement for LA-ART lingers the disquieting inequities that appeared during the early days of AZT through the evolution of NRTIs and the expansion of NNRTIs. Black Americans have been disproportionately affected by HIV/AIDS since the epidemic's beginning, and that disparity has deepened over time. While ART has helped millions of people living with HIV lead healthier lives, Black people living with HIV are more likely than other racial groups to postpone or discontinue medical care and become hospitalized. Add to that that in the U.S., Black people living with HIV have higher rates of virologic failure on ART and of death when compared to white individuals. As for Black women, we represent the majority—nearly 60%—of new HIV infections among U.S. women.

AIDS. Author manuscript; available in PMC 2020 Nov 1.

Published in final edited form as:

AIDS. 2019 Nov 1; 33(13): 2110–2112.

doi: 10.1097/QAD.0000000000002341

NIHMSID: NIHMS1536842 PMID: <u>31577579</u>

PMCID: PMC6777857

A shot at equity? Addressing disparities among Black men who have sex with men in the coming era of long-acting injectable pre-exposure prophylaxis

THE LANCET

Submit A

EDITORIAL | VOLUME 9, ISSUE 7, E449, JULY 2022

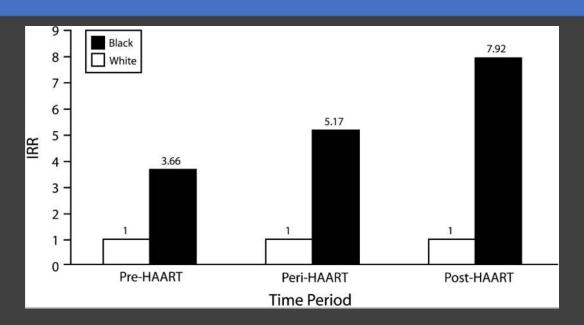
Equitable access to long-acting PrEP on the way?

The Lancet HIV

Published: July, 2022 • DOI: https://doi.org/10.1016/S2352-3018(22)00167-9 • 📵 Check for updates



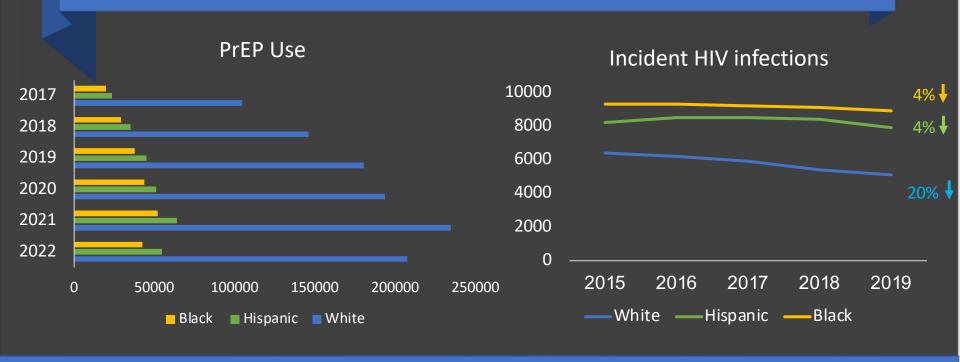
## Innovations in HIV treatment lead to disparities



HIV/AIDS mortality among Blacks and Whites during the pre-, peri-, and post-HAART periods: US, 1987–2005.



## Oral PrEP increases disparities in HIV







#### The ALAI UP Project



To support clinics across the United States develop injectable HIV treatment programs that prioritize the needs of underserved populations by providing ongoing technical assistance with the explicit goal of addressing inequity in health outcomes.

U1SHA46532-01-00 Special Project of National Significance – Minority HIV/AIDS Fund (PD Meyers)

### 8 SELECTED CLINICS WILL RECEIVE:



SAMPLE PROTOCOLS TO SUPPORT EQUITABLE DELIVERY OF INJECTABLE HIV TREATMENT



TECHNICAL ASSISTANCE TO IMPLEMENT PROTOCOLS



DATA SUPPORT TO INFORM CONTINUOUS QUALITY IMPROVEMENT



HELP ENGAGING COMMUNITIES TO DESIGN SERVICES YOUR PATIENTS WANT



PEER SUPPORT FROM OTHER
IMPLEMENTING CLINICS



#### ALAI UP Project Request for Application

Clinical sites interested in participating in ALAI UP were asked to submit an application that included the following information:

- Status of current iCAB/RPV program
- Priority patient populations for iCAB/RPV
- Projected reach of iCAB/RPV program
- Anticipated or experienced barriers
- Types of resources/supports needed

Interested in Delivering Long-Acting Injectable HIV Treatment to Underserved Populations?



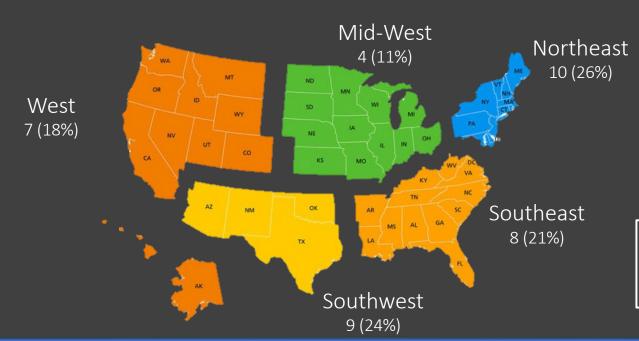
#### OVERVIEW

The ALAI UP Project is now accepting applications from clinics across the US and US territories providing HIV treatment to underserved populations and communities of color.

The goal of The ALAI UP Project is to support the implementation and delivery of injectable HIV treatment to reduce HIV-related health inequities.

Each clinic may apply for \$90,000 per year for three years for a total of \$270,000.

#### Widespread Interest from across US



Total number of applications:

38 clinics



#### Widespread Interest from Range of Clinic Types



AIDS Service Organizations 8 (21%)



Hospitals 5 (13%)



Academic Medical Centers 8 (21%)



Federally Qualified Health Centers 6 (16%)



Department of Health 3 (8%)



Primary Care 8 (21%)

#### Clinics at all Stages of Implementation

8 (21%)



We are just starting to consider iCAB/RPV for clinic 0 on iCAB/RPV

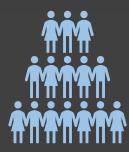
23 (61%)



We just started implementing iCAB/RPV

< 25 on iCAB/RPV

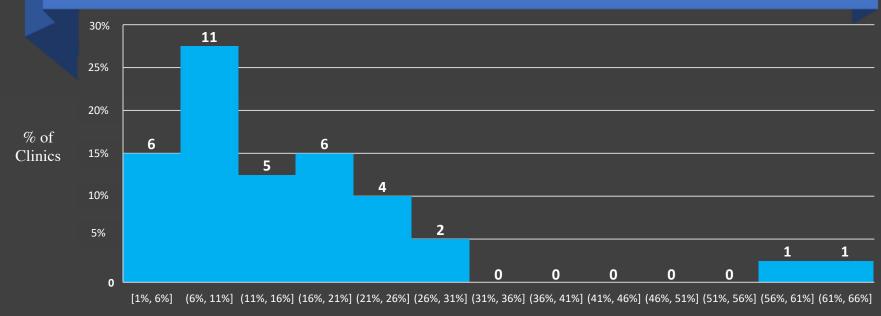
7 (18%)



iCAB/RPV fully integrated into HIV services

≥ 25 on iCAB/RPV

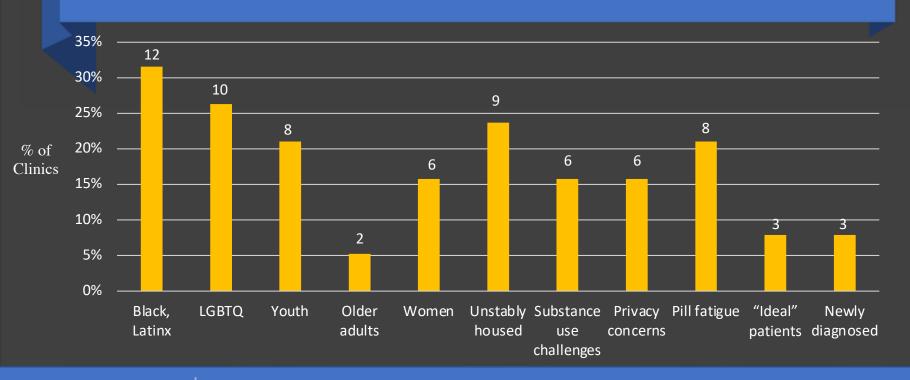
### Diversity in Projected Reach of Program



Proportion of patients with HIV on iCAB/RPV after 12 months



### Populations Prioritized for iCAB/RPV





#### Barriers to Implementation



Insurance Authorization 27 (71%)



New Workflows + Staffing 12 (32%)



Injection Scheduling + Coordination 16 (42%)



Patient Education 10 (26%)



Transportation + Expanded Hours 13 (34%)



Provider Education 7 (18%)



#### Insurance Barriers: Denial of Coverage



"This is a picture of the stack of paperwork for three of the patients I have prescribed for. Two were approved and one was denied twice after appeals. This takes hours of work and doesn't represent the phone calls and emails also related to the follow up after a prescription is sent."

#### Insurance Barriers: Prior Authorization

Each insurance plan has various administrative rules which are complex to navigate. Almost all require prior-authorization and again as a resource limited provider the increased administrative burden increases our operational cost which ultimately limits the care we can provide.

Moreover, the prior authorization process is not well understood at the insurer level as many plans are still asking for inappropriate information, e.g., request for coverage denied because patient has not failed other therapies. Providers are spending a great deal of time doing peer to peer reviews to educate insurers that they are not following FDA prescribing guidance.



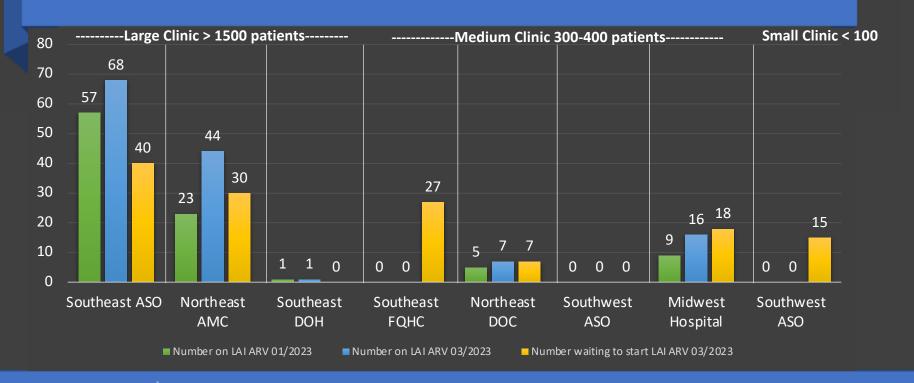
#### Insurance Barriers: Pharmacy vs. Medical



Finding out if the medication is covered under pharmacy or medical benefit is key. Many Ryan White providers lack infrastructure required to medically bill for specialty injectables.

While we are working on building this capability; we currently are unable to access for patients whose insurers designates as medical benefit.

#### Implementation has been Slow





#### Resources to Support Implementation



TA to Develop New Workflows + Protocols 18 (47%)



TA to Address Payor Challenges 8 (21%)



Additional Staff for Care Coordination + Benefits Navigation 17 (45%)



Share Experience with Other Clinics 12 (32%)



Patient Facing Materials to Educate + Increase Demand 7 (18%)

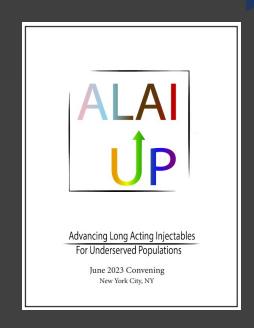


Support Engaging Communities 5 (13%)



#### Final Thoughts

- Diverse clinic types are interested in offering iCAB/RPV
- For iCAB/RPV to be a tool to help End the HIV Epidemic, dedicated resources centered on equity and relevant to context and population are needed to help deliver iCAB/RPV to patients not currently being well served by available oral ART
- Without this support, the introduction of iCAB/RPV risks exacerbating, not ameliorating, health disparities



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ALAI UP Clinical Demonstration Sites

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