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

Nadia Nguyen, PhD
Aaron Diamond AIDS Research Center
Columbia University Irving Medical Center

Adherence 2023 • June 11-13 • Puerto Rico
Long-Acting Injectables: “Gamechangers” & “Revolutionary”

New HIV treatment shot given only 'game changer'

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

Dec 30, 2022

Pharmacy Times

Long-Acting HIV Regimen May Prove Revolutionary

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

May 24, 2021

‘Revolutionary’ HIV prevention jab set to expand choices for consumers

By Andrew Green // 01 March 2023

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

Hill et al, 2023, AIDS, Single-Center Experience Evaluating and Initiating People with HIV on Long-Acting Cabotegravir/Rilpivirine; Collins et al, 2022, OFID, Early Experience Implementing Long-acting Injectable Cabotegravir/Rilpivirine for HIV-1 Treatment at a Ryan White-funded Clinic in the US South
Can these interventions be implemented in ways that decrease disparities in health outcomes?

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

Dali Adekunle
May 31, 2021

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:
doi: 10.1097/QAD.0000000000002941

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

William C. GOEDEL, BA,† Amy S. NUNN, ScD,‡ Philip A. CHAN, MD, MS,§ Dustin T. DUNCAN, ScD,‡ Katie B. BIELLO, PhD,¶,∥ Steven A. SAFREN, PhD,§∥ and Brandon D.L. MARSHALL, PhD¶

THE LANCET HIV

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
Innovations in HIV treatment lead to disparities


Rubin, 2010, AJPH, Examination of inequalities in HIV/AIDS mortality in the United States from a fundamental cause perspective
Oral PrEP increases disparities in HIV

PrEP Use

Incident HIV infections

- White
- Hispanic
- Black

CDC, 2022
The ALAI UP Project

ALAI UP
Advancing Long Acting Injectables
For Underserved Populations

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)
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

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

- West: 7 (18%)
  - States: CA, NV, WA, OR, ID, MT, WY, CO, UT, AZ, NM, TX, OK, LA, AR, MS, AL, GA, SC, FL, RI, VT, NH, ME, MA, CT, NY, PA, NJ, DE, MD, VA

- South: 9 (24%)
  - States: TX, OK, LA, AR, MS, AL, GA, SC, FL, RI, VT, NH, ME, MA, CT, NY, PA, NJ, DE, MD, VA

- Mid-West: 4 (11%)
  - States: IL, IN, WI, MI, OH, IA, MO, KS, NE, SD, WY, MT, ID

- Southeast: 8 (21%)
  - States: VA, NC, SC, GA, FL, MS, AL, TN

- Northeast: 10 (26%)
  - States: MA, CT, NY, NJ, PA, OH, MI, WI, IA, MO, KS, CO, NV, OR, WA, ID, MT, WY, CO, UT, AZ, NM, TX, OK, LA, AR, MS, AL, GA, SC, FL, RI, VT, NH, ME, MA, CT, NY, PA, NJ, DE, MD, VA
<table>
<thead>
<tr>
<th>Type</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS Service Organizations</td>
<td>8</td>
<td>21%</td>
</tr>
<tr>
<td>Hospitals</td>
<td>5</td>
<td>13%</td>
</tr>
<tr>
<td>Academic Medical Centers</td>
<td>8</td>
<td>21%</td>
</tr>
<tr>
<td>Federally Qualified Health Centers</td>
<td>6</td>
<td>16%</td>
</tr>
<tr>
<td>Department of Health</td>
<td>3</td>
<td>8%</td>
</tr>
<tr>
<td>Primary Care</td>
<td>8</td>
<td>21%</td>
</tr>
</tbody>
</table>
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

% of Clinics

- [1%, 6%] 6
- [6%, 11%] 11
- (11%, 16%] 5
- (16%, 21%] 6
- (21%, 26%] 4
- (26%, 31%] 2
- (31%, 36%] 0
- (36%, 41%] 0
- (41%, 46%] 0
- (46%, 51%] 0
- (51%, 56%] 0
- (56%, 61%] 1
- (61%, 66%] 1

Columbia University Irving Medical Center
Populations Prioritized for iCAB/RPV

- Black, Latinx: 12%
- LGBTQ: 10%
- Youth: 8%
- Older adults: 2%
- Women: 6%
- Unstably housed: 9%
- Substance use challenges: 6%
- Privacy concerns: 6%
- Pill fatigue: 8%
- “Ideal” patients: 3%
- Newly diagnosed: 3%

% of Clinics
Barriers to Implementation

- Insurance Authorization: 27 (71%)
- Injection Scheduling + Coordination: 16 (42%)
- Transportation + Expanded Hours: 13 (34%)
- New Workflows + Staffing: 12 (32%)
- Patient Education: 10 (26%)
- 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.
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 designate as medical benefit.
Implementation has been Slow

---

**Large Clinic > 1500 patients**
- Southeast ASO: 57
- Northeast AMC: 40
- Southeast DOH: 23
- Southeast FQHC: 44
- Northeast DOC: 30
- Southwest ASO: 74
- Midwest Hospital: 68
- Southeast ASO: 6

**Medium Clinic 300-400 patients**
- Southeast ASO: 0
- Northeast AMC: 0
- Southeast DOH: 0
- Southeast FQHC: 27
- Northeast DOC: 5
- Southwest ASO: 0
- Midwest Hospital: 16
- Southwest ASO: 18

**Small Clinic < 100**
- Southeast ASO: 0
- Northeast AMC: 0
- Southeast DOH: 0
- Southeast FQHC: 0
- Northeast DOC: 7
- Southwest ASO: 0
- Midwest Hospital: 0
- Southwest ASO: 15

Legend:
- Green: Number on LAI ARV 01/2023
- Blue: Number on LAI ARV 03/2023
- Yellow: Number waiting to start LAI ARV 03/2023
Resources to Support Implementation

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

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

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

- TA to Address Payor Challenges
  8 (21%)

- Share Experience with Other Clinics
  12 (32%)

- 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
ALAI UP Clinical Demonstration Sites

ALAI UP is an SPNS Project supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $7,000,000 with 0% financed with non-governmental sources. The contents of this presentation are my own and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.