Early implementation and clinical outcomes from real-world use of injectable cabotegravir/rilpivirine (iCAB/RPV) at 8 US clinics participating in the ALAI UP Project

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The first long-acting injectable antiretroviral therapy (LAI ART), injectable cabotegravir/rilpivirine (iCAB/RPV), was approved by the FDA in 2021.

Yet data from real-world use remains scarce and little is known about equity in access and use.

ALAI UP is a HRSA-funded SPNS project to accelerate the equitable implementation of LAI ARTs, starting with iCAB/RPV.

ALAI UP selected 8 diverse clinical sites and began supporting clinics in March 2023.
ALAI UP Sites

- Abounding Prosperity: 92 clients
- Sinai Infectious Disease Center: 388 clients
- Baltimore City Health Department Sexual Health Clinic: 459 clients
- Coastal Family Health: 555 clients
- San Antonio AIDS Foundation: 607 clients
- Positive Impact Health Center: 1,694 clients
- Sunshine Care Center at Florida Department of Health: 1,771 clients
- Mount Sinai-Harlem Health-Jack Martin Fund Center: 2,908 clients

Number of Clients with HIV served March 2023-February 2024

~8,500 clients with HIV across ALAI UP sites

ALAI UP Clinic Types
- Health Department
- Academic Medical Center
- Hospital-Based Infectious Disease Clinic
- AIDS Service Organization
- Community Based Organization
- Federally Qualified Health Center
Methods

- ALAI UP and clinics co-developed a clinical monitoring process to measure reach, equity, fidelity, and safety.

- Using client-level data, we report on the first 12 months of monitoring iCAB/RPV use at clinics participating in ALAI UP (March 2023-February 2024).

<table>
<thead>
<tr>
<th>Domain</th>
<th>Question</th>
<th>Indicators</th>
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<tbody>
<tr>
<td>Reach</td>
<td>How many clients have initiated iCAB/RPV?</td>
<td>Number and proportion of clients with HIV who have been initiated on iCAB/RPV</td>
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<tr>
<td>Equity</td>
<td>Which clients have initiated iCAB/RPV? Which clients have not?</td>
<td>The extent to which a clients’ race, ethnicity, gender, and age are not associated initiation of iCAB/RPV</td>
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<tr>
<td>Fidelity</td>
<td>Is iCAB/RPV being delivered according to protocol?</td>
<td>Number and proportion of iCAB/RPV injections within 7 days of injection window</td>
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<tr>
<td>Safety</td>
<td>What are clients’ outcomes after they initiate iCAB/RPV?</td>
<td>Number and proportion of clients with (1) VL&lt;50 copies/mL, (2) 2 consecutive VL 50-200 copies/mL, or (3) VL&gt;200 copies/mL after initiating iCAB/RPV. Number and proportion of clients discontinue iCAB/RPV for (1) non-clinical reasons, (2) clinical reasons, or are (3) lost to follow up</td>
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</tbody>
</table>
Reach: Proportion of Clients with HIV currently on and ever initiated on iCAB/RPV at end of Year 1 (Feb 29, 2024)

<table>
<thead>
<tr>
<th>Site</th>
<th>PWH currently on iCAB/RPV</th>
<th>PWH ever on iCAB/RPV</th>
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</thead>
<tbody>
<tr>
<td>S1</td>
<td>16</td>
<td>18</td>
</tr>
<tr>
<td>S3</td>
<td>23</td>
<td>27</td>
</tr>
<tr>
<td>S2</td>
<td>13</td>
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<td>S4</td>
<td>42</td>
<td>59</td>
</tr>
<tr>
<td>S5</td>
<td>48</td>
<td>52</td>
</tr>
</tbody>
</table>

6088 Clients with HIV across 6/8 ALAI UP sites

178 (2.9%) Clients with HIV ever initiated on iCAB/RPV
Reach: Clients ever initiated on iCAB/RPV

• Race: 73% Black, 13% White
• Ethnicity: 21% Hispanic/Latinx
• Gender: 71% Cisgender men, 21% Cisgender women, 5% Transgender
• Age: 84% age 30-65
Equity: Clients ever vs never initiated on iCAB/RPV by race, ethnicity, gender, and age

• Within clinics, race, ethnicity, gender or age were not associated with iCAB/RPV initiation
• Caveat 1: Other social determinants of health are important but not always measured in routine practice
• Caveat 2: Lower or higher iCAB/RPV initiation proportions in specific populations may reflect client preference not inequity
Fidelity: On-time injections among clients ever on iCAB/RPB at end of Year 1 (Feb 29, 2024)

iCAB/RPV maintenance injections delivered as of February 29, 2024

614

- Monthly Dosing
- Bi-Monthly Dosing

Previous Injection

Injection Window Start

Target Injection Date

Injection Window End

EARLY 3%

ON TIME 94%

LATE 3%

-7 days

+7 days
Fidelity: Late injections among clients ever on iCAB/RPB at end of Year 1 (Feb 29, 2024)

9% clients ever had a late injection
Safety: Viral suppression among clients ever on iCAB/RPV at end of Year 1 (Feb 29, 2024)

178 clients
Ever on iCAB/RPV

160 (90%) clients
With VL data at or before iCAB/RPV initiation

141 (88%) clients
Initiated iCAB/RPV with VL<50 copies/mL

125 (88.5%) clients
All VL<50 copies/mL

11 (8%) clients
Any VL 50-200 copies/mL*

5 (3.5%) clients
Any VL >200 copies/mL

17 (89.5%) clients
Achieved VL<50 copies/mL

17 (100%) clients
All VL<50 copies/mL

19 (12%) clients
Initiated iCAB/RPV with VL≥50 copies/mL

1 (5%) client
Did not achieve VL<50 copies/mL

1 (5%) client
Awaiting VL after iCAB/RPV initiation

96% clients on iCAB/RPV are durably virally suppressed
Safety: iCAB/RPV discontinuation among clients ever on iCAB/RPB at end of Year 1 (Feb 29, 2024)

Reasons for iCAB/RPV discontinuations

Non-Clinical Reasons
- Insurance loss/new insurance: 6
- Visit frequency: 4
- Cost: 2
- Clinic wait time: 1
- Missed injection appointments: 1
- Fear/dislike of needles: 0
- Satisfaction with previous regimen: 0
- Newness of modality: 0

Clinical Reasons
- Side effects: 5
- Failing treatment: 3
- Lost to Follow Up: 9

Total: 31/178 clients discontinued across sites
Conclusions

• iCAB/RPV reach after 1 year of ALAI UP support has been modest but matches early industry predictions. This may reflect significant, outer-context implementation barriers not addressed by ALAI UP.

• Among the clients who have initiated iCAB/RPV, the majority of injections were delivered on time.

• Nearly all clients on iCAB/RPV were virally suppressed, including clients who were initiated with VL ≥50 copies/mL.

• Loss of insurance coverage, visit frequency, and side effects were the most common reasons for planned discontinuation.

• The iCAB/RPV clients with low-level viremia, side effects, treatment failure, and clients who were lost to follow up warrant closer monitoring and investigation.
Acknowledgement

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The contents are those of the presenters 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.
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