HIV CARE CONTINUUM
Cutting Edge Services: Clinical Implementation of Long-Acting ART
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Adherence 2023 • June 11-13 • Puerto Rico
The speaker have stated that he have the following financial relationship(s) and he have agreed to see that all information present is done so fairly and without bias:

- **Research Grants**: Merck & Co., ViiV Healthcare, Gilead Science
- **Royalty**: None
- **Stockholder**: None
- **Member of Speaker’s Bureau**: Janssen Therapeutics, ViiV Healthcare
- **Consultant to**: Janssen Therapeutics, ViiV Healthcare
- **Salary**: N/A
- **Other**: None
About us:

• Centro Ararat, Inc., is a non-profit community-based organization with a mission to provide access to comprehensive primary care, mental health care, preventive healthcare and support services for diverse populations in underserved communities throughout Puerto Rico.


• Programs:
  – RWHAP Part A, B, C & F (SPNS) Provider
  – RWHAP Part C funded since 2014
  – 4 Primary Care Clinics
  – Sexual Health Clinic
  – Transgender Primary Care Clinic
  – 2 Pharmacies
A Status-Neutral HIV Prevention and Care Continuum

Ample efforts to provide HIV Test and Treat, which would provide early access to HIV treatment.

Complete access to PrEP services for interested/recommended participants; reinforcement of effective adherence strategies for PrEP treatment.

Widened support to engagement in comprehensive care for PLWHIV; specific support to enforce adherence.

Absolute viral suppression to PLWHIV.
CA Successes in HIV Care

• **Link to Care:**
  - 99.5% in less than 30 days
  - Average: 18 days

• **Initiation of ART/Adherence:**
  - 97% of all patients are on ARV.
  - 96% are adherent to treatment.
    - Treatment as prevention (U=U) campaign has improved patient adherence.
  - 92% have remained undetectable all the time.
  - **Fast Eligibility** procedures help to limit barriers to start treatment.
Long-Acting Benefits

• Change the current state of the HIV epidemic
• New strategies for retention in care.
• Eliminate the need for daily pill taking
• Engage with patients who face challenges to ADHERENCE
LAI - Patient Demographic – 57 patients

Gender Identity

<table>
<thead>
<tr>
<th>Identify as Female</th>
<th>Count</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6</td>
<td>10%</td>
</tr>
<tr>
<td>Identify as Male</td>
<td>50</td>
<td>88%</td>
</tr>
<tr>
<td>Male-to-Female (MTF)/Transgender Female/Trans Woman</td>
<td>1</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>57</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Medical Insurance

<table>
<thead>
<tr>
<th>Medical Insurance</th>
<th>Count</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Medicaid (GHI)</td>
<td>26</td>
<td>46%</td>
</tr>
<tr>
<td>Medicare HMO</td>
<td>20</td>
<td>35%</td>
</tr>
<tr>
<td>Commercial HI</td>
<td>9</td>
<td>16%</td>
</tr>
<tr>
<td>ADAP</td>
<td>2</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>57</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
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Long Acting by age groups

- 25-34: 8 / 4%
- 35-44: 13 / 23%
- 45-54: 14 / 24.5%
- 55-64: 14 / 24.5%
- 65+: 8 / 14%

Adherents Suppressed

Internal CA data May 2023
Type of Patients
Patient Comments – Good side

- The administration feels like a vaccine administration
- Feel free
- Hope and desire to live after the evolution of treatments for a disease brought much death to family and friends.
- It allows them to change their lifestyle by stopping taking a daily medication
The Good

- Medical and Psychological relieve
- Improve Adherence
- Reduce Polypharmacy
- Keep viral suppression
- Improvement in GI symptoms
- Fewer trips to the pharmacy
- Improve auto perception. Doesn’t seem like a sick person
- Long terms survivors see some hope
- Easy access to the oral lead + additional month
Patient Comments – Not so Good

- The increase in sensibility at the injection area, even days after the administration
- Tiredness
- The difficulty of approval by health insurance.
- The deficiency of distribution, shipment, and dispatch of the different pharmaceutical or pharmacy companies.
- The availability of the drug under HI
The Bad - Access to Medication

• Medication payer (Pharmacy or Medical benefit)
  – Medicaid
  – Medicare HMO
  – ADAP
  – Commercial Insurance

• Medication access
  – Specialty Pharmacy
  – Assistant Program
The Bad - Medication

- **Rilpivirine**
  - Painful
- **Mass in the injection area**
  - Both products
  - It can last up to 10 days
- **Needs of refrigeration**
- **Trypanophobia**
Patients that have received LAI: 68

Reasons for discontinuing

- Counterindication
- Allergic reaction
- Corporal absorption difficulty
- Drug interaction
- Detectable viral load
- Side effects

Internal CA data May 2023
Why NEW Technology Fail?

• Lack to identify population-specific barriers
• Inadequate representation of:
  – Racial, ethnic, and gender minorities,
  – Vulnerable groups
    • Youth, young adults, pregnant people,
    • People without stable housing
    • People who use drugs
    • People with mental health challenges

• Broad access to promising technologies is a myth

Equity FAIL

• Frequent clinic visits for LAI’s as patient POV:
  – Could worsen HIV stigma and stigmatization.
  – Increase the risk of unwanted disclosures.
  – Lead to increased costs from copays and travel.
  – Be prohibitive for people who are unable to miss work or for those without transportation.

POV – Point of View

Clinic Site Impact

• Clinicians point of view
  – Overwhelm staffing and other clinic resources.\textsuperscript{6}

• Each visit for injection of cabotegravir plus rilpivirine lasted about 32 minutes\textsuperscript{7}


\textsuperscript{7} Czarnogorski M, Garris C, D’Amico R, et al. CUSTOMIZE: overall results from a hybrid III implementation-effectiveness study examining implementation of cabotegravir and rilpivirine long-acting injectable for HIV treatment in US healthcare settings; final patient and provider data. IAS Conference on HIV Science; July 18–21, 2021 (abstr OAD0705).
Modifications to the Practice (1)

- Incorporate the Medical Case Manager into the medication access process.
  - Vital element
  - Time-consuming
  - Medication request
  - Medication Coordination
  - Specialty Pharmacy Delivery
Modifications to the Practice (2)

• The use of specialty pharmacy instead of our institutional pharmacy

• Develop a protocol to refer and link the patient to the treatment.
  – Clinic managers, Physicians, nurses, and case managers participate in the process.
Modifications to the Practice (3)

• Technology at the service of medicine
  – New appointment book at the EMR to provide the space for medication administration.
  – Table at institutional SharePoint to better access patient injection appointments and individual requirements to continue with the medication.
Modifications to the Practice (4)

• Technology at the service of medicine

A new group at institutional TEAMS includes Medical Case Managers, Nurses, and Front Desk personnel. Notifications about medication arrivals, administration dates, and other case updates.
Other Possible Modifications

• Mitigate the social structural issues:

• Administration in NO clinical settings
HIV PREVENTION
with Long-Acting Injectable
Black sexual minority men Vs White sexual minority men

More barriers accessing HIV PrEP
LAI Approved for PrEP
LAI on Research for PrEP

Pre-Exposure Prophylaxis Study of Lenacapavir and Emtricitabine/Tenofovir Alafenamide in Adolescent Girls and Young Women at Risk of HIV Infection (PURPOSE 1)

ClinicalTrials.gov Identifier: NCT04994509

Study of Lenacapavir for HIV Pre-Exposure Prophylaxis in People Who Are at Risk for HIV Infection (PURPOSE 2)

ClinicalTrials.gov Identifier: NCT04925752
Patients in LAI for HIV Prevention in CA

“For some people, PrEP is a license to go wild; for some wild people, PrEP is a seatbelt to manage the risk of the fun ride”
Causes

- HIV Viral load not cover by HI
- Medication not coverage by HI
  - ACA rule for at least one HIV Prevention medication at HI formulary not applicable in Puerto Rico

HI – Health Insurance; ACA – Affordable Care Act
Conclusions

• A one-size-fits-all approach to LAI delivery is not an effective public health strategy.
  – Adaptive interventions the needs of different populations are crucial.
• As we prepare to broaden the availability of LAIs, there is an urgent need to engage with patients and stakeholders to:
  – Enhance equitable access,
  – Increase patient willingness to use these new technologies
  – Maximize public health impact.
• Long-Acting Injectable Interventions are not just a program or a “stepchild” project in your clinic. It requires a full Clinical process and structure.

Equity in access to long-acting injectables in the USA Crossref DOI link: [https://doi.org/10.1016/S2352-3018(22)00031-5](https://doi.org/10.1016/S2352-3018(22)00031-5), Published Print: 2022-03, The Lancet HIV
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