



HIV CARE CONTINUUM

Cutting Edge Services: Clinical
Implementation of Long-Acting ART

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Disclosures

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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
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- **Consultant to:** Janssen Therapeutics, ViiV Healthcare
- **Salary:** N/A
- **Other:** None



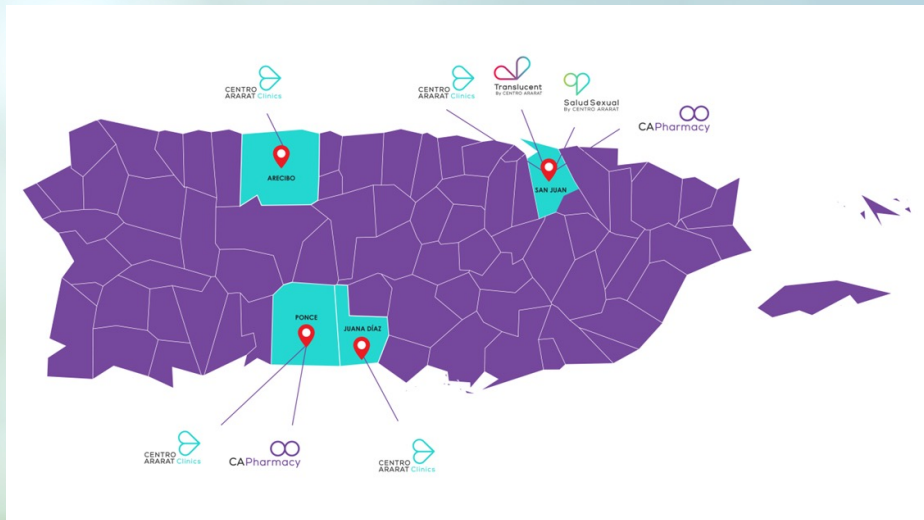
About us:

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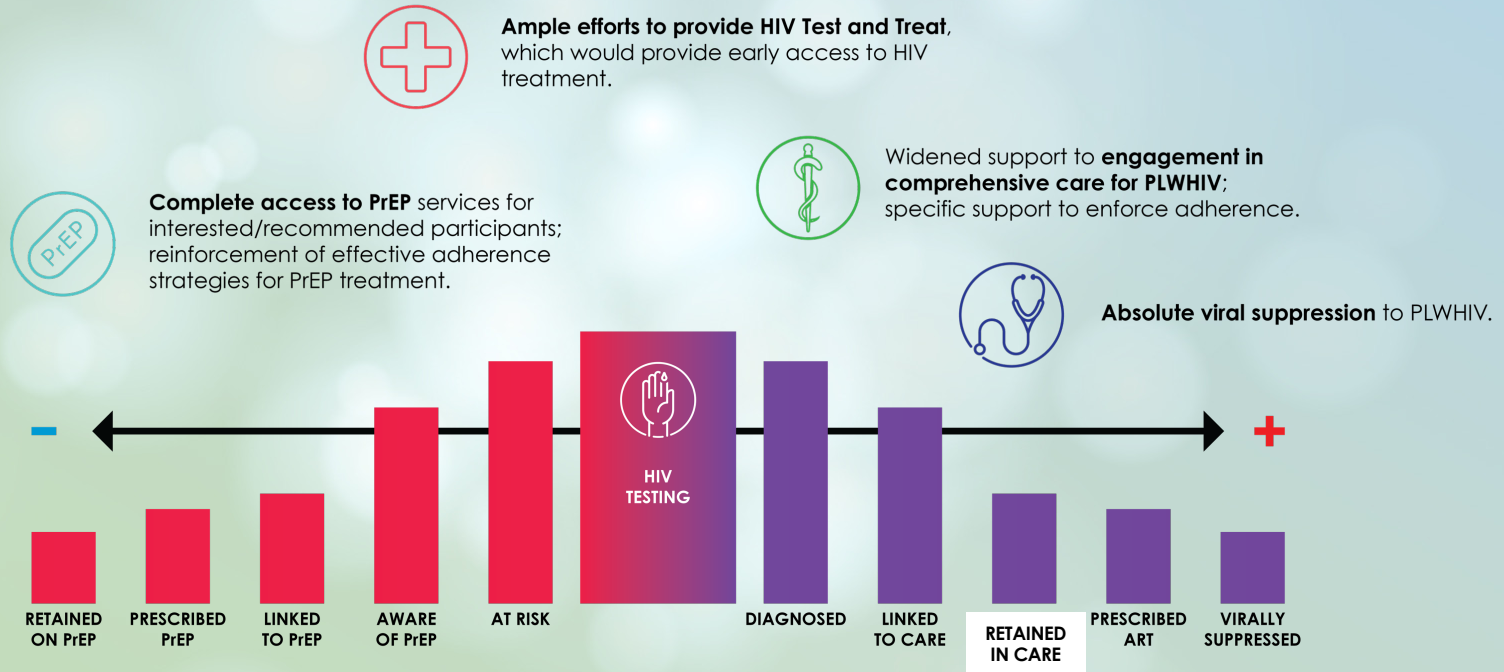
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- **Centro Ararat, Inc.**, is a non-profit community-based organization with a mission to provide access to comprehensive primary care, mental health care, preventive healthcare and support services for diverse populations in underserved communities throughout Puerto Rico.
- Founded in Ponce, Puerto Rico, in 2001.
- **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





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

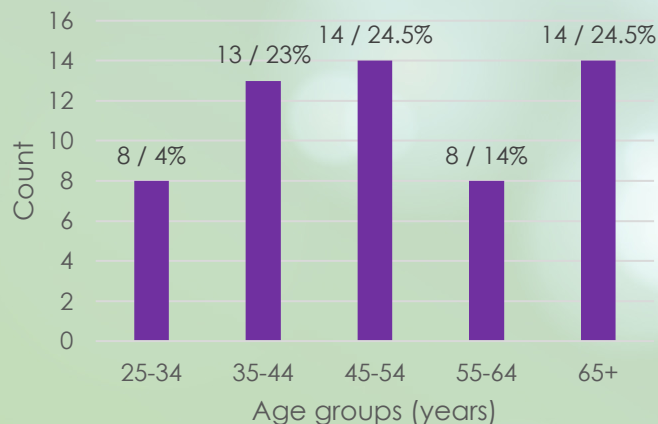
- Change the current state of the HIV epidemic
- New strategies for retention in care.
- Eliminate the need for daily pill taking
- Engage with patients who face challenges to **ADHERENCE**



LAI - Patient Demographic – 57 patients

| Gender Identity | Count | % |
|---|-----------|-------------|
| Identifies as Female | 6 | 10% |
| Identifies as Male | 50 | 88% |
| Male-to-Female (MTF)/Transgender Female/Trans Woman | 1 | 2% |
| Total | 57 | 100% |

Long Acting by age groups



| Medical Insurance | Count | % |
|--------------------|-----------|-------------|
| Medicaid (GHI) | 26 | 46% |
| Medicare HMO | 20 | 35% |
| Commercial HI | 9 | 16% |
| ADAP | 2 | 3% |
| Grand Total | 57 | 100% |

100%

Adherents
Suppressed



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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



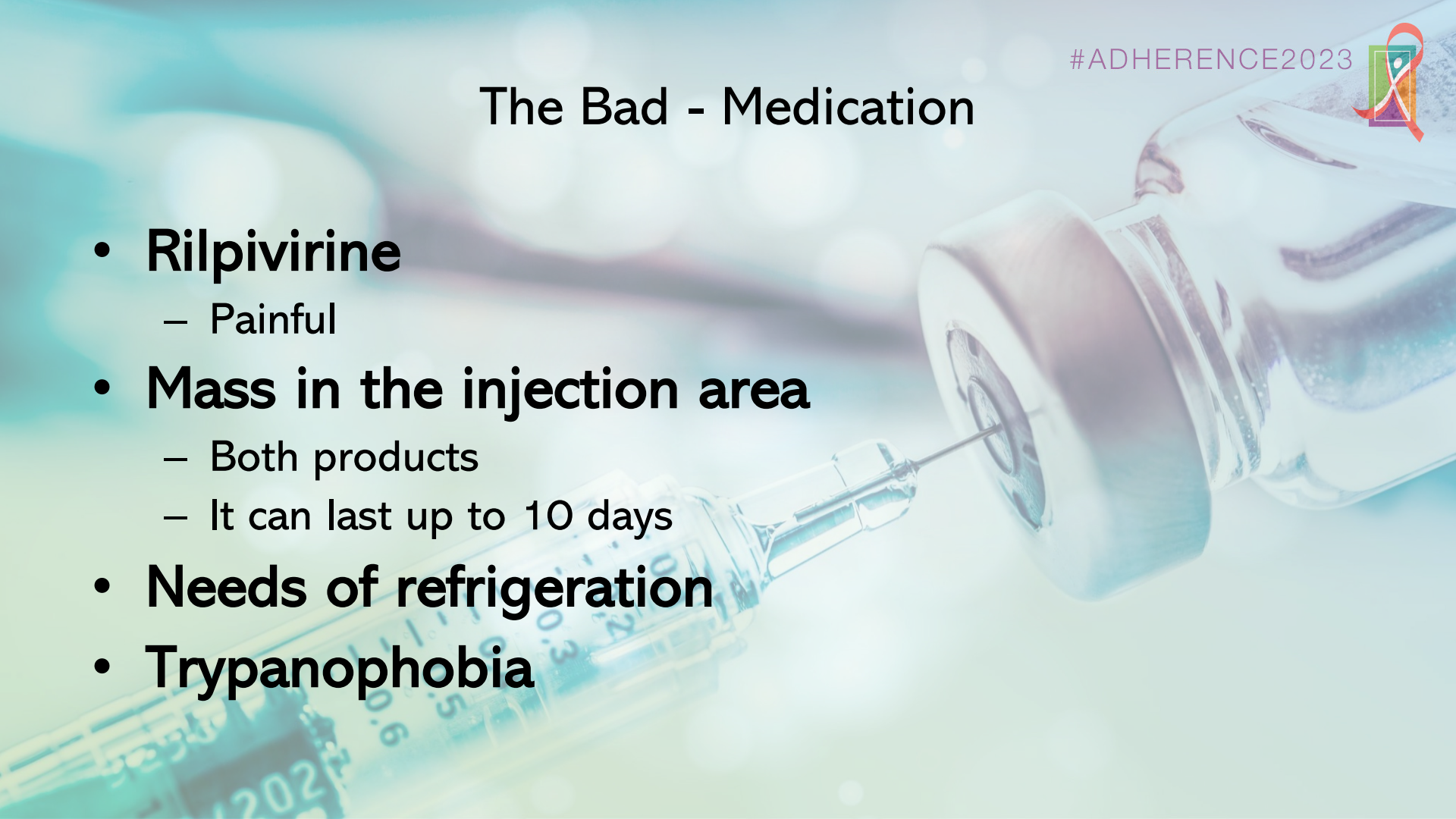
The Bad - Access to Medication

- **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**

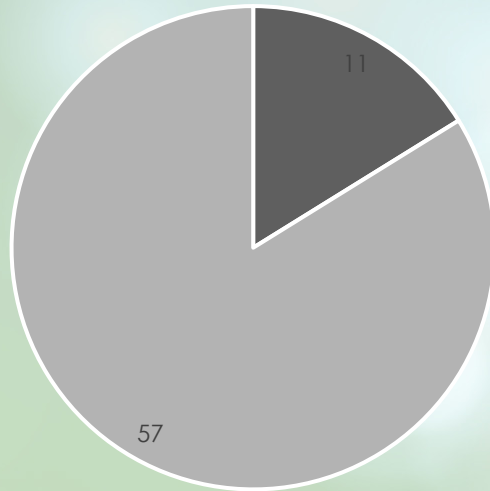


LAI Discontinuations

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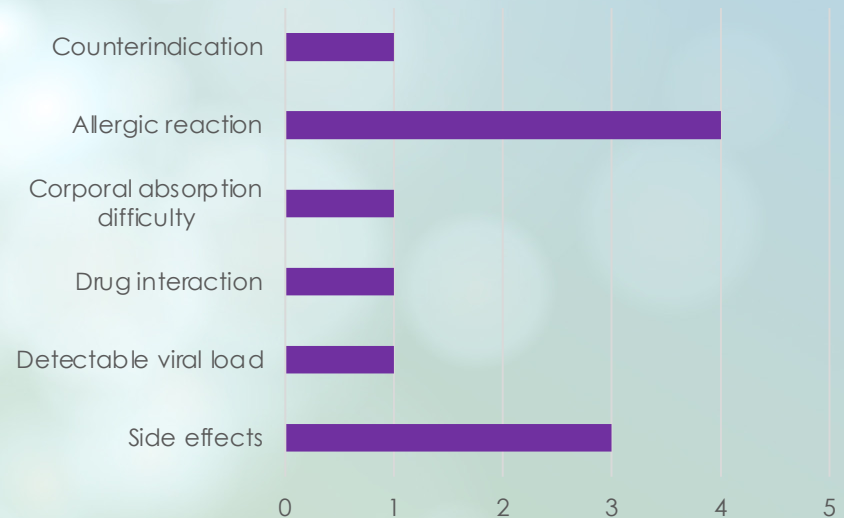


Patients that have received LAI: 68



■ Discontinued ■ Active

Reasons for discontinuing



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

4. M S, Beima-Sofie Kristin, H M et al. Long-acting injectable antiretroviral treatment acceptability and preferences: a qualitative study among US providers, adults living with HIV, and parents of youth living with HIV. AIDS Patient Care STDs. 2019; 33: 104-111

5. Kanazawa JT, Saberi P, Saucedo JA, Dubé K, The LAIs are coming! Implementation science considerations for long-acting injectable antiretroviral therapy in the United States: a scoping review. AIDS Res Hum Retroviruses. 2021; 37: 75-88

Clinic Site Impact

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- Clinicians point of view
 - Overwhelm staffing and other clinic resources.⁶
- Each visit for injection of cabotegravir plus rilpivirine lasted about 32 minutes⁷



6 -D'Amico R, Margolis DA, Long-acting injectable therapy: an emerging paradigm for the treatment of HIV infection., Curr Opin HIV AIDS. 2020; 15: 13-18

7 -Czarnogorski M, Garriss 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**



A man with glasses and a beard, wearing a grey shirt, is pointing at a whiteboard with his right hand. A woman with short dark hair, wearing a white shirt and a yellow vest, is looking at the whiteboard. The whiteboard has several colorful sticky notes attached to it. The background is a blurred clinical setting.

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)

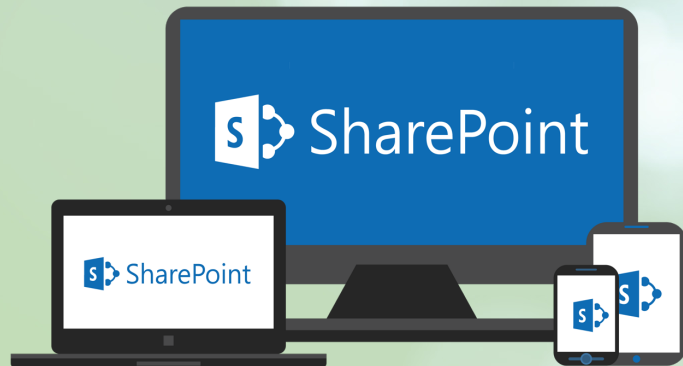
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| Time | Location | Patient | Reason | Plan / Copy | Phone # | Email / Call Resp. | Comments | Status |
|----------|----------|------------------|--------------|--------------------|--------------------|--------------------|----------|--------------|
| 8:00 AM | PODiatry | GARCIA, ALYSSA | NAIL CARE | ATTN:230 | | | | At Process |
| 8:15 AM | PODiatry | NAIL CARE | ATTN:230 | | | | | At Process |
| 8:30 AM | PODiatry | GREEN, SAMMY | NAIL CARE | 11/00/05 | | | | Check In |
| 8:45 AM | PODiatry | NAIL CARE | 11/00/05 | | | | | Check In |
| 9:00 AM | PODiatry | MOORE, ELIZABETH | REDSHINE | HANCHES110100 | | | | Scheduled |
| 9:15 AM | PODiatry | SMITH, DAVID | HEEL PAIN | ATTN:235 | RE: (905) 678-9325 | | | Check In |
| 9:30 AM | PODiatry | PHILLIPS, CARL | PRE-OP | CHOCHEALTHUS | | | | Scheduled |
| 9:45 AM | PODiatry | PRE-OP | CHOCHEALTHUS | | | | | Scheduled |
| 10:00 AM | PODiatry | PRE-OP | CHOCHEALTHUS | | | | | Scheduled |
| 10:15 AM | PODiatry | WEBB, LUCY | ANKLE PAIN | BANDS MCHAS | | | | Check In |
| 10:30 AM | PODiatry | ANKLE PAIN | BANDS MCHAS | | | | | Check In |
| 10:45 AM | PODiatry | HOLMES, SETH | BUNION | WISAKHAKI120 | | | | Scheduled |
| 11:00 AM | PODiatry | BUNION | WISAKHAKI120 | | | | | Scheduled |
| 11:15 AM | PODiatry | MADRY, GINA | CAST DETHRO | 20020795 | | | | Scheduled |
| 11:30 AM | PODiatry | PALMER, ANTHONY | ANKLE PAIN | ATTN:235 | RE: (905) 292-7234 | | | Scheduled |
| 11:45 AM | PODiatry | ANKLE PAIN | ATTN:235 | RE: (905) 292-7234 | | | | Scheduled |
| 12:00 PM | PODiatry | WEST, BILL | NEW PTC | | | | | Scheduled |
| 12:15 PM | PODiatry | NEW PTC | | | | | | Scheduled |
| 12:30 PM | PODiatry | JONES, DAVID | INJECTION | | RE: (514) 546-4054 | | | Confirmation |
| 12:45 PM | PODiatry | | | | | | | Open |
| 1:00 PM | PODiatry | | | | | | | Open |
| 1:15 PM | PODiatry | | | | | | | Open |
| 1:30 PM | PODiatry | | | | | | | Open |
| 1:45 PM | PODiatry | | | | | | | Open |
| 2:00 PM | PODiatry | | | | | | | Open |
| 2:15 PM | PODiatry | | | | | | | Open |
| 2:30 PM | PODiatry | | | | | | | Open |
| 2:45 PM | PODiatry | | | | | | | Open |

- 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.





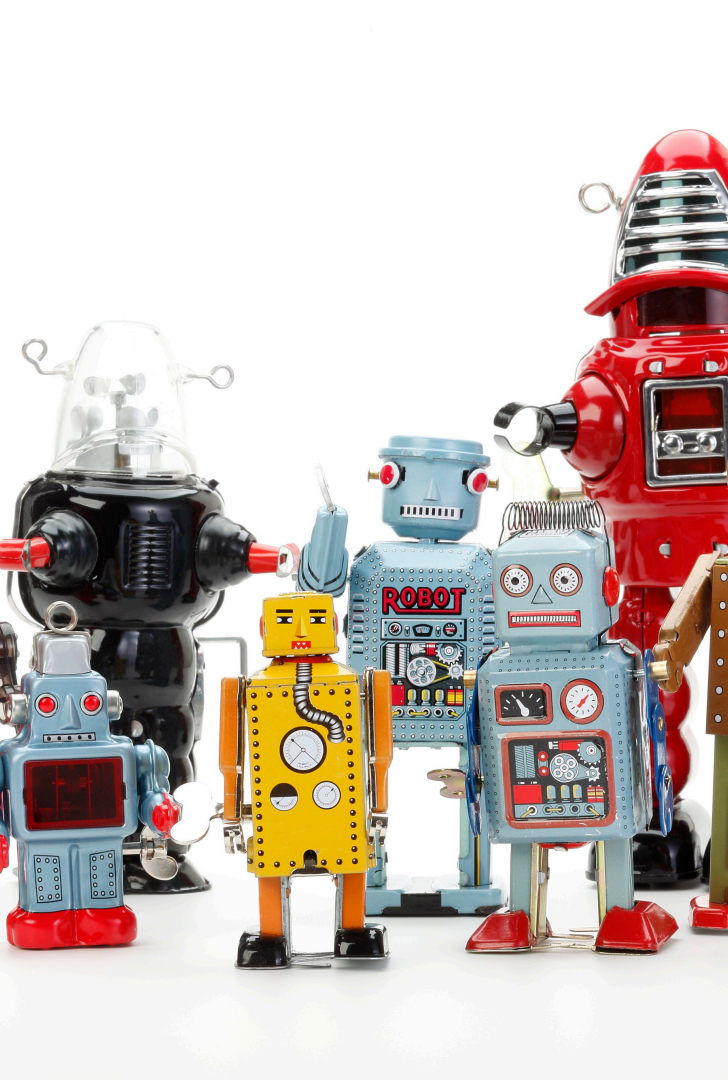
Modifications to the Practice (4)

- 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.



Microsoft Teams



Other Possible Modifications

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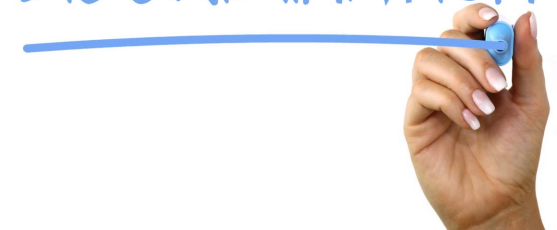
- Mitigate the social structural issues:



- Administration in **NO** clinical settings



DISCRIMINATION



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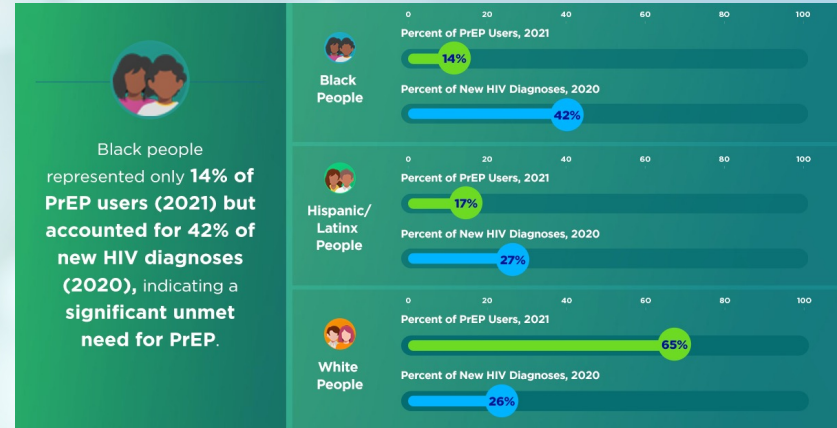
HIV PREVENTION

with Long-Acting Injectable



Black sexual minority men Vs White sexual minority men

More barriers
accessing HIV
PrEP



AIDSvu.ORG

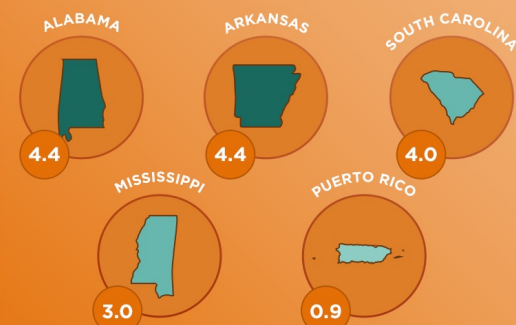
SOURCE: AIDSvu

AIDSvu

In 2021, these five states had the **lowest PrEP-to-Need Ratio (PnR)**, indicating the **highest unmet need for PrEP**.

*PrEP-to-Need Ratio (PnR) is the ratio of the number of PrEP users in 2021 to the number of people newly diagnosed with HIV in 2019. It is a measurement for whether PrEP use appropriately reflects the need for HIV prevention. A lower PnR indicates more unmet need.

States with Lowest PrEP-to-Need Ratio, 2021



*For purposes of analysis, Puerto Rico and the District of Columbia are treated as states.

AIDSvu.ORG

SOURCE: AIDSvu

AIDSvu



LAI Approved for PrEP

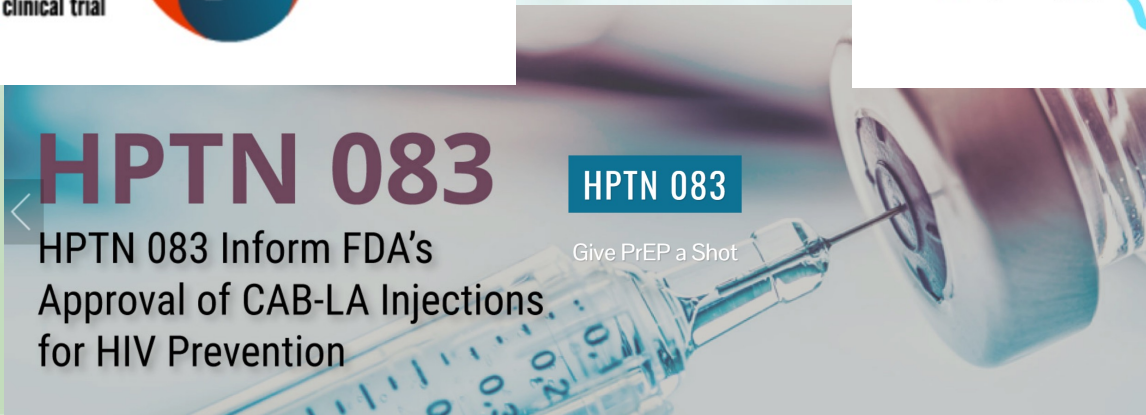


HPTN 083

HPTN 083 Inform FDA's
Approval of CAB-LA Injections
for HIV Prevention

HPTN 083

Give PrEP a Shot





LAI on Research for PrEP

NIH U.S. National Library of Medicine

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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

NIH U.S. National Library of Medicine

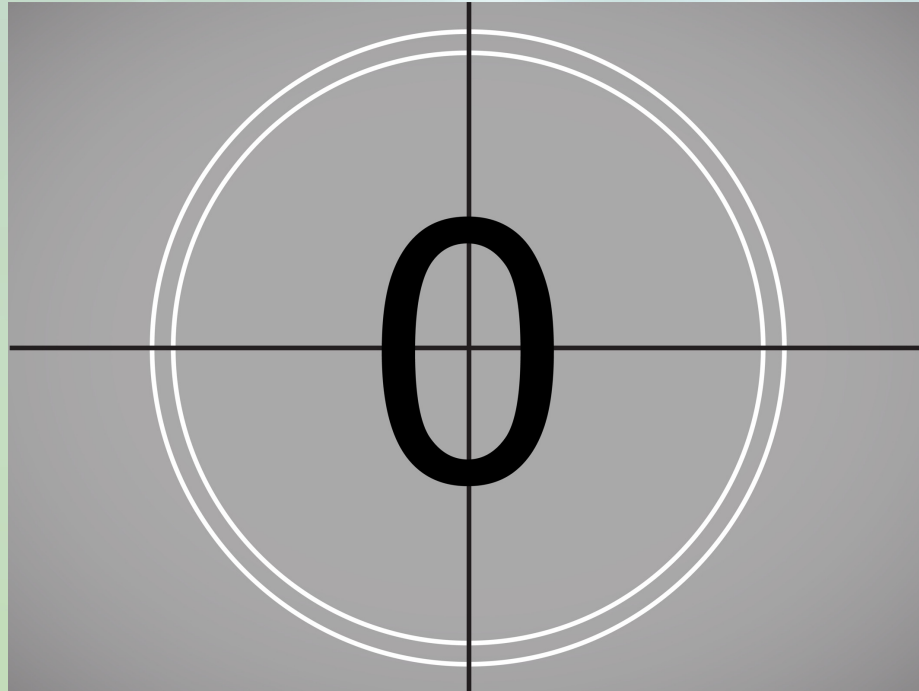
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Study of Lenacapavir for HIV Pre-Exposure Prophylaxis in People Who Are at Risk for HIV Infection (PURPOSE 2)

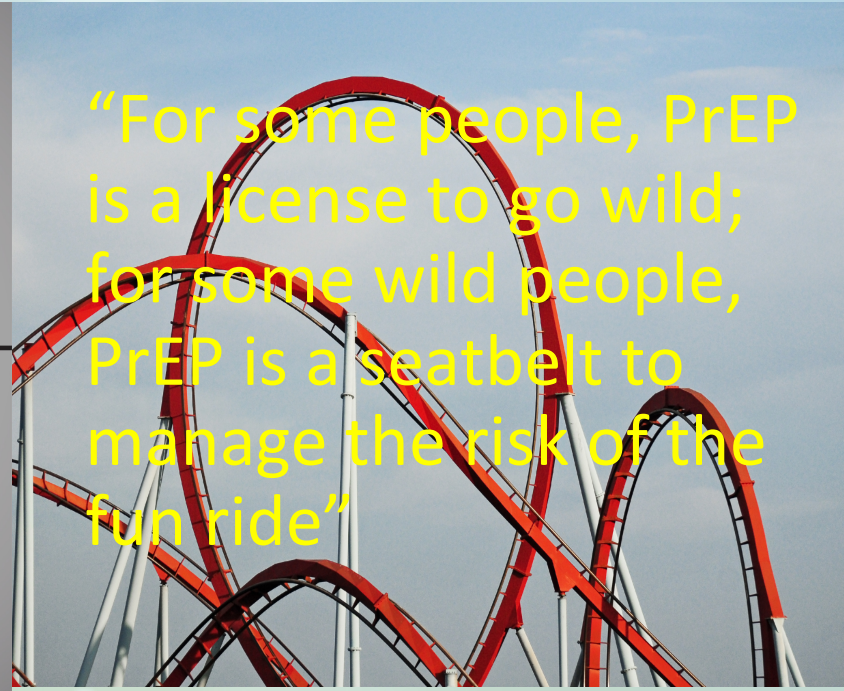
ClinicalTrials.gov Identifier: NCT04925752

Patients in LAI for HIV Prevention in CA

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“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

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- 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

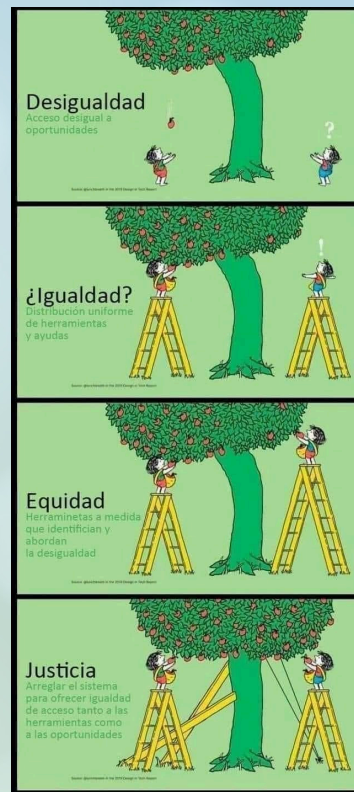


Conclusions

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- 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.





Contact Information

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