

Long Acting Injectable HIV Treatment and Prevention: Experience from Castro-Mission Health Center

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San Francisco
Health Network

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

Roadmap

Long Acting Injectable (LAI) HIV Treatment and Prevention Medication Landscape



Castro-Mission Health Center Rollout of LAI Treatment and Prevention



Keys to Success and Challenges in Rollout



Other DPH Clinics



Questions

Long Acting Injectable (LAI) HIV Treatment Landscape

- ▶ Cabotegravir/Rilpivirine aka CAB/RPV (Brand name: Cabenuva)
 - ▶ Every 1 month dosing (approved January 2021)
 - ▶ Every 2 month dosing (approved February 2022)
 - ▶ Intramuscular

- ▶ Lenacapavir aka LEN (Brand name: Sunlenca)
 - ▶ Every 6 month dosing (approved December 2022)
 - ▶ For people living with multi-drug resistant HIV, in combination with other ART
 - ▶ Subcutaneous (with 2 days of oral loading doses)

Long Acting Injectable (LAI) HIV Prevention (PrEP) Landscape

- ▶ Cabotegravir aka CAB (Brand name: Apretude)
 - ▶ Every 2 month dosing (approved December 2021)
 - ▶ Intramuscular
- ▶ Under review by FDA: Lenacapavir aka LEN
 - ▶ Every 6 months dosing
 - ▶ Subcutaneous (with 2 days of oral loading doses)

LAI Treatment: Cabotegravir/Rilpivirine

- ▶ Cabotegravir/Rilpivirine (brand name: Cabenuva) is an injectable medicine to treat HIV-1 infection in adults.
- ▶ It is approved for treatment for HIV-1 in virally suppressed adults and adolescents.
- ▶ It is not approved for initial therapy.

LAI Treatment: Eligibility Criteria for Cabotegravir/Rilpivirine

- ▶ Patients living with HIV who have been virologically suppressed for the last 6 months
 - ▶ May consider in patients who are not virologically suppressed based on recent real world data (including from Ward 86) and new DHHS guidelines
- ▶ Hepatitis B negative (or on additional Hepatitis B treatment)
- ▶ No history of known or suspected drug resistance to either of the two medications in the injection
- ▶ Not taking medications which interact with either of the two medications (more common with rilpivirine)
- ▶ Patient expresses willingness and demonstrates ability to attend appointments to receive injections, and has reliable contact information

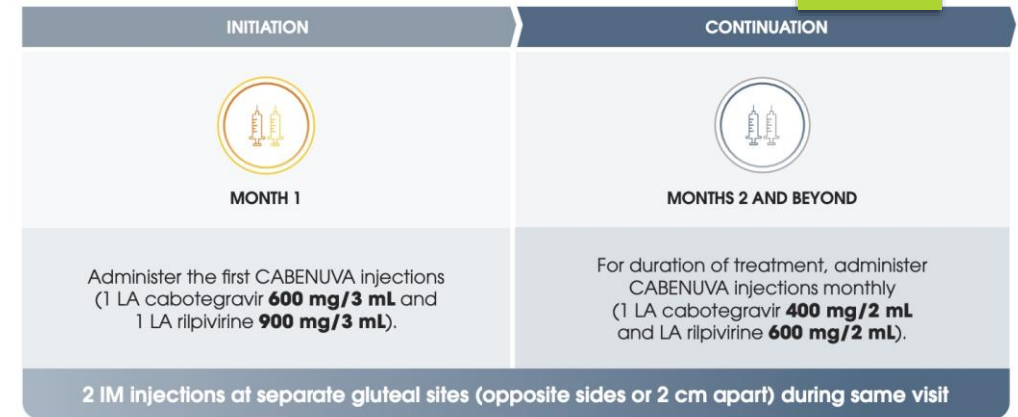
LAI Treatment: Eligibility Criteria for Cabotegravir/Rilpivirine

- ▶ DHHS Guidelines September 2024:
 - ▶ Some people with HIV cannot reach or maintain viral suppression on oral ART despite intensive support.
 - ▶ A complete regimen of long-acting injectable cabotegravir and rilpivirine (LA CAB/RPV) has been used in this population with some success, although long-term efficacy data are limited.
 - ▶ Based on very limited data, the Panel recommends the use of LA CAB/RPV on a case-by-case basis in select individuals with persistent virologic failure despite intensive adherence support on oral ART, who have no evidence of resistance to CAB or RPV, and with shared decision-making between providers and people with HIV.

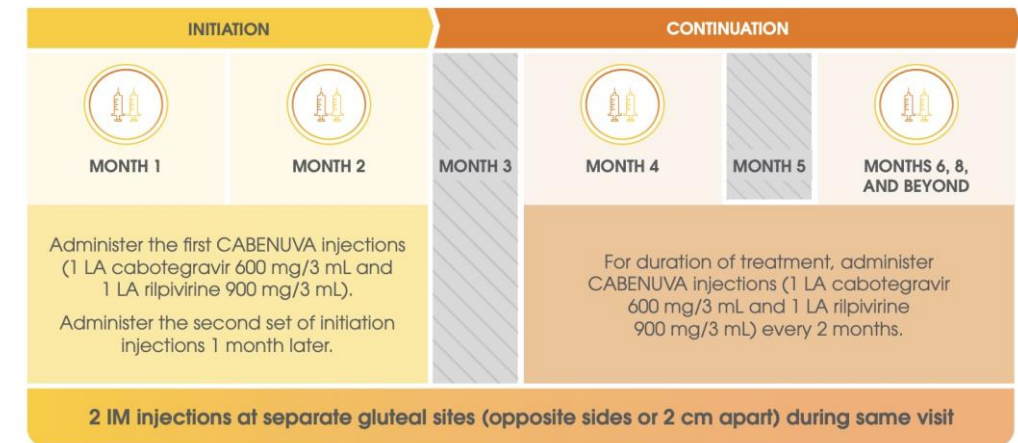
LAI Treatment: Cabotegravir/Rilpivirine Dosing and Administration

- ▶ Two separate injections for gluteal intramuscular injection (one on each side)
- ▶ Must be refrigerated, cannot be removed until patient is present
- ▶ Optional oral lead-in – most patients skip

Once-monthly dosing schedule



Every-2-month dosing schedule



LAI Treatment: Lab Monitoring

- ▶ Baseline/1st Injection
- ▶ 1st Maintenance Injection
- ▶ 2nd Maintenance Injection
- ▶ Every 3-4 months
- ▶ When switching between monthly and every 2 months

LAI Treatment: Cabotegravir/Rilpivirine

Side Effects

- ▶ Most common side effects: injection-site reactions (75-83%)
 - ▶ Pain, tenderness, hardened lump, swelling, redness, itching, bruising and warmth
 - ▶ Injection-site reactions are mostly mild to moderate and resolve within 3 days
 - ▶ Decreases the longer patients are on treatment
 - ▶ No significant difference in injection site reactions between every 1 and every 2 month dosing
- ▶ Others:
 - ▶ Fever
 - ▶ Tiredness
 - ▶ Headache
 - ▶ Muscle or bone pain
 - ▶ Nausea
 - ▶ Sleep problems
 - ▶ Dizziness
 - ▶ Rash
- ▶ In studies, less than 4% of people stopped treatment due to side effects

HIV Prevention

- ▶ What are the different pharmacologic options for HIV prevention?
 - ▶ 2 Different Pills approved by the FDA for use as PrEP
 - ▶ Truvada (Tenofovir Disoproxil Fumarate (TDF) / Emtricitabine)
 - ▶ Descovy (Tenofovir Alafenamide (TAF) / Emtricitabine)
 - ▶ 1 Shot approved by the FDA for use as PrEP
 - ▶ Apretude (Cabotegravir)

HIV Prevention: Comparing Options

	Truvada	Descovy	Apretude
Route	Pill/oral	Pill/oral	Shot/Intramuscular
Schedule	Daily or intermittent (2-1-1)	Daily	Every 2 months (after initiation doses 2 shots 1 month apart)
Efficacy	>99%	>99%	>99%
Approved for	People at risk through sex or injection drug use	People at risk through sex who are cis men who have sex with men and trans women (not for cis women)	People at risk through sex

LAI PrEP: Cabotegravir Eligibility Criteria

- ▶ Patient is at risk for acquisition of HIV by sexual activity
- ▶ Adult or adolescent weighing at least 35 kg
- ▶ HIV negative – documented negative HIV Ag/Ab test result within 1 week before initial Cabotegravir injection
- ▶ No signs/symptoms of acute HIV infection
- ▶ Not taking medications which interact with cabotegravir (uncommon)
- ▶ Patient expresses willingness and demonstrates ability to attend every 2 month appointments to receive injections, and has reliable contact information

LAI PrEP: Cabotegravir Dosing and Administration

- ▶ Single dose gluteal intramuscular injection (one side)
- ▶ Does not require refrigeration
- ▶ Optional oral lead-in – most patients skip



APRETUDE is administered by a healthcare provider as a single 600-mg (3-mL) gluteal intramuscular injection

LAI PrEP: Lab Monitoring

- ▶ Baseline/1st Injection:
 - ▶ HIV test (Antigen/Antibody and Viral Load)
 - ▶ STI testing
- ▶ Each Injection:
 - ▶ HIV test (Antigen/Antibody +/- Viral Load)
 - ▶ STI testing every 1-2 injections
- ▶ After discontinuation:
 - ▶ HIV test every 3 months for 12 months total

Latest guidance:

Viral Load should be done at baseline and if any delays in injection, but does not need to be done at every on time maintenance injection

LAI PrEP: Cabotegravir Side Effects

- ▶ Most common side effects: injection-site reactions (38-82%)
 - ▶ Pain, tenderness, hardened, swelling, redness, itching, bruising and warmth
 - ▶ Injection-site reactions are mostly mild to moderate and resolve within 3 days
 - ▶ Decreases the longer patients are on LAI PrEP
- ▶ Others:
 - ▶ Diarrhea
 - ▶ Headache
 - ▶ Fever
 - ▶ Fatigue
 - ▶ Sleep problems
 - ▶ Nausea
 - ▶ Dizziness
 - ▶ Muscle Aches
 - ▶ Dizziness
- ▶ In studies, less than 6% of people stopped treatment due to side effects

Castro-Mission Health Center



- ▶ Established in 1965, formerly known as Health Center 1
- ▶ Located in the Castro neighborhood at 3850 17th St
- ▶ CMHC was the first public health center to open in San Francisco and one of the first clinics to offer treatment for HIV/AIDS.
- ▶ Today the clinic serves about 4200 patients annually.
- ▶ The clinic provides a full range of primary care for adults, children and pregnant people
- ▶ CMHC is a warm and welcoming clinic whether you are a new immigrant or a life-long San Franciscan. Most of our staff are bilingual in Spanish and bicultural, and many identify as LGBT.
- ▶ CMHC is also home to the Dimensions Clinic which serves queer youth 12-24 years old

Castro-Mission Health Center LAI Rollout Timeline

Treatment:

- ▶ December 2021 – started work on LAI Treatment Protocol
- ▶ March 2022 – first patient started LAI Treatment
- ▶ March 2023 – started switching stable patients to every 2 month injections
- ▶ February 2024 – switched to routinely starting suppressed patients on every 2 month injections
- ▶ April 2024 – started first patient on Lenacapavir

Prevention:

- ▶ October 2022 – started work on LAI Prevention Protocol
- ▶ January 2023 - first patient started LAI PrEP
- ▶ Summer 2023 – able to offer LAI PrEP to any CMHC patient interested

CMHC LAI Program Eligibility and Referral Process - Treatment

Eligibility:

- ▶ HIV positive
- ▶ No known or suspected resistance to LAI meds
- ▶ Hep B negative (or on other treatment for Hep B)
- ▶ No med interactions
- ▶ Able to come to clinic for injections every 1-2 months
- ▶ Offered at any provider visit, including first visit if appropriate

Process:

Patient is offered LAI ART or requests it – Provider or Nurse

HIV Specialist provider reviews patient's history and eligibility

- In complex cases, 2nd HIV specialist reviews as well

Provider discusses LAI options with patient

- If patient wants to start, fills out Referral Form (In Epic – Electronic Medical Record system, using template)

Provider Orders Medication for Delivery from Pharmacy to Clinic

- CMHC uses AHF Pharmacy
- If PA required, Pharm Tech completes PA
- In most cases provider also sends backup oral ART prescription/refill

Patient scheduled for 1st injection (+/- Labs)

1 week telephone visit with nurse to check on patient for any side effects, questions, concerns

Subsequent appointments with Injection (+/- Labs, if due) at same appointment

- Nurse visits

Provider visits as needed, at minimum twice a year

CMHC LAI Program Eligibility and Referral Process - Prevention

Eligibility:

- ▶ Any adult or adolescent (>35 kg) patient who is at risk for HIV acquisition by sexual activity
- ▶ HIV negative
- ▶ Able to come to clinic for injections every 2 months
- ▶ Very few contraindications
- ▶ Low barrier – offered on first visit at CMHC, offered at all STI treatment visits

Process:

Patient is offered LAI PrEP or requests it – Provider, Nurse, or other staff

Provider, Nurse, or PrEP Coordinator discusses with patient, provides education

- If patient wants to start, fills out Referral Form (In Epic – Electronic Medical Record system, using template)

Provider Orders Medication for Delivery from Pharmacy to Clinic

- CMHC uses AHF Pharmacy
- If uninsured -> PrEP Coordinator or Pharm Tech completes Patient Assistance Program application and medication sent directly to clinic
- In most cases provider also sends backup oral PrEP prescription

Patient scheduled for Labs and 1st Injection

- can be same day if already on oral PrEP

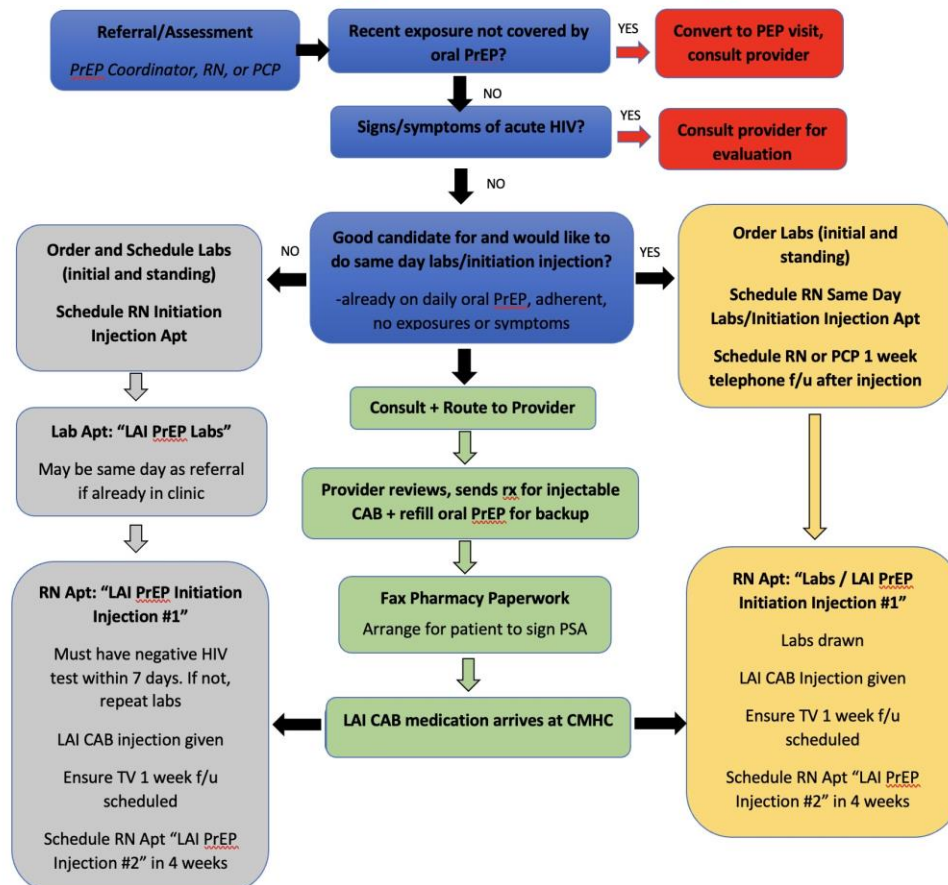
1 week telephone visit with nurse to check on patient for any side effects, questions, concerns

Subsequent appointments with Labs and Injection at same appointment

- Nurse visits

CMHC LAI Protocol Example

CMHC Injectable PrEP Workflow for Patients already on Oral PrEP



Castro-Mission Health Center Experience with Insurance Coverage

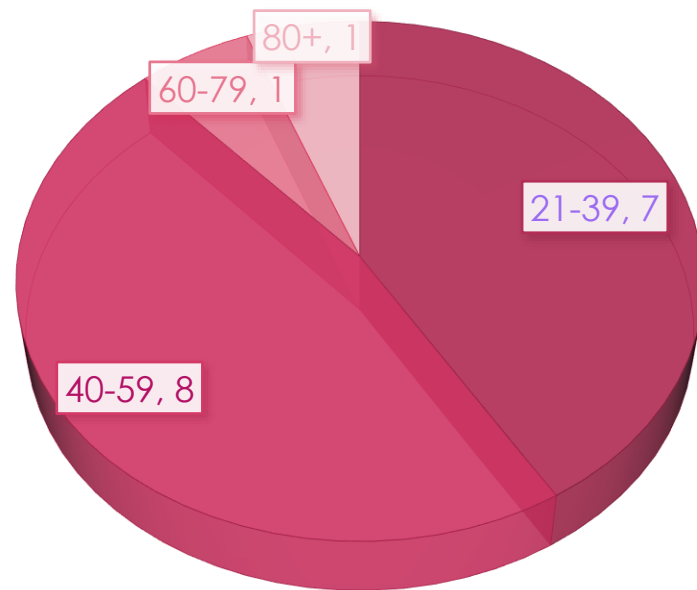
- ▶ Treatment
 - ▶ Covered by all public insurances or ADAP
 - ▶ For some Medicare or managed care plans, requires PA
- ▶ Prevention
 - ▶ Covered by MediCal or Medicare
 - ▶ Uninsured or Healthy SF: not covered, qualify for Patient Assistance Program
 - ▶ Healthy Workers: not covered and do not qualify for Patient Assistance Program
 - ▶ for select patients for whom oral PrEP is not a good option, clinic has bought this out of pocket with no reimbursement

CMHC Patients on LAI Treatment

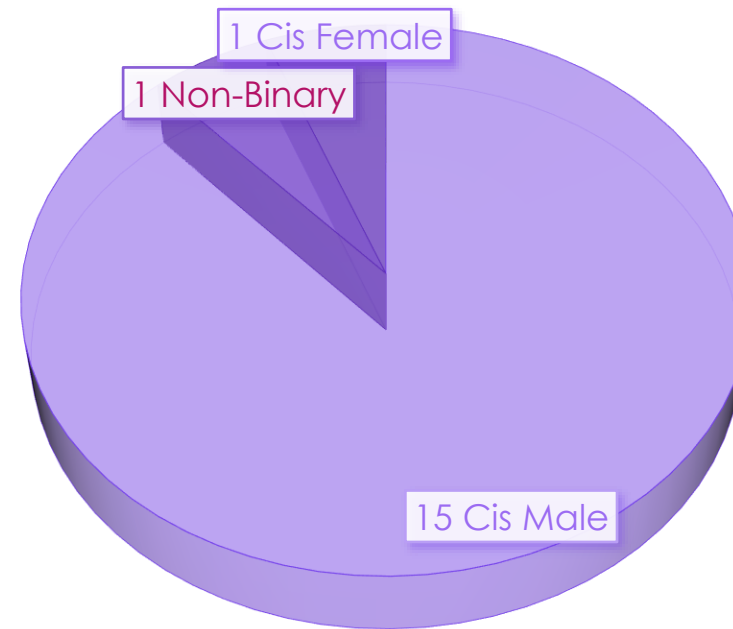
- ▶ CMHC total current/active patients living with HIV: 189
- ▶ Since initial rollout, we have treated **31 patients** with LAI ART
- ▶ Currently, **17 patients** are actively receiving LAI ART
- ▶ Most on **every 2 month** injections
- ▶ Some transitioned back to oral ART
- ▶ Some moved, transitioned to private insurance/other clinics
- ▶ **All undetectable viral load**
 - ▶ **1 started viremic** and suppressed on LAI ART

CMHC Patients on LAI Treatment

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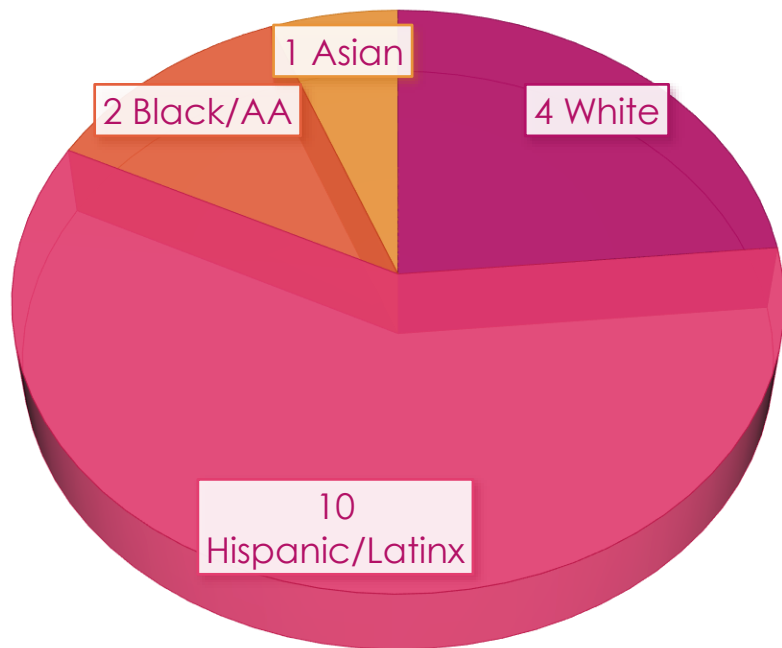


GENDER

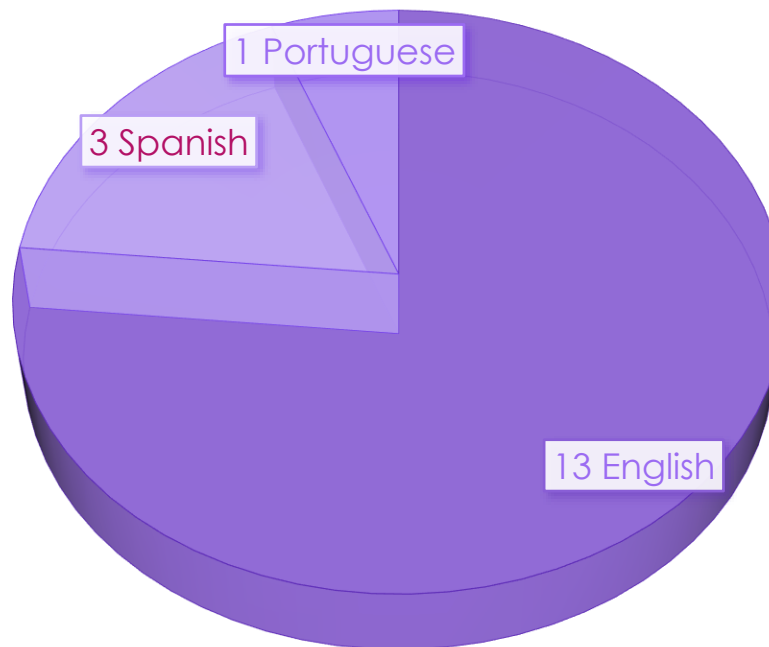


CMHC Patients on LAI Treatment

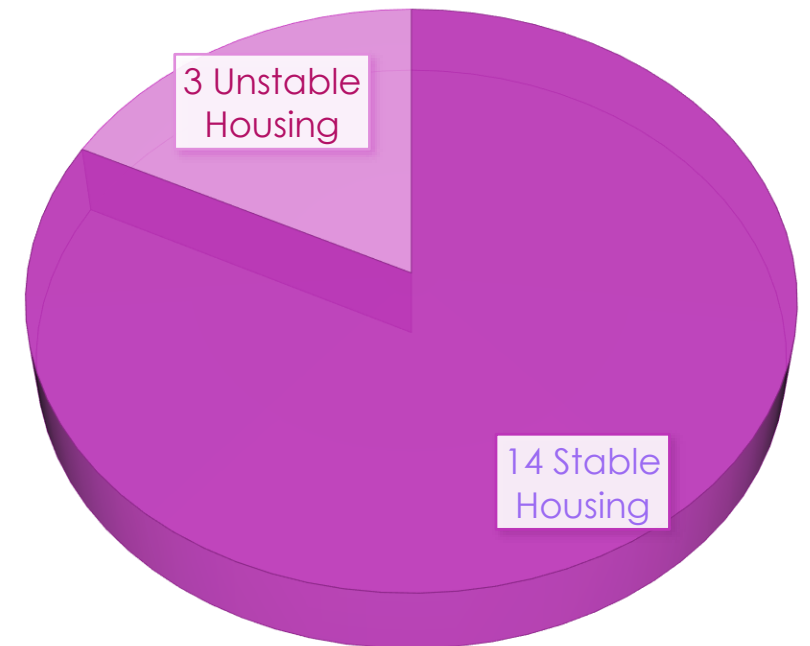
RACE/ETHNICITY



LANGUAGE



HOUSING

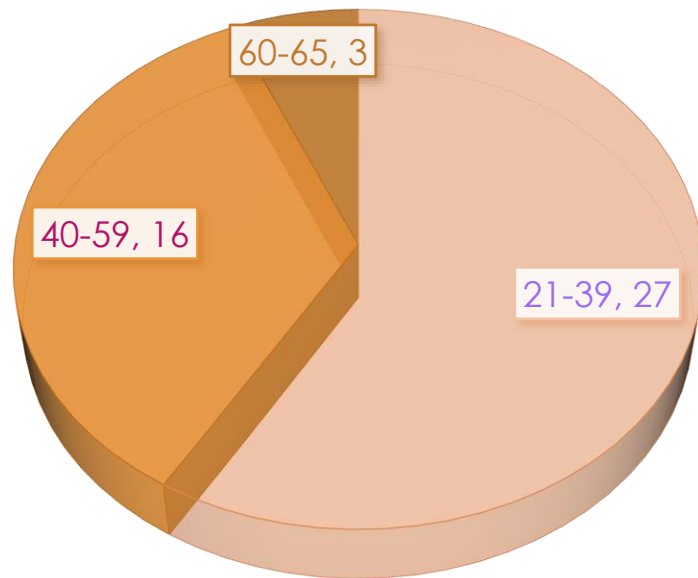


CMHC Patients on LAI Prevention

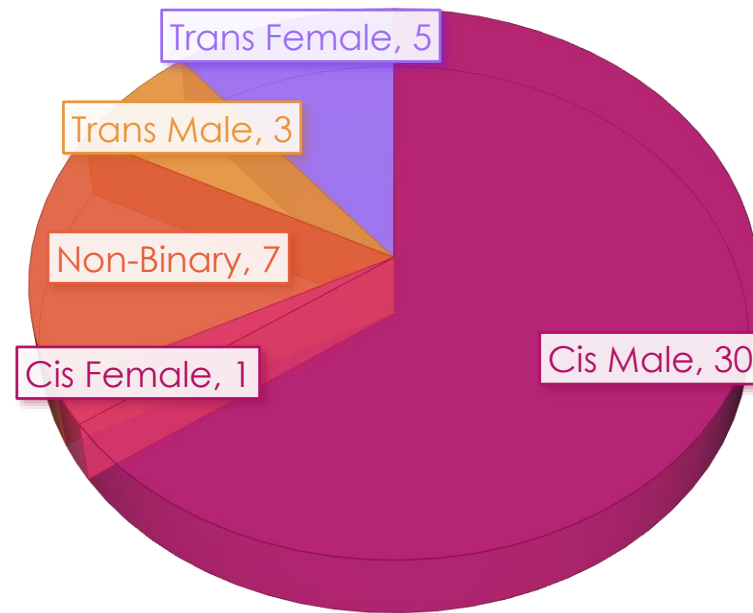
- ▶ CMHC total current/active patients on PrEP: 99
 - ▶ **Oral PrEP: 53**
 - ▶ **LAI PrEP: 46**
- ▶ Since initial rollout, we have treated **52 patients** with LAI PrEP

CMHC Patients on LAI Prevention

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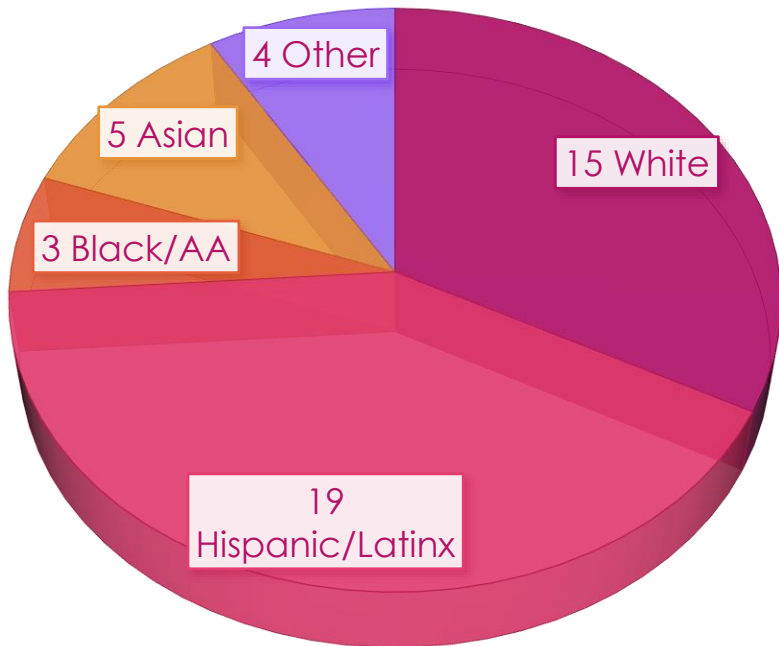


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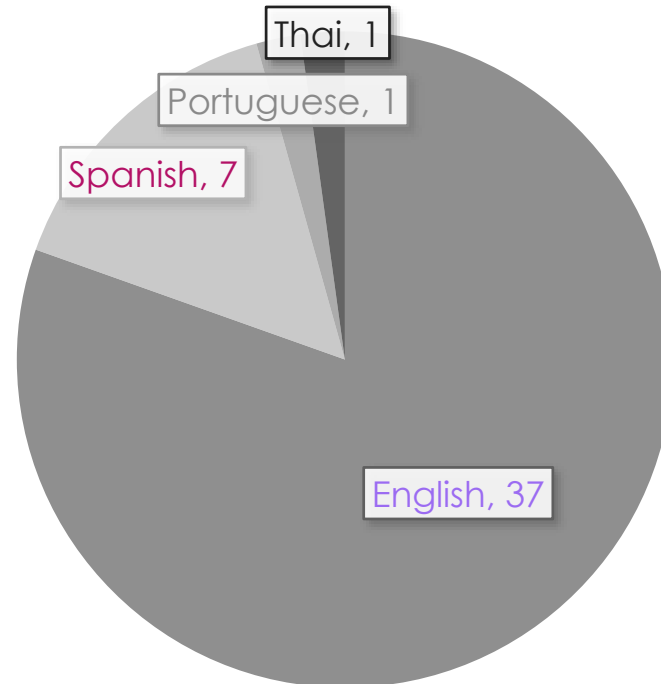


CMHC Patients on LAI Prevention

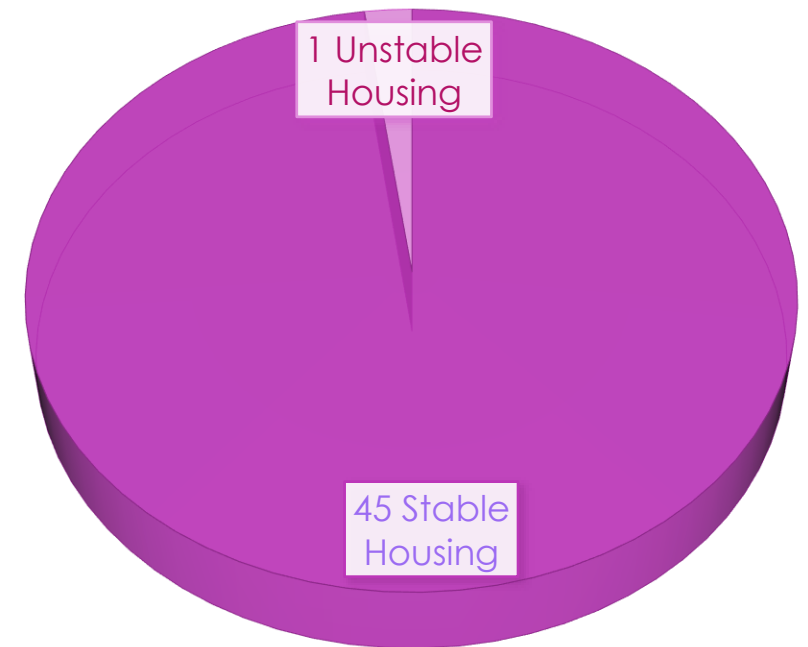
RACE/ETHNICITY



LANGUAGE



HOUSING



Keys to Success for LAI Rollout

- ▶ Staff champion(s)
- ▶ Supportive leadership
- ▶ Staff interest/engagement
- ▶ Protocol
 - ▶ Adapt from existing ones, do not need to reinvent the wheel
- ▶ Dedicated staff for tracking and outreach
- ▶ Others that can be very helpful:
 - ▶ Smartphrases (Electronic Medical Record Templates)
 - ▶ Peer Consults
 - ▶ Reports for Tracking
 - ▶ High patient enrollment in patient portal

Challenges in LAI Rollout

▶ Staff

- ▶ Lack of comfort with discussing sexual health
- ▶ Lack of training
- ▶ Competing priorities
- ▶ Lack of dedicated staff for tracking, outreach
- ▶ Lack of consistent staff who have rapport with patients

▶ Patient population

- ▶ Unstable housing
- ▶ Difficulty making appointments and getting on time injections
- ▶ Lack of reliable phone
- ▶ Lack of enrollment in patient portal
- ▶ Substance use
- ▶ Multidrug resistance HIV

▶ Insurance challenges

- ▶ More common with private insurance and Healthy Workers

Other SF Department of Public Health Clinics offering LAI

- ▶ Ward 86 (SF General HIV Clinic):
 - ▶ LAI Treatment and Prevention
- ▶ Southeast Health Center:
 - ▶ LAI Treatment and Prevention
- ▶ Tom Waddell Urban Health Center:
 - ▶ LAI Treatment only
- ▶ Maria X Martinez (MXM) Health Resource Center of Whole Person Integrated Care (WPIC):
 - ▶ LAI Treatment and Prevention

Other SF Department of Public Health Clinics: Future Directions

▶ Clinics Interested in offering LAI Prevention:

- ▶ Tom Waddell Urban Health Center
- ▶ Maxine Hall Health Center
- ▶ Chinatown Public Health Center

▶ DPH LAI PrEP Workgroup:

- ▶ Working on expansion of LAI PrEP services throughout DPH Primary Care, partnering with clinics
- ▶ Planning for rollout of twice yearly Lenacapavir when approved

Summary

- ▶ Injectable options for HIV treatment and prevention give individuals more options and flexibility.
- ▶ Castro-Mission Health Center rollout of LAI treatment and prevention as an example, providing access to patients, especially Latinx and LGBTQ
- ▶ Keys to success and challenges in LAI rollout
- ▶ Current LAI landscape within SF DPH Clinics, work underway to increase access to LAI Treatment and Prevention within SF DPH Clinics
- ▶ Exciting new options in the pipeline



Thank you!

QUESTIONS?