Long-Acting Injectable PrEP for LGBTQIA+ Populations: Implementation in Health Centers

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12/12/24







Acknowledgement

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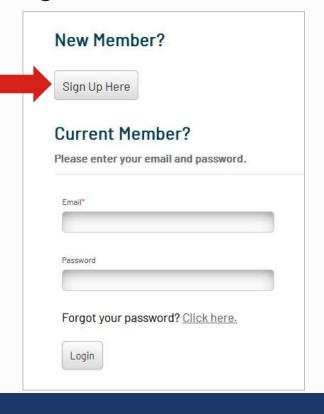
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- Independent 501(c)(3) FQHC
- Founded 1971
- Mission: To enhance the wellbeing of the LGBTQIA+ community as well as people in our neighborhoods and beyond through access to the highest quality health care, education, research, and advocacy
- Integrated primary care model, including HIV and transgender health services



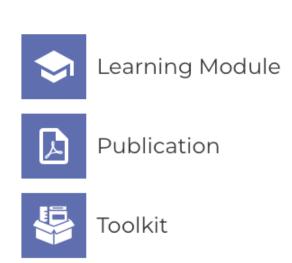
The Fenway Institute

Research, Education, Policy



The National LGBTQIA+ Health Education Center

- Training and Technical Assistance
- Grand Rounds
- Online Learning
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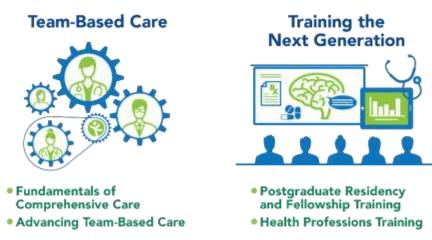
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A health program with international reach, focused on the most vulnerable among us.



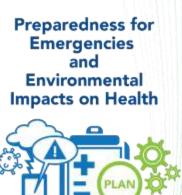
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Locations & Service Sites





THREE FOUNDATIONAL PILLARS				
1	2	3		
Clinical Excellence	Research and Development	Training the Next Generation		

Profile

Founding year: 1972

Annual budget: \$140M

Staff: 1,140

Active Patients: 150,000

SBHCs across CT: 153

Students/year: 14,522

Year	2021	2022	2023
Patients	99,598	102,275	107,225
Seen			

Technical Questions?

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Other Health Professionals	Confirm equivalency of credits with relevant licensing body.

Long-acting Injectable PrEP

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Disclosures

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Learning objectives

- 1. Summarize the evidence for long-acting injectable PrEP in a range of populations.
- 2. Address dilemmas in management of long-acting injectable PrEP and analyze how medical and logistical factors may impact PrEP implementation.
- 3. Describe new strategies for HIV prevention that may be available soon.

Case 1

A 27-year-old non-binary person assigned female at birth presents requesting PrEP.

They are overweight (BMI 29.4) but have no other chronic medical problems and take no medications.

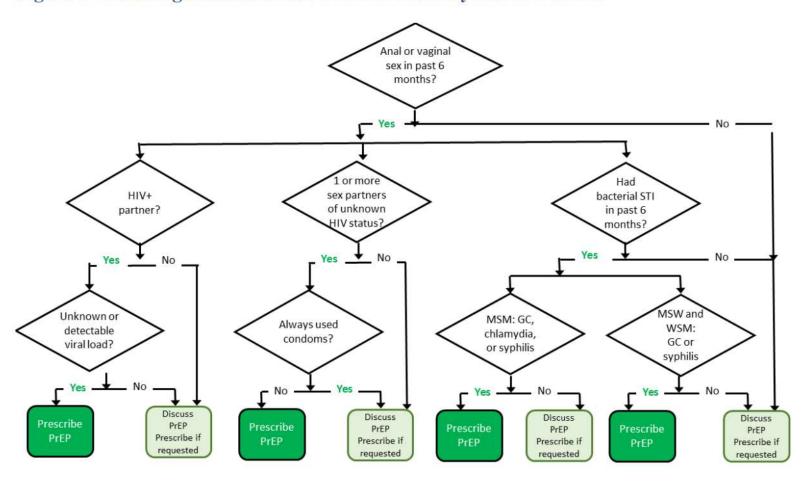
They have had condomless vaginal and anal sex with two cisgender men in the past 6 months.

Three months ago, they were treated for syphilis.

PrEP indications for sexually active people

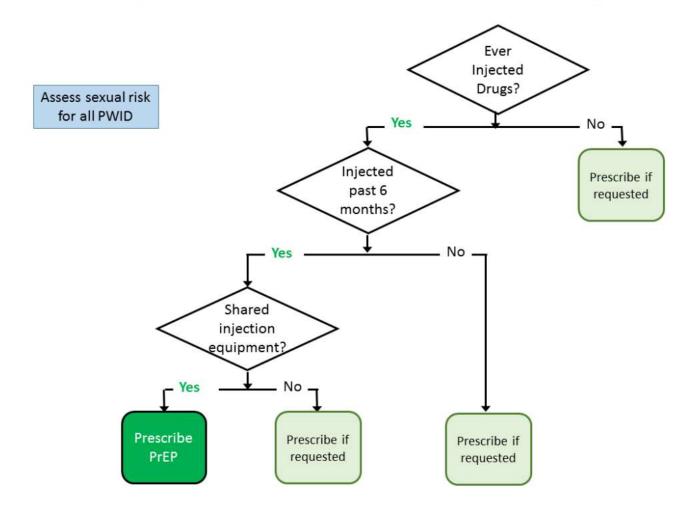
Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States – 2021 update: a clinical practice guideline. 2021. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

Figure 2 Assessing Indications for PrEP in Sexually Active Persons



PrEP indications for people who inject drugs

Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs



Cabotegravir (CAB, Apretude™)

• Evidence: Prevents HIV acquisition through sex; superior to TDF/FTC for PrEP among MSM, transgender women, and cisgender heterosexual women

Dosing:

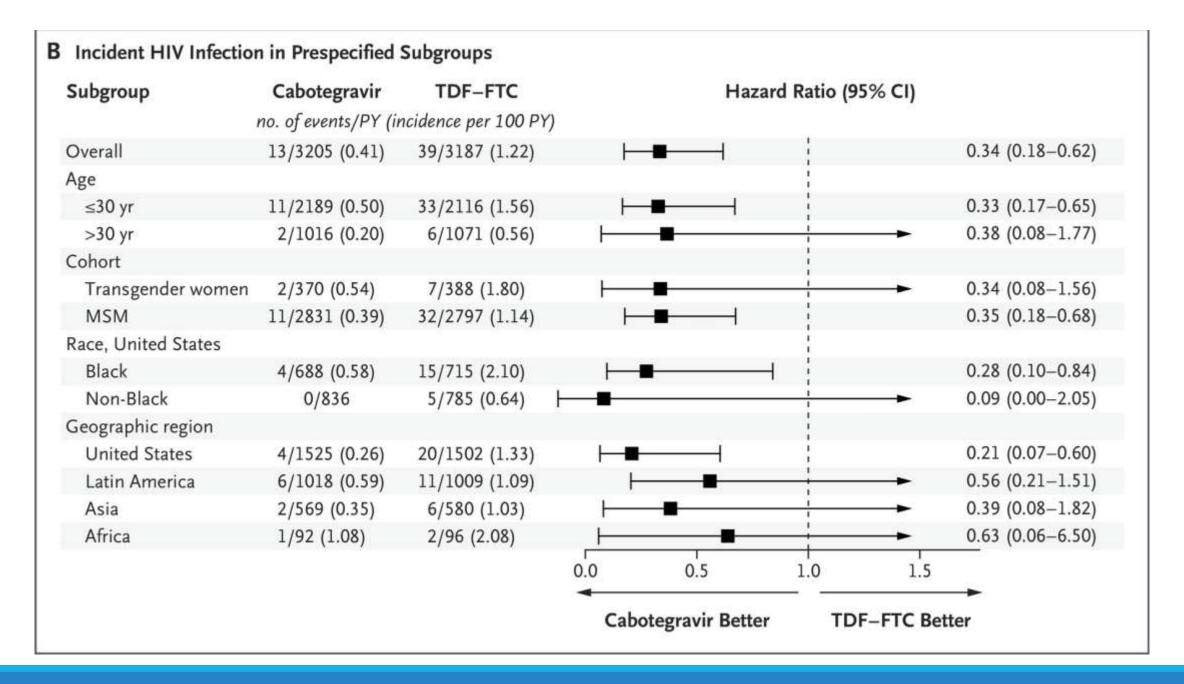
- Cabotegravir 600 mg intramuscularly once monthly for 2 doses, then every 2 months
- An oral lead-in phase of cabotegravir 30 mg once daily prior to the first injection is optional.

Advantages:

- Obviates the need for daily pill adherence
- Superior to TDF/FTC for PrEP in a range of populations

Disadvantages:

- Injection site reactions are common, although often mild.
- Benefits navigation may be time-consuming.
- Same-day initiation may not be possible currently.
- Implications of the medication's tail phase
- If HIV occurs despite CAB, HIV test interpretation may be challenging.



Laboratory monitoring for injectable PrEP

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM^/TGW~ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

^{*} HIV-1 RNA assay

X all PrEP patients

[^] men who have sex with men

persons assigned male sex at birth whose gender identification is female

Laboratory monitoring for oral PrEP

Test	Screening/Baseline Visit	Q 3 months	Q 6 months	Q 12 months	When stopping PrEP
HIV Test	X*	X			X*
eCrCl	X		If age ≥50 or eCrCL <90 ml/min at PrEP initiation	If age <50 and eCrCl ≥90 ml/min at PrEP initiation	Х
Syphilis	X	MSM /TGW	X		MSM/TGW
Gonorrhea	X	MSM /TGW	X		MSM /TGW
Chlamydia	X	MSM /TGW	X		MSM /TGW
Lipid panel (F/TAF)	Х			Х	
Hep B serology	X				
Hep C serology	MSM, TGW, and PWID only			MSM,TGW, and PWID only	

^{*} Assess for acute HIV infection (see Figure 4)

Laboratory tests NOT routinely recommended for PrEP

DEXA

Liver enzymes

Complete blood counts

Urinalyses

Considerations for selecting an agent for PrEP

What do they prefer?	Comorbidities	Nature of HIV exposure	Logistics
Which PrEP agent do they want, and why?	Renal or bone disease favors TAF/FTC or CAB	No efficacy data are available for TAF/FTC among cisgender women	A desire for telehealth/limited inperson visits favors oral PrEP
	Hepatitis B favors oral PrEP	TDF is the only agent studied among people who inject drugs	On-demand dosing favors TDF/FTC
	Hyperlipidemia, weight concerns favor TDF/FTC or CAB		Same-day initiation favors oral PrEP
			Insurance considerations may favor a specific agent

Case 2

- A 19-year-old cisgender man presents on-time for his 3rd injection of cabotegravir. He feels well and has no symptoms. One month ago, he had condomless anal sex with a cisgender man.
- Prior to initiation of cabotegravir, he had a negative HIV RNA and antibody/antigen test.
- At the time of his second injection, an HIV RNA assay and antibody/antigen test were negative.
- Today, he receives his injection and has blood drawn for routine monitoring. The results include:
 - HIV antibody/antigen test: Negative
 - HIV RNA assay: Detected but < 20 copies/mL</p>

What would you do next?

Managing ambiguous HIV test results for people taking PrEP

- Ask about medication adherence since the last test
- 2. Repeat blood testing for HIV antibody/antigen and HIV RNA after a few days
- 3. Manage antiretrovirals while repeating testing:

Strategy	Pros	Cons
Continue PrEP	For adherent patients, ambiguous results are likely false positives; provides ongoing protection against HIV	Risk of HIV drug resistance if HIV infection is present
Add a third antiretroviral	Provides a fully suppressive treatment regimen	HIV test results may remain ambiguous if the person has HIV
Stop PrEP for 1-2 weeks	Facilitates clarification of HIV status	Removes PrEP's protection if the person does not have HIV

Is this a false positive test or a breakthrough HIV infection?

- CDC guidelines recommend HIV RNA assays for PrEP monitoring, but how to adjudicate ambiguous results is not clear.
- In rare cases of breakthrough infection on cabotegravir, assay reversion was common.
- Some quantitative HIV RNA assays are not FDA-approved for diagnosis but a qualitative assay is.
- If the HIV RNA assay is 99% specific, one would expect one false positive result per year among 17 people on cabotegravir.

Assay Reversion

Days since 1st	Rapid test	Ag/Ab test	Qualitative RNA test	Confirmatory Ab test	Viral load	DNA test
HIV pos visit			LLOD 30 c/mL		LLOQ 40 c/mL or single copy	c/10 ⁶ cells
0	NR	NR	R		6.1	
42	NR	NR	NR			
55	NR	NR	R		ND	
98	NR	NR	NR			
105	R	R	NR	NEG		Detect <llod< td=""></llod<>
112	NR	R	NR	NEG		
119	NR	NR	NR			
132	NR	R	NR	INDET		ND
195	R	NR	NR			Detect <llod< td=""></llod<>
235	NR	R	NR	INDET		
280	NR	R	R	NEG	<40	Detect 5.8
333	R	R	R	INDET	<40	

Acute HIV versus the LEVI syndrome

Feature	Acute HIV	LEVI syndrome
Viral replication	Explosive	Smoldering
Symptoms	Fever, chills, malaise, lymphadenopathy	Minimal, often absent
Detection	HIV RNA assays, antigen/antibody tests	Often low/undetectable RNA, diminished/delayed antibody production
Assay reversion	Rare	Common
Duration	1-2 weeks	Months
Transmission	Likely	Unlikely
Drug resistance	No, unless transmitted	Yes, even when the viral load is low

LEVI = Long acting early viral inhibition syndrome

Case, continued

Repeat HIV antibody/antigen, quantitative HIV RNA, and qualitative HIV RNA were negative.

Our assessment:

- Likely a false positive result
- All subsequent HIV testing has remained negative, and he continues cabotegravir.

Same-day PrEP may improve access.





Reasons to consider same-day PrEP

- Minimise drop-off between PrEP evaluation and initial prescription
- Reduce barriers to PrEP access and delivery (eg, time)
- Standard of care for other medical conditions (eq, oral contraceptives)

Reasons not to consider same-day PrEP

- System barriers (absence of insurance or payment assistance, absence of referral network for PrEP continuity care, absence of laboratory services)
- Patient considerations (history of renal disease, inability to contact for follow-up if abnormal laboratory test results)
- Unknown effect on PrEP persistence and adherence

Facility considerations for providing same-say PrEP

- Ability to do point-of-care HIV testing
- Ability to test for creatinine and pregnancy
- Ability to draw blood for laboratory testing
- Ability to contact patients to discontinue PrEP if needed
- Access to insurance navigation and medication assistance programmes for uninsured and underinsured individuals
- Capacity to attend the 1 month or 3 month (or both) follow-up appointments for ongoing PrEP care (onsite or through referral network)





Rowan Se, et al. Lancet HIV. 2021.

Can we provide same-day access to cabotegravir?

- Recommendation for an HIV RNA assay at the time of initiation (although the results can be pending, provided an HIV antibody/antigen assay is nonreactive).
- Time-consuming benefits navigation



Advantages of telePrEP

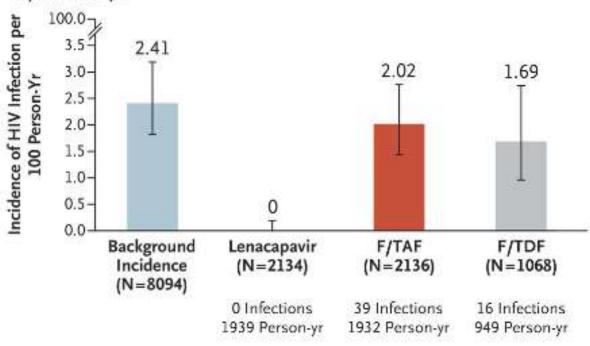
- Many core components of PrEP provision eliciting sexual and drug use histories, counseling about the medication can be performed virtually.
- May improve convenience for patients
- May improve access for people with transportation or scheduling constraints
- May overcome some confidentiality or stigma concerns

Can we provide injectable PrEP via telemedicine?

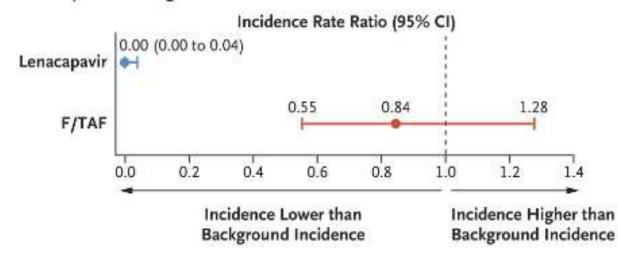
Step in PrEP care	Amenable to fully virtual care?	Potential solutions
Risk assessment and counseling	Yes	None needed
Benefits navigation	Probably, depending upon the documentation required	None needed
Medication administration	No - Intramuscular injection in the gluteus every 2 months	Community-based administration, home health visits
Baseline and monitoring laboratory studies	No – There is no FDA-approved home HIV RNA assay	New assay development/validation, hybrid care models

Lenacapavir is a promising agent for PrEP.

A Background HIV Incidence and HIV Incidence in Lenacapavir, F/TAF, and F/TDF Groups



B Incidence Rate Ratio Comparing HIV Incidence in Lenacapavir and F/TAF Groups with Background HIV Incidence



Summary

Long-acting PrEP is one of the three FDA-approved agents for PrEP, and its effectiveness has been shown in a range of populations.

Long-acting PrEP obviates the needs for taking a daily pill but may cause injection site reactions, and the logistics of initiation may take longer than those for oral PrEP.

In the rare cases in which someone acquires HIV despite long-acting PrEP, HIV test interpretation may be challenging.





Clinic Implementation Considerations

Jeannie McIntosh, APRN, FNP-C, AAHIVS



The Center for Key Populations is the first center of its kind that focuses on key groups who experience health disparities secondary to stigma and discrimination and who belong to communities that have suffered many barriers to healthcare.

The Center brings together healthcare, training, research, and advocacy for:

People who use drugs, LGBTQIA+ populations,
individuals experiencing housing instability,
the recently incarcerated, and sex workers.





HIV Primary Care and Testing

Hepatitis C Screening and Treatment Substance Use Health and Harm Reduction Health Care for the Homeless

LGBTQIA+focused Health Care Community Drop-In Center

HIV PrEP (Pre-Exposure Prophylaxis and PEP Post-Exposure Prophylaxis) Sexually Transmitted Infections



CHC'S PrEP Program



PREP TEAM

- Medical Director of CKP
 Dr. Marwan Haddad, MD, AAHIVS
- Nurse Practitioner, CKP
 Jeannie McIntosh, APRN, AAHIVS
- Community Based Services (CBS) Manager
 Maria Lorenzo
- CBS Coordinator

Aubree Buccino

- PrEP Navigators
 - Michael Judd and Julie Colon
- CBS Outreach Associate

Doug Janssen

Director of Clinical Pharmacy Services
 Kara Lewis, PharmD, AAHIVP

TRAINING / SUPPORT FOR PRIMARY CARE TEAMS

- Continuing education
 - Project ECHO Key Populations and Complex Care Mgmt. for Nurses
 - NP Residency and Key Pops. Fellowship
- Grand rounds
- Lunch and learns
- Educational materials, swag
- Outreach to identify PrEP candidates
- Clinical policy on PrEP
- PrEP templates in EMR
- Case consults
- Patient and provider support from navigators

QUALITY IMPROVEMENT

PrEP microsystems





Developing and Implementing a CAB LAI PrEP Workflow

- Start small and identify pain points before rolling out to entire organization
- Identify members of clinical team involved in process and what their roles will be
 - Provider, pharmacist, nurse, medical assistant, care coordinator, front desk staff
- Collaborate with a pharmacy partner
- Develop protocols, trainings, forms and visit workflows have this information readily available for reference





Pharmacist Role

- Providing up-to-date clinical information on CAB LAI to the medical team
- Maintaining communication with drug manufacturer medical science liaison
- Building and maintaining partnership with a pharmacy that can deliver medication
- Helping give trainings and develop workflows
- Supporting clinical teams with prescriptions, prior authorizations and patient assistance programs
- Helping troubleshoot when problems arise



For your eligible patients with **COMMERCIAL INSURANCE**

APRETUDE (cabotegravir) Savings Program¹

Eligible patients could pay as little as **\$0 copay** for their medicine[‡]

For your eligible patients with LIMITED OR NO INSURANCE

Patient Assistance Program (PAP)§

The ViiV Healthcare PAP offers our medicines at **no cost** to patients who qualify





PrEP Navigator Role

- Outreach and education
- Helping identify patients who are candidates for PrEP and connect them to care
- Supporting providers who are newer to prescribing CAB LAI
- Assistance with PAs and PAP enrollment
- Tracking when appointments and labs are due
- Helping address barriers to care transportation, insurance, difficulty remembering appointments, etc.





Nursing Role

- Nursing leadership
 - Coordinating trainings for nurses on administering the injection
 - Designing a medication storage protocol
 - Developing a nurse visit workflow
- RN visit
 - If serum HIV Ag/Ab + RNA testing not completed within week prior to visit
 - Encouraging pt to complete labs before or after visit
 - Rapid HIV test
 - Administering the injection (with chaperone)
 - Offering 3-site GC/CT testing
 - Asking about side effects and reporting any back to provider
 - ***Scheduling the next injection before patient leaves the clinic***
- Other nursing roles
 - Tracking rx delivery and appointments on a spreadsheet
 - Processing medication after it is delivered placing in storage, notifying provider





Medical Provider Role

- Medical leadership:
 - Training and supporting providers
 - Updating clinical policy and protocol for PrEP to include CAB LAI
 - PrEP EMR templates
- Medical providers:
 - Identifying clinically appropriate candidates
 - Counseling (efficacy, potential side effects, dosing intervals, lab monitoring, "tail" after discontinuation of CAB LAI, other related sexual health interventions such as DoxyPEP)
 - Ordering the medication and monitoring labs
 - Supporting the nurses and administering the injection if needed
 - Troubleshooting when problems with delivery, coverage and administration occur





Who might benefit from CAB LAI for PrEP?

- Difficulty remembering to take oral medications
- Side effects from oral meds
- Not wanting to take daily oral med due to infrequent sexual encounters
- Safety concerns around having PrEP pill bottle at home

- Willingness to get a gluteal injection on a regular basis
- Ability to come in for visit every 1-2 months







Policy Name: Pre-exposure Prophylaxis for HIV

Medical Department:

Location of Policy: Provision of Care, Treatment and Services

Date Effective:

Revision: December, 2014 (Dr. Huddleston)

August, 2015 (Dr. Haddad); May 3, 2021, July 2022, June 2024

April 19, 2022

Lewis, Kara

Moses/Weitzman Health System > Pharmacy **All Documents** Find a file Modified Modified By Name Apretude (how to start, where to send script, scheduling appts) November 28, 2022 Lewis, Kara Apretude Info Links (injection video, dosing guide, copay assistance) Lewis, Kara July 13, 2023 Apretude Injection Instructions (written directions)





Challenges

- Rx coverage
 - Some plans may require documented intolerance of oral PrEP med
 - Managing expectations
- Lab monitoring
 - Adding the HIV RNA test
 - Need for rapid HIV test if labs not completed prior to visit strain on nursing staff (we currently use the Alere which takes 20 minutes but are moving to INSTI for this reason)
- Larger gauge needle for patients with BMI ≥ 30
 - 2-inch needle recommended
- Administration outside of standard dosing window
 - Planned and unplanned late dose protocol on Viiv website
 - Safety data on early dosing
- Ownership of tracking rx delivery and appointments





Case #1: Jazmin

HISTORY

- 21 y/o trans woman, sexually active with male partners
- H/o T1DM and bipolar disorder, not engaged in care with endocrine or BH or taking any meds aside from a shortacting insulin
- Prior treatment for late latent syphilis; discussed PrEP at that time then patient was lost to follow-up
- Two years later has returned to re-establish care; now homeless and living in car; engaged in sex work
- Wants to start on PrEP; feeling very anxious about STI risk "I know I have something" (rectal swab + GC/CT)
- Endorses depressed mood related to gender dysphoria; has been on GAHT in past but struggled with adherence

PLAN

- Start on CAB LAI
- Biweekly estradiol injections in clinic
- Frequent follow-up allow for us to begin addressing other health issues and connecting with BH / case mgmt. over time





Case #2: Harrold

HISTORY:

- 62 y/o cis-male, sexually active with male partners
- H/o T2DM and HTN; sees outside PCP
- Sexual encounters every 2-3 months planned, multiple partners
- Interested in on-demand emtricitabine / tenofovir DF
- Baseline labs: eGFR 39, UACR 400 mcg/mg cr (medical records support dx CKD stage 3)

PLAN:

- Discussed renal dosing limitations with FTC/TDF
- Offered daily FTC/TAF or CAB LAI
- Pt opted to start on CAB LAI



Explore more resources!

National Learning Library: Resources for Clinical Workforce Development

National Learning Library



CHC has curated a series of resources, including webinars to support your health center through education, assistance and training. CLINICAL WORKFORCE
DEVELOPMENT
Transforming Teams, Training the Next Generation

The National Training and Technical Assistance Cooperative Agreements (NCAs) provide free training and technical assistance that is data driven, cutting edge and focused on quality and operational improvement to support health carriers and look alikes. Community Health Center, inc. (CHC, Inc.) and its Weltzman Institute specialize in providing education and training to interested health centers in Trainforming Teams and Training the Next Generation through.

National Webinars on advancing team based care, implementing pinti-graduate residency training programs, and health professions student training in FQHCs.

Invited participation in Learning Collaboratives to advance team based care or implement a post-graduate residency training program at your health center.

Please keep watching this space for information on future sessions. To request technical assistance from our NCA, please email NCA@chcl.com for more information.

Learn More

https://www.weitzmaninstitute.org/ncaresources

Health Center Resource Clearinghouse



https://www.healthcenterinfo.org/

Questions?









Get Connected with The National LGBTQIA+ Health Education Center NTTAP

The National LGBTQIA+ Health Education Center provides educational programs, resources, and consultation to health care organizations with the goal of optimizing quality, cost-effective health care for lesbian, gay, bisexual, transgender, queer, intersex, asexual, and all sexual and gender minority (LGBTQIA+) people.

The Education Center is part of The Fenway Institute, the research, training, and health policy division of Fenway Health, a Federally Qualified Health Center, and one of the world's largest LGBTQIA+ focused health centers.

617.927.6354

□ education@fenwayhealth.org

mww.lgbtqiahealtheducation.org

www.acponline.org/fenway









Get Connected with Community Health Center Inc.'s NTTAP

For information on future webinars, activity sessions, and learning collaboratives: please reach out to nca@chc1.com or visit https://www.chc1.com/nca