

Understanding Injectable PrEP and Oral PrEP

JSI Research & Training Institute (JSI)

Massachusetts General Hospital

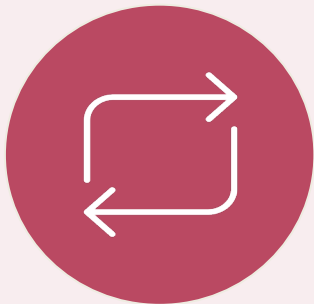
Harvard Medical School

The Fenway Institute

2023 PrEP Webinar Series: Oral and Injectable PrEP

Session 1: Monday, April 17, 2023 | 3PM - 4PM ET

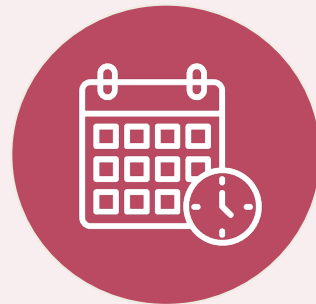
Learning Objectives



Recall the PrEP continuum of care and the main barriers to oral PrEP uptake as described in TA4SI's 2021 *PrEP Group Learning series*.



Identify oral and injectable PrEP as options for HIV prevention.



Explain the similarities and differences between oral and injectable PrEP, including eligibility, dosing schedule, laboratory test requirements, and other clinical considerations.

Presenters



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Today's Agenda

1

Recap of 2021 PrEP
Learning Series

2

The Basics of
Oral and
Injectable PrEP

3

Looking Ahead

4

Q&A





Poll



1

Recap of 2021 PrEP Learning Series

Recap: PrEP Continuum of Care



Awareness



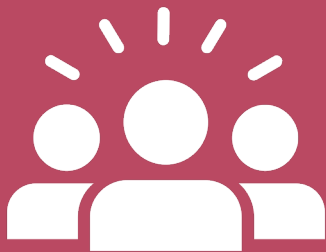
Access



Initiation



**Adherence and
Retention**



Agency Staff
PrEP
Awareness

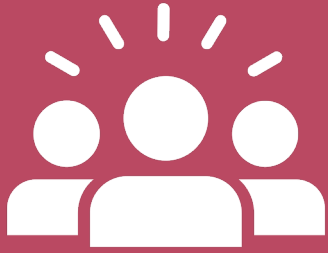
How PrEP works to prevent HIV

Indications and contraindications for PrEP

PrEP prescribing requirements

PrEP access challenges and limitations

Their agency's PrEP service model



Best Practices to Increase PrEP Awareness

Routinize sexual health screening and education

Communicate with patients about the benefits of PrEP

Continually assess and follow-up with PrEP patients



Barriers to PrEP Access

Structural

Systemic

Social / Interpersonal

Individual



Best practices
to improve
PrEP
Access

Address financial barriers for all aspects
of PrEP

Address stigma and medical mistrust

Address social needs and provide support
services

Increase availability of PrEP prescribers



Barriers to PrEP Initiation

In-person visits

Laboratory testing requirements

Access to a PrEP prescriber

Delayed access to PrEP prescription (Rx)



Best Practices to Streamline **PrEP Initiation**

Initiate PrEP within one week of Rx, ideally same-day PrEP

Provide PrEP education and counseling to address client concerns (ideally via a dedicated case manager or PrEP Navigator)

Implement PrEP at STI clinics

Minimize delays between receiving and filling an Rx



Challenges to PrEP Adherence and Retention

Financial and insurance barriers

Sticking to a daily routine and scheduling ongoing laboratory testing

Stigma around HIV and taking PrEP

Clinical side effects



Best Practices
to Promote
PrEP
Adherence
and
Retention

Tailor strategies to the specific needs of each community

Plan ahead for challenges to adherence (pill boxes, med storage, alarms/texts)

Build client relationships and incorporate technological support

Adherence counseling at follow-up visits

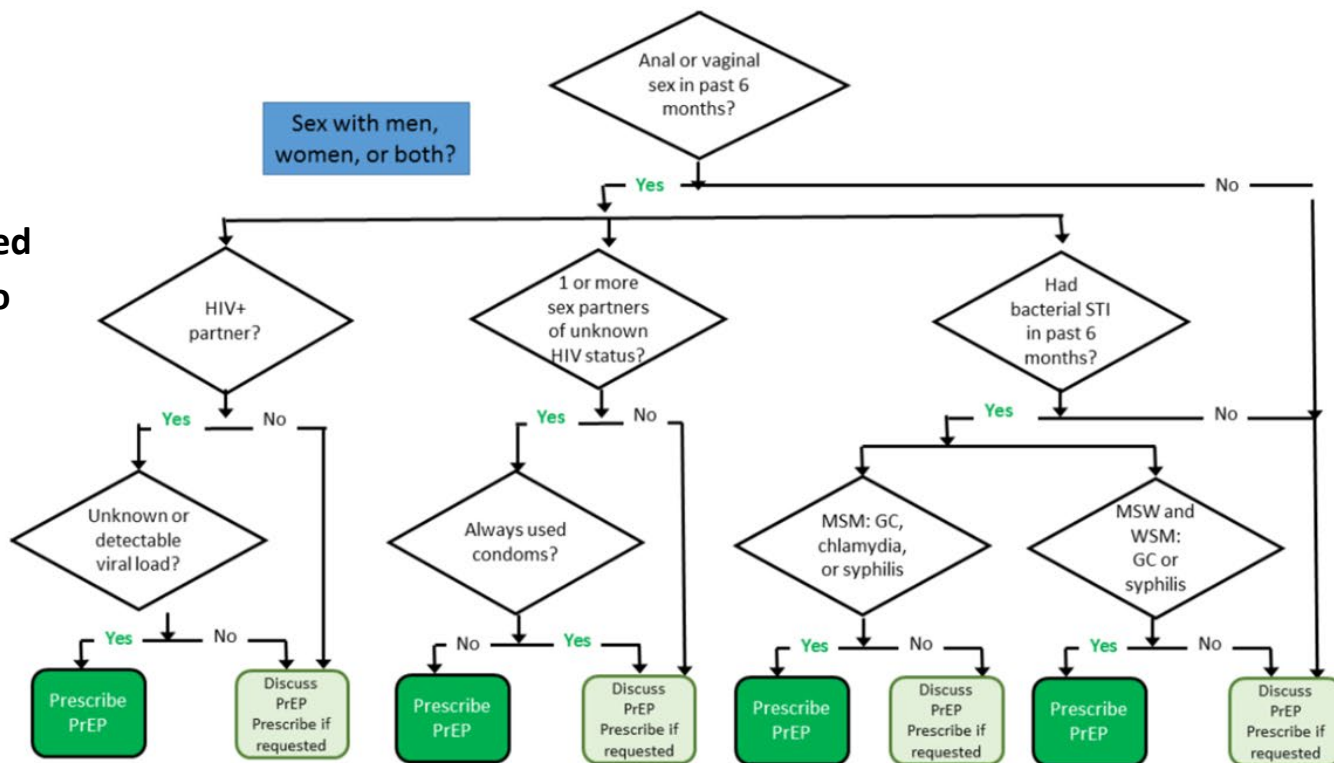


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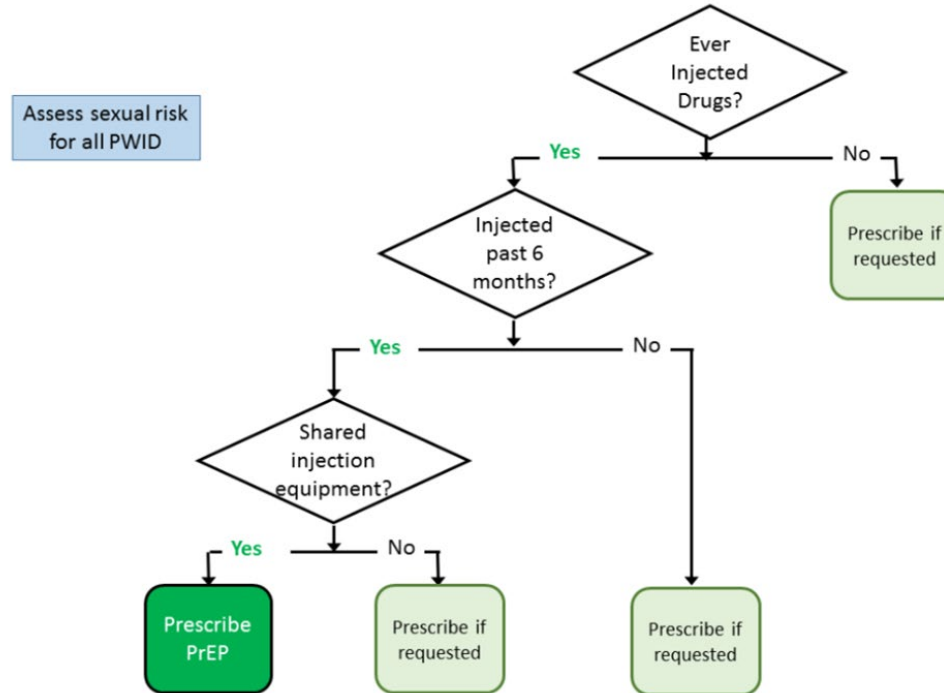
The Basics of Oral and Injectable PrEP

PrEP indications for sexually active people

PrEP is indicated for people who request it, regardless of the behaviors they report.



PrEP indications for people who inject drugs



PrEP Options in 2023

Option 1A: Oral PrEP: TDF/FTC (Truvada)

Evidence: Prevents HIV acquisition through sex and injection drug use; efficacy has been demonstrated among men who have sex with men (MSM), transgender women, and cisgender heterosexual men and women

Dosing: One tablet (emtricitabine [FTC] 200 mg and tenofovir disoproxil fumarate [TDF] 300 mg) once daily*



Option 1A: Oral PrEP: TDF/FTC (Truvada)

Advantages

Longest clinical experience among PrEP agents, including in pregnancy

Available as a generic

Can be used in an on-demand fashion by MSM*

Disadvantages

Renal toxicity and decreased bone mineral density

Requires baseline hepatitis B testing

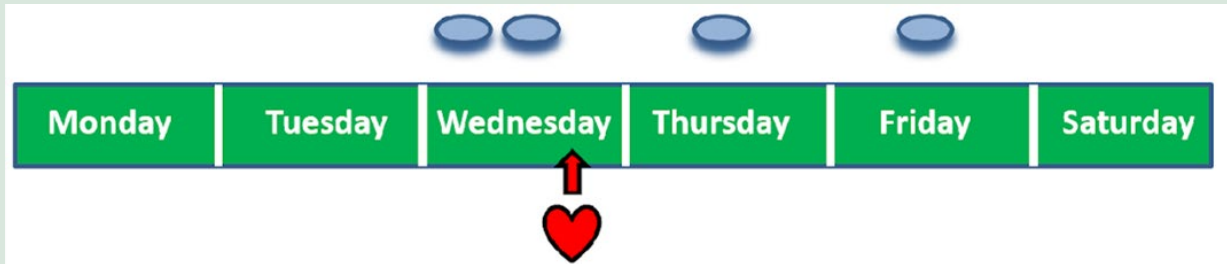
Option 1B: On-demand TDF/FTC (“2-1-1”)

Considered an alternative for MSM without chronic hepatitis B

With TDF/FTC only; no published data with other PrEP agents

Prescribe no more than 30 tablets at a time before retesting for HIV

Follow the same laboratory monitoring strategy as for daily oral TDF/FTC



Option 2: Oral PrEP: TAF/FTC (Descovy)

Evidence: Prevents HIV acquisition through sex; non-inferior to TDF/FTC among men who have sex with men (MSM) and transgender women

Dosing: One tablet (emtricitabine [FTC] 200 mg and tenofovir alafenamide [TAF] 25 mg) once daily



Option 2: Oral PrEP: TAF/FTC (Descovy)

Advantages

Fewer renal and bone effects in comparison to TDF/FTC

Disadvantages

Efficacy for people whose HIV risk arises from receptive vaginal sex is unknown

Has mild deleterious effects on lipids and weight

Requires baseline hepatitis B testing

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	X
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)	X			X	
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)

Option 3: Injectable PrEP: 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.



Option 3: Injectable PrEP: Cabotegravir (CAB, Apretude)

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

Same Day PrEP

Same-day PrEP may improve access.



Panel: Considerations for same-day PrEP

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 (eg, 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-day 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)



Example: Same Day PrEP Process

Person responsible	Step
Administrative assistant	1. Checks in patient, obtains preferred contact information and consent to text
Patient (clinician during Covid-19)	2. Completes standardized questionnaire with questions about sexual behavior and drug use
Nurse practitioner	3. Discusses PrEP, asks about symptoms of acute HIV, obtains baseline laboratory studies at the same time as STI testing, writes prescription
PrEP navigator	4. Provides on-demand benefits assistance and enrollment
Administrative assistant	6. Books follow-up appointment
Nurse practitioner or nurse	7. Performs follow up visits

Potential barriers to same-day access for 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 non-reactive).

Time-consuming benefits navigation



TelePrEP

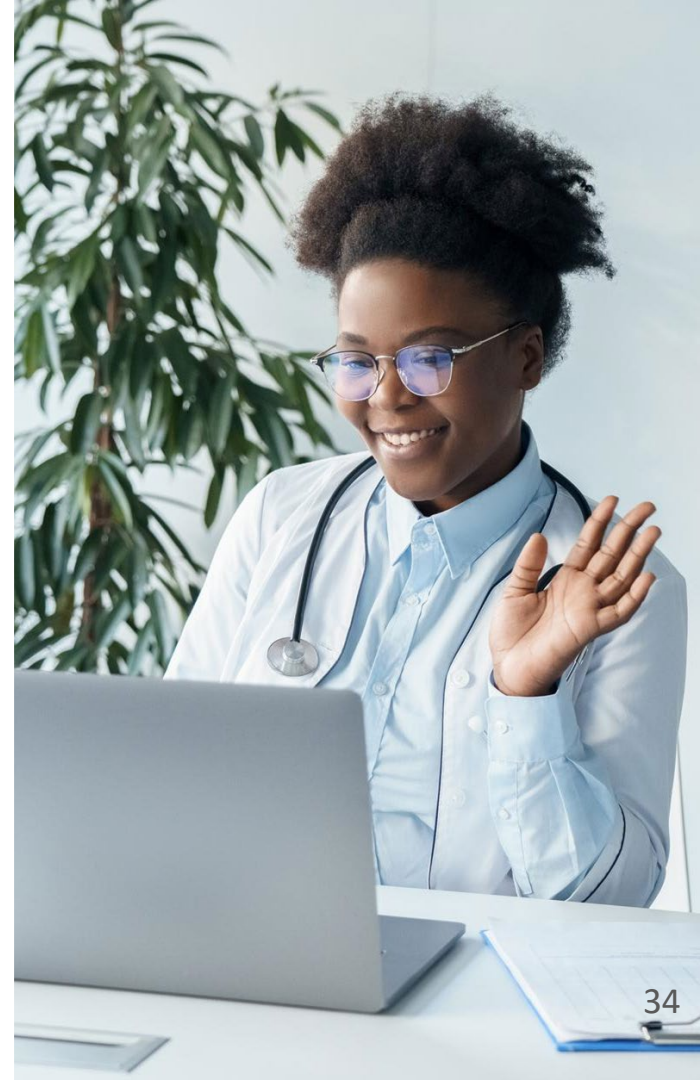
Advantages of telePrEP

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



Disadvantages of telePrEP

Need for laboratory studies

Home-based syphilis testing may not be optimal for those with prior syphilis.

Dependence of uninsured patients on at-no-cost laboratory testing provided in limited locations

Injectable medications may be required for sexually transmitted infection treatment

Lack of technology or privacy to engage in telePrEP

CAB must be given by a health care professional



CAB may require changes to existing telePrEP models

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 viral load assay	New assay development/validation, hybrid care models

Considerations for selecting a PrEP agent with a patient/client

What do they prefer?

Which PrEP agent do they want, and why?

Comorbidities

Renal or bone disease favors TAF/FTC or CAB

Hepatitis B favors oral PrEP

Hyperlipidemia, weight concerns favor TDF/FTC or CAB

Considerations for selecting a PrEP agent with a patient/client

Nature of HIV exposure

No efficacy data are available for TAF/FTC among cisgender women

TDF is the only agent studied among people who inject drugs

Logistics

A desire for telehealth/limited in-person visits favors oral PrEP

On-demand dosing favors TDF/FTC

Same-day initiation favors oral PrEP

Insurance considerations may favor a specific agent

Summary

- Currently available options for PrEP include oral TDF/FTC, oral TAF/FTC, and injectable CAB.
- All forms of PrEP are highly effective when taken as prescribed, and generally well-tolerated.
- On-demand PrEP with TDF/FTC is an alternative dosing strategy studied among MSM.
- Same-day PrEP initiation may improve access and uptake and is most feasible with oral PrEP.
- Consider preferences, comorbidities, the nature of an individual's HIV exposure, and logistics when working with a patient/client to select a PrEP option.



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Looking
Ahead

PrEP Payment and Financing

What are the billing and reimbursement requirements for PrEP?

For clients with insurance, how are all the components of PrEP services covered?

What financial supports are available to clients who are uninsured or underinsured?

Session 2: PrEP Financing and Payment

Monday, May 8 from 3PM - 4PM ET



Provider-Client Decisions

What concerns do clients have about PrEP?

What type of PrEP do they prefer?

What indications or contraindications do they have?

What is their risk of HIV exposure?

What insurance do they have, if any?

Session 3: PrEP Decision-Making: Client and Provider Communication

Monday, June 5 from 3PM - 4:30PM ET



PrEP Workflows

What is your agency's current PrEP service model, and (how) can it be adapted to incorporate injectable PrEP?

What is your agency's staff capacity to prescribe PrEP?

How does your agency review and revise workflows to ensure successful implementation?

**Session 4: Integrating PrEP Into Clinical,
Non-Clinical, and Inter-agency Workflows**

Monday, June 26 from 3PM - 4PM ET





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Q&A

Thank you!

Please take a moment to complete the brief feedback form!

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