

2021 PrEP Guideline Update

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I have no financial conflicts of interest.

PrEP turns 10!



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What has changed?

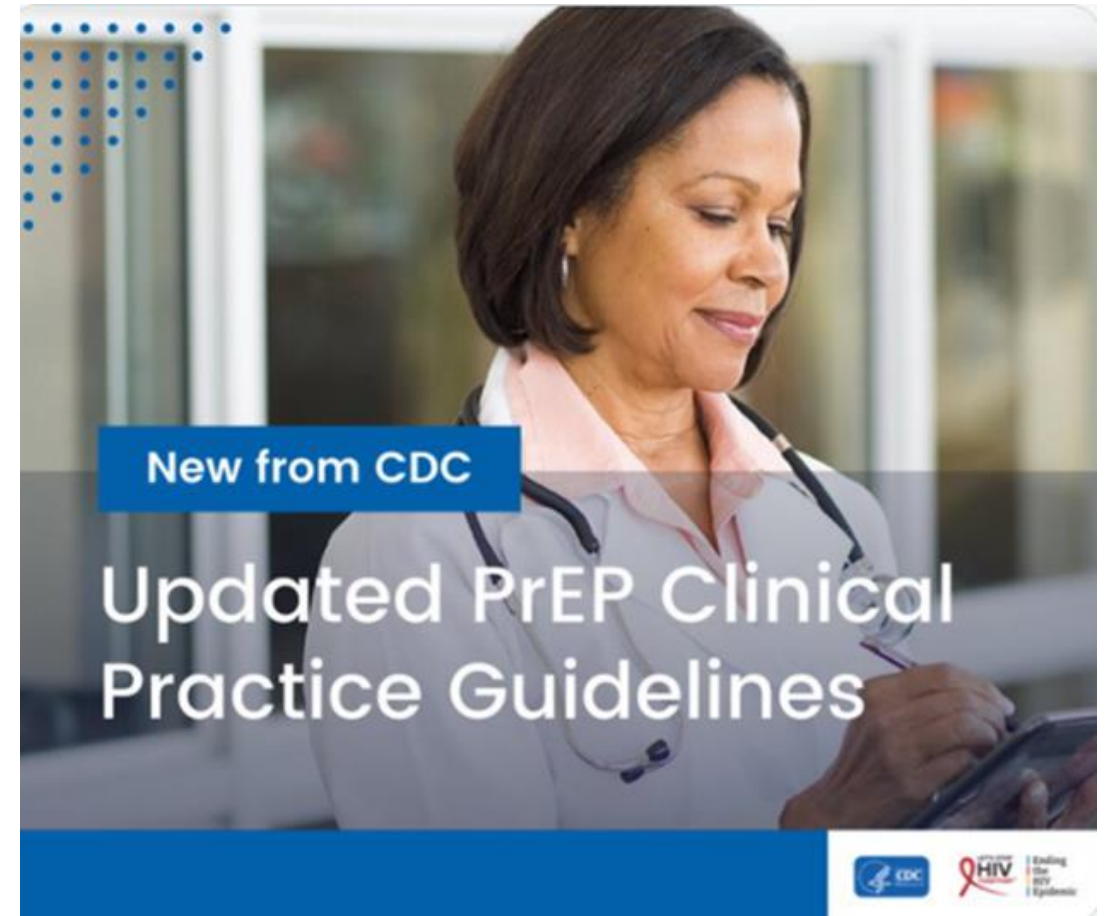
- Recommendation that all sexually active people be informed about PrEP
- PrEP indications?
- A new option: long-acting cabotegravir (CAB-LA)
- On-demand PrEP for MSM
- Laboratory monitoring on PrEP

What's Unchanged from the 2017 Guideline

■ No changes to:



- Indications for PrEP use
- Frequency of follow-up visits for oral PrEP
- Schedule for HIV and STI testing for oral PrEP



PrEP indications for heterosexually active people in 2017

BOX B2: RECOMMENDED INDICATIONS FOR PREP USE BY HETEROSEXUALLY ACTIVE MEN AND WOMEN

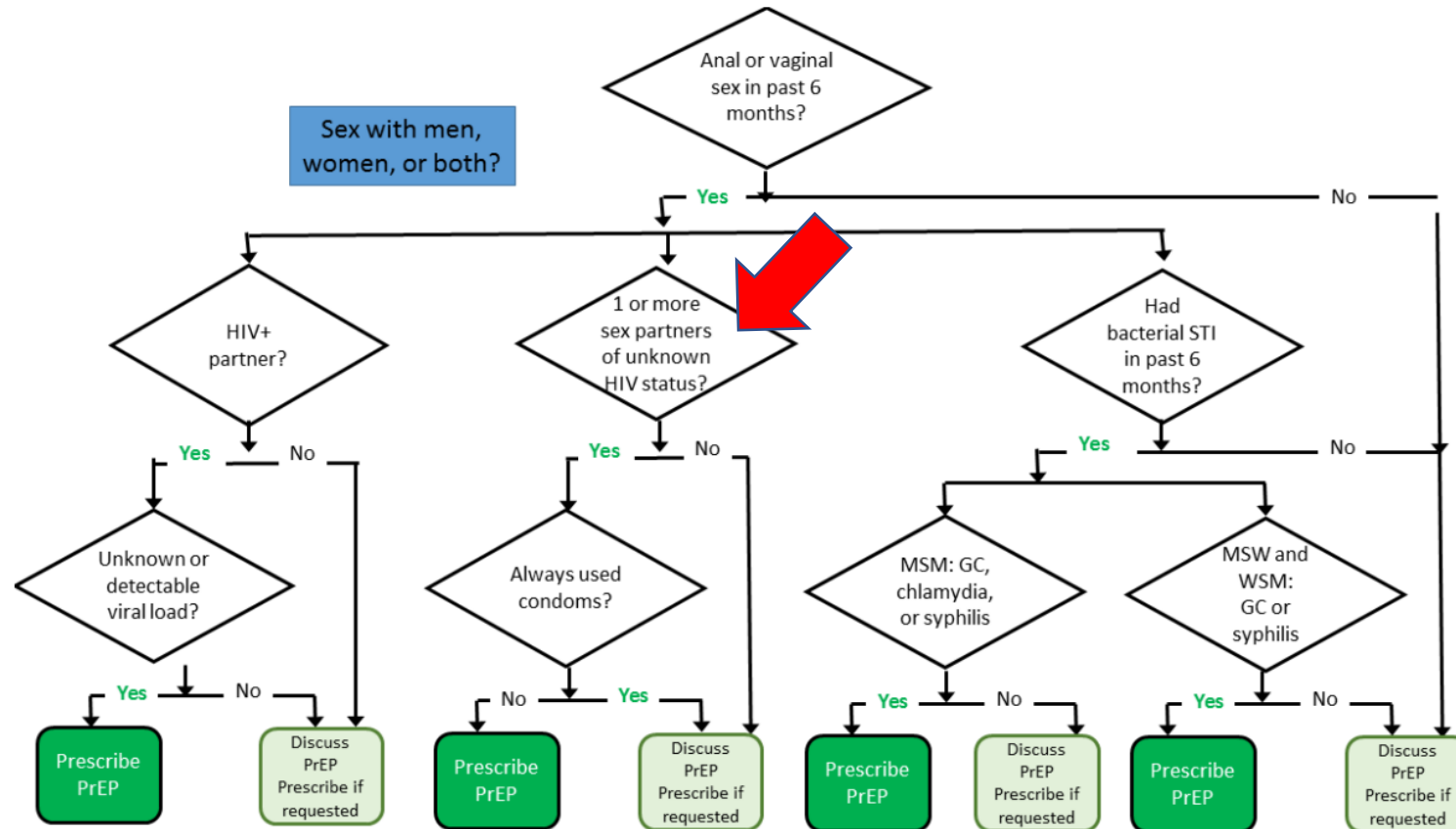
- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A **bacterial STI (syphilis, gonorrhea in women or men)** diagnosed or reported in past 6 months

PrEP indications for sexually active people in 2021

Figure 2 Assessing Indications for PrEP in Sexually Active Persons

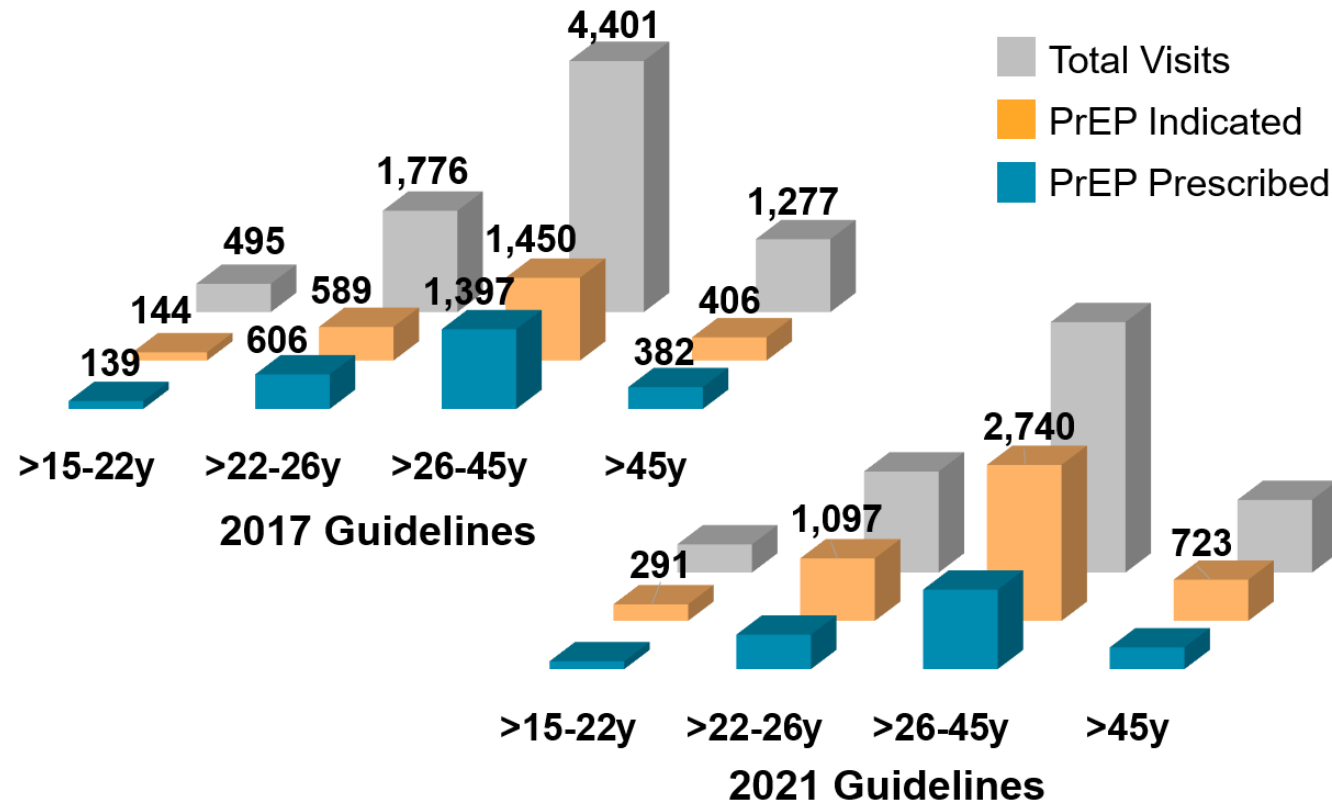


This change increases the proportion of patients with a PrEP indication.

PrEP Cascades Based on 2017 versus 2021 CDC Guidelines, MGH Sexual Health Clinic

Applying the change increased the proportion of visits with a PrEP indication from 33% to 61%.

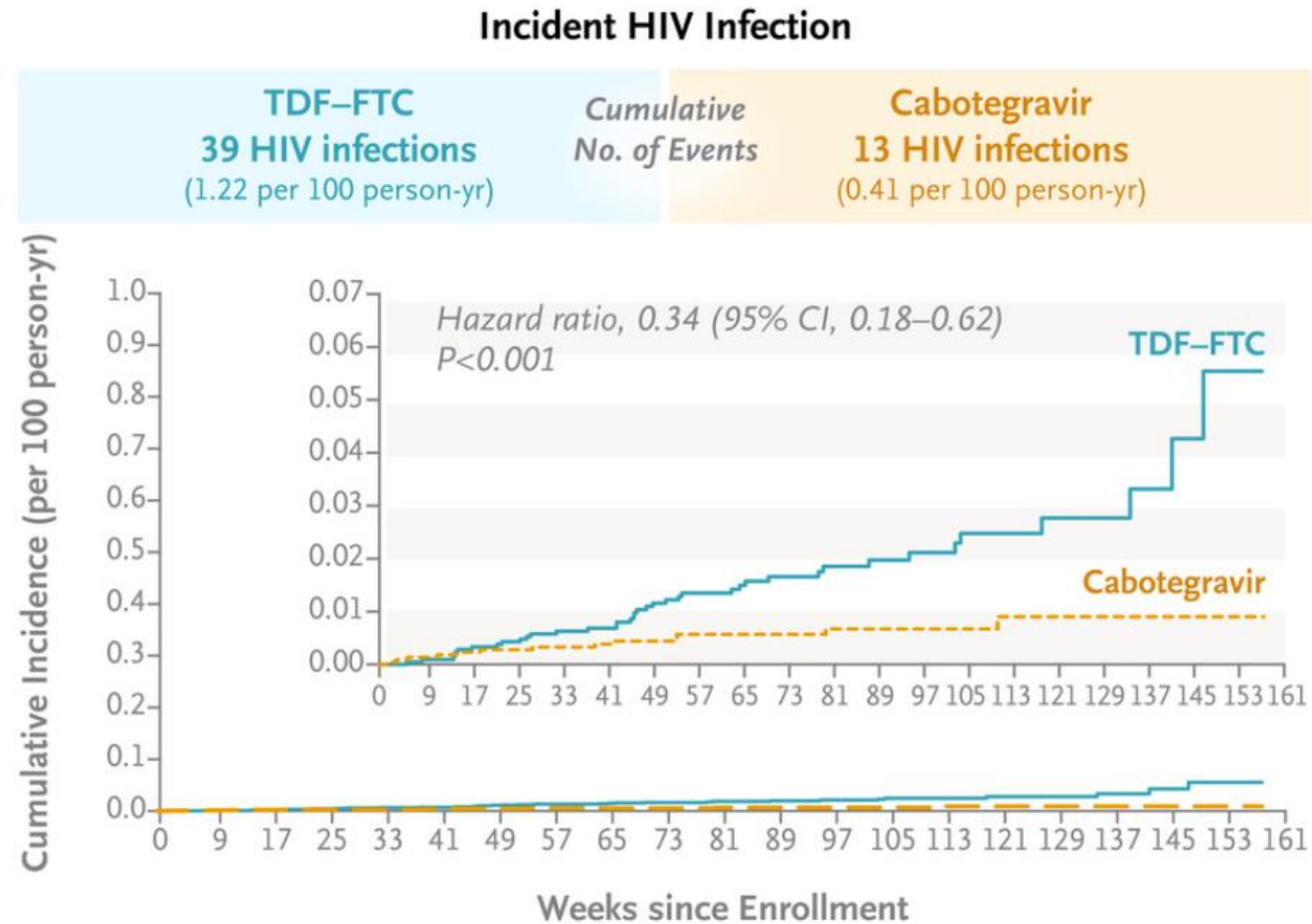
Increases were similar across age groups.



Case

- A 27-year-old cisgender man presents in follow-up.
- He injects methamphetamine a few times each week, often sharing injection equipment with others.
- He has anal sex with cisgender men and does not use condoms.
- 2 months ago, he was diagnosed with early latent syphilis and was treated with long-acting benzathine penicillin.
- He is prescribed oral TDF/FTC for PrEP but misses weeks of pills at a time.
- Today, he is asymptomatic, and a routine HIV antibody/antigen test and HIV RNA assay are negative.

CAB-LA is superior to TDF/FTC for PrEP.



Questions about CAB-LA

Will it prevent HIV transmission from injection drug use?

- **CDC:** “PWID are likely to benefit from PrEP with any FDA-approved medication with or without an identified sexual behavior risk of HIV acquisition.”

Can CAB-LA be used in adolescents?

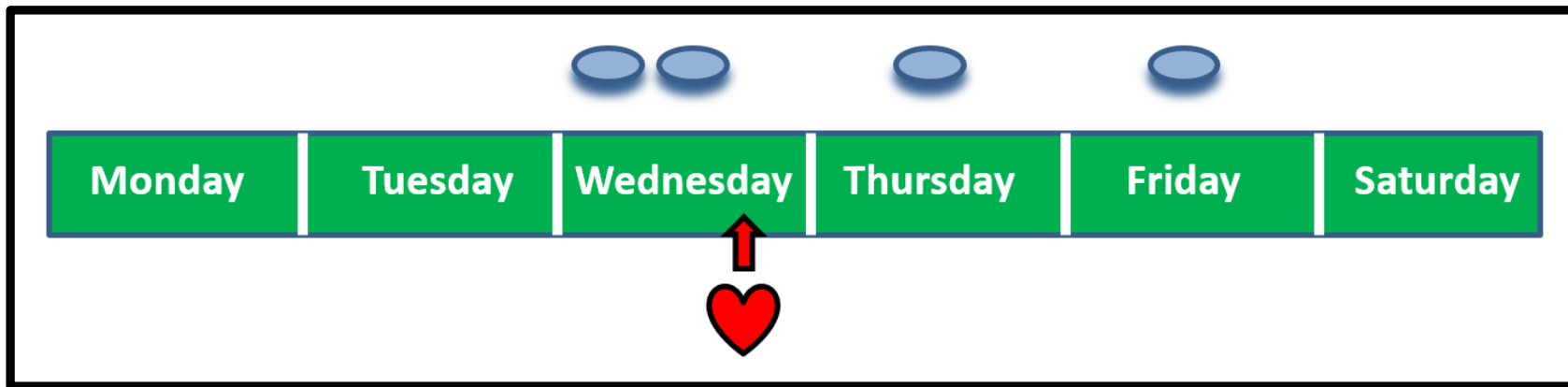
- The FDA approved the drug for adults *and* adolescents.
- **CDC:** “CAB is not recommended for adolescents < 18 years old.”
- The HPTN 083-01 study is assessing CAB-LA among people < 18 years.

1. 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>.

2. FDA news release. 2021 Dec 20. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>.

On-demand PrEP

- Described as an alternative for MSM without chronic hepatitis B
- With TDF/FTC only
- Prescribe no more than 30 tablets at a time before retesting for HIV



Laboratory tests NOT routinely recommended for PrEP

DEXA

Liver enzymes

Complete blood counts

Urinalyses

Table 5 Timing of Oral PrEP-associated Laboratory Tests

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)

Table 7 Timing of CAB PrEP-associated Laboratory Tests

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

Why no assessment for viral hepatitis in those at risk?

HIV RNA assays for monitoring those with antiretroviral exposure

Rationale:

- Antiretrovirals impact HIV test performance
- Antigen/antibody positivity may be delayed beyond that of an HIV RNA assay for incident infections by a mean of
 - 98 days in those receiving CAB-LA
 - 31 days in those receiving TDF/FTC

Questions and challenges:

- Is this truly warranted for oral PrEP?
- Obtaining HIV RNA assays for people who are un- or underinsured
- Limitations of the USPSTF/ACA provision

Case

- 35-year-old man taking TAF/FTC for PrEP returns for routine follow-up; no symptoms
- Forgets doses 1-2 times per month
- HIV antibody/antigen **non-reactive**, HIV RNA **84**

What would you do for this patient now?

Case, continued

Clinical course:

- **Day 3:** Asymptomatic, TAF/FTC stopped, testing repeated, HIV antibody/antigen **non-reactive**, HIV RNA **1,820**
- **Day 9:** Fevers, chills, myalgias, nausea
- **Day 10:** HIV antibody/antigen **reactive**, HIV confirmatory assay **non-reactive**, HIV RNA **4,850,000**; TAF/FTC/BIC started
- **Day 36:** HIV confirmatory assay **reactive**, HIV RNA **153**

An HIV genotype obtained on day 3 ultimately returned without reverse transcriptase mutations.

Summary

- Inform all sexually active people about the availability of PrEP.
- Consider on-demand TDF/FTC for MSM and CAB-LA for all.
- Obtain HIV RNA assays for monitoring for those taking PrEP, especially those taking CAB-LA.