2021 Draft Clinical Practice PrEP Guideline Public Comment Webinar

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Webinar Agenda

- 1:00 Welcoming remarks
- 1:05 Brief introduction
- 1:10 Overview of draft guideline changes and additions
    - Comments on guideline
- 2:10 Overview of draft supplement changes and additions
    - Comments on supplement
- 2:30 Adjourn

Introduction

- The purpose of the webinars is to provide a public comment opportunity for stakeholders
- Clinicians who provide care to persons at risk of acquiring HIV infection are the primary target audience for the PrEP clinical practice guideline and supplement
- Each webinar will present both the guideline and supplement changes for comment
- Each webinar will be audiotaped to provide complete and accurate records of the comments made
- All comments provided during the webinars will be considered.
- There is no written comment period

Instructions for Public Comment

- Webinar participants can make comments
  - Verbally by unmuting themselves
    - We will ask for comments in groups alphabetically by last name
  - By entering comments in the “chat”
- Commenters should
  - Identify themselves by name and organization
  - Keep verbal comments short (e.g., no more than 3 minutes) to allow participation of the maximum number of webinar participants
  - Do not repeat comments/questions already raised by others
- CDC staff will not make any specific responses to comments during the webinar

To provide a comment

- Chat (at any time)
  - Select Chat at the bottom of the screen
  - Select “to everyone” near bottom of the chat panel
  - Type in your comment
- Verbal comments (during the comment periods)
  - We have muted all the participants
  - We will let you know what group is eligible to speak
  - Raise your hand (found under “reaction”) at bottom of screen
  - We will unmute folks one at a time

Disclaimers

- The recommendations about PrEP include the use of commercial products, Truvada®, generic F/TDF, Descovy,® and cabotegravir, when approved for PrEP by the FDA.

- The draft documents are distributed solely for the purpose of pre-dissemination review. They have not been formally disseminated by the Centers for Disease Control and Prevention. The draft documents shared for review do not represent and should not be construed to represent any agency determination or policy.

Draft Guideline Changes and Additions for Public Comment

Additions to the PrEP Guideline

- A recommendation to inform all sexually active adults and adolescents about PrEP
- F/TAF as an FDA-approved choice for some populations
- A recommendation and guidance for cabotegravir PrEP (when FDA approved)
- Guidance for
  - PrEP by telehealth
  - same-day PrEP initiation
  - off-label prescription of TDF/FTC to MSM on a non-daily regimen (“2-1-1”)
- A brief section on primary care considerations for PrEP patients
- Expanded guidance for transgender persons

Changes to the PrEP Guideline

- Revised and reordered the sections to
  - describe guidance applicable to all PrEP patients and that applicable only to selected patients
  - create sections for oral PrEP and injectable PrEP
- Replaced boxes with flow charts for assessing indications for PrEP
- Revised the HIV testing algorithm to
  - clarify preferred and less preferred options
  - harmonize with the acute infection section of the DHHS HIV Treatment Guidelines
- Revised frequency of assessing eCrCl by baseline age and eCrCl

Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drugs
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[2] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[3] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descrovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV test, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[2] – oral, rectal, urethral, blood • Pregnancy testing for women (with reproductive potential) • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[2] – [vaginal, oral, rectal, urine- as indicated], blood • For patients on F/TAF, assess weight, triglyceride and cholesterol levels **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for women - vaginal	

[1] adolescents weighing at least 35 kg (77 lb)

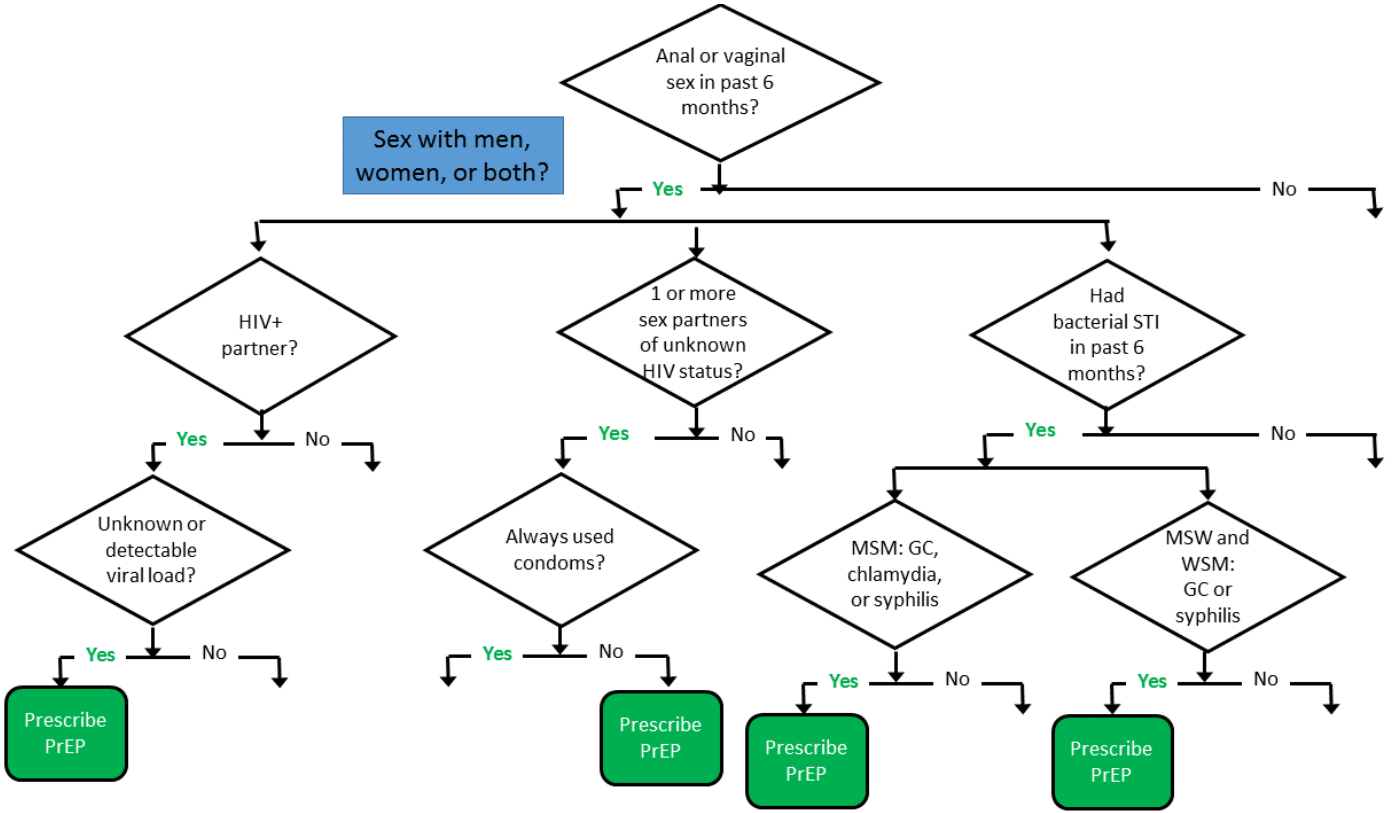
[2] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

[3] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

Table 1b: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use

	Sexually-Active Adults	Persons Who Inject Drugs[1]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[2] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV test result within 1 week before initial cabotegravir injection • No signs/symptoms of acute HIV infection • No contraindicated medications or conditions	
Dosage	• 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle o Initial dose o Second dose 4 weeks after first dose (month 1 follow-up visit) o Every 8 weeks thereafter (month 3,5,7, follow-up visits etc)	
Follow-up care	**At follow-up visit 1 month after first injection** • HIV test **At follow-up visits every 2 months (beginning with the third injection – month 3) provide the following:** • HIV test • Pregnancy testing for persons with childbearing potential • Access to clean needles/syringes and drug treatment services for PWID **At follow-up visits every 4 months (beginning with the third injection- month 3) provide the following:** • Bacterial STI screening[1] screening[2] for MSM and transgender women who have sex with men[2] – oral, rectal, urine, blood **At follow-up visits every 6 months (beginning with the fifth injection – month 7) provide the following:** • Bacterial STI screening[1] for all sexually-active women – [vaginal, rectal - as indicated], blood **At follow-up visits at least every 12 months (after the first injection) provide the following:** • Assess desire to continue injections for PrEP	

Figure 2 Assessing Indications for PrEP in Sexually Active Persons



Patients may request PrEP because of concern about acquiring HIV infection but not feel comfortable reporting sexual or injection behaviors to avoid anticipated stigmatizing responses in health care settings.[33-36] For this reason, after attempts to assess patient sexual and injection behaviors, patients who request PrEP should be offered it, even when no specific risk behaviors are elicited.

Figure 3 Assessing Indications for PrEP in Persons Who Inject Drugs

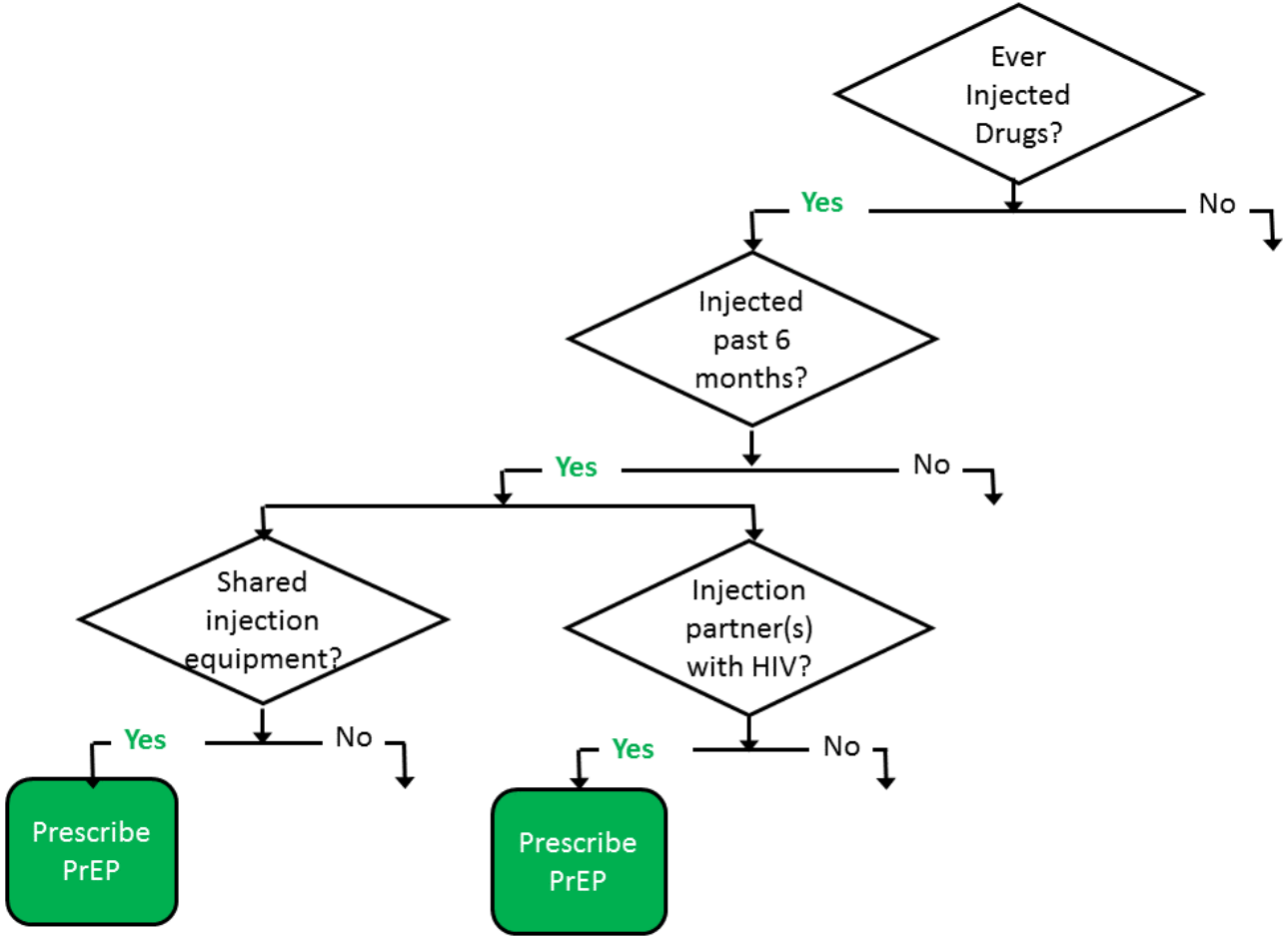


Figure 4 Clinician Determination of HIV Status for PrEP Provision

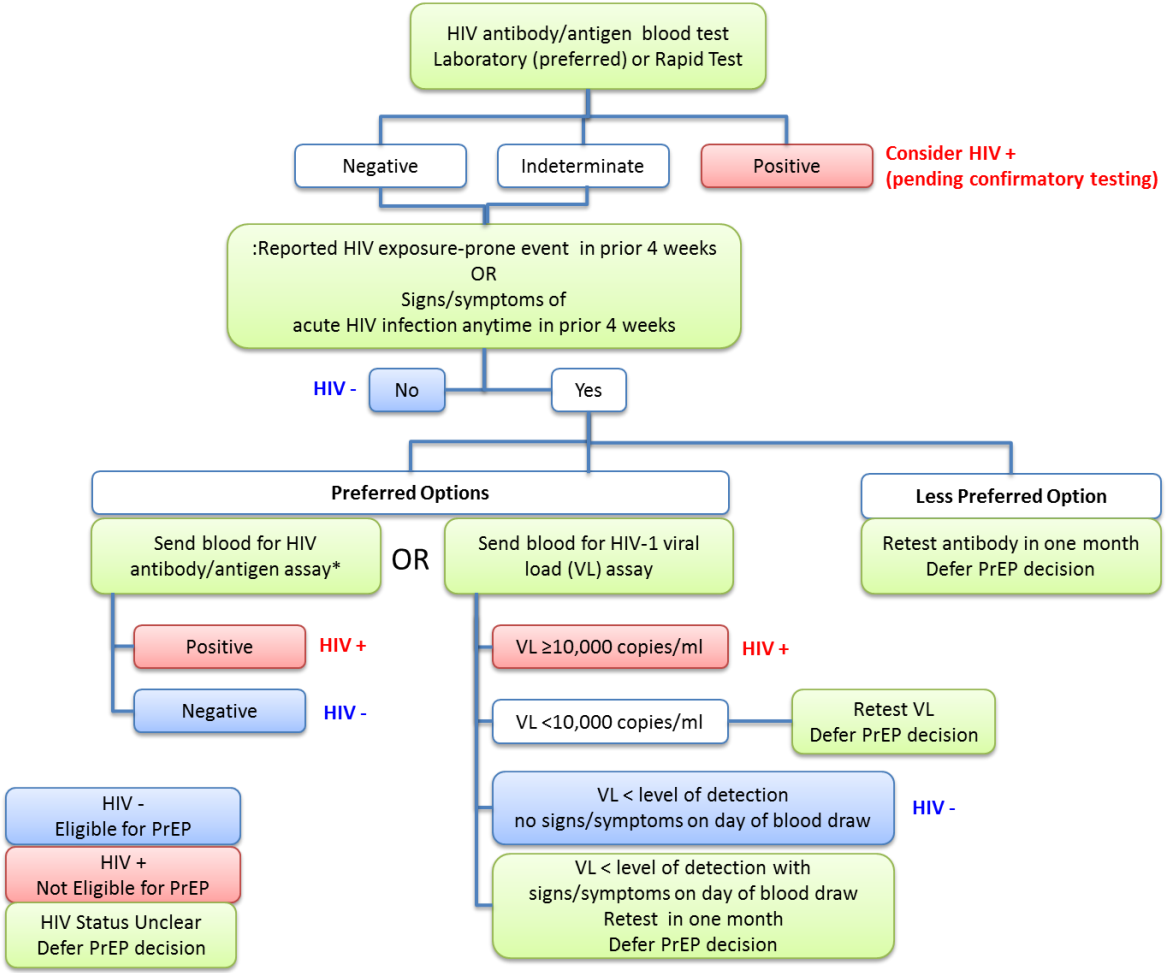


Table 8 Primary Care Health Measures

		MSM	MSW*	Women*	PWID
Vaccines# (if not previously vaccinated)	Hepatitis A vaccine	Yes	Yes	Yes	Yes
	Hepatitis B vaccine	Yes	Yes	Yes	Yes
	HPV vaccine	Through age 26	Through age 26	Through age 26	Through age 26
	Meningococcal B vaccine	Ages 16-18	Ages 16-18	Ages 16-18	Ages 16-18
	Influenza vaccine	Yes	Yes	Yes	Yes
General Health	Hepatitis C infection^	Ages 18-79	Ages 18-79	Ages 18-79	Ages 18-79
	Screen for depression^	Yes	Yes	Yes	Yes
	Screen for unhealthy alcohol use^	Ages 18 and older	Ages 18 and older	Ages 18 and older	Ages 18 and older
	Screen for smoking^	Yes	Yes	Yes	Yes
	Screen for Intimate Partner Violence^			Yes	If female, Yes
Women's Health	Mammography^			Ages 50-74 every two years	If female, Ages 50-74 every two years
	Screen for cervical cancer^~			Ages 21-65 every three years	If female, Ages 21-65 every three years
Men's Health	Screen for prostate cancer^	Ages 55-69	Ages 55-69		If male, Ages 55-69

Draft Supplement Changes and Additions for Public Comment

Changes and Additions to Supplement

- Patient visit checklist updated to include
  - F/TAF
  - 2-1-1 F/TDF
  - Cabotegravir
- Added information about F/TAF to the Patient Information Sheet for F/TDF
- Added a Patient Information Sheet about cabotegravir
- Added text specific to cabotegravir to several sections

What Happens Next

Next Steps

- The audio recording and a transcript will be posted by June 15, 2021
  - The transcript will not include names and affiliations of persons who have made comments
- The guidelines writing team will consider the recorded comments received
- A written response to comments will be available by June 30, 2021 at https://www.cdc.gov/hiv/programresources/planning.html
- Indicated revisions will be made to the draft documents prior to final publication

Thank you

- Your participation in the webinar and the provision of comments is very much appreciated

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2021 Guideline Revision Steps

- Update systematic review of PrEP literature (through Dec 2020)
- Make format changes
- Revise content as indicated by decisions of the writing team
- Review and approval of draft through CDC offices (“clearance”)
- Peer review by external clinicians
- Post for public comment
- Revise guideline as indicated by decisions of the writing team
- Reclear revisions
- Post final approved guideline version