



HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) PROVIDER REFERENCE KIT

May 2018

Dear Colleague,

This PrEP Provider Reference Kit includes information and resources needed to become a PrEP provider.

Its purpose is to set you and your clinic up for success in prescribing PrEP to patients who are at risk for acquiring HIV.

If you have questions or need further support, please contact our PrEP providers:

IDVIRTUALHEALTH@mail.mil

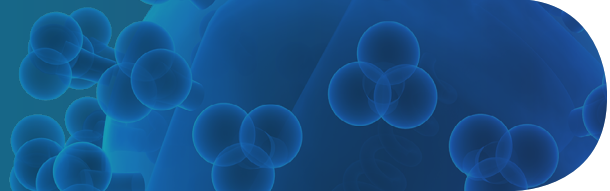
or

dha.bethesda.wrnmmc.mbx.infectious-diseases-prep-clinic-wrb@mail.mil

Sincerely,

The Tri-Service HIV Working Group

What is PrEP?



- Pre-exposure prophylaxis (PrEP) is indicated in combination with safer sex practices to reduce the risk of sexually acquired HIV infection in adults at high risk.
- The medication used for PrEP is a single pill comprised of 300 mg of tenofovir disoproxil fumarate (TDF) and 200 mg of emtricitabine (FTC) (brand name Truvada).
- Truvada was approved for >18 years of age by the United States Food and Drug Administration (FDA) in 2012 for PrEP.
- PrEP is taken before (pre-) an exposure which is different than post-exposure prophylaxis (PEP), which is a medication regimen taken after exposure (e.g., after a needle stick).
- PrEP is meant to be used along with other prevention methods, including consistent and correct use of condoms, and reducing sexual risk behavior.
- HIV prevention options continue to expand, and as PrEP becomes more well known as a prevention strategy, more patients may approach with questions.
- The CDC has released guidelines for PrEP and offers a variety of resources for both providers and patients (see Resources for more information).
- PrEP should not be started until HIV-negative status is confirmed and baseline testing completed.
- The most common side effects: nausea, headache, weight loss, small increases in serum creatinine.
- Acknowledge side effects from the medicine that could interfere with life.
- Coadministration of Truvada with drugs that are eliminated by active tubular secretion (such as acyclovir, valacyclovir, or high-dose NSAIDs) may increase concentrations of emtricitabine, tenofovir, and/or the coadministered drug. Monitor for dose-related renal toxicities.

Candidates for, and delivery of, PrEP

	Men Who Have Sex With Men (MSM)	Heterosexual Women and Men	Injection Drug Users (IDU)
Consider for HIV-negative people at substantial risk for acquiring HIV infection	HIV-positive sexual partner Recent bacterial sexually transmitted infection (STI) ¹ High number of sex partners Inconsistent or no condom use Commercial sex work In high-prevalence area or network		HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection ² Creatinine clearance ≥ 60 mL/min; no contraindicated medications Hepatitis B infection status known and, if appropriate, vaccination given		
Regimens preferred	Truvada (TDF/FTC 300/200 mg) daily, continuing, oral dose, ≤ 90-day supply		
Alternative regimens	None	Tenofovir DF (300 mg) daily, continuing, oral dose, ≤ 90-day supply	
Specific tests/services	Oral/rectal gonorrhea and chlamydia NAAT Syphilis serology	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services
Other services	Every 3 months: HIV antibody and STI screening tests ³ , medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter: Assess renal function (creatinine clearance ≥60 ml/min) Every 3-6 months: Test for bacterial STIs at exposure sites		

¹For MSM: gonorrhea, chlamydia, syphilis; For Heterosexual Men and Women: gonorrhea, syphilis

²Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update: A Clinical Practice Guideline (see Table 1) <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

³Consider HIV RNA testing if acute HIV infection is suspected.

CDC PrEP Index for MSM

The **MSM Risk Index** is a tool that can be used by providers to determine the risk of HIV negative MSM for HIV Infection. The provider simply asks the questions and tallies the amount equated with the responses in the spaces provided. The total score can help providers determine the extent to which HIV negative MSM are at risk and respond accordingly with appropriate services.

Note: A low score does not suggest that an individual should not receive any preventative services

<p>1. How old are you today?</p>	<p>If <18 years, score 0. If 18-28 years, score 8. If 29-40 years, score 5. If 41-48 years, score 2. If 49 years or more, score 0.</p>	<p>_____</p>
<p>2. In the last 6 months, how many men have you had sex with?</p>	<p>If >10 male partners, score 7. If 6-10 male partners, score 4. If 0-5 male partners, score 0.</p>	<p>_____</p>
<p>3. In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man without a condom?</p>	<p>If 1 or more times, score 10. If 0 times, score 0.</p>	<p>_____</p>
<p>4. In the last 6 months, how many of your male sex partners were HIV-positive?</p>	<p>If >1 positive partners, score 8. If 1 positive partner, score 4. If <1 positive partner, score 0.</p>	<p>_____</p>
<p>5. In the last 6 months, how many times did you have insertive anal sex (you were the top) without a condom with a man who was HIV-positive?</p>	<p>If 5 or more times, score 6. If 0 times, score 0.</p>	<p>_____</p>
<p>6. In the last 6 months, have you used methamphetamines such as crystal or speed?</p>	<p>If yes, score 6. If no, score 0.</p>	<p>_____</p>
<p>Add down entries in right column to calculate total score.</p>		<p>_____ TOTAL SCORE*</p>

***If score is 10 or greater, evaluate for intensive HIV prevention services including PrEP.
 If score is below 10, provide indicated standard HIV prevention services.**

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update: Clinical Providers' Supplement
<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>

PrEP Schedule: At a Glance

Clinical Eligibility Visit:

- Assess HIV status – preferably using combination antigen/antibody (4th or 5th generation) test within the week before initiating (or reinitiating) PrEP medications
- Assess for acute retroviral syndrome
 - Consider delaying PrEP for at least 1 month and retesting for HIV if clinical symptoms of acute HIV infection are present and exposures within past month are suspected
- Hepatitis B and C serology
- Estimate creatinine clearance, serum creatinine
 - Determine renal function and test for infection with hepatitis B virus (both decreased renal function and active hepatitis B virus infection are potential safety issues for the use of TDF/FTC as PrEP)
- Baseline screening for STIs (syphilis, gonorrhea, chlamydia)
- Pregnancy test
- Discuss risks vs. benefits of taking PrEP
- Assess for contraindicated medications

Prescribe PrEP for 30 days

30-Day Visit:

- Assess for side effects
- Assess adherence and counsel
- Discuss risk reduction and provide condoms
- Serum creatinine and calculated creatinine clearance for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)

Prescribe 60-day refill; patient must come in for 3-month visit for HIV test and follow-up assessments, then 90 day schedule can begin

3-Month Visit:

- HIV test
- Assess adherence and counsel
- Obtain STI screening tests
 - for sexually active persons with symptoms
 - for MSM with recent bacterial STIs or multiple sex partners
- Serum creatinine and calculated creatinine clearance
- Discuss risk reduction and provide condoms
- Pregnancy test
- Assess for side effects

6-Month Visit:

- HIV test
- Assess adherence and counsel
- Obtain STI screening tests
 - for sexually active persons with symptoms
 - for MSM with recent bacterial STIs or multiple sex partners
- Discuss risk reduction and provide condoms
- Pregnancy test
- Assess for side effects

9-Month Visit:

- HIV test
- Assess adherence and counsel
- Obtain STI screening tests
 - for sexually active persons with symptoms
 - for MSM with recent bacterial STIs or multiple sex partners
- Serum creatinine and calculated creatinine clearance
- Discuss risk reduction and provide condoms
- Pregnancy test
- Assess for side effects
- Evaluate need to continue PrEP

12-Month Visit:

- HIV test
- Assess adherence and counsel
- Obtain STI screening tests
 - for sexually active persons with symptoms
 - for MSM with recent bacterial STIs or multiple sex partners
- HCV serology and serum liver enzymes for MSM, IDUs, and those with multiple sexual partners
- Discuss risk reduction and provide condoms
- Pregnancy test
- Assess for side effects
- Evaluate need to continue PrEP
- Urinalysis

Adapted from NYSDOH AI guidance: www.hivguidelines.org

Clinical Site Checklist

An easy to follow checklist for your clinic and resources for providers and staff

- Clinic is culturally competent to provide care to LGBT population
- Front-desk staff are aware that PrEP is provided and are able to triage patient calls and visits appropriately
- Healthcare providers are willing to prescribe PrEP and have knowledge of:
 - How to take a detailed sexual history
 - PrEP indications
 - PrEP contraindications/considerations
 - PrEP laboratory monitoring and follow up guidelines
- Laboratory capacity for:
 - HIV testing every 3 months
 - Monitoring creatinine clearance every 3-6 months
 - STI screening (chlamydia, gonorrhea, and syphilis) every 6 months, focusing on all anatomical exposure sites
 - Hepatitis B and C screening
 - Pregnancy testing
 - Urinalysis
- Adherence and risk reduction counseling available on-site

Are you PrEPared?

Is your clinic ready to offer PrEP?

The checklist can be a helpful tool to ensure everyone in your clinic is able to deliver the most knowledgeable and appropriate care for each patient. LGBT training links and general PrEP resources can be found at the end of this toolkit.

APPENDIX

6

7

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The 5 "P"s of Sexual Health

1. Partners

Number and gender of partners over a given time

2. Practices

Types of sexual practices – oral, vaginal, anal

3. Protection from STIs

Use of condoms and other methods

4. Past history of STIs

Establish risk of repeat infections, HIV status and hepatitis risk

5. Prevention of pregnancy

Intention of pregnancy and use of prevention methods

Adapted from A Guide to Taking a Sexual History, Centers for Disease Control and Prevention, www.cdc.gov/std/treatment/SexualHistory.pdf 1/2015

Talking about Risk

Any doctor, nurse practitioner, and/or physician assistant can prescribe PrEP. But not all providers are equally familiar with PrEP or HIV. Talking about PrEP means discussing HIV risks including sex and/or drug use. Not all medical providers are at ease with these topics.

Show your patient that you are able to comfortably discuss sexual behavior and/or drug use without judgment; if you cannot, refer the patient to another provider.

Use plain language when discussing sexual behaviors with your patients.

Screening Patients

- Is your primary sexual partner HIV-positive? In other words, are you part of a mixed-status couple?
- Has a man — particularly an HIV-positive man or a man whose status you aren't sure about — penetrated you during vaginal or anal sex without a condom recently?
- Have you been treated recently (last 6 months) for a sexually transmitted infection in your vagina or butt, such as gonorrhea?
- Have you used post-exposure prophylaxis (PEP) more than once within the past year?
- Have you been in prison; or, has your sex partner(s)?
- Do you use drugs and alcohol heavily; or, does your sex partner(s)?
- Do you have to exchange sex for money, housing or other needs; or, does your sex partner(s)?
- Has your partner threatened you with violence or physically harmed you recently?
- Are you in a mixed status relationship and one of you is trying to have a baby?

From http://www.projectinform.org/pdf/prepbooklet_provider.pdf

Beginning PrEP

All patients whose sexual or drug injection history indicates consideration of PrEP and who are interested in taking PrEP must undergo laboratory testing to identify those for whom this intervention would be harmful or for whom it would present specific health risks that would require close monitoring.

Counseling: Is PrEP Right for You?

Establish trust and 2-way communication

Provide feedback on HIV risk factors identified during sexual and substance use history taking

- Elicit barriers to, and facilitators of, consistent condom use
- Elicit barriers to, and facilitators of, reducing substance abuse

Support risk-reduction efforts

- Assist patient to identify 1 or 2 feasible, acceptable, incremental steps toward risk reduction
- Identify and address anticipated barriers to accomplishing planned actions to reduce risk

Monitor behavioral adherence in a non-judgmental manner

- Acknowledge the effort required for behavior change
- Reinforce success
- If not fully successful, assess factors interfering with completion of planned actions and assist patient to identify next steps

Provide simple explanations and education

- Medication dosage and schedule
- Management of common side effects
- Relationship of adherence to the efficacy of PrEP
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence

- Tailor daily dose to patient's daily routine
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence

Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence

From <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>
<http://www.siecus.org>

Clinical Trial Findings

The Partners PrEP Trial

- In one clinical trial of Truvada for a PrEP indication in serodiscordant (mixed-status) couples, Truvada was shown to reduce HIV-1 infection acquisition by 75% for the uninfected individuals exposed to the virus through heterosexual sex
- In a post hoc case control study of plasma drug levels in about 10% of clinical trial subjects, risk reduction appeared to be the greatest in subjects with detectable plasma tenofovir. Efficacy was therefore strongly correlated with adherence

Baeten J, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women N Engl J Med. 2012;367:399-410

The iPrEx Trial

- In another clinical trial of Truvada for a PrEP indication, Truvada was shown to reduce the risk of HIV-1 infection acquisition by 44% for high risk men who have sex with men
- In a post hoc case control study of plasma and intracellular drug levels in about 10% of clinical trial subjects, risk reduction appeared to be the greatest in subjects with detectable intracellular tenofovir. Efficacy was therefore strongly correlated with adherence
- Self-reported risk behavior among the subjects in this clinical trial declined overall during the trial, both in terms of decreases in the number of sexual partners and increases in condom use

Grant RM, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010 Dec 30;363(27):2587-99

Common PrEP Questions

How long does it take before it starts to work?

- When taken every day, PrEP is safe and highly effective in preventing HIV infection. PrEP reaches maximum protection from HIV for receptive anal sex at about 7 days of daily use. For all other activities, including insertive anal sex, vaginal sex, and injection drug use, PrEP reaches maximum protection at about 20 days of daily use.

What is the follow-up schedule?

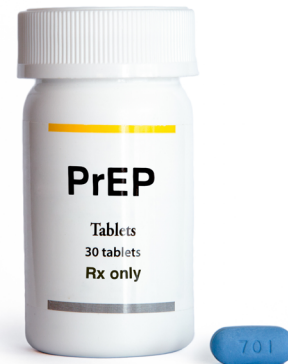
- Every 3 months: repeat HIV test, prescription refill, assess side effects and adherence, and obtain STI tests for sexually active person with symptoms and for asymptomatic MSM at high risk for recurrent bacterial STIs (e.g. those with recent bacterial STIs or multiple sex partners).
- Every 6 months: monitor kidney function.

How often must PrEP be taken?

- PrEP must be taken daily for it to work.

Is PrEP forever?

- If the patient's risk of acquiring HIV infection becomes low, they may want to stop PrEP. Evaluate need to continue PrEP at least annually.
- If PrEP is discontinued, document the following: HIV status and recent sexual risk behavior at the time of discontinuation, the reason for discontinuation, and recent adherence to medication.



CLIENT QUESTIONS ABOUT PrEP AND DOCTORS

Deciding to use PrEP is an important decision that requires the patient to think about one's own needs and how best to work with a medical provider. The document at the link below gives patients three sets of questions: (A) Questions to help decide if PrEP is right; (B) Questions about special issues; and (C) Questions to help assess provider knowledge and patient comfort discussing PrEP about with your provider. Clients can review it, and take the sheet into a visit as a reminder of things they might want to talk to the provider about when contemplating or obtaining PrEP.

https://www.aidsunited.org/data/files/Site_18/PrEP/questions.pdf

¹Obtain STI screening tests for sexually active persons with symptoms and for asymptomatic MSM with recent bacterial STIs or multiple sex partners

Resources

PROVIDER

CDC PrEP Clinical Providers' Supplement

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>

CDC PrEP Clinical Practice Guideline

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

AIDS.gov

<https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/>

What is PrEP?

<http://www.whatisprep.org/>

Truvada package insert

http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_pi.PDF

Prescribing PrEP – Provider PrEP Educational Training Video (AltaMed)

<https://youtu.be/WQ0cH7MCB3Y>

PrEP Watch

<http://www.prepwatch.org/about-prep/prep-resources/>

LGBT Health

<https://www.lgbthealtheducation.org/lgbt-education/webinars/>

Glossary of LGBT Terms for Healthcare Teams

<https://www.lgbthealtheducation.org/publication/lgbt-glossary/>

HIV and STI Prevention Strategies for Gay/Bisexual Men and Transgender People in Primary Care

<https://www.lgbthealtheducation.org/lgbt-education/online-courses/neaetc2014/>

Providing Inclusive Services and Care for LGBT people

<https://www.lgbthealtheducation.org/learning-module/providing-quality-care-lesbian-gay-bisexual-transgender-patients-introduction-staff-training/>

Online Learning: Acknowledging Sex and Gender

http://transhealth.ucsf.edu/video/story_html5html?lms=1

PATIENT

My PrEP Experience - Real stories by readers of their own experiences, in text, audio, and video files.

<http://myprepexperience.blogspot.com/>

Project Inform - videos and stories about the PrEP experience

<https://www.projectinform.org/>

PrEP Facts

<https://men.prepfacts.org/the-basics/>

PrEP Facts: Rethinking HIV Prevention and Sex (Facebook group, closed)

<https://www.facebook.com/groups/PrEPFacts/permalink/692805047505330/>

Prepared by The HIV/Bloodborne Pathogen (BBP) Threat Reduction Program, executed with U.S. Military HIV Research Program (MHRP) and Infectious Disease (ID) and Preventive Medicine (PM) leads from the Services.

All information herein is as of May 4, 2018