

**Hawai'i Department of Health, STD/AIDS Prevention Branch  
PrEP Guidelines**

**May 2015**

The State of Hawai'i Department of Health STD/AIDS Prevention Branch recommends the addition of PrEP to establish, evidence-based interventions for the prevention of HIV transmission.

Pre-Exposure Prophylaxis (PrEP) is a new method to help prevent the transmission of the human immunodeficiency virus (HIV) to uninfected people by daily taking a pill. In July 2012, the U.S. Food and Drug Administration (FDA) approved the once a day, combination pill emtricitabine/tenofovir disoproxil fumarate (Truvada®) for use as PrEP in adults who did not have HIV and met other criteria for its use.

In May 2014, the U.S. Public Health Service (USPHS) released the first comprehensive clinical practice guidelines for PrEP. These guidelines were developed by a federal inter-agency working group led by the U.S. Centers for Disease Control and Prevention (CDC), and reflect input from providers, HIV patients, partners and affected communities:

- Centers for Disease Control and Prevention. CDC, (2014). *US Public Health Service Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 A Clinical Practice Guideline*. <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>
- Centers for Disease Control and Prevention. CDC, (2014). *US Public Health Service Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 Clinical Providers' Supplement*. <http://www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf>

The State of Hawai'i Department of Health along with CDC recommends the **addition of PrEP for people who are at ongoing substantial risk of HIV infection**. PrEP works best against HIV-infection with daily adherence. Because no prevention strategy for sexually active people is 100% effective, patients taking PrEP are encouraged to use other effective prevention strategies to maximally reduce their risk, including:

- Using condoms consistently and correctly
- Getting HIV testing with partners
- Choosing less risky sexual behaviors, such as oral sex
- For people who inject drugs, getting into drug treatment programs and using sterile equipment. Visit The CHOW Project for more information: <http://www.chowproject.org/>

We looked to the successful model laid out by the New York State Department of Health AIDS Institute (NYSDOH AI) in the *Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission* to ensure inclusion of essential information for providers. Additional useful resources can be found at the [New York State Department of Health AIDS Institute](#) and via the following reference:

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- New York State Department of Health AIDS Institute. New York State Department of Health AIDS Institute (NYSDOH AI), (2014). *Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) To Prevent HIV Transmission*. [http://www.hivguidelines.org/wp-content/uploads/2015/03/PrEP-Guidance\\_3-27-15.pdf](http://www.hivguidelines.org/wp-content/uploads/2015/03/PrEP-Guidance_3-27-15.pdf)

**Post-Exposure Prophylaxis (PEP)** is another HIV prevention method that is different than PrEP and works by taking anti-HIV medications immediately after exposure to HIV, rather than before exposure. PEP works to reduce the chance of becoming HIV-infected after exposure to the virus by keeping HIV from making copies of itself and spreading through the body.

More information on PEP may be accessed via this link:

<http://www.cdc.gov/hiv/basics/pep.html>

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**Key Principles for Prescribing PrEP**

- **PrEP should be prescribed as part of a comprehensive prevention plan in combination with condoms and risk reduction counseling, among other appropriate prevention tools including regular screenings for STDs**
  - **PrEP is indicated for HIV negative individuals who are at ongoing risk for acquiring HIV**
  - **PrEP may offer protection to HIV negative partners in sero-discordant relationships (where one partner is HIV positive and another partner is HIV negative) during attempts to conceive**
  - **Efficacy of PrEP is highly dependent on adherence**
  - **PrEP is contraindicated in individuals with documented HIV-infection or creatinine clearance <60 mL/min, and in those who are not ready to adhere to daily PrEP**
  - **The first prescription of PrEP should only be for 30 days**
  - **Regular patient visits and laboratory tests, at least every three months, are required to monitor HIV status, adherence and side effects**
  - **If patient presents with acute HIV infection, an HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay**
  - **Discontinuation of PrEP should be immediate for patients who receive a reactive or positive HIV test result**
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**PrEP Information Sheet**

**General Information**

- The goal of PrEP is to prevent HIV-infection if exposure to the virus occurs. This is accomplished with daily adherence to one pill that contains two HIV medications (the same medicines used to stop the virus from multiplying in people who are already infected).
- Since the HIV epidemic in the U.S. continues to be a persistent public health problem, PrEP can serve as an essential component of a comprehensive prevention plan to help decrease the high burden of HIV-infection.
- Unlike a vaccine, PrEP must be used continuously to effectively prevent infection.
- Medical providers prescribe PrEP for some patients who have a very high-risk of infection from high-risk behaviors that expose them to HIV.

**Evidence-Based Practice**

Several studies showed that PrEP significantly reduced the risk of acquiring HIV infection.

- Men who have sex with men (MSM) who were given PrEP medication were 44% less likely to acquire HIV than were those men who took an inactive pill (placebo). Forty-four percent was an average that included men who did not adhere to the medicine every day and those who did. Among men who reported they took most of their daily doses, PrEP reduced the risk of HIV-infection by 73% or more, and up to 92% for some.
- Among heterosexual couples who were HIV sero-discordant, those negative partners who received PrEP were 75% less likely to become infected with HIV than those who took an inactive pill (placebo). Among those who stated daily adherence to the medication, PrEP reduced the risk of acquiring HIV-infection by up to 90%.
- PrEP safety has also been evaluated in clinical trials. Early side effects such as upset stomach or loss of appetite are common among some. These mild side effects usually subside after one month. Mild headaches were also reported. No serious side effects were observed. All symptoms and persisting symptoms should be reported to a medical provider.

**Expectations from Interested PrEP candidates**

- Anyone who believes they are at risk for contracting HIV should discuss PrEP with their medical provider to determine if they are candidates for PrEP. If the medical provider agrees that PrEP might reduce the individual's risk of HIV infection, the medical provider will order tests, including blood tests for HIV and other infections that may be contracted from sexual partners and blood tests to evaluate kidneys and liver function. If these tests show that PrEP medicines are likely to be safe for a patient to use and that patient would benefit from PrEP, the medical provider may prescribe PrEP after discussing it with patient.
- Duration of PrEP regimen should be discussed with a medical provider. There are several reasons why individuals may want to discontinue PrEP. If the patient's risk of acquiring HIV-infection is reduced because of behavioral changes, the patient may elect to stop taking PrEP. If the patient finds it difficult to adhere to a daily pill, other methods of HIV prevention may be more effective. If side effects are interfering with

the patient's daily life or if blood tests show that patient is reacting to PrEP in potentially unsafe ways, the medical provider may stop prescribing PrEP.

- Taking PrEP medicines will require regular follow-up with a medical provider. Follow-up appointments should include continued counseling on sexual behaviors, blood tests for HIV-infection and for potential medication side-effects. The medical provider should advise the patient about methods to ensure the patient regularly adheres to PrEP in order to provide the best protection against HIV infection. The medical provider should be receptive to consulting with the patient should the patient experience difficulty remembering to take their medicine or if they want to stop PrEP.

#### **Key Protocols for Medical Providers**

- A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given. Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available (preferably with a 4<sup>th</sup> Generation HIV test or an RNA HIV viral load test) to prevent against prescribing PrEP to individuals with acute infection.
- The first prescription of PrEP (Truvada®1 tablet by mouth daily) should be for 30 days only, to ensure a follow-up visit to assess adherence, tolerance, and commitment. At the 30-day visit, a prescription for 60 days may be given. The patient should return three months after starting Truvada® for an HIV test and other laboratory tests. Prescriptions can be given subsequently for 90 days, provided that the patient is adherent.
- Follow-up and monitoring of clients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, STI screening, and mental health and substance abuse screening, when indicated. PrEP should not be offered as a sole intervention for HIV prevention. As part of a comprehensive prevention plan, PrEP should be prescribed in combination with condoms. If PrEP is adhered to daily, it offers significant protection against HIV infection, but it does not offer 100% protection. If condoms are used correctly and consistently, they too offer significant protection against HIV but condoms also do not guarantee 100% protection. PrEP medications do not provide protection against other sexually transmitted infections, but condoms do. Thus, the best protection from HIV and other sexual infections is dependent on daily adherence to PrEP and consistent condom use in addition to other prevention strategies, including but not limited to dental dams and lower risk sexual behaviors.
- Although consistent condom use is a critical part of an HIV prevention plan for all people prescribed PrEP, lack of use of barrier protection is not a contraindication to PrEP.

In addition to this information, refer to Section 1, Patient/Provider Checklist of the *PrEP-Clinical Provider's Supplement* (reference 2).

**The subsequent sections include information on the following:**

- Potential Candidates for PrEP
- Contraindications to PrEP
- Important considerations when prescribing PrEP

In addition, Table 4 Pre-Prescription: Assessment Checklist of the *New York State Guidance for the Use of PrEP to Prevent HIV Transmission* (reference 3) should be consulted.

**I. Potential Candidates for PrEP**

Medical providers should consider discussing PrEP with the following HIV-uninfected individuals who have substantial and ongoing risk for acquiring HIV:

- MSM who engage in unprotected anal intercourse
- Individuals in a sero-discordant sexual relationship with a known HIV-infected partner
- Transgender individuals (male-to-female and female-to-male) engaging in high-risk sexual behaviors
- Individuals engaging in transactional sex (e.g. sex for money, drugs or housing)
- Injection drug users (IDU) who engage in the following high-risk behaviors: sharing injection equipment, injecting one or more times daily, injecting cocaine or methamphetamine, engaging in high-risk sexual behaviors
- Individuals who use stimulant drugs associated with high-risk behaviors, such as methamphetamine
- Individuals diagnosed with more than one anogenital sexually transmitted infection in the last year
- Individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) who demonstrate continued high-risk behavior or have used multiple courses of nPEP

**II. Contraindications to PrEP**

Efficacy of PrEP is heavily dependent on adherence to the medication. Adherence is important to ensure that plasma drug levels reach a protective level. Lack of readiness or willingness to adhere to a daily PrEP regimen is a contraindication.

- Medical contraindications include:
  - **Documented HIV infection.** Drug-resistant HIV has been identified in patients with undetected HIV who subsequently received TDF/FTC for PrEP

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- **Creatinine clearance <60 mL/min.** Any person with an eCrCl of <60 ml/min should not be prescribed PrEP with TDF/FTC. This can be determined by means of a serum creatinine test.

**III. Important Considerations when Prescribing PrEP**

The following considerations should be reviewed when prescribing PrEP. The following are not absolute contraindications to prescribing PrEP. Medical providers should carefully consider these factors and proceed with caution:

- Chronic active hepatitis B Virus (HBV) infection
  - Although not FDA-approved for the treatment of HBV, the medication used for PrEP (TDF/FTC) is active against HBV infection and can be used as treatment for HBV infection and as PrEP.
  - Due to the concern over rebound viremia, discontinuation of TDF/FTC requires close monitoring in patients with chronic hepatitis B infection.
- Pregnant patient or attempting to conceive
  - During attempts to conceive, PrEP may be one of several options to protect the HIV seronegative partner from acquiring HIV-infection in a sero-discordant relationship.
  - Refer to Table 3 and bottom of Table 5 of the *New York State Guidance for the Use of PrEP to Prevent HIV Transmission* (reference 3) for detailed information on known risks and benefits of taking TDF/FTC during pregnancy.
- Continued STD Screening
  - Regular screening for STDs such as syphilis, gonorrhea and chlamydia should be conducted based on risk.
- Drug Interactions
  - A thorough medication history should be obtained to determine if the patient is taking any concomitant nephrotoxic drugs or drugs that have interactions with TDF/FTC.
- Bone loss risk in patients with osteopenia/osteomalacia/osteoporosis
  - There may be a risk of bone loss associated with tenofovir. This risk should be discussed with individuals with pre-existing risk factors or demonstrated osteopenia/osteomalacia/osteoporosis.
- Time to achieving protection
  - The time from initiation of daily oral doses of TDF/FTC to maximal protection against HIV-infection has not been thoroughly investigated. Exploratory pharmacokinetic studies conducted with HIV-uninfected men and women provides preliminary data on the lead-time required to achieve steady state levels of tenofovir diphosphate (TFV-DP, the activated form of the medication) in peripheral blood mononuclear cells, rectal, and vaginal tissues. These data suggest that maximum intracellular concentrations of TFV-DP are reached in blood after approximately 20 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervicovaginal tissues at approximately 20 days.



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Refer to page 37 of *PrEP- A Clinical Practice Guideline* (reference 1) for more detailed information.

**References:**

1. Centers for Disease Control and Prevention. CDC, (2014). *US Public Health Service Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 A Clinical Practice Guideline*. Retrieved from website:  
<http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>
2. Centers for Disease Control and Prevention. CDC, (2014). *US Public Health Service Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2014 Clinical Providers' Supplement*. Retrieved from website:  
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3. New York State Department of Health AIDS Institute. New York State Department of Health AIDS Institute (NYSDOH AI), (2014). *Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) To Prevent HIV Transmission*. Retrieved from website:  
[http://www.hivguidelines.org/wp-content/uploads/2015/03/PrEP-Guidance\\_3-27-15.pdf](http://www.hivguidelines.org/wp-content/uploads/2015/03/PrEP-Guidance_3-27-15.pdf)