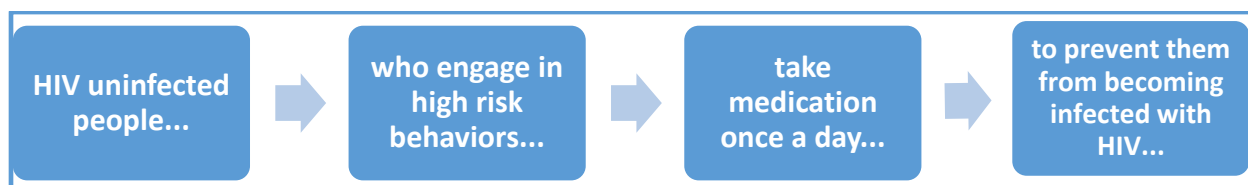


What Support Services Providers Should Know About HIV Clinical Guidelines: Improving Health Outcomes Series

New York State Department of Health AIDS Institute

TOPIC: Pre-exposure Prophylaxis to Prevent HIV Infection

KEY POINT: WHAT IS PrEP?



BACKGROUND

Pre-exposure prophylaxis (PrEP) is a common practice in which medication is provided to a healthy person in order to prevent an unwanted health condition or illness. In PrEP for HIV, an uninfected person who engages in high risk behaviors is provided a prescription for antiretroviral medications to prevent him or her from becoming infected with HIV. In July 2012, the Food and Drug Administration (FDA) approved the use of tenofovir + emtricitabine (TDF/FTC), commonly known as Truvada, for HIV PrEP in adults who are at high risk for becoming HIV-infected. Clinical trials found PrEP for HIV to be safe and four trials found PrEP to be effective for preventing HIV infection when taken as prescribed.

Common Examples of Pre-Exposure Prophylaxis

It may seem unusual to give medication to a healthy person, but here are some common examples:

1. A woman taking birth control pills to prevent pregnancy;
2. A traveler taking anti-malaria medications when going to an area where there is high likelihood of exposure to malaria;
3. A person taking antibiotics prior to dental surgery to prevent infection;
4. A person with HIV taking certain medications to prevent an opportunistic infection.

THE ROLE OF NON-CLINICAL PROVIDERS IN PROMOTING PrEP

Nonclinical providers can play an important role in promoting appropriate use of PrEP by:

1. Discussing PrEP with clients who engage in on-going high risk activities and referring these clients to a health care provider that prescribes PrEP;
2. Reinforcing the importance of treatment adherence to clients taking PrEP;
3. Working as part of a team to provide condoms, behavioral counseling, STI screening and HIV testing to clients who are taking PrEP;
4. Educating clients that PrEP does not offer protection against other STIs and reinforcing the importance of condom use;
5. Educating clients who receive a confirmed positive HIV test that they should discontinue PrEP immediately and get into HIV clinical care.

PrEP: PART OF A COMPREHENSIVE PREVENTION PLAN, INCLUDING HIV TESTING

The NYS PrEP Guidance and FDA guidelines indicate that PrEP should be one component of a comprehensive HIV prevention plan that includes counseling about the following:

1. Consistent and correct condom use to avoid STIs;
2. Safer sex practices and risk-reduction options;
3. Frequent screening for sexually transmitted infections;
4. Mental health and substance use screening, when indicated.

Overview of Clinical Guidelines

PrEP is only for clients with a documented negative HIV test result. A negative HIV test result needs to be confirmed, ideally, on the same day the prescription for PrEP is given. HIV testing is repeated every three months.

Schedule of Medical Appointments and HIV Testing

- **Initial:** HIV testing; PrEP is provided for only 30 days
- **One Month:** Assess patient adherence, tolerance, and commitment; A prescription for 60 days may be given;
- **Three Months:** HIV testing and other assessments; prescription for 90 days if HIV negative and adherent;
- **Every Three Months:** HIV testing and other assessments repeated every three months; prescription for 90 days if HIV negative and adherent.

Other Important Facts

- PrEP should be discontinued immediately for patients who receive a positive HIV test result;
- Clients on PrEP who are in an on-going relationship with a person living with HIV should be educated about the importance of HIV treatment for the HIV-infected partner because this treatment will also help reduce the likelihood of passing the virus to the client on PrEP;
- Although consistent condom use is a critical part of a prevention plan, lack of use of barrier protection should not be a reason to deny a client PrEP.

Who is Eligible for PrEP?

- Men who have sex with men (MSM) who engage in unprotected anal intercourse.
- Individuals who are in a sexual relationship with a partner known to have HIV.
- Male-to-female and female-to-male transgender individuals engaging in high-risk sexual behaviors.
- Individuals who trade sex for money, drugs or housing.
- Injection drug users who share injection equipment.
- Individuals who use stimulant drugs associated with high-risk behaviors, such as methamphetamine.
- Individuals diagnosed with more than one 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.

PrEP requires consistency and adherence to be effective. PrEP should only be prescribed to patients who are willing and able to adhere to it. Clients on PrEP should never start and stop taking the medication based on when they anticipate engaging in risky behavior. **It is not known how long before or after an exposure PrEP must be taken to be effective.**

Clients should consult with the clinician about how to discontinue PrEP.

For information about PrEP visit: <http://www.health.ny.gov/publications/0265/>

To access a copy of the NYS PrEP guidance document, visit: www.hivguidelines.org

ASSISTANCE WITH PAYING FOR PREP

The NYSDOH provides up to date information about programs available to assist clients with the full range of expenses associated with PrEP. For information, visit <https://www.health.ny.gov/diseases/aids/general/prep/#prep> and scroll to the heading “Addressing the Cost”.

PROVIDERS REIMBURSED UNDER PrEP ASSISTANCE PROGRAM (PrEP-AP)

The NYSDOH Pre-exposure Prophylaxis Assistance Program (PrEP-AP) now reimburses health care providers for the costs associated with providing health care and laboratory services associated with PrEP to uninsured or under-insured patients.

These services include, but are not limited to: patient visits for PrEP; HIV testing; STD testing; and supportive care services consistent with New York State’s HIV Clinical Guidelines: www.hivguidelines.org/PrEP

Enrolled providers can submit claims for the covered services provided to these PrEP-AP patients and will be reimbursed based on Medicaid primary care fee-for-service rates. Providers will be also responsible for helping patients apply to the drug manufacturer’s patient assistance program to cover the cost of the medication.

For more information about how health care providers can participate in PrEP-AP, call 1-800-542-2437.