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New Pre-exposure Prophylaxis Recommendations for the Prevention of HIV Infection

Background

Pre-exposure prophylaxis (PrEP) is a new strategy for HIV prevention in which HIV-negative individuals take a daily antiretroviral (ARV) medication to reduce their risk of acquiring HIV infection. Truvada®, a daily fixed-dose combination of 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine (TDF/FTC), was approved for PrEP in 2012 by the U.S. Food and Drug Administration (FDA). It should be used in combination with safer sex practices. On May 14, 2014, the Centers for Disease Control and Prevention (CDC) released the first comprehensive clinical practice guidelines for PrEP.¹

Medication adherence is critical to achieving the maximum benefit. When taken daily as directed, PrEP reduces the risk of HIV infection by more than 90%.¹ Inconsistent use of PrEP medication results in much lower levels of protection. The guidelines provide key components for adherence counseling.

Some commercial insurance and employee benefits programs offer coverage of PrEP; public insurance plans vary in their coverage policies, and the drug manufacturer for Truvada® will provide patient assistance for the medication.

Indications for PrEP

The new guidelines recommend that PrEP be considered for the following HIV-negative persons:

- anyone who is in an ongoing sexual relationship with an HIV-infected partner;
- gay, bisexual or other men who have sex with men who have had sex without a condom, or have been diagnosed with a sexually transmitted disease (STD) within the past 6 months, and are not in a mutually monogamous relationship;
- heterosexual men and women who do not always use condoms when having sex with partners known to be at risk for, or infected with, HIV; and
- anyone who has injected illicit drugs in the past 6 months.¹

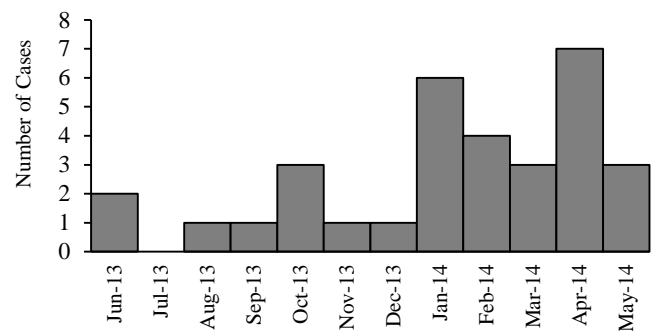
Maximizing the public benefit of PrEP depends largely on clinicians successfully identifying persons at-risk for HIV infection, which requires routinely taking sexual and Injection Drug Use (IDU) histories on patients. Such histories should include the number of sexual partners the patient has had in the past 6 months, the gender of their partners, the number of sexual encounters without a condom and encounters with persons known to be HIV-infected, and IDU. Surveys indicate that patients do not often disclose same-sex or IDU behaviors without health care providers specifically requesting this

information. Additional sexual history questions are available in the CDC guidelines.¹ The CDC guidelines also recommend that specific laboratory testing be performed on all patients prior to initiation of PrEP in order to identify persons for whom this intervention would be harmful or for whom it would present specific health risks that require close monitoring.¹

Increase in HIV Case Reports in 2014

In 2013, 24 cases of HIV infection were diagnosed in Alaska and reported to the Section of Epidemiology (SOE).² From January 1 through May 31, 2014, 23 cases of HIV infection have already been diagnosed in Alaska and reported (Figure).

Figure. Newly Diagnosed HIV Cases, by Month — Alaska, June 2013 through May 2014



Of the 23 persons newly diagnosed with HIV in 2014,

- 20 (87%) were in men, of whom, 12 (52%) self-identified as men who have sex with men (MSM);
- 8 (35%) were aged ≤25 years (7 of the 8 were MSM);
- 8 (35%) reported having sex with anonymous partners that they met online or through the use of mobile phone applications (all 8 were MSM); and
- 5 (22%) were co-infected with chlamydia or gonorrhea.

Many of the newly diagnosed persons in 2014 had identified risk factors that would have warranted PrEP, including having multiple sexual partners, having an HIV-infected sexual partner, having a recent infection with a bacterial STD, or having inconsistent condom use.¹

References

1. CDC. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States, 2014 – A Clinical Practice Guideline. Available at: <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>
2. Alaska Epidemiology *Bulletin*. “Summary of HIV Infection–Alaska, 1982–2013. No. 5 April 17, 2014. Available at: http://www.epi.alaska.gov/bulletins/docs/b2014_05.pdf

Table. Summary of Guidance for PrEP¹

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting persons at increased risk for acquiring HIV infection	<ul style="list-style-type: none"> ○ HIV-positive sexual partner ○ Recent bacterial STD ○ High number of sex partners ○ History of inconsistent or no condom use ○ Commercial sex work 	<ul style="list-style-type: none"> ○ HIV-positive sexual partner ○ Recent bacterial STD ○ High number of sex partners ○ History of inconsistent or no condom use ○ Commercial sex work ○ In high-prevalence area or network 	<ul style="list-style-type: none"> ○ HIV-positive injecting partner ○ Sharing injection equipment ○ Recent drug treatment (but currently injecting)
Persons who are clinically eligible for PrEP	<ul style="list-style-type: none"> ○ Documented negative HIV test result before prescribing PrEP ○ No signs/symptoms of acute HIV infection ○ Normal renal function; no contraindicated medications ○ Documented hepatitis B virus infection and vaccination status 		
Prescription	A daily, continuing, oral, fixed-dose combination of 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine (Truvada®), ≤90-day supply		
Other services	<ul style="list-style-type: none"> ○ At least every 3 months provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment ○ At 3 months and every 6 months thereafter, assess renal function ○ Every 6 months, test for bacterial STDs 		
	Do oral/rectal STD testing	<ul style="list-style-type: none"> ○ Assess pregnancy intent ○ Pregnancy test every 3 months 	Access to clean needles/syringes and drug treatment services