KAISER PERMANENTE

HIV (Human Immunodeficiency Virus) Screening and Pre-Exposure Prophylaxis (PrEP) Guideline

Last guideline approval: November 2013

Guidelines are systematically developed statements to assist patients and providers in choosing appropriate health care for specific clinical conditions. While guidelines are useful aids to assist providers in determining appropriate practices for many patients with specific clinical problems or prevention issues, guidelines are not meant to replace the clinical judgment of the individual provider or establish a standard of care. The recommendations contained in the guidelines may not be appropriate for use in all circumstances. The inclusion of a recommendation in a guideline does not imply coverage. A decision to adopt any particular recommendation must be made by the provider in light of the circumstances presented by the individual patient.

Background

Of the approximately 1.2 million people living with HIV (human immunodeficiency virus) in the United States, 20–25% are unaware that they are infected. In Washington State, about 12,000 people are living with HIV, 10–20% of whom do not know their HIV status.

Early diagnosis of HIV infection not only reduces the risk of morbidity and mortality in affected individuals, it also reduces the risk of HIV transmission to others.

Screening Recommendations

Table 1. Screening for HIV
The HIV screening test for all populations is a fourth-generation antigen and antibody combo assay with reflex to the confirmatory HIV-1/HIV-2 and RNA viral load tests.

Eligible population	Frequency
General population (ages 15 through 64)	One time
Adolescents and adults at increased risk	Use clinical judgment: • For patients with frequent exposure to HIV risks, every 3–6 months • For patients with occasional exposure to HIV risks, consider screening at least annually (See the "Indications for Periodic HIV Screening" section on page 3.)
Pregnant women	• At first prenatal visit for each pregnancy • For women at high risk of STIs, consider also testing in 3rd trimester (For women presenting in labor without prior testing, use rapid HIV screening test.)

For additional information on HIV screening, contact the HIV/PrEP Program at 206-326-3609.

HIV Test Ordering and Consent

Use **HIV screening test** to order the test in Epic, and consider ordering **STD LAB PANEL (FEMALE)** or **STD LAB PANEL (MALE)** as well.

> **Note:** Patients who are at increased risk for HIV infection are also at increased risk for other sexually transmitted infections (e.g., gonorrhea, chlamydia, syphilis) and for hepatitis B and hepatitis C, so consider screening for those at the same time. Patients must be screened at all exposed sites, so consider using rectal and/or oral swabs if appropriate.

Patients must be informed—verbally or in writing—that a test for HIV will be done. In Epic, the order includes an alert that asks, "HIV test discussed with pt, pt agrees, has plan to get results?" A yes response is required for the order to be placed.

Written consent is **NOT** a requirement for an HIV test. Patient consent can be part of the consent for multiple routine tests, as long as the patient is specifically informed that an HIV test is included.

Note that adolescents aged 14–17 years do **NOT** need parental consent to be screened for HIV and other STIs.

Clinicians ordering HIV tests must also offer an opportunity for patients to decline testing. If a patient chooses not to have the test, use the SmartPhrase **.hivdeclined** in Epic to document his/her decision.

Establish with the patient ahead of time how the HIV test result will be communicated. For a positive or indeterminate result, face-to-face notification is encouraged but not required. For a negative result, the following options are available:

- Use the SmartPhrase **.hivresultnegativetelephone** to document a phone encounter.
- Use the SmartPhrase **.hivresultnegative** for a secure e-mail.
- The same text that is in the SmartPhrase .hivresultnegative is automatically attached to the negative result posted in the Lab & Test Results section.

Indications for Periodic HIV Screening

- Men who have sex with men (MSM). [High risk of HIV infection]
- Men and women having unprotected vaginal or anal intercourse with more than one partner. [High risk]
- Men and women who exchange sex for drugs or money. [High risk]
- People with a history of or current illicit drug use. [High risk]
- People seeking treatment for other STIs. [High risk]
- People whose past or current sex partners are HIV-infected, bisexual, or illicit drug users. [High risk]
- People who do not report one of these risk factors but who request HIV testing.
- People who have medical procedures, injections, or blood transfusions in countries without sterile standard techniques.
- People who are uncertain about a sexual partner's risk behaviors.
- People with 3 or more sexual partners in the past year.

Referrals

Western Washington
Refer all Western Washington patients with confirmed positive HIV test results to the HIV/PrEP Program. In Epic, type **Ref HIV** to pull in the referral automatically. Positive HIV patients—both newly diagnosed and new to Kaiser Foundation Health Plan of Washington—are reported to public health by the HIV/PrEP Program.

The **HIV/PrEP Program** coordinates the care of HIV-positive patients within Western Washington clinics. The program assists with referrals to HIV providers; talks with newly positive patients, and provides educational and resource tools for them and for providers; assists with insurance and financial issues; and monitors standard quality measures for HIV care.

Eastern Washington and Idaho
In Eastern Washington and Idaho, refer patients with confirmed positive HIV test results to one of the contracted Infectious Disease specialists. (Care for HIV patients in Eastern Washington and Idaho is not currently centralized.) Contracted Infectious Disease specialists report out to their respective county health departments.

Follow-up and Monitoring

Individuals with risk factors for HIV infection should receive the following:

- Immunizations for hepatitis A and hepatitis B.
- Encouragement to use condoms consistently and to avoid sexual risk behaviors.
- Encouragement to use clean needles/works, if they are injection drug users.

HIV Pre-Exposure Prophylaxis (PrEP)

Patients who are HIV-negative but who are at high risk of HIV infection should have a conversation with their provider about pre-exposure prophylaxis (PrEP).

PrEP is an HIV prevention method in which patients take daily medication—a combination of the antiretroviral drugs emtricitabine and tenofovir—to reduce their risk of becoming infected, along with several other risk-reduction activities. Evidence has shown that when used consistently, PrEP can reduce the risk of HIV infection among adults at high risk of becoming infected through sex and injection drug use.

As part of shared decision making on whether or not to use PrEP, clinicians and patients must have a frank discussion about patient drug use, condom use, sexual risk behaviors, and possible side effects of PrEP. Patients also must understand that PrEP is only one part of an overall HIV prevention strategy.

Good candidates for PrEP can commit to the following criteria:

- Daily adherence to PrEP. Adherence is critical to reduce the risk of HIV infection.
- Adherence to lab monitoring requirements. See the PrEP Prescribing Protocol on the staff intranet for details.
- Open dialog with providers about risk behaviors.

For more information about PrEP, see the Centers for Disease Control and Prevention fact sheet and the PrEP Prescribing Protocol on the staff intranet for details.

A patient handout on PrEP is also available as the AVS SmartPhrase **.avsprepforhivexposure**.

Order **Ref PrEP** in Epic for any patients interested in PrEP. Please order **Ref PrEP** for any patients who are already on PrEP or will be starting it. The PrEP program monitors all patients on PrEP. Call the program at 206-326-3609 with any questions.

Evidence Summary

To develop the HIV Screening and Pre-Exposure Prophylaxis Guideline, the guideline team:

- Adapted recommendations from the following externally developed evidence-based guidelines:
  - U.S. Preventive Services Task Force (USPSTF). Screening for HIV: U.S. Preventive Services Task Force recommendation statement. 2013.
  - Centers for Disease Control and Prevention (CDC). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. 2006.
- Reviewed additional evidence using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis.

Pre-Exposure Prophylaxis (PrEP)

PrEP is an HIV prevention method in which people who do not have HIV take a daily pill to reduce their risk of becoming infected. For some individuals at high risk for HIV infection, PrEP may represent a much-needed additional prevention method, but it will not be right for everyone and is not intended to be used in isolation but, rather, in combination with other methods to reduce the risk of HIV infection. If it is delivered effectively and targeted to those at highest risk, PrEP may play a role in helping to reduce the significant continuing toll of new HIV infections in the United States.

Men who have sex with men (MSM)

A multinational, randomized, double-blind, placebo-controlled, phase 3 clinical trial evaluated using the antiretrovirals tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) to prevent the acquisition of HIV infection among uninfected but exposed MSM. Results indicated that TDF plus FTC taken orally once a day is safe and partially effective in reducing HIV acquisition among MSM when provided with regular monitoring of HIV status and ongoing risk-reduction and PrEP medication–adherence counseling. Results from the trial showed that participants randomized to the PrEP arm experienced a 44% reduction in HIV acquisition (95% CI, 15%–63%). TDF/FTC treatment was generally well tolerated, although nausea in the first month was more common among those taking the medication than among those taking placebo (9% versus 5%). No differences in severe (grade 3) or life-threatening (grade 4) laboratory abnormalities were observed between the active arm and the placebo arm. In addition, no drug-resistant virus was found in the 100 participants who were seronegative at enrollment but later found to have been infected at enrollment (Grant 2010).

Heterosexually active adults

Three studies were completed evaluating oral PrEP in HIV-uninfected, heterosexually active adults. The first study, the Partners PrEP trial, evaluated a daily combination dose of TDF and FTC compared with TDF alone in the uninfected male and female partners in HIV-discordant couples. The study found 75% efficacy for the TDF/FTC arm of the trial (95% CI, 55%–87%) and 67% efficacy for TDF alone (95% CI, 44%–81%), with no statistically significant difference in efficacy between the two regimens (Baeten 2012). The second trial, the TDF2 trial, evaluated daily TDF/FTC in adult men and women and found 62% efficacy (95% CI, 22%–83%) (Thigpen 2012). The third trial, the FEM-PrEP study, evaluated daily TDF/FTC in women and was terminated due to a lack of evidence of efficacy (Van Damme 2012). The investigators reported very low levels of medication adherence, with the frequency of drug detection in the blood of treatment participants < 27% among women who acquired HIV infection.

In all three trials, participants received regular risk-reduction counseling, condoms, medication-adherence counseling, and testing for sexually transmitted infections with treatment as indicated. No serious toxicities were reported in any of the trials; however, in the first 1–2 months on medication, nausea and vomiting were more common in those receiving treatment compared with those receiving placebo.

Injecting drug users

The Bangkok Tenofovir Study enrolled HIV-uninfected people who reported injecting illicit drugs in the prior year into a phase 3, randomized, double-blind, placebo-controlled trial to determine the safety and efficacy of daily oral TDF to reduce the risk for HIV acquisition. Ultimately, the results of the trial showed a 51.8% reduction in HIV incidence (95% CI, 15.3%–73.7%) in the TDF group compared with the placebo group. Reports of nausea or vomiting were higher in the TDF group; however, the number and severity of other adverse events reported were similar in participants in both groups. No TDF-associated resistance mutations were detected in the participants who acquired HIV infection (Choopanya 2013).

References

Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med*. 2012;367(5):399-410.

Branson BM, Handsfield HH, Lampe MA, Centers for Disease Control and Prevention, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep*. 2006;55(RR-14):1-17.

Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*. 2013;381(9883):2083-2090.

Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010;363(27):2587-2599.

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Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med.* 2012;367(5):423-434.

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Guideline Development Process and Team

Development process

To develop the HIV Screening and Pre-Exposure Prophylaxis Guideline, the guideline team recommendations from externally developed evidence-based guidelines and/or recommendations of organizations that establish community standards. The guideline team reviewed additional evidence in the following area: pre-exposure prophylaxis. For details, see Evidence Summary and References.

This edition of the guideline was approved for publication by the HIV Screening and Pre-Exposure Prophylaxis Guideline team in November 2013.

Team

The HIV Screening and Pre-Exposure Prophylaxis Guideline development team included representatives from the following specialties: clinical laboratory, family medicine, pharmacy, and the HIV/PrEP Program.

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