

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

Major Changes as of October 2019	2
Background	2
Screening Recommendations	2
HIV Test Ordering and Consent.....	2
Indications for Periodic HIV Screening	3
Referrals.....	3
Follow-up and Monitoring.....	3
Pre-Exposure Prophylaxis (PrEP).....	4
Evidence Summary	6
Guideline Development Process and Team	7

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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.

Major Changes as of October 2019

- As of June 2018, written consent for HIV testing is no longer required in Washington state. (See [Washington Senate Bill 6580](#).)
- HPV immunization is now recommended for patients aged 45 or under at high risk for HIV who have not been previously immunized.
- The U.S. Preventive Services Task Force (2019) issued a grade “A” recommendation that pre-exposure prophylaxis (PrEP) be offered to all persons at risk of HIV infection. The population eligible for PrEP has been expanded considerably since the previous guideline recommendation. See page 4.

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 in 2017](#), about 14,000 people were living with HIV, 9% of whom did not know their HIV status.

Early diagnosis of HIV infection not only reduces the risk of morbidity and mortality in affected individuals, but 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: <ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• At first prenatal visit for each pregnancy• For women at high risk of STIs, consider also testing in third trimester (For women presenting in labor without prior testing, use rapid HIV screening test.)

HIV Test Ordering and Consent

Use **HIV screening test** to order the test in KP HealthConnect, and consider ordering **STD LAB PANEL (FEMALE)** for patients with a vagina or **STD LAB PANEL (MALE)** for patients with a penis 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.

Written consent is **not** a requirement for an HIV test in Washington state. Patient consent can be part of the consent for multiple routine tests (the STD panels), 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 patients choose not to have the test, use the SmartPhrase **.hivdeclined** in KP HealthConnect to document their decision.

The KPWA lab notifies the KPWA HIV/PrEP Program if there is a positive HIV test result. The HIV/PrEP Program usually reaches out to the ordering provider to discuss communicating the results to the patient; the provider can also contact the HIV/PrEP Program provider on call to discuss next steps.

Indications for Periodic HIV Screening

- Men who have sex with men (MSM)
- Persons:
 - Having unprotected vaginal or anal intercourse with more than one partner
 - Who exchange sex for drugs or money
 - With a history of or current illicit drug use
 - Seeking treatment for other STIs
 - Whose past or current sex partners are HIV-infected, bisexual, or illicit drug users
 - Who have medical procedures, injections, or blood transfusions in countries without sterile standard techniques
 - Who are uncertain about a sexual partner's risk behaviors
 - With three or more sexual partners in the past year
 - Who do not report one of these risk factors but do request HIV testing

Referrals

Western Washington

Refer all Western Washington patients with confirmed positive HIV test results to the HIV/PrEP Program. In KP HealthConnect, type **Ref HIV** to pull in the referral automatically. HIV-positive 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; provides educational and resource tools for newly positive patients and for providers; assists with insurance and financial issues; and monitors standard quality measures for HIV care.

Eastern Washington

In Eastern Washington, refer patients with confirmed positive HIV test results to one of the contracted infectious disease specialists. (Care for HIV patients in Eastern Washington 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:

- Immunizations for hepatitis A and hepatitis B
- Immunization for HPV if not previously immunized *and* age 45 or under
- 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 at risk of HIV infection should have a conversation with their provider about whether to start pre-exposure prophylaxis (PrEP).

The U.S. Preventive Services Task Force (2019) now recommends that PrEP be offered to all persons at risk of HIV infection. This is a Grade A recommendation, which means that the USPSTF found convincing evidence that PrEP is of substantial benefit in decreasing the risk of HIV infection in persons at high risk of HIV acquisition.

The USPSTF recommends that the following persons be considered for PrEP:

1. **Men who have sex with men**, are sexually active, and have 1 of the following characteristics:
 - A serodiscordant sex partner (i.e., in a sexual relationship with a partner living with HIV)
 - Inconsistent use of condoms during receptive or insertive anal sex
 - A sexually transmitted infection (STI) (syphilis, gonorrhea, or chlamydia) within the past 6 months
 2. **Heterosexually active women and men** who have 1 of the following characteristics:
 - A serodiscordant sex partner (i.e., in a sexual relationship with a partner living with HIV)
 - Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g., a person who injects drugs or a man who has sex with men and women)
 - An STI (syphilis or gonorrhea) within the past 6 months
 3. **Persons who inject drugs** and have 1 of the following characteristics:
 - Shared use of drug injection equipment
 - Risk of sexual acquisition of HIV (see above)
- ∅ **Persons who engage in transactional sex**, such as sex for money, drugs, or housing, including commercial sex workers or persons trafficked for sex work, constitute another group at high risk of HIV acquisition and should be considered for PrEP based on the criteria outlined above.
- ∅ **Men who have sex with men and women** are at risk of HIV acquisition and should be evaluated for PrEP according to the criteria outlined above for men who have sex with men and heterosexually active men.
- ∅ **Transgender women and men** who are sexually active may be at increased risk of HIV acquisition and should be considered for PrEP based on the criteria outlined above. Transgender women are at especially high risk of HIV acquisition. The CDC estimates that approximately one-fourth of transgender women are living with HIV, and more than half (an estimated 56%) of black/African American transgender women are living with HIV. Although trials of PrEP enrolled few transgender women and no trials have been conducted among transgender men, PrEP has been shown to reduce the risk of HIV acquisition during receptive and insertive anal and vaginal sex. Therefore, its use may be considered in all persons (cisgender and transgender) at high risk of sexual acquisition of HIV.
- ∅ Consistent use of condoms decreases risk of HIV acquisition by approximately 80% and also decreases the risk of other STIs. However, sexually active adults often use condoms inconsistently. PrEP should be considered as an option to reduce the risk of HIV acquisition in **persons who use condoms inconsistently**, while continuing to encourage and support consistent condom use.

Note: Men who have sex with men and heterosexually active persons are **not** considered to be at high risk if they are in a mutually monogamous relationship with a partner who has recently tested negative for HIV. In addition, all persons being considered for PrEP must have a recently documented negative HIV test result.

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. PrEP includes these additional risk-reduction strategies:

- Consistent use of condoms
- Treatment of HIV-positive partner
- Treatment for drug abuse
- Use of clean injection equipment if injectable drug user

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. PrEP may be used in adults and adolescents who weigh at least 77 pounds. HIV-negative women who wish to become pregnant with an HIV-positive partner may also be good candidates for PrEP.

As part of shared decision-making about using 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 can also call the KPWA PrEP Program to talk with a PrEP specialist.

Patients must understand that antiretroviral medication is only one part of the 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.

PrEP Tools for Providers

- Order **Ref PrEP** in KP HealthConnect for any patient who is interested in, already on, or about to start PrEP. The PrEP program monitors all patients on PrEP. Call the HIV/Prep Program at 206-326-3609 with any questions.
- For more information about PrEP, see the Centers for Disease Control and Prevention [clinical practice guideline for PrEP](#)
- For talking points when having a shared decision-making conversation with patients considering PrEP, use the SmartPhrase **.prepconsult**, which provides guidance on risk factors, medication risks, and lab testing.

PrEP Tools for Patients

- AVS SmartPhrase **.avsprepforhivexposure**
- The CDC [fact sheet](#), which is in both English and Spanish.

Evidence Summary

The HIV Screening and PrEP Guideline was developed using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis.

As part of our improvement process, the Kaiser Permanente Washington guideline team is working towards developing new clinical guidelines and updating the current guidelines every 2–3 years. To achieve this goal, we are adapting evidence-based recommendations from high-quality national and international external guidelines, if available and appropriate. The external guidelines should meet several quality standards to be considered for adaptation. They must: be developed by a multidisciplinary team with no or minimal conflicts of interest; be evidence-based; address a population that is reasonably similar to our population; and be transparent about the frequency of updates and the date the current version was completed.

In addition to identifying the recently published guidelines that meet the above standards, a literature search was conducted to identify studies relevant to the key questions that are not addressed by the external guidelines.

External Guidelines Eligible for Adapting

USPSTF June 2019 Screening for HIV Infection

USPSTF June 2019 Preexposure Prophylaxis for the Prevention of HIV Infection

Kaiser Permanente National June 2019 HIV/STI Screening & Prevention Clinical Practice Guideline

Key questions addressed in the KPWA guideline

What is the effectiveness of intermittent (“on-demand” PrEP) pre-exposure prophylaxis (PrEP)?

Although the evidence (from two randomized controlled trials) is moderate and seems to support the use of intermittent PrEP for reducing the incidence of HIV infection in sexually active high-risk women and men (including men who have sex with men), more studies are warranted to draw a conclusion. In addition, adherence might be a concern. (Kibengo 2013, Molina 2015)

References

Kibengo FM, Ruzagira E, Katende D, et al. Safety, adherence and acceptability of intermittent tenofovir/emtricitabine as HIV pre-exposure prophylaxis (PrEP) among HIV-uninfected Ugandan volunteers living in HIV-serodiscordant relationships: a randomized, clinical trial. *PLoS One*. 2013 Sep 26;8(9): e74314. doi:10.1371/journal.pone.0074314

Molina JM, Capitant C, Spire B, et al; ANRS IPERGAY Study Group. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. *N Engl J Med*. 2015 Dec 3;373(23):2237-2246. doi:10.1056/NEJMoa1506273

Guideline Development Process and Team

Development process

The HIV Screening and Pre-Exposure Prophylaxis (PrEP) Guideline was developed using an evidence-based process, including systematic literature search, critical appraisal, and evidence synthesis.

This edition of the guideline was approved for publication by the Guideline Oversight Group in October 2019.

Team

The HIV Screening and PrEP Guideline development process included representatives from the following specialties: adolescent medicine, clinical lab, family medicine, gender health, HIV/PrEP Program, infectious disease, pharmacy, and residency.

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Disclosure of conflict of interest

Kaiser Permanente requires that team members participating on a guideline team disclose and resolve all potential conflicts of interest that arise from financial relationships between a guideline team member or guideline team member's spouse or partner and any commercial interests or proprietary entity that provides or produces health care–related products and/or services relevant to the content of the guideline.

Team members listed above have disclosed that their participation on the HIV Screening and PrEP Guideline team includes no promotion of any commercial products or services, and that they have no relationships with commercial entities to report.