



TECHNICAL ASSISTANCE RESOURCE

Technical Assistance Resource: Health Center Provision of HIV Pre-Exposure Prophylaxis

Purpose

This Health Center Program technical assistance resource (TAR) highlights information and resources for the provision of HIV Pre-exposure Prophylaxis (PrEP) in health centers, including: summary guidelines for PrEP; information on reimbursement for PrEP; and links to resources for providers and consumers about this service. HRSA strongly encourages health centers to offer PrEP to individuals who are at substantial risk of becoming HIV infected.

Background

An estimated 1.1 million people currently live with HIV. After substantial decline over a period of five years, the number of newly diagnosed HIV infections leveled off in 2013, to about 39,000 per year.¹ Opportunities to reduce HIV transmission and improve health outcomes are too frequently missed. Seven in 10 people with HIV saw a healthcare provider in the 12 months before diagnosis and failed to be identified as infected.² Early diagnosis is critical because the nearly 15 percent of persons living with HIV whose infections are undiagnosed account for almost 23 percent of all new HIV infections.³

Risk for contracting HIV can be significantly reduced by prescribing and supporting the use of PrEP. Among people for whom sexual behavior is their primary HIV risk, PrEP can reduce the risk of contracting HIV by more than 90 percent. Among people who inject drugs, PrEP can reduce the risk of contracting HIV by more than 70 percent. Of the estimated 1.1 million American adults at substantial risk for HIV, fewer than 10 percent have been prescribed PrEP. About 7,300 are in need of financial assistance for both PrEP medication and clinical care to

¹ Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2010–2016. HIV Surveillance Supplemental Report 2019;24(No. 1). Published February 2019. Accessed June 25, 2019. Available at: <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-24-1.pdf>.

² Dailey AF, Hoots BE, Hall HI, et al. Human Immunodeficiency Virus Testing and Diagnosis Delays — United States. MMWR Morb Mortal Wkly Rep 2017;66:1300-1306.

³ Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV Epidemic: A Plan for the United States. JAMA. 2019;321(9):844–845.

prevent HIV infection.^{4,5} Increasing PrEP use among groups at high risk of contracting HIV could prevent almost 50,000 HIV infections by 2020.⁶

Pre-Exposure Prophylaxis (PrEP)

PrEP is a daily regimen of two oral antiretroviral drugs in a single pill that HIV-negative adolescents and adults who are at substantial risk of HIV infection take to lower their chances of becoming infected. There is currently one medication that is available for PrEP, the fixed-dose drug combination of *emtricitabine (200mg)* and *tenofovir disoproxil fumarate (300 mg)*. However, new medicines are in the pipeline. PrEP, combined with condom use and other prevention methods, provides protection against HIV as well as other sexually transmitted infections (STIs).

[The Centers for Disease Control and Prevention \(CDC\) recommends](#) PrEP for individuals who are at substantial risk for contracting HIV. [The US Preventive Services Task Force](#) also recently gave a Grade A recommendation for clinicians to offer PrEP for persons who are at high risk of acquiring HIV.

The [CDC 2017 PrEP Clinical Guidelines](#) recommend that PrEP be considered for HIV negative people who have had sex in the last six months and who are either:

1. In an ongoing sexual relationship with an HIV-positive partner, *or*
2. *Not* in a monogamous relationship with a partner who recently tested HIV-negative
and who is one of the following:
 - a man who has sex with both women and men (behaviorally bisexual), *or*
 - a gay or bisexual man who has had anal sex without using a condom in the last six months or has been diagnosed with a bacterial sexually transmitted infection (STI) (gonorrhea, chlamydia, syphilis) in the past six months, *or*
 - a heterosexual man or woman who does not regularly use condoms during sex with partners whose HIV status is unknown and who are at substantial risk of HIV infection (for example, people who inject drugs or have bisexual male partners), *or*
 - a heterosexual man or woman who has had a bacterial STI (syphilis, gonorrhea) in the last six months.

⁴ Huang YA, Zhu W, Smith DK, Harris N, Hoover KW. HIV Preexposure Prophylaxis, by Race and Ethnicity — United States, 2014-2016. *MMWR Morb Mortal Wkly Rep* 2018;67:1147-1150.

⁵ Smith, D. K., Van Handel, M., & Huggins, R. (2017). Estimated coverage to address financial barriers to HIV preexposure prophylaxis among persons with indications for its use, United States, 2015. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, 76(5), 465–472.

⁶ Ending the HIV Epidemic: A Plan for America. HIV.gov. Published February 5, 2019. Accessed June 25, 2019. Available at <https://www.hiv.gov/blog/ending-hiv-epidemic-plan-america>.

PrEP is also recommended for HIV negative people who have:

3. Injected drugs in the past six months and have shared needles or drug preparation equipment, or who have a risk of sexual acquisition of HIV, as above.

PrEP care delivery includes an initial assessment and baseline laboratory tests, including HIV testing; education, and counseling on PrEP and other HIV prevention strategies; and routine follow-up visits with laboratory testing for HIV, STIs, and renal function. PrEP delivery and adherence are often enhanced with the addition of a care coordinator or PrEP navigator.

In 2018, the Food and Drug Administration (FDA) extended its approval of *emtricitabine* and *tenofovir disoproxil fumarate* for use as PrEP in adults and adolescents who weigh at least 35kg (77 lb). The indications for PrEP, laboratory testing, prescribing and follow-up are the same for adolescents and adults. PrEP use by adolescents will be included in the next update of the CDC PrEP guidelines but is not noted in the 2017 version, due to the more recent FDA approval.

The Health Center Program and PrEP

Health centers are uniquely positioned to use their patient-centered service delivery models, clinical expertise, and structural capacity to provide HIV prevention, care and treatment services. Prevention of infectious diseases, including HIV, is part of routine primary care delivery. In 2017, 1.8 million health center patients received an HIV test, and of those who tested positive for HIV, 85 percent were successfully linked to HIV care. Health centers can also prevent individuals at risk for HIV from contracting the virus by prescribing and supporting the use of PrEP.

Health centers are a key point of entry for individuals at risk for or undiagnosed with HIV. Successful HIV prevention does not require an HIV specialist, but does require routine testing for HIV infection^{7,8} and risk assessment to identify HIV-negative, at-risk individuals, including taking sexual histories and screening for substance use. It may also require new workflows and training on a PrEP protocol, as well as interventions to reduce stigma and promote a welcoming environment for at-risk patients.

PrEP may be administered through primary care visits, appropriate prescribing and dispensing of medications, and related primary and additional services within a health center's scope of project. Of note, services provided by health centers within their scope of project must comply with all Health Center Program requirements, as well as federal and state laws.

⁷ CDC, [Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings](#). September, 2006. Accessed April 15, 2019.

⁸ US Preventive Services Task Force, [Human Immunodeficiency Virus \(HIV\) Infection: Screening](#). June, 2019. Accessed June 19, 2019.

Health centers that also receive Ryan White HIV/AIDS Program (RWHAP) funds may not use RWHAP funds to pay for PrEP medications, diagnostics or PrEP-related provider visits (i.e., initial visit, screening, follow-up) because RWHAP funds may only be used for the care and treatment of people diagnosed with HIV. While RWHAP funds cannot be used to support PrEP, RWHAP funds can be used for risk reduction counseling and targeted testing, which are part of a comprehensive PrEP program. In addition, existing RWHAP expertise and administrative and clinical infrastructures can be leveraged towards the establishment of a comprehensive PrEP program.

Paying for PrEP

Health centers are expected to maximize all opportunities to reduce the cost of care for patients including programs to increase access to effective HIV prevention, care and treatment services. Health centers are expected to utilize national PrEP donation programs as available and appropriate to support the needs of their uninsured and underinsured patients. Health centers that are eligible and enrolled as a covered entity in the 340B Drug Pricing Program (section 340B of the Public Health Service Act) may also utilize the 340B Program to purchase medication used for PrEP at a discounted price, as permitted by 340B Program requirements. Visit the [340B Program webpage](#) for more information.

Most public and private insurers cover PrEP, but co-pay, co-insurance, and prior authorization policies differ.⁹ Some states have developed PrEP drug assistance programs to help insured patients with co-pays or help financially eligible uninsured/underinsured patients with PrEP-related visits and lab testing. The PrEP drug manufacturer also has programs that may assist health centers in providing access to PrEP.

Resources

Additional technical assistance and training resources are available on the [HRSA Ending the Epidemic](#) and [HRSA HIV and Health Centers](#) webpages; some are listed below.

1) Clinician Resources

- [U.S. Public Health Service Pre-exposure Prophylaxis for the Prevention of HIV infection in the United States – 2017 Update Clinical Practice Guidelines](#) has the most current CDC PrEP clinical practice guidelines.
 - [Clinical Providers Supplement - Updated 2017](#) includes risk assessment tools, provider checklist, PrEP FAQs for patients, and counseling and monitoring guidance.
- [US Preventive Services Task Force Prevention of Human Immunodeficiency Virus \(HIV\) Infection: Preexposure Prophylaxis](#), 2019. Provides a Grade A recommendation and includes assessment of risk and implementation considerations.
- [CDC Pre-Exposure Prophylaxis](#) includes fact sheets, guidelines, and resources for providers and patients.

⁹ CDC, [Pre-exposure Prophylaxis for the Prevention of HIV infection in the United States – 2017 Update](#). A Clinical Practice Guideline. Accessed April 15, 2019.

- [CDC: Act Against AIDS](#) includes up-to-date HIV prevention resources for clinicians and patients
- [PrEPline: National Clinician Consultation Center](#) provides clinical consultation for PrEP decision-making.
- [National LGBT Health Education Center](#), a HRSA-funded National Cooperative Agreement, provides educational programs, resources, and consultation to health centers to optimize care for LGBT people.
- [HRSA HIV/AIDS Bureau \(HAB\) Program Letter to RWHAP grantees about PrEP](#)
- [CDC: Paying for PrEP](#)
- [National Alliance of State and Territorial AIDS Directors \(NASTAD\): PrEP assistance programs](#)

2) Patient Resources

- [HHS Using HIV Medication to Reduce Risk: Pre-Exposure Prophylaxis](#) includes a tool that locates a nearby PrEP provider.
- [CDC: PrEP](#) includes videos and frequently asked questions about PrEP.
- [CDC PrEP 101 infographic](#) (English and Spanish)