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HIV Pre-Exposure Prophylaxis in Wisconsin

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HIV pre-exposure prophylaxis, also known as PrEP, is a way a person who is HIV-negative can prevent HIV infection by taking a daily pill. This prescription medication (trade name Truvada) is a combination of two HIV medications (tenofovir and emtricitabine). Truvada is used along with other medications to treat people who are HIV-positive and has also been effective to prevent HIV in those not infected. When taken daily, Truvada can reduce the risk of contracting HIV infection in uninfected people by over 90% among men who have sex with men (MSM), transgender women, and heterosexuals, and by 70% among people who inject drugs (PWID).

The Wisconsin AIDS/HIV Program strongly supports the use of PrEP as an effective prevention intervention for those who are at substantial risk for HIV infection. This article describes activities in Wisconsin that are being done to promote PrEP among people at high risk for HIV infection.

Background

In May 2014, the Centers for Disease Control and Prevention (CDC) released guidelines for medical providers regarding the use of PrEP. These recommendations were based on several research studies that showed the safety and effectiveness of Truvada as an HIV prevention intervention among people who take the medication daily. The studies were conducted throughout the world among populations at higher risk for HIV, including MSM, heterosexuals, and PWID. One example is the study known as IPrEx (conducted in Peru, Ecuador, Brazil, Thailand, South Africa, and the United States), which found a 99% reduction in HIV infection among MSM who strictly adhered to the medication.

Key Points of CDC's PrEP Guidance

PrEP is a clinical prevention intervention involving frequent health care provider visits and regular testing for liver function, HIV, hepatitis B, and other sexually transmitted infections (STIs). Because of the intensity of this intervention, CDC's guideline recommends PrEP for only those HIV-negative people who are at substantial risk for HIV infection. Taking a sexual history is a necessary first step for clinicians to assess whether a patient is appropriate for PrEP.

CDC's guidance indicates that gay men and other MSM may benefit from PrEP if they are not in a monogamous partnership with a recently tested, HIV-negative man and have had:

- Anal sex without condoms (receptive or insertive) in the past six months.
- Any sexually transmitted infection (STI) diagnosed or reported in the past six months.
- An ongoing sexual relationship with an HIV-positive male partner.

These indicators are also applicable for transgender women.

PWID should be offered PrEP if they have been:

- Sharing injection or drug preparation equipment in the past six months.
- In a methadone, buprenorphine, or suboxone treatment program in the past six months.
- At risk of sexually acquiring HIV (e.g., in an ongoing sexual relationship with an HIV-positive partner).

¹ U.S. Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: A clinical practice guideline. http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.

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The guidance also identifies PrEP indicators for heterosexuals at high risk for HIV.

The CDC has estimated the numbers of people who may benefit from PrEP nationwide.² These numbers have been adapted to provide estimates for Wisconsin and are detailed in the March 2016 supplement <u>issue</u> of *Wisconsin AIDS/HIV Program Notes*.³

To determine clinical appropriateness for PrEP, clinicians must test for HIV infection, including evaluating for acute HIV infection. Persons who are HIV-positive must be seen by an HIV specialist and be prescribed HIV medication in addition to Truvada to treat HIV infection and reduce viral load.

PrEP should not be prescribed to those with reduced renal function. Prior to prescribing PrEP, the medical provider should evaluate the person's renal function based on a serum creatinine test. Testing for hepatitis B virus (HBV) is recommended since people infected with HBV require special clinical management when taking Truvada.

Clinical follow-up for people on PrEP includes:

- Every three months, test for HIV and assess for medication adherence.
- Every six months, test for STIs and evaluate renal function.
- Every year, assess whether the patient is still an appropriate candidate for PrEP. CDC's guidance provides more details on the clinical workup and monitoring recommended for PrEP.

When taken daily, PrEP is very effective at preventing HIV; however, it does not prevent pregnancy or the acquisition of other STIs. Clinicians should discuss with patients ways to prevent pregnancy and STIs, including using condoms regularly. PrEP should be discontinued if a person no longer has high-risk behaviors for HIV, if the person becomes HIV-infected, or if the person cannot adhere to the medication regimen.

Wisconsin AIDS/HIV Program activities promoting PrEP

In January 2016, the Wisconsin AIDS/HIV Program released PrEP guidance for Wisconsin providers. The guidance is intended for health care providers (medical staff, nurses, pharmacists, social workers, case managers, and other professionals) who are working with persons interested in PrEP. The guide includes patient education recommendations, financial information and resources, and a tool to assist patients in assessing their appropriateness for PrEP. The guide is available on the AIDS/HIV Program website under the tab "Resources for Clinicians" at https://www.dhs.wisconsin.gov/aids-hiv/clinicians.htm. Also included on this website is a link to a sample protocol developed by the Wisconsin HIV Primary Care Support Network that may be adapted by medical providers.

² Smith DK, et al. Vital Signs: Estimated percentages and numbers of adults with indications for preexposure prophylaxis to prevent HIV acquisition – United States, 2015, Morbidity and Mortality Week Report (MMWR), November 27, 2015/64(46): 1291-1295. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a4.htm?s cid=mm6446a4 w.

³ Gasiorowicz M. Estimated number of men who have sex with men and people who inject drugs with indications for HIV pre-exposure prophylaxis in Wisconsin. Wisconsin AIDS/HIV Program Notes, March 2016 Supplement. https://www.dhs.wisconsin.gov/publications/p00792-16-march-sup.pdf

⁴U.S. Public Health Service, Preexposure prophylaxis for the prevention of HIV infection in the United States, 2014, http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.

⁵ Wisconsin Department of Health Services, Guide for Wisconsin PrEP Providers, https://www.dhs.wisconsin.gov/publications/p01197.pdf.

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In addition to clinician resources, the AIDS/HIV Program has developed a PrEP web page for consumers at https://www.dhs.wisconsin.gov/aids-hiv/prep.htm. This web page provides information and links to information about:

- The basics of PrEP.
- People who could benefit from PrEP.
- Ways to pay for PrEP.
- Clinical settings in Wisconsin offering PrEP.

While CDC's clinical guidance was released nearly two years ago, many primary care physicians remain unaware of PrEP. The AIDS/HIV Program is identifying clinics that are willing to be listed as PrEP providers in Wisconsin to make it easier for consumers and service providers (case managers, Partner Services staff, and HIV prevention staff) to access and make referrals to health care providers offering PrEP in their communities. Initial lists for Milwaukee and Madison are posted on the consumer web page (https://www.dhs.wisconsin.gov/aids-hiv/prep-where.htm) and will be updated as additional providers express interest in being included in this list.

The AIDS/HIV Program will be developing training for case managers, Partner Services staff, and HIV prevention staff in the first half of 2016 to provide basic information on PrEP, screening criteria to identify appropriate candidates, financial issues, and referral and medication adherence guidelines.

One deterrent for consumers is the cost associated with Truvada and the required medical testing and follow-up for people on PrEP. While many health insurance policies cover PrEP, there may be high copays or deductibles. The manufacturer of Truvada (Gilead Sciences) has two patient assistance programs. One helps cover the deductibles or co-pays for Truvada. Another program assists uninsured people in getting a monthly supply of Truvada. Both programs cover only the cost of Truvada and not the associated medical care. BadgerCare Plus, a health care coverage program for low-income Wisconsin residents, covers PrEP in its entirety. A summary of financial coverage options for PrEP are listed on the AIDS/HIV Program website at https://www.dhs.wisconsin.gov/aids-hiv/prep-pay.htm. Clinics that offer PrEP to low income people may need to help patients in accessing these programs. The AIDS/HIV Program is encouraging grantee agencies to support clients by helping them navigate financial coverage options for PrEP.

Ensuring success with PrEP

In the absence of a vaccine, PrEP is one of the most effective interventions available to prevent HIV infection in persons at high risk for HIV; however, two critical factors are:

- Provider awareness and willingness to prescribe PrEP.
- Patient acceptance of and adherence to PrEP.

CDC reports that a 2015 survey indicated that 34% of primary care providers had never heard of PrEP. ⁶ For those who have heard of PrEP, providers may be reluctant to prescribe because:

- The use of antiretroviral medication has typically been the domain of HIV specialists.
- Providers may have concerns that PrEP use by patients may increase high-risk behaviors.
- Broaching the subject with patients may be difficult or embarrassing.

CDC is promoting PrEP among primary care providers and recently devoted an issue of *Vital Signs* to this topic (http://www.cdc.gov/vitalsigns/hivprep/). In early 2016, the AIDS/HIV Program will be

⁶ DocStyles, unpublished data, 2015.

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promoting PrEP among Wisconsin providers by sending information about Wisconsin's guidance and other resources to provider associations to include in their newsletters or on their websites.

Even with access to PrEP, many people at substantial risk for HIV may be reluctant to consider PrEP or may have difficulty in accessing or adhering to daily medication use. This may be particularly true for African American MSM in Milwaukee, a group with the highest rate of HIV infection in the state. In order to reduce HIV infection in this population, Dr. Ryan Westergaard of the University of Wisconsin-Madison School of Medicine and Public Health is leading a two-year research study to identify barriers to PrEP use among African American MSM. Diverse and Resilient (D&R), a nonprofit that addresses health disparities among LGBT population in Milwaukee, is a partner in the study. D&R has completed a community readiness assessment to identify the community's level of awareness regarding PrEP. The results of this assessment, along with findings from in-depth individual interviews, are guiding the development of an intervention to increase awareness and acceptance of PrEP among African American MSM.

Adherence is critical to PrEP effectiveness. Adhering to a routine of taking medication may be difficult if people are living in unstable housing, feel the need to keep their medication secret from others, or simply do not have the habit of taking a daily medication. Prior to prescribing PrEP, providers should discuss and counsel patients about the challenges they might face in taking a daily pill. People who live in challenging circumstances may need extra support, but are also the candidates who would likely benefit from PrEP the most. A recent study from the National Institutes of Health found that a majority of African American MSM who were provided coordinated care for PrEP were able to successfully adhere to the medication over a period of a year.⁷

How you can help

If you are a health care provider or are aware of a health care provider who is willing to be listed as a PrEP provider on the AIDS/HIV Program website, please contact Kathleen Krchnavek at kathleen.krchnavek@dhs.wisconsin.gov.



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⁷ National Institutes of Health http://www.niaid.nih.gov/news/newsreleases/2016/Pages/CROI-HPTN073.aspx.