

EXPANDING PREVENTION THROUGH COMMUNITY MOBILIZATION

PRE-EXPOSURE PROPHYLAXIS
(PrEP) TOOLKIT



May 12, 2015

Dear Community Partners,

This letter is to communicate that Centers for Disease Control and Prevention and the U.S. Public Health Service have released new clinical guidelines recommending health care providers consider prescribing pre-exposure prophylaxis (PrEP) for patients at substantial risk for HIV. The strategy of providing daily oral antiretroviral drugs continuously to uninfected individuals prior to HIV exposure has been shown to reduce HIV acquisition among all populations at high risk.

The new guidelines were developed by CDC in close partnership with health care providers, public health experts, community leaders and other federal agencies. The guidelines recommend providers consider PrEP as a prevention option for patients who meet specified risk criteria. They also underscore the importance of counseling that covers adherence and HIV risk reduction and recommend regular monitoring of HIV status, side effects, toxicities, and risk behaviors.

More specifically, the guidelines recommend PrEP for HIV-uninfected patients with any of the following indications:

- Is in an ongoing relationship with an HIV-infected partner
- Is not in a mutually monogamous relationship with a partner who recently tested HIV-negative, and who is:
a gay or bisexual man who has had sex without a condom or been diagnosed with a sexually transmitted infection within the past six months
- A heterosexual man or woman who does not regularly use condoms when having sex with partners known to be at risk for HIV (for example, injection drug users or bisexual male partners of unknown HIV status) or whose partners are from communities with high rates of HIV infection
- Has injected illicit drugs within the past six months and has shared equipment or been in drug treatment within the past six months

For sexually-active people, since no prevention strategy is 100 percent effective, the guidelines also recommend that physicians encourage patients to use PrEP with other proven prevention strategies such as condoms to provide even greater protection than when used alone.

CDC issued interim guidance in 2011, 2012, and in 2013 as trial results on PrEP within various populations became available. These new guidelines replace the interim guidance and are the first to offer detailed and comprehensive clinical guidance on PrEP for both sex and injection drug use.

The new guidelines also include a providers' supplement with additional materials and tools for clinicians who prescribe PrEP. Materials include a checklist for providers to use in discussions with patients, fact sheets to help providers and patients increase their knowledge about PrEP and a risk assessment tool.

The recently published guidelines are an important step forward in the fight against HIV as they give health care providers on the front lines of this epidemic the information needed to effectively deliver this powerful new prevention tool. With 2.7 million new infections estimated to occur each year worldwide – and approximately 50,000 in the United States –



safe and effective new approaches to prevent HIV are urgently needed. PrEP has the potential to alter the course of the U.S. epidemic, if targeted to populations in need and used as directed. In fact, CDC estimates that as many as 275,000 uninfected gay men and 140,000 sero-discordant heterosexual couples could benefit from this intervention.

Ultimately the role of PrEP in preventing new HIV infections will depend on: its acceptability to users; how effectively it is delivered by health care providers, including support for patients to achieve high medication adherence and prevent increases in risk behavior; and access to the drug by those at substantial risk of HIV.

As a clinician, you play a critical role in helping to realize the promise of PrEP for HIV prevention in the United States. Research shows that the doctor-patient relationship is a powerful one – what you say to your patients can have a great impact on their behaviors and health care choices.

Starting today, there are several key steps you can take to help expand uptake of PrEP and help address some of the practical issues for its effective delivery. These include:

- Prescribing PrEP to those patients with indications for its use
- Increasing awareness of this safe and effective HIV prevention intervention
- Create an open dialogue with patients to communicate prevention messages, reinforce safer behaviors, and screen for behaviors that may result in HIV acquisition.
- Communicating to patients in HIV-discordant relationships that PrEP is an available option for their HIV-negative partner

The new guidelines and clinical providers' supplement are published in full at:

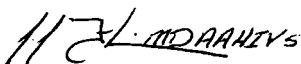
<http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf>

<http://www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf>

http://www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf

Your role in ensuring PrEP is delivered effectively is crucial. We trust that these guidelines will give you the information and confidence you need to prescribe and support PrEP use for patients who meet the risk criteria.

Sincerely,



Gregory S. Felzien, MD, AAHIVS
Diplomat: Internal Medicine and Infectious Disease
Medical Advisor
Department of Health Protection/IDI-HIV
Georgia Department of Public Health
2 Peachtree St., NW, Suite 15-228
Atlanta, GA 30303-3142



PRE-EXPOSURE PROPHYLAXIS (PrEP) TOOLKIT



What is PrEP?

Pre-exposure prophylaxis (PrEP) is an HIV prevention strategy where HIV-negative individuals take anti-HIV medications before coming into contact with HIV to reduce their risk of becoming infected. The medications work to prevent HIV from establishing infection inside the body.

PrEP has been shown to reduce risk of HIV infection through sex for gay and bisexual men, transgender women, and heterosexual men and women, as well as among people who inject drugs. It does not protect against other sexually transmitted infections (STI) or pregnancy. It is not a cure for HIV.

What is the difference between PrEP and PEP? **Post-exposure prophylaxis (PEP)** is an HIV prevention strategy where HIV-negative individuals take HIV medications after coming into contact with HIV to reduce their risk of becoming infected. PEP is a month-long preventative medical therapy of drugs and should be started within 1 to 3 days of exposure.

Key Principles for Prescribing PrEP

PrEP should not be offered as a sole intervention for HIV prevention.

PrEP should only be prescribed as part of a comprehensive prevention plan.

PrEP may help protect the HIV seronegative partner in a serodiscordant relationship during attempts to conceive.

PrEP is indicated for individuals who have a documented negative HIV test result and are at ongoing high risk for HIV infection.

A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible, ideally on the same day the prescription is given.

Clinicians should wait to prescribe PrEP until confirmation of a negative test result is available.

Efficacy of PrEP is dependent on adherence. PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so. Although consistent condom use is a critical part of a prevention plan, lack of use of barrier protection is not a contraindication to PrEP.

PrEP is contraindicated in individuals with documented HIV infection or creatinine clearance <60 mL/min, and in those who are not ready to adhere to daily PrEP. The first prescription of PrEP (Truvada 1 tablet PO daily) should only be for 30 days to allow for a follow-up visit to assess adherence, tolerance, and commitment. At the 30-day visit, a prescription for 60 days may be given; the patient should then return for 3-month HIV testing and other assessments. After that visit, prescriptions can be given for 90 days, provided that the patient is adherent.

A GUIDE FOR UNDERSTANDING PRE-EXPOSURE PROPHYLAXIS.

The Georgia Department of Public Health (DPH) will continue to make information available to the community. In an effort to align DPH's HIV Prevention efforts with National HIV/AIDS Strategy (NHAS) expected efforts are focused on HIV positives, high-risk negatives, and those with unknown status. While the Georgia Department of Public Health supports efforts of PrEP, currently funding is unavailable through DPH.





Patients receiving PrEP require regular visits, at least every 3 months, to monitor HIV status, adherence, and side effects. Follow-up and monitoring of patients receiving PrEP also includes prevention services that are part of a comprehensive prevention plan, such as risk-reduction counseling, access to condoms, STI screening, and mental health and substance use screening, when indicated.

Whenever patients present with symptoms of acute HIV infection, an HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay. Discontinue PrEP immediately for patients who receive a positive HIV test result. Obtain a genotypic assay, and refer and link to HIV care.

Medications Approved for PrEP

TRUVADA (also called FTC/TDF)

The U.S. Food and Drug Administration (FDA) approved Truvada for PrEP use in 2012. This medication is taken as a once-daily oral pill, which combines two medicines in one: Emtriva (also called emtricitabine or FTC) and Viread (also called tenofovir disoproxil

fumarate or TDF). Truvada works by blocking an enzyme called HIV reverse transcriptase. By blocking this enzyme, it prevents HIV from making more copies of itself in the body.

Effectiveness

Truvada for PrEP provides 92%-99% reduction in HIV risk for HIV-negative individuals who take the pills every day as directed. If a daily dose is missed, the level of HIV protection may decrease. It only works if you take it. People who use PrEP correctly and consistently have higher levels of protection against HIV.

A few things to note:

- When starting PrEP, it takes at least seven days to reach high levels of protection against HIV.
- When stopping PrEP, individuals should continue using PrEP for four weeks after the last significant exposure.
- PrEP does not protect against other sexually transmitted infections (STI) or pregnancy. It is not a cure for HIV.

Pre-Exposure Prophylaxis (PrEP) Toolkit



PHOTO COURTESY OF GILEAD

Side Effects

Truvada for PrEP is generally safe and well tolerated. Most people on PrEP report experiencing no side effects, but some side effects were reported in clinical trials. Participants in the iPrEx study reported side effects that fall into four main categories (ordered here as most to least common):

Nausea: 9% of those who received Truvada reported nausea in the first month.

Headaches: 4.5% of participants who received Truvada reported headaches.

Weight loss: 2.2% of those who received Truvada reported unintentional weight loss of more than 5%.

Small increases in serum creatinine: Truvada is known to cause small increases in serum creatinine, a naturally occurring molecule filtered by the kidneys. In this study, 0.3% of those who received Truvada experienced mild increases in serum creatinine that persisted until the next test. Creatinine levels went back down once these participants stopped taking PrEP. Four of the five participants restarted PrEP without recurrence of the creatinine increase. Investigators monitored kidney function throughout the study and found no serious problems.

For most people, these side effects went away on their own after the first few weeks of taking Truvada, or when the medication was stopped.

PrEP Questions

It's important to remember that Pre-exposure prophylaxis (PrEP) is a prevention option for people who are at high risk of getting HIV. It's meant to be used consistently, as a pill taken every day, and to be used with other prevention options such as condoms.

Is PrEP a vaccine?

No. PrEP medication is not injected into the body and does not work the same way as a vaccine. You will take a pill every day by mouth. These medicines work by blocking important pathways that the HIV virus uses to set up an infection; and the presence of the medication in your bloodstream can often stop the HIV virus from establishing itself and spreading in your body.

How can I start PrEP?

If you think you may be at high risk for HIV, talk to your doctor about PrEP. Doctors prescribe PrEP for individuals who have a very high risk of coming in contact with HIV by having unprotected sex with a person who has an HIV infection.

How do I speak to my doctor about PrEP?

See the CDC brochure: www.cdc.gov/hiv/pdf/risk_PrEP_TalkingtoDr_FINALcleared.pdf

Other Resources

Truvada Payment Assistance: www.truvada.com/truvada-patient-assistance

CDC Website on PrEP: www.cdc.gov/hiv/prevention/research/prep/

Gilead Sciences PrEP Website: contains information about the drug, its use for PrEP, and information about the Medication Assistance Program. <https://start.truvada.com>

PrEPLine: 855-448-7737 (toll-free) provides expert guidance to clinicians about prescribing PrEP