



Fact Sheet

For immediate release: November 23, 2010

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Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: Promoting Safe and Effective Use in the United States

New Tool to Reduce the Risk of HIV infection among Gay and Bisexual Men

In November 2010, the National Institutes of Health (NIH) announced the results of the iPrEx trial, a large research study examining whether a pill containing drugs used to treat HIV can also help prevent HIV infection – an approach called pre-exposure prophylaxis, or PrEP. These findings represent a major advance in HIV prevention research, providing the first evidence that PrEP, when combined with other prevention strategies, can reduce HIV risk among men who have sex with men (MSM) (see box).

iPrEx Trial: Key Findings

- *Efficacy:* The trial found that a once-daily pill containing tenofovir plus emtricitabine (brand name Truvada) provided an average of 44 percent additional protection to men who have sex with men (MSM) who also received comprehensive prevention services which included monthly HIV testing, condom provision, counseling, and management of other sexually transmitted infections (95% CI 15 to 63%).
- *Consistent use of PrEP:* The level of protection shown varied widely depending on how consistently participants used PrEP. Among those whose data (based on self-

reports, bottles dispensed, and pill counts) indicates use on 90 percent or more days, HIV risk was reduced by 73 percent (95% CI 41 to 88%), while among those whose adherence by the same measure was less than 90 percent, HIV risk was reduced by only 21 percent (95% CI, from a 52% reduction to a 31% increase).

- *Risk behavior:* Risk behavior among participants declined overall during the trial both in terms of decreases in the number of sexual partners and increases in condom use, likely as a result of the intensive risk reduction counseling provided as part of the trial.

The iPrEx results have immediate implications for the U.S., since tenofovir-emtricitabine pills are already FDA-approved and available with a prescription for the treatment of HIV infection. As the agency responsible for protecting public health, CDC is taking steps to promote the safe and effective use of PrEP in the United States.

HIV among MSM in the U.S.: The HIV epidemic among MSM in the U.S. is severe, and additional risk reduction strategies for this population are urgently needed. MSM represent more than half of new HIV infections and nearly half of all people living with HIV in the U.S., and the rate of new HIV diagnoses among MSM is more than 44 times that of other men. Moreover, data suggests that HIV infections have been steadily increasing in this group since the mid-1990s.

Implications of findings for other PrEP trials: While we don't yet know if PrEP will work for preventing HIV transmission in other populations, these findings give us hope that this approach might also prove effective among heterosexuals at high-risk for HIV and injection drug users. CDC, NIH, and other institutions are conducting trials around the world to determine the safety and effectiveness of PrEP for these populations; those results are expected within the next few years. The iPrEx results may also be the first step toward other effective and potentially more feasible options for PrEP, as other regimens and dosing strategies are also being evaluated.

CDC next steps: CDC will pursue two primary goals in the wake of the iPrEx trial findings: developing guidance on the safe and effective use of PrEP and determining how to most effectively use PrEP in combination with other prevention strategies to reduce new infections in the U.S. The following pages describe these goals in greater detail, and discuss key remaining questions about PrEP as an HIV prevention tool.

Working Toward Safe and Effective Use in the U.S.

Given the availability of the medication proven effective in this trial and the possibility of immediate interest in using PrEP among some high risk gay and bisexual men and their physicians, CDC's most urgent priority is to develop guidance for health-care providers, public health agencies, and gay and bisexual men on its safe and effective use.

CDC will fully review the trial data and publish interim guidance for physicians in the coming weeks in the *Morbidity and Mortality Weekly Report*, to be followed by formal U.S. Public Health Service guidelines. We urge individuals and providers to wait for those guidelines. However, because the drug is commercially available in the U.S. with a prescription, CDC is providing a number of immediate cautions (see box).

Immediate Cautions from CDC

What Gay and Bisexual Men and Doctors in the U.S. Should Know Now About PrEP

For MSM at high risk for HIV infection, PrEP may represent a much-needed additional prevention tool. However, PrEP should be used only in combination with other strategies, requires strict adherence, and is an intensive approach that won't be right for everyone. Anyone considering using or prescribing PrEP should know:

- To date, PrEP has only been shown to reduce HIV infection among men who have sex with men, and there are no data regarding its benefit among heterosexuals or injection drug users.
- Truvada taken once daily is the only regimen shown to be safe and effective for PrEP, and therefore Truvada is the only medication that should be prescribed for PrEP. Providers and patients should be aware that HIV prevention is not a labeled indication for use of the medication.
- PrEP should only be used among individuals who have been confirmed to be HIV-negative. Initial and regular HIV testing are critical for anyone considering using PrEP. All individuals considering PrEP must also be evaluated for other health conditions that may impact PrEP use.
- PrEP should never be seen as the first line of defense against HIV. It was only shown to be partially effective when used in combination with regular HIV testing, condoms, and other proven prevention methods, and it does not protect against other sexually transmitted infections. Men who have sex with men should still:
 - Use condoms consistently and correctly
 - Get tested to know their status and that of their partner(s) for certain
 - Get tested – and treated if needed – for other sexually transmitted infections that can facilitate HIV transmission, such as syphilis and gonorrhea
 - Get information and support to reduce drug use and sexual risk behavior
 - Reduce their number of sexual partners
- Taking PrEP daily is critical. This study found that PrEP provided a high level of protection only to those who took the pills regularly; protection was very low among those who did not adhere to the daily regimen well.
- PrEP must be obtained and used in close collaboration with health care providers to ensure regular HIV testing, risk reduction and adherence counseling, and careful safety monitoring.

Developing Guidelines for Health Care Providers on PrEP Use

CDC will be the lead federal agency in developing U.S. Public Health Service guidelines, in

collaboration with other federal health agencies. The guidelines will be based on a full review of trial data and other research, and will incorporate input from providers, HIV prevention partners, and affected communities. The guidelines will help ensure both physicians and MSM have accurate information to guide decisions about the use of PrEP.

Topics to be addressed in the guidelines will include:

- Specific populations of MSM for which PrEP is recommended
- Procedures for health care providers to assess whether PrEP is appropriate for individual patients (e.g., methods for evaluating patients' risk behavior)
- Recommended support services to help ensure adherence to the daily PrEP regimen
- Recommended risk reduction counseling to prevent inadvertent increases in risk behavior (known as "risk compensation" or "disinhibition"), as well as to provide referrals to—and/or transition individuals to—other, more effective prevention interventions
- Procedures for initial HIV testing and health screening, as well as ongoing monitoring for side effects, clinical toxicities, HIV infection, and possible drug resistance among those who become infected despite taking PrEP

Maximizing the Potential Benefits of PrEP in the U.S.

The iPrEx trial findings offer a new tool to help combat HIV among MSM, one of the hardest hit populations in the U.S. and many areas of the world.

We will have to carefully consider how to most effectively use this tool in combination with other prevention strategies to reduce the continuing toll of HIV and AIDS. There are a significant number of HIV-positive individuals in the U.S. and around the world who do not have access to antiretroviral drugs to treat their infection, and we know that treatment not only benefits infected individuals, but can also reduce transmission to others. But, we also know that treatment alone will not end the epidemic. With 2.7 million people becoming infected annually worldwide, including approximately 56,000 in the U.S., we must capitalize on every available prevention tool.

Ultimately, the impact of PrEP on the U.S. HIV epidemic will depend on difficult decisions and many things that remain unknown, including the feasibility, cost, and impact of this strategy in real-world settings.

Available data suggest that PrEP, used strategically and effectively among MSM, could have a positive impact on the U.S. epidemic and be cost-effective, but only if certain conditions are met, including:

- Reaching the MSM at highest risk for HIV infection
- Effectively delivering PrEP in tandem with effective risk reduction counseling, condoms, and other prevention tools as were delivered in the trial setting. This will be critical to prevent increases in risk behavior that could offset the benefits of PrEP
- Identifying ways to achieve the high levels of adherence needed for maximum protection

CDC's Next Steps

CDC will be implementing a range of activities to promote the effective and strategic use of PrEP in the U.S. In addition to developing public health guidelines, CDC will:

- Conduct research to determine how to most effectively communicate about the use of PrEP in conjunction with other risk reductions strategies
- Develop comprehensive risk reduction guidelines for MSM, which will incorporate PrEP and all proven strategies
- Adapt national HIV surveillance and program monitoring systems to help evaluate the use and impact of PrEP in the U.S.
- Examine potential program costs, impact, and cost-effectiveness compared to other interventions
- Communicate guidance to providers and MSM through multiple information channels
- Hold a consultation with public and private insurers to better assess the potential barriers and facilitators of PrEP coverage

CDC has also identified other activities that could help address remaining research questions and is currently exploring all avenues to identify resources to support them. Key among these is the need for demonstration projects in clinics serving MSM to assess feasibility, acceptability, and the impact of PrEP in real-world settings. It will also be critical for public and private sector partners to begin to collectively address the significant financial barriers that may place PrEP out of reach for many MSM at highest risk for HIV infection.

Given the urgency of addressing the HIV epidemic among gay and bisexual men in this nation, CDC is working to maximize the impact of this important new intervention in combination with all available HIV prevention strategies.

For more information on PrEP and HIV prevention, please visit www.cdc.gov/hiv/prep (<http://www.cdc.gov/hiv/prep>).

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  (<http://www.hhs.gov/>)

Page last reviewed: November 23, 2010

Page last updated: November 24, 2010

Content source: National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention

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