NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
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- **A once-daily combination antiretroviral pill (FTC-TDF, or Truvada) used in combination with standard risk reduction strategies has been shown to reduce the risk of HIV acquisition in high-risk MSM and transgender women who have sex with men.**
- **There may be some patients at extremely high, ongoing risk for HIV acquisition for whom providers may consider prescribing this preventive treatment. However, providers considering this off-label use must be aware of the limitations and risks of this treatment and should follow CDC recommendations regarding medical evaluation, prevention counseling, adherence counseling, and monitoring.**

Dear Colleagues:

The purpose of this letter is to call your attention to a recent study evaluating the potential for an antiretroviral regimen started before exposure to HIV for preventing HIV transmission and to alert you to interim guidance from the Centers for Disease Control and Prevention (CDC) regarding its use in medical practice.

Standard strategies for HIV prevention include delaying sexual initiation, abstaining from sex, using condoms when engaging in sex, reducing partner number, male circumcision (to prevent heterosexual transmission), and promptly treating other sexually transmitted infections. For HIV-infected persons, there is increasingly good evidence that reaching or maintaining an undetectable viral load may prevent secondary HIV transmission. An additional tool is now available for certain persons who are not infected with HIV.

A recently-published multinational study (the 'iPrEx' trial) suggests that once-daily tenofovir disoproxil fumarate plus emtricitabine (FTC-TDF, brand name Truvada) in combination with standard risk reduction strategies can further reduce the risk of HIV acquisition (Grant et al. N Engl J Med 2010;363:2587-99). This study was conducted in uninfected men who have sex with men (MSM) and transgender women (genetic males who identify as female) who have ongoing high risk sexual behavior (multiple partners, receptive anal sex, inconsistent condom use) despite counseling on standard risk reduction strategies. Although it is a single study, the findings are sufficiently encouraging and important enough that the Centers for Disease Control and Prevention (CDC) published interim guidelines on the use of Pre-Exposure Prophylaxis (PrEP) on January 28, 2011. These guidelines can be found at **cdc.gov/hiv/prep**. FTC-TDF (Truvada) is currently widely available for the treatment of HIV infection. However, use of this medication for HIV prevention has not been approved by the Food & Drug Administration (i.e., it is currently considered an off-label use). Study results suggest that providers might consider initiating PrEP for those individuals who face extremely high, ongoing risk of HIV acquisition, such as HIV negative partners in a serodiscordant MSM partnership, or male sex workers who do not use condoms despite repeated counseling.

However, before considering PrEP for any patient, providers are urged to thoroughly review the CDC guidelines and note the following:

- **KEY POPULATIONS: The only completed study to date of PrEP involved MSM and transgender women who continued to engage in high risk sexual activities (e.g., multiple partners, receptive anal sex, inconsistent condom use) with men despite risk reduction counseling. There are no equivalent data for the use of antiretroviral agents including FTC-TDF for pre-exposure prophylaxis among heterosexuals, injection drug users or any other population at risk for HIV infection, although a study on high-risk women was terminated early in April 2011 because of lack of measurable benefit.**

- **OFF-LABEL USE: No other antiretroviral regimen to date, except once-daily FTC-TDF, has been shown to effectively prevent HIV infections or to be safe for this purpose. Providers and patients should be aware that HIV prevention is NOT a labeled indication for use of any medications. Prescription of FTC-TDF to HIV negative individuals for the purpose of preventing HIV is currently considered an OFF-LABEL USE.**

- **COMBINATION STRATEGY: PrEP should never be undertaken as a first-line prevention strategy or as an isolated strategy. PrEP should be used only in combination with other evidence-based HIV prevention strategies, including regular and consistent condom use, partner reduction, behavioral risk reduction messaging and management of other sexually transmitted infections. All persons in the iPrEX study had regular counseling and the frequency of risky behavior was reduced while enrolled in the study.**

- **DOCUMENT SEROSTATUS: PrEP should not be initiated without documenting HIV negative serostatus immediately prior to starting drug, and persons who remain on PrEP should be tested for HIV at regular, frequent intervals.**

- **ADHERENCE COUNSELING: To receive maximal benefit, PrEP must be taken daily with regular adherence counseling. The iPrEx study found that greater adherence (as measured by serum FTC-TDF levels) was associated with greater protection. PrEP provided a significantly higher level of protection for those who took pills regularly, and particularly for those who had evidence of FTC-TDF in their blood. Protection was very low and not statistically significant among those who did not adhere well to the daily regimen. Personal reports of pill usage over-estimated adherence when compared with measures of blood drug levels.**

- **MEDICAL EVALUATION: Any individual being considered for PrEP should be evaluated for other health conditions that may impact PrEP use, including renal dysfunction. Patients taking immunomodulators should not be prescribed FTC-TDF. All individuals who are prescribed PrEP should be followed closely by a health care provider experienced in HIV treatment for careful safety monitoring.**

- **CONSISTENT, DAILY DOSING: In addition, we note that to be effective, PrEP must be taken daily both before and after exposure. Based on current study results, it is not intended to be taken only around individual risky sexual encounters.**

Finally, all new HIV diagnoses must be reported to the New York City Department of Health and Mental Hygiene by completing the required New York State 'Provider Report Form' (NYS DOH Form #4189). Copies of this form can be ordered from New York State by calling (518)-474-4284. A sample Provider Report Form can be viewed on our NYC DOHMH website (www.nyc.gov/health/hiv, click 'HIV Epidemiology Program'). For assistance in notifying a patient's sex and/or needle-sharing partners about their HIV exposure, please call the Contact Notification Assistance Program at (212)-693-1419.

Thank you very much for your continued efforts in the fight against HIV in New York City.

Sincerely,

Thomas A. Farley, M.D., M.P.H
Commissioner