CDC PrEP Program Guidance for
HIV Prevention Health Department Grantees
August 2012

Introduction:

The purpose of this document is to provide updated guidance to health department HIV prevention programs funded by the Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) on which preexposure prophylaxis (PrEP) related services for MSM and heterosexually-active men and women can be supported with PS12-1201 HIV prevention funding.

In November 2010, the results of the international iPrEx clinical trial were published. The trial found that daily oral use of tenofovir plus emtricitabine (brand name Truvada®) provided an average of 44% additional protection in preventing HIV infection among trial participants that included gay, bisexual, and other men who have sex with men (MSM), as well as transgendered women who have sex with men. The participants also received a comprehensive package of prevention services that included monthly HIV testing, condom provision, counseling, and management of other sexually transmitted infections. In January 2011, CDC issued interim guidance for PrEP for the prevention of HIV infection in men who have sex with men.

In August 2012, researchers published the results of two PrEP studies finding strong evidence that PrEP is effective and safe among heterosexually-active men and women. The Partners PrEP study found that that daily doses of tenofovir plus emtricitabine or daily doses of tenofovir alone reduced HIV transmission among heterosexual HIV discordant couples (in which one partner is infected with HIV and the other is not) by 75% and 67%, respectively. The trial found that PrEP was equally effective among men and women, and that there was no statistically significant difference in efficacy between the two medication regimens. The TDF2 study found that a once-daily tablet containing tenofovir plus emtricitabine reduced the risk of acquiring HIV infection by roughly 62% overall in the study population of uninfected heterosexually-active men and women. A third study published in August 2012, Fem-PrEP, did not find efficacy for PrEP with tenofovir plus emtricitabine, primarily due to very low adherence to daily use of the medication.

As with the iPrEx study, both Partners PrEP and TDF2 showed that the level of protection offered by PrEP is strongly related to the level of adherence to the daily medication doses. In Partners PrEP, participants in the tenofovir-plus-emtricitabine group with detectable levels of the medication experienced a 90% reduction in risk for HIV infection; in the tenofovir- only group, the presence of medication in the blood was associated with an 86% reduction in risk. In TDF2, only half of the participants in the tenofovir-plus-emtricitabine group who became infected with HIV had any detectable medication in their blood, and even those participants had very low levels of medication present. This suggests that they had not taken PrEP consistently. In contrast, over 80% of matched participants who remained uninfected had detectable medication in their blood and the average medication level was substantially higher. In a substudy of the Fem-PrEP trial, detectable drug was <27% among women who acquired HIV infection and <38% among matched uninfected controls. Based on the data from these and other PrEP studies, in July 2012, the FDA approved a label indication for the use of Truvada® for the prevention of sexual acquisition of HIV infection in adults. In August 2012, CDC issued interim guidance for clinicians considering the use of PrEP for the prevention of HIV infection in heterosexually-active adults.
Guiding Principles for using DHAP funding for PrEP-related activities:

- Participation in PrEP-related activities is optional under PS12-1201.
- PrEP-related activities to support prevention services for MSM and heterosexually-active men and women must be implemented as part of a comprehensive HIV prevention program that includes, as appropriate, linkage and referral to prevention and treatment services for sexually transmitted diseases (STD) and viral hepatitis, substance abuse and mental health, and other prevention support services.
- To minimize duplication of effort, DHAP health department grantees should coordinate and collaborate with other agencies, organizations, and providers involved in PrEP-related activities, STD, viral hepatitis, and substance abuse prevention and treatment, and HIV prevention activities.
- Funds for PrEP-related activities should ensure that referral and linkage to existing HIV prevention and treatment services are maintained.
- PrEP-related activities are subject to the terms and conditions incorporated or referenced in the grantee’s current cooperative agreement or grants.

Funds may be used for, but are not limited to, the following:

- Planning for how to most effectively incorporate PrEP into prevention education and services, including evaluating what collaborations will be needed.
- Educational materials about how to use PrEP in conjunction with other HIV prevention and care services, as well as STD, viral hepatitis, mental health and substance abuse treatment.
- Development and delivery of the HIV risk-reduction counseling and behavioral interventions that must be provided with PrEP.
- Communication activities related to disseminating information about PrEP.
- Evaluation activities for PrEP-related activities.
- Personnel (e.g., program staff) conducting the above PrEP-related activities.

Funds may not be used for:

- PrEP medications (antiretrovirals).
- Laboratory testing related to PrEP (other than HIV tests or hepatitis screening).
- Personnel costs for the provision of PrEP medication and recommended clinical care associated with PrEP.

Applicable cooperative agreements:

Funds provided under PS12-1201 (Comprehensive HIV Prevention Programs for Health Departments) may be used to support PrEP-related activities. Please refer to that Funding Opportunity Announcement (FOA) for guidance on submission of programmatic and budget requirements. Funds provided under CDC DHAP FOAs for community-based organizations may not be used for implementing PrEP-related activities. However, grantees funded under those announcements are encouraged to incorporate messages regarding PrEP into the counseling they provide as part of HIV counseling and testing and to provide appropriate referrals. These grantees may also collaborate with state or local health departments to implement PrEP-related activities in conjunction with state, local, or other federally funded programs.
Process for Programs to use Current Cooperative Agreement Funding for PrEP-related activities:

- Contact your HIV prevention project officer to discuss your program plans before submitting plans to CDC or revising budgets.
- Consider activities to support PrEP for those adult MSM and heterosexually-active men and women who are at very high risk of acquiring HIV infection.
- Work in partnership with CDC to determine the appropriate process measures to capture PrEP-related activities.
- Contact your HIV prevention project officer to discuss specific capacity building assistance needs or to request training and technical assistance.
- CDC will implement a streamlined process for consideration of PrEP-related activities.