

CALL TO ACTION

A Comprehensive Plan for PrEP Demonstration Projects is Quickly and Urgently Needed

Thirty years into the HIV epidemic in the United States, we are at an important crossroads. Exciting new data have emerged in the last year from several clinical trials demonstrating that pre-exposure prophylaxis (PrEP)—whereby HIV-negative individuals take antiretroviral (ARV) drugs to protect themselves from infection—can significantly reduce the chance of HIV acquisition when offered as part of a comprehensive prevention package (including condoms, risk-reduction counseling, and screening and management of other sexually transmitted infections). However, worrisome statistics from the U.S. Centers for Disease Control and Prevention (CDC) were also recently reported, showing sharp increases in new HIV infections in African American gay men and other men who have sex with men (G/MSM). These data highlight the urgency of knowing how to translate the efficacy of PrEP in these clinical trials into effectiveness—that is, the ability to reduce new HIV infections in the real world.

Proving real-world effectiveness will require leadership, resources, and the engagement of multiple stakeholders: three key ingredients that have yet to be fully realized. As such, we—the undersigned groups—are calling on the Department of Health and Human Services (DHHS) to lead an expedited process to clearly outline and commit to a plan for implementing PrEP demonstration projects focused on G/MSM. The data suggest that PrEP can be an important HIV prevention strategy for G/MSM and transgender women, who continue to bear the brunt of the HIV epidemic in the United States. We look forward to the further analysis of existing PrEP efficacy data in other populations and to the results of other ongoing trials, yet we feel it is critical to act *now* to address how to successfully deliver PrEP to G/MSM and transgender women while we await those additional results.

We urge the DHHS to develop a comprehensive plan addressing:

- the number and geographic location of projects that will be needed to assess the relevance, feasibility, and potential efficacy of PrEP for different communities of G/MSM and transgender women;
- the questions to be addressed through these projects; and
- the human and financial resources (both governmental and non-governmental) necessary to implement the projects.

Additionally, in keeping with the spirit of the National HIV/AIDS Strategy to not only coordinate government activities, but to also foster public-private partnerships, it is essential that Gilead Sciences, the maker of the drugs tested for PrEP so far, comes to the table to support demonstration project efforts—which could include providing free drug to the projects and/or funding the projects themselves.

At least two demonstration projects targeting G/MSM have been proposed and are under discussion among researchers, program implementers, and funders, but these two projects will not be sufficient to determine how to implement PrEP in diverse communities of G/MSM. Moreover, robust funding of a suite of projects, a critical next step, remains uncertain. It is time for the DHHS and its partner agencies to put into effect a thorough, integrated, and strategic plan for demonstration projects that are fully funded, complementary rather than duplicative, and able to answer critical questions related to the feasibility, desirability, and potential impact of PrEP programs in G/MSM communities across the country.

A detailed discussion is attached to this call for action that further describes the need for PrEP demonstration projects and the questions that must be answered in the interest of determining what place PrEP has in reducing new HIV infections among G/MSM and transgender females.

While robust discussion and debate of any new discoveries are welcome, they should not stymie action where it is appropriate and necessary. We believe the nation needs a clear and comprehensive path forward on PrEP, where the evidence supports its implementation, and we need it now.

We encourage other groups and individuals to join our voices in calling for rapid action on this important endeavor. To sign on for your organization write to: piadvocacy@gmail.com.

AIDS Foundation of Chicago

AIDS United

amfAR: The Foundation for AIDS Research

AVAC: Global Advocacy for HIV Prevention

Black AIDS Institute

International Rectal Microbicide Advocates

National Alliance of State & Territorial AIDS Directors

National Minority AIDS Council

Project Inform

San Francisco AIDS Foundation