Working Group on U.S. Women and PrEP

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Coalition of U.S. Women's Health and HIV Advocates Call for Accelerated US Government Plan for Demonstrating Feasibility of PrEP for Women

VOICE Results Underscore Need for Clear, US-Based PrEP Implementation Agenda

Atlanta, March 4, 2013 – The *U.S. Women and PrEP Working Group*, a coalition of more than 50 women from leading AIDS and women's health organizations, today called on US government agencies to coordinate a national agenda that will quickly and accurately answer questions about how the antiretroviral (ARV) drug Truvada can best be made available as an HIV prevention option for women at risk of HIV infection.

The Working Group called for a US federal coordinating group to be convened with the goal of ensuring that plans and funds are in place for demonstration projects that will answer key questions about the use of daily tenofovir/emtricitibine (TDF/FTC, brand name Truvada) as pre-exposure prophylaxis (PrEP) among women in the United States, as well as plans for educational campaigns for women, their partners and health care providers as PrEP is rolled out.

"Many women in the US are at high risk for HIV. In some communities African American women are at as much risk of HIV as in many African communities and they need new HIV prevention options that they can control and use to protect themselves. PrEP can be that option for some women. The scientific evidence is clear, and last year's FDA approval of Truvada as PrEP for all men and women at risk of HIV paved the way for the next steps," said Dazon Dixon Diallo, MPH, Executive Director of SisterLove and convener of the Working Group.

"While the clinical science is clear, the social and behavioral implications are less so, and we now need to develop and fund demonstration projects that will help answer a range of questions about real-world use of PrEP by American women and move toward an integrated plan for PrEP rollout in our communities that includes support for healthcare providers, social workers and others who will help women use PrEP effectively," Diallo added.

Researchers reported today at the 20th Conference on Retroviruses and Opportunistic Infections (CROI) in Atlanta that none of three interventions tested in a large scale trial among African women, known as VOICE (Vaginal and Oral Interventions to Control the Epidemic) – daily oral tenofovir, daily oral TDF/FTC and daily 1% vaginal tenofovir gel – provided additional protection against HIV, likely because of low adherence in across all three interventions.

PrEP trials in Africa have provided key data about women in different populations and life circumstances. Trials have shown high rates of effectiveness among African women in stable relationships in which one partner is HIV-positive and low or flat rates of effectiveness among young women who were less likely to be in stable relationships. In all of these trials, including the VOICE trial, higher rates of effectiveness were linked with higher rates of adherence.

“The VOICE results were disappointing. The fact that few women in a trial which had very high rates of HIV incidence chose to, or were able to, use the products daily shows that we have much work to do to understand what social, cultural and other factors affect adherence to the prescribed dose and how we can support women in effectively using new prevention tools. But PrEP remains a valuable option for many women who will want to and can use it as prescribed,” said Manju Chatani-Gada, Senior Program Manager at AVAC and co-convener of the Working Group. “Well-designed demonstration projects will help us understand adherence and other real-world issues for women who choose to use PrEP.”

The Working Group calls for a coordinated, timely and adequately funded U.S. government response to PrEP for women that involves the full participation and leadership of individuals and communities most in need of effective, comprehensive HIV prevention. The federal coordinating group must look to answer critical questions not answered by current data about daily Truvada for PrEP, including:

- How will daily PrEP be used for HIV prevention by women in the United States?
- What data are needed regarding daily PrEP’s acceptability and effectiveness among those women?
- How will daily PrEP be promoted, made accessible and financed for use by U.S. women?

The Working Group calls for prompt action from federal agencies, led by the Office of National AIDS Policy (ONAP) and the Centers for Disease Control and Prevention (CDC**)** to develop a plan that will fill the gaps in PrEP research, public and provider education, social marketing and public policy, and that defines the next steps required for real-world use and development of a comprehensive rollout plan for PrEP among at risk women in the United States.

“Male and female condoms are wonderful HIV prevention options that work for many women and their partners. But some women can’t insist their partners use condoms, and many young women and their HIV-positive partners want to have children,” said Erika Aaron, a nurse practitioner at Drexel University School of Medicine, Division of Infectious Diseases and HIV Medicine. “Those women need other options to protect themselves from HIV. PrEP can help them stay HIV-negative. We have a moral imperative to find ways to make it available to women who need it and who can use it.”

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The Working Group on U.S. Women and PrEP Statement and other information about PrEP and women is available at http://www.prepwatch.org/#women.