U.S. WOMEN AND PREP WORKING GROUP POSITION STATEMENT
Key Points

March 4, 2013

Background

- Daily oral TDF/FTC (Truvada) is FDA-approved for HIV-negative women and men to reduce risk of HIV infection. The data to support this approval come from several HIV prevention clinical trials and these data are clear: those who are able to take daily TDF/FTC reduce their risk of HIV. What is not yet clear is how best to deliver this intervention and support those interested in taking it.
- Daily oral Truvada is a valuable tool that some U.S. women, including transwomen, may use to reduce their HIV risk.
- There are still key unanswered questions about how and to whom PrEP use should be promoted in the U.S.
- The U.S. Women and PrEP Working Group – a group of leading women's health advocates from across the country – is working to help define these questions, and propose a way forward.

Key Unanswered Questions for PrEP for U.S. Women

Access and adherence

- Which women in the U.S. could most benefit from PrEP?
- How will their health care providers be trained on PrEP use?
- What is the role of social marketing for PrEP in different communities?
- What will safety, efficacy, and eventual use of PrEP among women look like over the long term?
- What factors affect PrEP adherence among women and how can women who use PrEP best be supported in taking it as prescribed?

Possible risks and side effects

- What issues will PrEP raise for women who are at high risk of HIV? How will the availability of PrEP affect women's choices?

  Will some sex workers, for example, be pressured by their business managers to use PrEP because male clients dislike condoms?

  Will some women be pressured by their partners to use PrEP instead of condoms?
- Are the possible interactions between Truvada and the female hormones many transgender women use? Will there be drug interactions between PrEP and recreational drugs?
- Are there long-term health effects from Truvada for children whose mothers use PrEP during pregnancy or breast-feeding? How can these be tracked beyond the first year of life covered by current PrEP registries?

Next steps

Answering these questions quickly and accurately will require investment, collaboration and some restructuring of the current PrEP research agenda.

The U.S. Women and PrEP Working Group calls on the Office of National AIDS Policy and the Centers for Disease Control and Prevention (CDC) to coordinate a collaborative effort that involves the National Institutes of Health (NIH), the CDC, other Health and Human Services entities, Gilead Sciences, city health departments, civil society groups, service providers, and HIV/AIDS, sexual and reproductive health, and other community-based service-providing organizations.

The Working Group is looking for specific outcomes for this effort, including:

- A well-articulated pathway to answering these critical questions about PrEP
- Substantial, ongoing civil society engagement in the process
- A national plan for provider education and social marketing about PrEP
- A clearly delineated, detailed plan for incorporating PrEP education and access for women into implementation of the National HIV/AIDS Strategy (NHAS)
- A process that includes milestones, feedback mechanisms, sufficient resources and accountability

Time is of the essence and the Working Group proposes the following deadlines for the next critical steps in this process:

July 15, 2013 Coordinating group is established to develop an integrated plan of PrEP rollout for women

Sept. 30, 2013 Funding is identified and mechanisms in place to support the needed range of demonstration projects on women's uptake and use of PrEP

Bottom Line

PrEP has potential to be a powerful prevention tool for some women. But this promise will not be fully realized unless specific actions are taken without delay. Further, planning for meaningful rollout of PrEP for women must be done with the full participation and leadership of individuals and communities most in need of comprehensive HIV prevention.

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