

WORKING GROUP ON U.S. WOMEN AND PREP STATEMENT

4 March 2013

INTRODUCTION

We are a group of U.S.-based women's health advocates and other interested parties who have been meeting since March 2012 to build a common understanding of what pre-exposure prophylaxis (PrEP) as a new HIV prevention tool could mean for women in the United States.

In July 2012, the US Food and Drug Administration (FDA) approved the use of daily oral Truvada[®] (Emtricitabine/Tenofovir Disoproxil Fumarate, a combination anti-retroviral drug already used to treat HIV infection) for HIV prevention as PrEP in HIV-negative adult men and women at risk for HIV infection.ⁱ The FDA approval was based on data from clinical trials that had demonstrated the efficacy of Truvada in preventing HIV acquisition in populations of gay and other men who have sex with men (MSM), transwomen, and heterosexual women and men in a number of sites around the world.ⁱⁱ

However, none of these trials included U.S. women, leaving critical questions unanswered:

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

This *Statement* summarizes the recommendations of our Working Group for ways to respond to these critical questions; fill the corresponding gaps in research, public and provider education, social marketing and public policy, and define the next steps required for "real-world use" of PrEP among women in the United States. Our recommendations address three "Key Points" made in order to advance discussion of:

- The rollout of PrEP for use by U.S. women;
- How to pinpoint and address the gaps in research regarding PrEP implementation among U.S. women; and
- How and by when federal agencies and other stakeholders need to collaborate on joint collection of the data needed to answer those questions.

THREE KEY POINTS

1. Daily oral Truvada has the potential to be a prevention tool that women, including transwomen, can use to reduce their risk of HIV infection.
2. A coherent and comprehensive vision of how implementation of PrEP use among U.S. women will occur has yet to be well articulated. Neither has there been a consistent voice for women on the subject of PrEP implementation that is proportionate to women's presence in the U.S. epidemic. Establishing better communication and coordination among thought leaders and public health agencies/implementers to correct this is imperative.
3. Available clinical trial data justify exploring daily oral Truvada as PrEP, but many unanswered questions remain about how best to offer this intervention to women. These include questions about the female target populations for PrEP, strategies for training their health care providers, the role of social marketing directed to women in this rollout, and the safety, efficacy, uptake, and adherence to PrEP use over the long term – in both women and men.

Key Point 1

Daily oral Truvada has the potential to be a prevention tool that women, including transwomen, can use to reduce their risk of HIV infection.

In 2010, the large-scale iPrEX trial demonstrated the effectiveness of using daily oral Truvada (FTC/TDF) as PrEP among men who have sex with men (MSM) and transwomen who have sex with men. Subsequently, Truvada was shown to greatly reduce HIV risk among both men and womenⁱⁱⁱ in the Partners PrEP Study. This large trial enrolled heterosexual couples in which one partner was HIV infected, the other was HIV negative (also called serodiscordant couples or serodifferent partners),^{iv,v} Another, smaller study ("TDF2") in men and women who were not couples also showed use of daily Truvada helped reduce HIV risk.

In contrast, the FEM-PrEP trial and the VOICE trial- both of which enrolled African women who were not necessarily in stable serodiscordant relationships - did not provide evidence of the intervention's effectiveness among trial participants. In both, it appeared that participants' overall adherence to the daily pill-taking regimen was too low to have shown significant benefit.^{vi,vii,viii} Many questions about the use of Truvada for preventing HIV in women remain, chief among them the question of why daily adherence rates, especially among younger and unmarried women, tend to be low and what other approaches might be more successful. While this study underscores the critical importance of supporting adherence to prevention products, it does not nullify the proven biological plausibility of using Truvada as PrEP to prevent HIV infection for women.

Based primarily on the results of iPrEx in MSM and Partners PrEP in serodiscordant couples, in July 2012 the FDA approved daily oral Truvada as PrEP for HIV-negative adults. In August 2012, the US Centers for Disease Control and Prevention (CDC) released guidelines for PrEP for HIV Prevention among heterosexually-active adults in the United States.^{ix} Many civil society groups participated in active discussion leading up to the FDA review, submitted input to the FDA hearings, and assessed the impact of the strategy after the FDA hearings.

While concerns about all that is unknown about PrEP persist, additional women-controlled HIV prevention tools are urgently needed as there is strong interest in exploring PrEP's desirability, feasibility, real-world safety and effectiveness for women. Qualitative data from a four-site focus group study on U.S. women and PrEP presented at the XIX International AIDS Conference in July 2012 found that most U.S. women at risk of HIV infection (and those who work with them) are unaware of PrEP.

Yet when educated about PrEP, women believe that, given a demonstrated high level of efficacy, correct and complete information from trusted sources, and an assured way of paying for it, PrEP should be available to all women who are sexually active, whether or not they see themselves at risk of HIV infection.^x In this study, women identified as primary concerns side effects, including PrEP's interaction with other drugs they may be taking, level of efficacy, and its cost of and payment requirements.

Key Point 2

A coherent and comprehensive vision of how PrEP implementation among U.S. women will occur has yet to be well articulated. Neither has there been a consistent voice for women on the subject of PrEP implementation proportionate to women's presence in the U.S. HIV/AIDS epidemic. Establishing better communication and coordination among thought leaders and public health agencies/implementers to correct this is imperative.

Entities on the frontlines of PrEP programs (planned or already in place) throughout the country have roles to play in structuring the PrEP research agenda. These include city health departments and the many civil society groups, service providers and AIDS service organizations, as well as the National Institutes of Health (NIH), the

CDC and other agencies in the Department of Health and Human Services (DHHS), and Gilead Sciences (manufacturer of Truvada).

The productive involvement of *all* these players requires thoughtful coordination. These groups should be organized to participate collectively in gathering data, discussing plans for social marketing campaigns, identifying gaps, and developing a strategic mechanism for coordinated action. This coordinated process should include milestones, feedback mechanisms, sufficient resources and accountability. This process and its outputs should be developed as soon as possible--at the latest, by the beginning of the third quarter of 2013. The outcomes from this process should include:

- *A well-articulated pathway to answering critical questions about PrEP and women*

A range of questions appear below under *Key Point #3* that are fundamental to safe, effective use of daily oral Truvada as PrEP in women. Some of these questions can be addressed in clinical trials, but many others can only be addressed through well-designed pilot programs, demonstration projects, and qualitative research – research that will require collaboration among NIH, CDC, other HHS entities, and city health departments, as well as strong civil society input. A single document is needed describing how each of the questions raised can best be addressed — what sorts of data should be collected, in which geographical locations should research take place, and where the gaps are in information and/or funding.

- *A structure that provides for substantial, ongoing civil society engagement*

As the approach to PrEP introduction and implementation is spelled out, the expertise of civil society individuals and organizations as educators, advocates, critics and communities of potential users must be harnessed. The decision-making processes that emerge as a result of the national coordination effort must include their full participation, both as experts and as recipients of the kinds of funding and technical assistance they will need in order to provide critical support for PrEP implementation.

- *A national plan for provider education and social marketing*

Most U.S. women have never heard of PrEP. Yet it is essential that women at risk of HIV acquisition receive information about PrEP in easily accessible forms: in the languages, literacy levels, formats, and media that are comfortable for them, they must also receive this information from trusted sources. The history of female condom uptake demonstrates that introduction of a new prevention tool must include extensive provider education, as well as active provider and community involvement, to be successful.

The CDC and HHS need to be at the forefront of a coordinated education and social marketing plan, not be led by a pharmaceutical company. A broader and more comprehensive strategy is required to educate the full range of health care providers who need to be engaged in PrEP roll-out. This is essential to ensuring women can make educated decisions about whether or not PrEP is right for them.

- *A national strategy outlining in detail how PrEP education and access for women will be incorporated into implementation of the National HIV/AIDS Strategy (NHAS)*

The Office of HIV/AIDS Policy (OHAP) should present a strategy showing how a woman-centered PrEP education component will be incorporated into NHAS implementation, the 12-Cities Project implementation^{xi}, and in the context of the Affordable Care Act. This strategy should include materials and curricula designed -- and implementation efforts resourced -- to meet the needs of the targeted audiences. Civil society organizations must be integral in this process and funded to provide the forms of community support that assist PrEP users with medication adherence.

Key Point 3

Available clinical trial data justify exploring daily oral Truvada as PrEP, but many unanswered questions remain about how best to offer this intervention to women. These include questions about the female target populations for PrEP, strategies for training their health care providers, the role of social marketing directed to women in this rollout, and the safety, efficacy, uptake, and adherence to PrEP use over the long term – in both women and men.

Demonstration projects to gather information on PrEP uptake and use by men and transwomen who have sex with men are underway. Research to gather additional information on PrEP's implications for women -- individually and as part of a couple – is urgently needed. Although PrEP is now available to women in the United States, very little is known about how women will use it and for whom it will be most effective.

The Partners PrEP trial, for instance, indicated that PrEP was very effective among women in committed relationships with an infected partner. Since participants in this study understood fairly well their risk of infection, they were likely motivated to use Truvada consistently. How well PrEP will work among women who may have more than one sex partner and/or who may not necessarily know their partners' HIV status is unknown. PrEP offers women the possibility of using protection without a partner's permission or knowledge, but before these crucial benefits of PrEP can be widely and confidently promoted and realized, more data are needed in several areas including:

- *Efficacy and effectiveness – what affects whether daily oral Truvada provides protection — or does not?*

The three trials (iPrEx, Partners PrEP and TDF2) demonstrated that Truvada's effectiveness in various populations depended on adherence to using it as prescribed. Oral PrEP's lack of effectiveness among the women in the FEM-PrEP and VOICE trials was most likely due to poor adherence. Unlike the women in Partners PrEP, many of the women in FEM-PrEP and VOICE may not have known the HIV status of their sex partners, some of whom could likely have had acute infection. Moreover, many of the participants in the FEM-PrEP study reported that they did not perceive themselves at risk of HIV infection, despite living in a high prevalence area. Information about how risk perception and a host of other factors may have influenced women's use or non-use of the study products in VOICE are not yet available. Results of VOICE sub-studies looking at these issues are expected in the coming months.

The question of how best to support adherence among women taking PrEP is absolutely vital. Women – and other PrEP stakeholders – need to understand all the factors (behavioural and biomedical) affecting PrEP efficacy and effectiveness. Some data may come from additional analysis of clinical trial data. More data must also be collected through pilot and demonstration projects that can assess how well PrEP works at the population level, in real-world settings beyond clinical trials.

- *Adherence -- what factors affect it? How can it best be supported among women?*

As with most medications, PrEP is most effective among those who take it as prescribed. Yet adherence to any regimen can be difficult due to a wide range of structural, psychosocial, and practical challenges. To really understand the contribution of such variables, evidence of effective behavioral, social and structural interventions will have to be gathered through research, monitoring, and evaluation of pilot and demonstration projects to determine factors supporting or inhibiting adherence among women choosing to use PrEP. Such research will not only maximize the individual's chances of avoiding HIV but prevent the generation of drug-resistant HIV. The latter is a risk among those who take PrEP and seroconvert while using it. Regular HIV testing, adherence to the regimen, and attendance at clinic visits can all help to maximize PrEP's effectiveness and prevent undetected sero-conversions among PrEP users which could lead to development of drug-resistant HIV virus. Providing explicit material and woman-focused support to female PrEP users, therefore, has both a public health and an individual benefit.

- *Sexual disinhibition and partners' sexual risk behavior*

There are few data on how PrEP availability in the real world will affect adherence to other HIV risk reduction tools such as male and female condom use, partner reduction, and other prevention strategies. Qualitative research in this area is limited and has been done mainly among MSM. Thus, more behavioral and social science research and program monitoring and evaluation will be required in these areas as PrEP is rolled out.

The concerns of key populations must also be addressed. For example, the rights of sex workers, as well as their health, may be further compromised if public awareness of PrEP leads clients to negotiate more aggressively for condomless sex.^{xii} If research reveals PrEP use by either partner is likely to significantly reduce women's ability to insist on condom use, this information must be addressed. In general, insistence on condom use has always been the weakest link in HIV prevention for women. Ideally, PrEP should be part of a "combination prevention" package that includes condom promotion. But this expectation is unrealistic if not balanced by the data demonstrating women have substantially less control over condom use (even with female condoms) than do men.^{xiii}

- *Impact on pregnancy, breastfeeding and infant development*

As a Category B drug (one not shown to cause fetal toxicity in animal studies), Truvada is routinely prescribed to HIV-positive pregnant women in the United States since its benefits have been judged to outweigh the potential risks. The CDC specifies, however, that PrEP should not be prescribed to women who are breastfeeding.^{xiv} Important data on the safety of Truvada in pregnant and breastfeeding HIV- negative women and their babies is being generated by the federal ARV and Pregnancy Registry (<http://apregistry.com>) and Gilead's post-marketing studies of Truvada. But these registries only track infants through the first year of life and prospective studies have not been undertaken to assess their progress between birth and age 5. Given that being pregnant raises one's risk of seroconversion^{xv}, the option to continue PrEP use throughout pregnancy would be valuable to women at risk of HIV if research confirms that such continued use is safe.

- *Liver toxicity, reduced bone mineral density (BMD) risks and potential drug interactions in HIV negative women*

Tenofovir (a component of Truvada) has been linked to reduced bone mineral density (BMD) and liver toxicity. One PrEP study enrolling MSM showed small but statistically significant^{xvi} changes in BMD among men taking tenofovir versus placebo. The TDF2 study also showed a "statistically significant but clinically ambiguous" reduction in BMD among male and female participants receiving Truvada.^{xvii} VOICE B, a sub-study of the VOICE trial, will provide more data on BMD changes among women using PrEP.

Neither Partner's PrEP nor TDF2 had significant adverse events, including liver or kidney toxicities. In the FemPrEP trial, however, fewer than 5% of participants using Truvada stopped taking medication due to liver or kidney toxicities, compared to 3% of women in the placebo arm, though this was not statistically significant.^{xviii} Additional research on liver toxicity and women is needed.

- *Addressing the needs of transgender women*

In PrEP discussions it is important to be clear who is meant by references to "women" and "men". What is often termed biological sex generally refers to the sex (male, female) to which one is assigned based on the physical appearance of genitals at birth. The term gender refers to the social identity, roles, and expectations that are assumed to be associated with biological sex. When biological sex and gender identity are the same, the appropriate term of use is cisgendered; when those identities differ, the appropriate term is transgender. Due to social, structural and psychological challenges, transgender individuals are at an increased risk of HIV. Some, but not all, transgender individuals seek medical care to align biological sex and gender identity through surgery and hormonal means.

Transgender women have been included in small numbers in some PrEP studies, but there are a number of important unanswered questions about transwomen who use PrEP. For example, what (if any) drug interactions should be anticipated among transwomen who take hormones and PrEP. This question arises

from data suggesting use of some forms of hormonal contraception use may increase vulnerability to HIV infection, an unresolved question being further investigated. It is logical to ask if and how the hormones used by transwomen might affect their vulnerability to HIV infection and, if so, how PrEP use might affect such interaction. Transwomen may also face other unique challenges as a result of their marginalized status. In sum, research is needed to identify the best approach for PrEP access, counselling and support among transwomen.

- *Addressing the needs of women who use drugs or alcohol*

Similar questions arise in relation to drug interactions that might be experienced by active drug-using women choosing to use PrEP. Evidence suggests, for example, that raising the levels of central nervous system dopamine in human subjects may increase the rate of HIV replication.^{xx,xxi} Animal studies have shown methamphetamine, specifically, increases HIV replication,^{xxii} which might mean a woman using cocaine, crack, methamphetamine, heroin, and/or comparable substances (all of which increase dopamine levels) could be more likely to develop HIV infection after exposure because of increased viral replication due to drug use. Research is needed to determine how PrEP use may or may not impact the vulnerability to HIV infection faced by women using drugs. The best approach to PrEP counselling and support for substance-using women, including those with alcohol abuse problems, is another area where research is needed.

CONCLUSION

PrEP for women must be viewed as one tool in a combination prevention package that includes male and female condoms; regular access to screening for HIV, other STIs and intimate partner violence (IPC); as well as accessible sexual and reproductive health services offered in conjunction with HIV prevention education and support.^{xxiii} PrEP has potential to be a powerful prevention tool for some women. But this promise will not be fully realized unless the actions described above are taken without delay. It is also critical that these actions be taken with the full participation and leadership of individuals and communities most in need of effective, comprehensive HIV prevention.

The Working Group proposes the following timeline for implementation of its recommendations:

July 15, 2013 Coordinating group is established to develop an integrated plan of PrEP rollout for women. This group should include representatives from NIH, CDC, other HHS 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. It should be coordinated by the Office of National AIDS Policy and the CDC:

1. Thought leaders, public health agencies and other implementers convened to develop a plan to identify gaps, and develop a mechanism for coordinated action with milestones, feedback mechanisms, and sufficient resources and accountability. This plan should be linked with the efforts undertaken by the coordinating group described above, and should be widely disseminated.
2. Develop a national database for collection of specific data points that will help answer to the questions outlined above.

Sept. 30, 2013 Funding identified and mechanisms in place to support demonstration projects to gather information on PrEP uptake and use by women.

APPENDIX - Members of the U.S. Women and PrEP Working Group

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| Erika Aaron, RN, CRNP, MSN | Drexel University College of Medicine |
| Ada Adimora, MD, MPH | University of North Carolina at Chapel Hill |
| Amy Allina | National Women's Health Network |
| Judith Auerbach, PhD | Consultant |
| Dawn Averitt Bridge | The Well Project |
| Emily Bass | AVAC |
| Sarah Jenny Bleviss, MPS | Sex Workers Organizing Project – New York |
| Dee Borrego | HIV Prevention Justice Alliance |
| Dee Dee Chamble | LaGender, Inc. |
| Hadiyah Charles, MA | Harm Reduction Coalition |
| Manju Chatani Gada, MPH | AVAC |
| Deborah Cohan, MD, MPH | Bay Area Perinatal AIDS Center |
| Jenna Conley | Conley Communications |
| Cheryl Courtney-Evans | Transgender Individuals Living Their Truth, Inc. |
| Julie Davids | AIDS Foundation of Chicago |
| Dazon Dixon Diallo, MPH | Sisterlove, Inc. |
| Anna Forbes, MSS | Consultant |
| Deirdre Grant | AVAC |
| Angela Green, MPH | Iris Women's Center |
| Polly Harrison, PhD | AVAC |
| Rebekah Horowitz, MPH, JD | The Women's Collective |
| Coco Jervis, JD | Treatment Action Group |
| Jennifer Johnson, MD, MPH | The Well Project |
| Ebony Johnson | PxROAR |
| Naina Khanna | Positive Women's Network — USA |

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|---------------------------|--|
| Stacey Little, PhD, MPH | FHI360 |
| Nicole Little | SHERO |
| Ellen Liu, MA | Ms. Foundation |
| Kate MacQueen, PhD, MPH | FHI360 |
| Krista Martel | The Well Project |
| Tracee McDaniel | Juxtaposed Center for Transformation Inc. |
| Terry McGovern, JD | Columbia University |
| Kate Miller, MA | AIDS Legal Council of Chicago |
| Jessica L. Mooney, MA | Women's HIV Research Collaborative (Legacy Project/HANC) |
| Kieta Mutepfa, MSW | Black Treatment Advocates Network Los Angeles |
| Patricia Nalls | The Women's Collective |
| Kimberly Parker, PhD, MPH | Texas Women's University |
| Julie Patterson, MPH | PxROAR |
| Sarah Patterson, M.Ed. | Persist Health Project |
| Cindy Pearson | National Women's Health Network |
| Shanebrae Price | Sisterlove, Inc. |
| Sonia Rastogi | Positive Women's Network – USA |
| Maura Riordan | AIDS United |
| Bamby Salcedo | Coalición Trans-Latina |
| Linda Scruggs | Altarum Institute |
| Serra Sippel, MA | Center for Health and Gender Equity |
| Kimberleigh Smith, MPA | Harlem United |
| Kathleen Squires, MD | Thomas Jefferson University Hospital |
| Shannon Weber, MSW | Bay Area Perinatal AIDS Center |
| Lisa Diane White | Sisterlove, Inc. |

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- ⁱ Truvada®, first approved by the U.S. FDA in 2004 for use in AIDS therapy, combines two anti-HIV medications, Emtriva® (emtricitabine) and Viread® (tenofovir disoproxil fumarate/TDF), in a single tablet taken once daily.
- ⁱⁱ For brevity's sake, this *Statement* does not include detail on PrEP and how it works. Such information can be found at <http://www.prepwatch.org>
- ⁱⁱⁱ *Cisgender* refers to one whose birth-assigned gender and current gender identify are the same. According to San Francisco State University researchers, "Cis- is the Latin prefix for "on the same side as." Thus, a cisgender person is on the same side of his or her birth-assigned gender label." Retrieved from <http://bss.sfsu.edu/ctate/cisgenderid.html>
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