In February 2012, the FDA agreed to conduct a priority review of Truvada’s use as PrEP on the basis of a couple of large scale trials showing that, if taken daily, it could reduce an HIV-negative person’s risk of becoming HIV-positive if exposed to the virus. One trial, called iPrEx, had enrolled 2,499 HIV-negative men and transgender women who have sex with men in six countries to test Truvada as PrEP. The results showed a 44% overall reduction in new HIV infections among participants taking Truvada versus those taking a placebo. The highest percentage of reduction in new infections (up to 96%) was among those who took the medication daily without missing doses. However, blood sample screening revealed that only about 50 percent of iPrEx participants had any level of drug in their bloodstream, thus bringing down the overall average.

The Partners PrEP study, enrolling over 2,300 serodiscordant heterosexual couples (one partner is HIV-positive and the other isn’t) in Kenya and Uganda, showed 75% effectiveness and an 80% adherence rate among participants. Though not part of the FDA hearing, in a CDC trial, HIV-negative individual men and women in Botswana who took tenofovir (one of the drugs in Truvada) for PrEP with similarly high adherence rates showed 63% fewer sero-conversions in the tenofovir arm of the trial.

While most advocates for HIV/AIDS services welcomed the news of the FDA’s first review of PrEP, showing
that, if taken daily, it could reduce an HIV-negative person’s risk of becoming HIV-positive if exposed to the virus, it caused concern among some.

Trials enrolling only women produced a very different picture from those with men. FEM-PrEP, a Truvada PrEP trial enrolling nearly 2,000 women in three African countries, was discontinued in April 2011 when it became apparent that the trial would not be able to demonstrate effectiveness. Another all-woman trial, MTN-003, named VOICE, enrolled over 5,000 African women but stopped its tenofovir arm in September 2011 for the same reason. VOICE’s oral Truvada arm (as opposed to the vaginal gel also studied) was continued as planned but, unfortunately, produced results in 2012 that showed no effectiveness.

While further analyses of both the FEM-PrEP and the VOICE data are underway, it appears that the lack of effectiveness in both trials was likely related to very low adherence among study participants. Post-study analysis of blood levels showed that only 25–30% of VOICE trial participants were using the products as instructed.

In addition to this marked difference in adherence among trials, concern among women and HIV advocates about domestic introduction of PrEP was also exacerbated by the fact that none of the PrEP trials had enrolled women in the U.S. Further, U.S. demonstration projects enrolling MSM and transwomen were funded and moving ahead in two U.S. cities to gather more data on the use of PrEP among men, but the one domestic demonstration project proposing to include U.S. women among its participants was stalled at the CDC due to lack of funding.

One activist asked online: Would the FDA be considering U.S. approval of PrEP if the results were reversed? What if we had solid data on PrEP’s effectiveness for women but highly conflicting data about its effectiveness among men who have sex with men, including data from two trials suggesting that PrEP didn’t work for men?

Women’s health advocates quickly realized that, if the debate became polarized, people would be distracted from the central questions: if PrEP works in all sexes when taken regularly, why weren’t the VOICE and FEM-PrEP trial participants taking it? How could we obtain more data on this and decipher what it might mean when PrEP is available to women in “real world” (non-trial) settings? On the domestic front, what would it take to get demonstration projects and other research with U.S. women that yield data on the reasons and obstacles that could keep PrEP from being a useful, and regularly used, HIV prevention tool for women?

Having a voice in setting the research agenda around PrEP requires strong collective advocacy; and unified advocacy doesn’t happen when communities are divided. So a meeting was convened by Dázon Dixon Diallo, Founder and President of SisterLove (and co-author of this article), in Washington, D.C. in March 2012 called “U.S. Women & PrEP: What Are We Saying?”

Attended by 26 women (representing civil society, activists, and academic/government researchers) and one man (who represented Truvada’s manufacturer), the meeting included presentations on the current status of PrEP research involving women and the upcoming FDA hearing. Consensus around some of the key concerns began to emerge as a discussion took place about what was known, what was unknown, and what was seen as the essential next step. Although its members still went into the FDA hearings with their own specific messages, the U.S. Women and PrEP Working Group had already begun to take shape. There was agreement on the need for a collective voice that affirmed PrEP’s potential value for women while simultaneously demanding answers to the crucial questions that would determine whether this potential would be realized or not.

Many women in the U.S. are at high risk for HIV. In some communities, African American women bear as high a risk for HIV as many women do in Africa, and we
need new HIV prevention options that they can control and use to protect themselves.

After the FDA’s June 16 approval of Truvada as PrEP, the Working Group met via conference calls and in small writing groups to draft a position statement summarizing the full breadth of their concerns and spelling out the actions required for addressing them. It took 16 drafts to come to agreement on how best to state their case and demand answers to critical questions including:

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

It was agreed that a federal coordinating group comprised of the relevant federal offices, researchers, and strong and diverse civil society representation was needed to oversee the work of answering these questions. Signed by 50 women from leading AIDS and women’s health organizations, the Working Group’s statement called on the Office of National AIDS Policy (ONAP) and the CDC to work with them on putting in place what U.S. women need to be able to use PrEP safely and effectively.

In the press release accompanying the statement Diallo observed, “Many women in the U.S. are at high risk for HIV. In some communities, African American women bear as high a risk for HIV as many women do in Africa, and we need new HIV prevention options that they can control and use to protect themselves. PrEP can be that option for some women.”

She added that the Working Group had defined specifically how federal agencies need to collaborate with non-governmental organizations (NGOs), researchers, and advocates 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.”

The position statement was released to the press on March 3, 2013, the same day as the final VOICE trial results were made public, and was sent to key federal officials with a letter requesting an appointment to discuss their plans for moving forward on the statement’s recommendations.

The federal response to the Working Group’s request came quickly and, on April 3, a six-woman Working Group delegation met with ONAP Director Dr. Grant Colfax, Dr. Ron Valdisseri of the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), Dr. Carl Dieffenbach, Director of DAIDS/NIAID/NIH, Dr. Rima Khabbaz, Acting Director of the CDC’s Division of HIV/AIDS, and other relevant federal staffers.

The next steps are to monitor the federal partners’ responses, and continue the national conversation by producing three webinars that the Working Group will co-sponsor with the AIDS Vaccine Advocacy Coalition (AVAC), the HIV Prevention Justice Alliance, and the National Women’s Health Network. More information on the webinars is available at sisterlove.org and avac.org.

The U.S. Women and PrEP Working Group, now comprised of 66 individuals, came together because they recognized that a coherent and comprehensive vision of how PrEP implementation could and should occur among U.S. women had not been well articulated. They accepted responsibility for that omission and set out to become, as the statement declares, a “consistent voice for women on the subject of PrEP implementation proportionate to women’s presence in the U.S. HIV/AIDS epidemic.” So far, so good—but the journey continues.

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