## PrEP: What Does It Mean For Women?

#### What is PrEP?

PrEP stands for "pre-exposure prophylaxis." It means using medicine in advance (before you are exposed to something) to prevent yourself from getting a disease or condition. We use several kinds of medicines this way.

An example is taking anti-malaria medication when we travel to areas where we may be bitten by mosquitoes carrying malaria. When the medicine is already in a person's system before the bite, the chances of the person getting malaria are greatly reduced.

When we talk about PrEP in connection with HIV, we are referring to the idea of HIV-negative people taking antiretroviral drugs (ARVs) in order to reduce their risk of becoming infected with HIV if they are exposed to it.

### How might PrEP prevent the spread of HIV?

Here is how PrEP would work. When cells are infected with HIV, they become little factories that make thousands of new HIV viruses every day. ARVs work by blocking some of the production steps that HIV uses to make copies of itself. If an HIV-negative person already has an ARV in her blood stream when she is exposed to HIV (during unprotected sex, for example), the medicine might be able to keep the HIV from making enough copies of itself to "take hold" and cause her to become infected.

#### Has PrEP been shown to be effective?

Yes we have the first proof-of-concept that an oral pill taken once a day can help to prevent HIV. A study sponsored by the US Institute of National Health (NIH) and co-funded with the Bill & Melinda Gates Foundation called Global iPrEx found that daily use of oral emtricitabine (FTC) with tenofovir (TDF) in one tablet shows promise to safely and effectively help to prevent HIV infection among men who have sex with men (MSM).

#### What is iPrEx?

The Phase III study, which was conducted among 2,499 HIV-negative gay men, male to female transgendered women and other MSM at 11 sites in Brazil, Ecuador, Peru, South Africa, Thailand, and the United States, demonstrates that Pre Exposure Prophylaxis (PrEP), such as FTC/TDF, is likely to be a useful addition to combination approaches, including safer sex counseling and condom use, to prevent HIV in MSM. The study also offers significant insights into human behaviour, risk perceptions and the importance of adherence, all of which will be valuable for existing and future trials.

#### Does this mean that PrEP will work in women?

While the trial did not study the effectiveness of FTC/TDF in women, it gives us the reason to be optimistic about its potential. Women around the world continue to bear the greatest burden of HIV and findings from other PrEP trials that are currently underway, such as <a href="VOICE">VOICE</a>, will be an important milestone in demonstrating success and the move toward licensure of both the gel and oral pills for women who are most at risk.

## How might PrEP prevent the spread of HIV?

PrEP medication would keep HIV from being able to reproduce in the body of someone who is taking it regularly (or possibly just at the time of exposure to the virus). Here is how this would work. When cells are infected with HIV, they become little factories that make thousands of new HIV viruses every day. ARVs work by blocking some of the production steps that HIV uses to make copies of itself. If an HIV-negative person already has an ARV in her blood stream when she is exposed to HIV (during unprotected sex, for example), the medicine might be able to keep the HIV from making enough copies of itself to "take hold" and cause her to become infected.





PAGE 2 OF 2

### What would PrEP mean for women at high risk of HIV?

While we now have proof-of-concept that PrEP works in MSM, a lot more work will have to be completed before PrEP could be marketed for public use. This includes improving health care systems so people could access PrEP effectively. HIV testing, for example, will need to be more widely adopted **because only people who know that they are HIV negative can use PrEP safely.** If people use it when they are already HIV positive, they are very likely to develop drug-resistant virus, which they may then pass on to other people. Having drug-resistant virus may also make it harder to treat that HIV infection.<sup>1</sup>

PrEP is a promising tool for women who want and need HIV-prevention strategies they can use without their partners' cooperation. Around the world, women have opinions about what PrEP means and have raised some important questions. How would they access HIV testing, especially if their partner opposes getting tested? How would taking PrEP affect pregnancy or breastfeeding? Would they be able to get PrEP if they do not know their partner's HIV status? Would a man be likely to refuse to use condoms if he knows his partner is taking PrEP? Would women be able to keep the PrEP pills prescribed to them? Some women worry that the pills may be taken away from them and given to another family member who is viewed as "needing them more."

### What are the advocacy issues? What needs to be done?

We need to advocate not only for the additional research (such as studies on the impact of PrEP on pregnancy and breastfeeding) but also for "PrEP readiness"—putting systems in place <u>before</u> PrEP is marketed to make sure that people can use it safely.

More widespread HIV testing is one of the things communities will need. Right now, about 80 percent of all HIV-positive people in the countries hit hardest by HIV do not know their HIV status. Creative solutions will be required to overcome barriers to testing.

Large-scale targeted community education about the benefits and risks of using PrEP is also vital. Especially in poor communities, there will be a temptation for people to sell their PrEP pills or share them with other people who do not have prescriptions. This kind of casual drug distribution could promote drug-resistant HIV, so systems will be needed to prevent this from happening. People will need to understand clearly that they endanger their own health—and their families', friends', and communities' health—if they use PrEP without a prescription or buy it on the street.

If PrEP is shown to work in women, they will need to be involved in determining:

- 1. how to make HIV testing as easily and safely accessible to women as possible:
- 2. where and how PrEP should be distributed and packaged for women; and
- 3. what messages will help women understand and explain their need for PrEP in such a way that pills will not be taken away from them and given to someone else to use.

Most of all, we need to persuade policymakers that these social and educational supports are essential. Without them, it is likely that PrEP—like condoms and circumcision—will primarily become an HIV-prevention tool for men, if it is effective. Addressing some of the barriers to prevention that women experience is what can help to put much-needed HIV-prevention tools into women's hands.

# As an advocate for HIV prevention, what should I do?

Inform your community about this important trial result. If you work with MSM communities in Africa or anywhere else or with women at high risk of HIV, be informed of what the study means for them.

We invite you to work with the Global Campaign to support our efforts in making HIV prevention a safe and effective reality for women, and all those vulnerable to HIV.

<sup>&</sup>lt;sup>1</sup> To learn more about this, see the Global Campaign for Microbicides' fact sheet *Understanding Drug Resistance*, at <a href="http://www.global-campaign.org/clientfiles/FS-DrugResistance%5bE%5d.pdf">http://www.global-campaign.org/clientfiles/FS-DrugResistance%5bE%5d.pdf</a>.