

# ARV-Based Prevention: What Does It Mean For Women?

## What do we mean by “ARV-based prevention”?

Some HIV-prevention options use antiretroviral drugs (ARVs) that are primarily used as treatment for people who are already infected with HIV.

Some methods of using ARVs for HIV prevention are already known to work such as:

Post-exposure prophylaxis (PEP): This is when someone takes ARVs for a full month right after an occupational exposure to HIV, as with a needle stick in a hospital. Most commonly, PEP is given to health care workers after occupational exposures to HIV. It may also be given in other situations of known exposure to HIV, such as unprotected sex and sharing needles with a partner known to be HIV-positive, especially if the situation was involuntary (such as after rape or when the condom breaks).

Prevention of vertical transmission: To prevent vertical transmission (transmitting HIV to the child of an HIV-positive mother) it is most important to provide ARVs to the mother during her pregnancy and labour, and to provide ARVs to the infant during the first few weeks after birth. When possible, delivery by Caesarian section and avoiding breastfeeding can also significantly reduce transmission risk. If avoiding breastfeeding is not possible, exclusively breastfeeding the baby is less risky than alternating between breastfeeding and using formula.

Some approaches are still in the research stage such as:

Microbicides: A microbicide would be a substance that can substantially reduce the risk of acquiring HIV when it is applied in the vagina or rectum. Some candidate microbicides are made with ARVs (such as tenofovir in gel form) while others would work without ARVs.

Pre-exposure prophylaxis (PrEP): PrEP 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 medicine this way already. We take malaria medication when we travel to areas where we may be bitten by mosquitoes that carry malaria, for example. With medicine already in a person's system before the bite, the chances of getting malaria are greatly reduced. Using ARVs for PrEP might work similarly to prevent HIV infection if a person is exposed.

Treatment for the HIV-positive partner: There are two ways in which providing treatment for the HIV-positive partner is thought to work.

- 1) At the individual level: we already know that individuals who take prescribed ARVs regularly every day have a reduced amount of virus (sometimes called viral load) in their blood. Trials are underway to find out if the risk of HIV transmission in sero-discordant couples (those with one HIV-positive and one HIV-negative partner) is reduced when the HIV-positive partner is on ARV treatment.
- 2) At the population or community level: some people argue that doing HIV testing on a massive scale and providing treatment to anyone who tests HIV-positive could significantly reduce the number of new infections. The argument goes something like this: massive testing campaigns would make more people aware of their status; HIV-positive people could then reduce their risk-taking and seek treatment; both a decrease in risk-taking and a decrease in viral load as a result of successful treatment could decrease the rate of HIV spread.<sup>1</sup> This differs from calls for universal access to voluntary counselling and testing, followed by universal access to treatment to anyone who needs it. Treatment is proposed immediately upon testing HIV-positive, which in some cases may be earlier than what is currently recommended by most guidelines.

<sup>1</sup> R. Granich et al. “Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model”. *The Lancet*, Volume 373, Issue 9657, Pages 48 - 57, 3 January 2009

**Neither microbicides nor PrEP has yet been proven to work to prevent HIV.** In the case of treatment for the HIV-positive partner, although many observational studies have found that HIV-positive people on effective treatment are less likely to transmit the virus to their partners, no controlled study has yet been completed to demonstrate conclusively that this approach works.

## How widely are proven ARV-based prevention options available for women?

Post-exposure prophylaxis (PEP): Access to PEP varies greatly. It can be difficult for women to access after non-occupational exposure. Even after rape, women sometimes have difficulty getting access to PEP, even though the medication must be started soon after exposure in order to be effective.

Prevention of vertical transmission: Ideally, we should scale up prevention programmes to ensure that fewer women become HIV-positive. By far, the greatest numbers of HIV-positive pregnant women live in sub-Saharan Africa. But in this region, fewer than half (45%) had access to ARVs for prevention of vertical transmission in 2008.<sup>2</sup>

## What could new ARV-based prevention tools now in development mean for women?

PrEP and ARV-based microbicides: Even if trials show that PrEP and ARV-based microbicides are effective, a lot more work would have to be completed before they could be marketed for public use. HIV testing, for example, will need to be more widely used because these ARV-based prevention tools should only be used by people who know for sure that they are HIV-negative.

If you use PrEP when you are already HIV-positive, you may develop drug resistant virus, which you may pass on to other people and which is likely to make it much harder to treat your HIV infection on an on-going basis.<sup>3</sup> This may also occur when HIV-positive women use an ARV-based microbicide, although the risk of drug resistance developing is likely less than with PrEP. This is because a higher dose of the ARV enters the bloodstream when you take it orally (as with PrEP) than when it is applied topically (as with a microbicide).

PrEP and ARV-based microbicides are a hopeful idea for women who want and need HIV-prevention tools they can use without their partner's cooperation. Around the world, women have opinions about what these new prevention options might mean in their lives and have raised some important questions.

- How would they access HIV testing, especially if their partner opposes getting tested?
- How would taking ARV-based products affect pregnancy or breast-feeding?
- Would they be able to get them if they don't know their partner's HIV status?
- Would a man be likely to refuse to use condoms if he knows his partner is using an ARV-based prevention tool?
- Would women be able to keep the PrEP pills prescribed to them for their own use? Some women worry that the pills would likely be taken away from them and be given to another family member who is viewed as "needing them more."

Treatment for the HIV-positive partner: The effectiveness of this prevention option depends on the idea that a critical mass of people who are HIV-positive become aware of their status and have access to treatment. Globally, only a small minority of people who are HIV-positive know their status. Even among people who know they are HIV-positive we have not yet achieved universal access to treatment. Only 42% of people in low- and middle-income countries who needed ARVs for HIV treatment had access to them by the end of 2008.<sup>4</sup>

<sup>2</sup> World Health Organisation (WHO). *Toward universal access: Scaling up priority HIV/AIDS interventions in the health sector*. <http://www.who.int/hiv/pub/2009progressreport/en/> Accessed October 26, 2009.

<sup>3</sup> To learn more about this, see GCM's fact sheet, "Understanding Drug Resistance", available at [http://www.global-campaign.org/clientfiles/FS-DrugResistance\[E\].pdf](http://www.global-campaign.org/clientfiles/FS-DrugResistance[E].pdf).

<sup>4</sup> World Health Organisation (WHO). *Toward universal access: Scaling up priority HIV/AIDS interventions in the health sector*. <http://www.who.int/hiv/pub/2009progressreport/en/> Accessed October 26, 2009.

Even if considerable data eventually show that successful treatment reduces the chances of transmission, several stumbling blocks to implementation still need to be overcome, in addition to ensuring universal access to treatment. For example, this intervention depends on knowing your HIV status promptly after infection, because people are most infectious (likely to transmit the virus) during first few weeks of sero-conversion. This is when a person's body has a very high viral load but it is also the "window period"—the time when HIV antibody tests can produce a false negative result (because antibodies to the virus have not yet built up). Currently, the only tests that show someone is HIV-positive during this window period are the more expensive ones that test for the virus itself. The added cost—along with the difficulty of getting people tested frequently—may make it extremely challenging to do the wide-spread testing needed to identify people as HIV-positive during this highly infectious period.

Another difficulty is that—under current treatment guidelines in most countries—it is highly unlikely that people would start taking ARVs immediately after becoming HIV-positive. Some supporters of this approach to prevention recommend access to treatment earlier than most guidelines suggest. Most countries do not have the health system capacity to supply early and ongoing ARV treatment for everyone as soon as they test HIV-positive.

### What is the state of research on new ARV-based prevention options?<sup>5</sup>

The first late-stage clinical trial of a microbicide containing an ARV will be completed in 2010. This trial is testing the drug tenofovir in gel form for vaginal use among women in South Africa.

PrEP research is further advanced. Nine late-stage PrEP trials are now under way or planned in various regions of the world. Results from the first PrEP late-stage trials could be available in 2010; these trials are among men who have sex with men (MSM) and persons who use injection drugs. By 2011-2012, more efficacy trials will be completed, which will include thousands of women and men all over the world.

In 2012, trial data are expected on the effectiveness of using ARV treatment to prevent the sexual transmission of HIV in HIV-serodiscordant couples.

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

HIV prevention advocates need to demand improved access to existing prevention options that have been proven to work. In most populations at greatest risk, including women, there is still inadequate access to male and female condoms, needle exchanges, medical male circumcision, PEP, prevention of vertical transmission and voluntary counselling and testing.

We must also advocate for stronger support for the research and development of new prevention options, including both ARV and non-ARV-based tools. Once effective ARV-based prevention options are identified, additional research will be needed to assess the impact of ARV-based prevention on pregnancy and breast-feeding. We must also demand that a greater variety of drugs be tested, particularly for PrEP. This would ensure that alternatives are available if the drugs currently in testing do not work. It will also help create a separate product pipeline for ARV options for treatment and those for prevention, helping to reduce the likelihood of competition for access to drugs and drug sharing between sero-discordant couples. A greater range of options is always ideal as well, since no one prevention tool will work or be acceptable to everyone.

Finally, we need to call for "ARV-based Prevention Readiness"—putting systems in place before these new tools are marketed to make sure that communities can use them safely. More wide-spread HIV testing has to be one of the first priorities, since access to ARV-based prevention without testing to make sure that users are HIV-negative is exactly what could trigger the widespread development of drug resistant HIV. Right now, about 80%-90% of all HIV-positive people in the countries hit hardest by HIV do not know their status. Creative solutions and better and cheaper diagnostics, such as HIV tests without a long window period, are urgently needed to overcome the barriers that are causing this situation.

Massive, targeted community education about the benefits and risks of using ARV-based prevention is also vital—so that people understand the importance of getting tested before using ARV-based prevention.

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<sup>5</sup> AIDS Vaccine Advocacy Coalition (AVAC). *HIV prevention research: A comprehensive timeline*. [http://www.avac.org/pdf/px\\_timeline\\_print.pdf](http://www.avac.org/pdf/px_timeline_print.pdf). Accessed June 9, 2009.

Women in high risk communities need to be involved in determining:

1. How to expand women's access to existing proven ARV-based prevention options (PEP and PTMTC);
2. How to make HIV testing as easily and safely accessible to women as possible;
3. Where and how ARV-based prevention should be distributed and packaged for women.
4. How to involve their sexual partners (if they want) to get couples counseling and testing and get access to products, without putting themselves at risk of sexual violence or other stigma-related consequences.

Most of all, we need to persuade policymakers that these social and educational supports are necessary. Without them, it is very likely that new ARV-based prevention methods—as with condoms and medical male circumcision—will primarily become an HIV-prevention tool for men, and the pattern of inequality will continue.