

WHAT DO THE **2013** GUIDELINES SAY?  
WHAT DOES THIS MEAN FOR MY COUNTRY?

# Antiretroviral therapy for pregnant and breastfeeding women

Every year there are an estimated 1.5 million pregnant women living with HIV. While pregnant women's access to antiretroviral therapy (ART) for their own health is increasing, it is still lower than for other adults. Additionally, only 62% of pregnant women living with HIV worldwide currently receive antiretroviral medicines (ARVs) to prevent HIV transmission to their infant. Without any interventions, 15–45% of children born to these women will acquire HIV.

Recent efforts to scale up programmes to prevent vertical transmission prevented over 670,000 children from acquiring HIV between 2009 and 2012. However, the pace needs to be accelerated for the world to achieve the 2015 targets set by the Global Plan to:<sup>1</sup>

- ▶ reduce the number of new HIV infections among children by 90%
- ▶ reduce the number of AIDS-related maternal deaths by 50%.

The 2013 Guidelines provide simpler recommendations to ensure earlier uptake of ARVs among pregnant and breastfeeding women and their children. This includes recommending HIV testing to all pregnant women as part of their basic antenatal care in all settings. The 2013 Guidelines suggest bringing services closer to communities, and better integration of HIV care with maternal and child services in order to address the challenges that women living with HIV face in accessing comprehensive care.

The 2013 Guidelines also recommend giving pregnant and breastfeeding women living with HIV triple-combination ART, rather than the sequence of single and/or dual combination drug regimens used in the past. Women who do not need ART for their own health are advised to keep taking ART at least until breastfeeding ceases. In certain circumstances, the 2013 Guidelines recommend providing lifelong ART to pregnant women living with HIV. These include settings with limited access to CD4 cell monitoring, or where there are high fertility rates or prolonged breastfeeding periods. Put more simply: ART should be offered to all pregnant and breastfeeding women living with HIV. The big question for mothers living with HIV to consider is whether to stop ART after breastfeeding ends or continue treatment for life.

## What do the 2013 Guidelines say?

### When to start antiretroviral therapy

- ▶ All pregnant and breastfeeding women with HIV should initiate ART (triple-combination ARVs) regardless of their CD4 cell count, and should continue taking it for *at least* the duration of the vertical transmission risk.
- ▶ Women who are eligible (with CD4 cell count  $\leq 500$  cells/mm<sup>3</sup>) and need treatment for their own health should continue taking ART for life.



**In 2012, 50%  
of women or  
their children  
did not receive  
ARVs during  
breastfeeding to  
prevent vertical  
transmission of  
HIV.**

Forward



Link

This module links to Chapter 7: Clinical guidance across the continuum of care: antiretroviral therapy, in the 2013 WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*. Available at: [www.who.int/hiv/pub/guidelines/art2013/art/en/](http://www.who.int/hiv/pub/guidelines/art2013/art/en/)

1. The Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive was launched in 2011. See [www.zero-hiv.org](http://www.zero-hiv.org)

- ▶ Particularly in generalised epidemics, all pregnant and breastfeeding women should initiate lifelong ART for operational and programmatic reasons. In some countries, consideration can be given to stopping the ARV regimen after the period of vertical transmission risk has ended, for women who are not eligible for ART for their own health.

### What antiretroviral regimens

- ▶ First-line ART: a once-daily, fixed-dose combination of tenofovir disoproxil fumarate (TDF) + lamivudine (3TC) (or emtricitabine (FTC)) + efavirenz (EFV) is recommended as first-line ART in pregnant and breastfeeding women, including women of childbearing age and pregnant women in the first trimester of pregnancy. The recommendation applies both to lifelong treatment and to ART initiated for preventing vertical transmission and then stopped.
- ▶ The recommendations for use of viral load testing and second-line ART is the same for pregnant women as for other adults (see module C). After failure on a TDF + 3TC (or FTC)-based first-line regimen, zidovudine (AZT) + 3TC should be used in second-line regimens.

### What does this mean for my country?

The first HIV programmes launched in developing countries two decades ago were prevention of mother-to-child transmission (PMTCT) programmes. Many of these failed to reach women of reproductive age and pregnant women living with HIV. Although the programmes had been designed to provide comprehensive care to women using the four-pillar framework (see box), most focused narrowly on preventing vertical HIV transmission to the child during pregnancy and delivery, using less-effective and potentially toxic drugs that compromised women's own treatment options.

Prioritising women's right to live healthy and productive lives is essential for effective prevention of vertical HIV transmission. Countries will need to improve access and uptake of services across all four pillars within a human rights framework (free from coercion, with informed decision making).

The 2013 Guidelines and the Global Plan begin to prioritise women's health. However, national programmes will have to do much more to place women at the centre; in particular, viewing them as primary beneficiaries rather than secondary to their children. They also need to address structural challenges such as the stigma, discrimination and gender-based violence faced by women living with HIV (including pregnant women and mothers living with HIV) in their families, communities and healthcare settings.

While countries begin to implement the 2013 Guidelines, more needs to be done to ensure that women's health and rights are not compromised in the rush to meet global goals. For example, in mid-2011, the Malawian national programme started offering lifetime ART to all pregnant and breastfeeding women living with HIV. This made it easier to scale up services in a

context where there was a shortage of CD4 machines and led to a dramatic increase in the number of pregnant and breastfeeding women receiving ART. However, when women were interviewed about the programme in 2012, many raised concerns about inadequate counselling and support received by women who were diagnosed HIV positive.<sup>2</sup> Women were often given their medications to take home on the same day as they received their test results, before they were psychologically prepared and ready for treatment.

#### The four pillars

- ▶ Preventing HIV among women of reproductive age.
- ▶ Providing appropriate counselling and support, and contraceptives, to women living with HIV to meet their unmet needs for family planning.
- ▶ Ensuring HIV testing and counselling, and access to ARVs, for pregnant women living with HIV, to prevent infection being passed on to their babies during pregnancy, delivery and breastfeeding.
- ▶ Providing HIV care, treatment and support for women, children with HIV and their families.

#### Review!

Improve programmes to ensure comprehensive care for pregnant women and mothers living with HIV, and their families.



2. See [www.gnpplus.net/option-b-understanding-the-perspectives-experiences-of-women-living-with-hiv-in-uganda-and-malawi/](http://www.gnpplus.net/option-b-understanding-the-perspectives-experiences-of-women-living-with-hiv-in-uganda-and-malawi/)

Women need to be given a real choice. They need to be well informed about lifelong treatment and prepared for safe disclosure. Otherwise, programmes may compromise women's adherence to treatment, increase their risk of developing resistance to ARVs, and increase their exposure to intimate partner violence. Community-led initiatives are a particularly effective way of supporting women.

Support groups can help to ensure that programmes and services respond to the health needs of women and their children, and improve access to and uptake of these services. In many countries, community health workers, peer or mentor mothers and adherence counsellors have been trained and supported to take on PMTCT-related tasks. When countries develop programmes they should involve community groups across all four pillars, including: providing community education; offering peer support on HIV prevention, nutrition and infant feeding; addressing stigma and discrimination; encouraging greater partner engagement; providing psychosocial and other support; providing follow-up and referrals; addressing gender-based violence; and implementing income-generating activities. Monitoring and advocacy led by women living with HIV and their communities have resulted in improvements in the quality of health services, as well as laws and policies to better promote women's rights.

There are also ethical factors to be considered as national programmes decide whether to offer lifelong treatment to all women with HIV during pregnancy or breastfeeding. For instance, providing lifelong treatment to women regardless of CD4 count may result in temporary disparities in access to treatment. A pregnant woman with a high CD4 count may continue to receive ART after delivery, whereas her partner, other family members, neighbours or other non-pregnant women with a lower CD4 count may not yet be eligible for treatment. This may expose women on treatment to violence from their partners or family members. Communities need to engage with these debates, and their values, preferences and priorities be taken into consideration.

In countries with generalised epidemics, increasing access to ART for pregnant women living with HIV could have a major impact on maternal mortality. It may also help to reduce HIV transmission among sero-discordant sexual partners. However, this requires financial commitment from countries to improve integration and decentralisation of HIV, maternal and child health, and sexual and reproductive health services.

### Operational changes to current PMTCT programmes

Changes needed to successfully implement the 2013 Guidelines, include:

- ▶ community education, training for community health workers, and adequate funds to include providing lifelong treatment and care in services that previously only focused on providing ARV prophylaxis during pregnancy and delivery
- ▶ clearer guidance and support, including financial support and guidance on infant feeding choices for mothers living with HIV
- ▶ clear plans and adequate funds to expand and integrate HIV treatment, prevention of vertical transmission services, and maternal and child health services in some settings
- ▶ funding of interventions to address structural barriers such as stigma, gender-based violence and human rights violations to ensure programmes have a women-centred approach.

Countries need more evidence to design effective programmes and enable women to make informed choices about whether to start lifelong treatment. In particular, more research is needed to understand:

- ▶ the long-term effects of starting lifelong ART when CD4 count is high and viral load low/undetectable

### Advocate!

More investment is needed for community-led initiatives that support women living with HIV to take up health services free from coercion and without the fear of stigma or violence.



### Respect!

Women living with HIV must be involved in making decisions about whether to move towards offering all pregnant and breastfeeding women ART for life, and how best to implement this approach.



- ▶ the toxicity and potential adverse events of the preferred first-line regimens in pregnant and breastfeeding women
- ▶ the comparative health impact of the two strategies (providing ART during the period of vertical transmission risk or providing it for life) in terms of improving maternal health, reducing paediatric HIV incidence, and increasing HIV-free survival
- ▶ the strategies to improve adherence, retention and safety, particularly for women who are choosing to start lifelong ART, especially if they might not otherwise be eligible for treatment.

The 2013 Guidelines present an opportunity to enhance a family-centred approach, including getting partners and other household members tested for HIV and offering treatment to all family members who need it. If women and their families are to truly benefit, communities will need to support women living with HIV to engage in the decision-making process and advocate for their rights as programmes to prevent vertical transmission of HIV are adapted and scaled up.

## Take stock! Take action!

- What is the current coverage of services to prevent vertical transmission of HIV? What key challenges stop women from accessing or taking up services?
- Is the national programme comprehensive, with adequate focus on all four pillars? What efforts are in place to ensure a more comprehensive, women- and family-centred, and rights-based approach to preventing vertical transmission of HIV, including providing HIV prevention, family planning, and HIV treatment to women, children and families? Is there enough investment in initiatives to tackle stigma and gender-based violence?
- How does the community help to deliver or support the uptake of services to prevent vertical transmission of HIV? How are we, as communities, planning to review and revise our policies and programmes to take account of the new recommendations?
- What regimens are currently used to prevent vertical transmission of HIV? Is single-dose nevirapine (NVP) still used as a prophylaxis to prevent vertical transmission of HIV? Are plans to phase it out well under way? If not, what are the obstacles and what are the plans to overcome these?
- Are there discussions in my country on the different options (ART during vertical transmission risk period or ART for life) that are recommended in the 2013 Guidelines? Has there been adequate consideration given to local infrastructure and operational and financial implications of each option? Are there any pilot phases planned?
- Are women living with HIV and community organisations engaged and able to influence discussions about which approach is most suitable for my country? Is there enough consideration being given to ethical and human rights issues in offering lifelong ART to all pregnant and breastfeeding women? Are women able to choose whether or not to start treatment during pregnancy, and whether or not to continue for life?
- If my country is considering lifelong treatment for pregnant and breastfeeding women, is there adequate planning and funding to ensure counselling, linkages to care, patient transfer and the integration of ART sites with PMTCT sites? Are there plans to build capacity, implement task shifting and support community health workers to successfully take on the additional responsibility of providing lifelong ART, and enable communities to scale up their complementary services?
- Are drug stock-outs common? Can the programme guarantee a reliable supply of the preferred first-line regimen for maternal ART and infant prophylaxis?
- Are there plans to put in place adequate monitoring and evaluation frameworks to measure the impact of the new strategies on maternal health and HIV-free survival of infants?