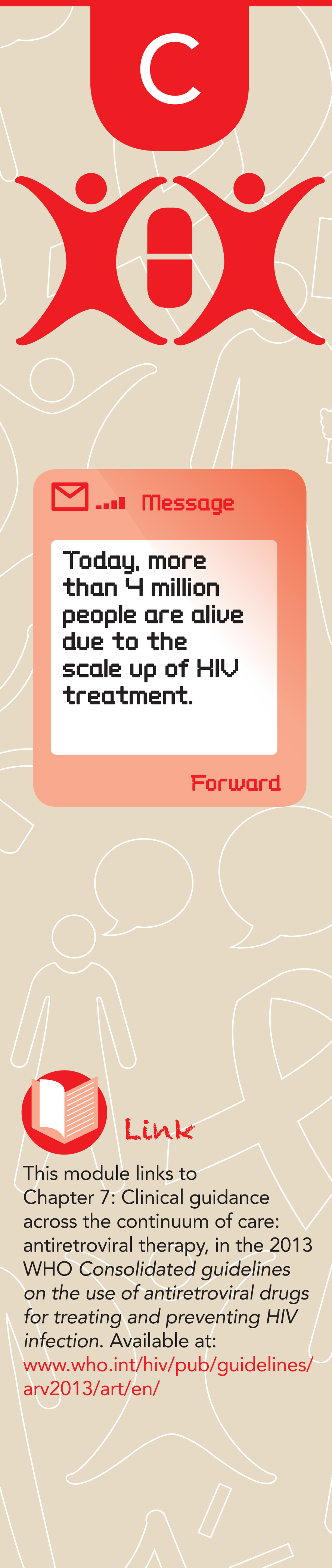
Antiretroviral therapy for adults



The worldwide scale up of antiretroviral therapy (ART) has only been possible through the ownership, involvement and action of people living with HIV and their communities. But in many regions (especially rural areas in resource-limited settings) and for many populations (such as key populations), ART coverage remains low and people initiate treatment too late or struggle to adhere. This makes their care more complicated and increases the chances of poor health outcomes.

One of the most publicised recommendations in the 2013 Guidelines is starting treatment earlier for people living with HIV. This is based on new science that has demonstrated that early treatment benefits an individual's own health and also helps prevent HIV transmission to others. The recommendation is also centred on a number of other supporting recommendations that would make providing early treatment safer, more effective and operationally achievable.

The 2013 Guidelines recommend standardised first-line and second-line ART regimens for adults. Simpler, safer, once-daily, single-pill treatments have become more affordable and more widely available. They do not require refrigeration and are suitable for use among most populations and age groups. These pills are not just better for an individual's health, but also simplify procurement, distribution and prescription of drugs. The recommendations reiterate that more toxic drugs, such as stavudine (d4T), should *no longer* be used in first-line treatment.

To ensure successful treatment, the 2013 Guidelines also recommend the use of viral load testing as the best available tool for monitoring an individual's response to ART and achievement of virologic suppression, or for diagnosing treatment failure.

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/arv2013/art/en/

What do the 2013 Guidelines say?

When to start

Treatment should be offered to anyone living with HIV with CD4 counts ≤500 cells/mm^3. However, the priority should still be to get people with severe or advanced HIV disease and with CD4 counts ≤350 cells/mm^3 onto treatment.

Provide ART as soon as possible regardless of the CD4 cell count to:

- people with HIV and active tuberculosis
- people coinfected with HIV and hepatitis B with evidence of severe chronic liver disease
- partners with HIV in serodiscordant relationships (where one partner is living with HIV and the other is HIV negative) to reduce HIV transmission to uninfected partners
- pregnant and breastfeeding women living with HIV (see Module D).

What antiretroviral therapy 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 the preferred option for all adults initiating ART. Countries should discontinue d4T use in first-line regimens because of its well-recognised toxicities.
- **Second-line ART:** After failure on a TDF + 3TC (or FTC)-based first-line regimen, zidovudine (AZT) + 3TC should be used in second-line regimens.
- **Third-line ART:** National programmes are advised to develop policies for third-line ART and include new drugs with minimal risk of cross-resistance to previously used regimens.

How to diagnose treatment failure

Programmes should shift to using viral load as the preferred monitoring approach to diagnose and confirm antiretroviral treatment failure.

Engage!

People living with HIV must be involved in making decisions about when and how to move towards earlier treatment.

What does this mean for my country?

Earlier treatment The 2013 Guidelines *do not* assume that every national programme will be ready to offer earlier treatment immediately. Programmes will first need to assess and ensure the acceptability of earlier treatment among affected communities. In addition, programmes need to have a plan to *guarantee* that treatment of the sickest patients (those who are symptomatic or with a CD4 count ≤350 cells/mm^3) is prioritised. It is critical to first focus on making sure that everyone for whom ART may immediately save their life is able to access it. Programmes will also need to assess whether health systems have everything in place to make certain that early treatment is a safe option for people.

Antiretroviral therapy for people with HIV and hepatitis C at CD4 ≤500[3]

The 2013 Guidelines *do not* recommend ART for people living with HIV with CD4 counts >500 cells/mm^3 who are coinfected with hepatitis C, no matter how severe their hepatitis C liver damage is. The 2013 Guidelines development group felt there was not enough data to show that ART at CD4 counts >500 cells/mm^3 offered any benefit to people with hepatitis C (the ART regimen has no known direct effect on hepatitis C as it does on hepatitis B) and that it might even be harmful. This omission has been seen as controversial by some, and is of particular concern to people who inject drugs due to the high rate of hepatitis C virus among that population. In April 2014, WHO issued its first guidance for the treatment of hepatitis C,[1] a chronic infection that affects between 130 million and 150 million people and results up to 500,000 deaths a year.

Advocate!

Give us the best treatment available and make drugs affordable for all. No more second-rate drugs! No to patents on medicines!

Simpler and safer treatment Even though some countries have negotiated a low cost for the preferred first-line regimen, this will need to come down further for the poorest countries to be able to afford it. In addition, antiretrovirals need to be made more affordable in middle-income countries where the scale up of ART has been slower. Programmes that have not already phased out d4T need to develop and start implementing a plan to do so. The 2013 Guidelines include detailed advice for countries on phasing out d4T, including ways to secure funds to assist them in the process.

Improving adherence Patient readiness is crucial to support the high levels of adherence necessary to suppress HIV. Support mechanisms in communities and at health facilities need to be strengthened and better linked in order to create an environment in which people can make informed choices, especially about whether they are willing to start treatment when they feel healthy. Support also needs to be provided to help individuals to stay on treatment, be

1. WHO (2014). *Guidelines for the screening, care and treatment of persons with hepatitis C infection.* Available at: www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/

retained in care and have their psychosocial needs met together with those of their families and caregivers. As part of a holistic package of support services, adherence tools and strategies should be provided since people may have different support needs. Community-based adherence services play a crucial role in these packages. Evidence suggests that for some communities, SMS reminders may be useful. Nutritional support, peer support, management of depression and substance use disorders, and patient education are other examples of community-based adherence support tools.[2]

Ensuring successful treatment WHO recommends viral load testing as the preferred approach, rather than immunological and clinical monitoring. Ideally, viral load assays should be performed routinely six months after starting treatment, and at least once every year to assess adherence and detect treatment failure. Without this, failing regimens may not be switched soon enough, leading to an increased risk of disease progression and the development of drug resistance.

Communities need to prepare for the shift from CD4 count to viral load testing, including through treatment literacy programmes. However, scaling up access to viral load testing is an enormous challenge. Countries with limited health spending should prioritise improving access to ART. The 2013 Guidelines clearly state that "lack of laboratory tests for monitoring treatment response should not be a barrier to initiating ART".

Reaching key populations Even in those countries where ART scale up has been impressive, key populations[3] do not enjoy the same access to treatment. Despite widespread recognition of how important it is to reach key populations in both concentrated and generalised epidemics, evidence across countries shows neglect, exclusion and denial of their rights. The 2013 Guidelines state, "This requires addressing any structural barriers that may prevent these populations from seeking and accessing care. Integrating HIV services into drug dependence treatment and harm reduction services and TB clinics can be a highly effective approach to reaching these populations." The programmatic and policy guidelines (see Modules F and G) discuss structural barriers in greater depth and what policymakers should do to address these.

A further challenge is the lack of data on the safety and effectiveness of using ART to reduce HIV incidence among key populations. The 2013 Guidelines development group concluded that there is insufficient evidence to recommend earlier initiation of ART among key populations regardless of CD4 cell count. The initiation of ART among key populations should follow the same general principles and recommendations as for other adults and adolescents with HIV.

Review!

Adapt and roll out treatment and rights literacy programmes to prepare and support people to adjust to earlier treatment, new regimens and viral load monitoring.

Respect!

Individuals have the right to make an informed choice, and their consent is essential for initiating ART. We oppose any form of coercion!

Respect!

Including key populations and upholding our human rights are central to an effective HIV response.

Consolidated guidelines for key populations

WHO is in the process of developing consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (due for publication in July 2014). It is important for us as communities to engage with these new guidelines and use them to ensure that national programmes uphold the rights of key populations and better serve their needs.[4]

2. See Annex 11.1 of 'Section 8: Phasing out stavudine: progress and challenges', in the March 2014 supplement to 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/arv2013/arv2013supplement_to_chapter09.pdf?ua=1

3. See a definition of key populations in Module A.

4. As this community guide is a living document, we will add a module on key populations once WHO publishes consolidated guidelines for key populations.

Take stock! Take action!

- What is my country's current HIV treatment policy? What is the current ART coverage? Who has access; who lacks access? What is our current role as communities and civil society in treatment scale up?
- Is my country implementing, or planning to implement, initiating treatment with CD4 counts ≤350 cells/mm^3 as a priority in compliance with the 2013 Guidelines? How can we as communities and civil society enhance our engagement in the implementation or planning?
- Is d4T still part of first-line treatment? Are plans to phase it out sufficiently advanced? If not, what are the obstacles and what are the plans to overcome these?
- Are drug stock-outs common? Can the programme guarantee a reliable supply of the preferred first-line regimen? Is there action to address supply chain management issues associated with delivery of medicines and other supplies at peripheral sites across the country?
- Do key populations living with HIV have access to treatment? What are the challenges they face, including structural barriers such as laws and policies that criminalise them or hinder sufficiently advanced enjoyment of their rights? What action is being taken to address these challenges? How can we, as communities, ensure improved access to treatment and care for key populations?
- What operational research is being undertaken to identify the best models to use in delivering ART and other key interventions to key populations, particularly in hostile and repressive contexts? What has worked and should be scaled up? What hasn't worked and should be stopped? What new models should be piloted?
- Has my ministry of health or health department convened meetings to review national treatment guidelines in light of the 2013 Guidelines? Is the process transparent? Are civil society and communities, including key populations, involved and meaningfully engaged?
- Is my country planning to adopt any of the new recommendations, such as earlier treatment to specific populations (e.g. those with tuberculosis or in serodiscordant relationships) or viral load testing? If so, have communities contributed to this decision-making process? Has there been an assessment of both the community's and the country's readiness to implement these new recommendations?
- Do we, as communities have plans to review and revise our own policies and programmes to reflect the new guidelines (e.g. community education and counselling on the benefits of earlier treatment with better regimens, treatment adherence initiatives and stronger advocacy for the rights of key populations)?
- Is the new treatment plan adequately funded? Is the funding sustainable? Is there a campaign for greater national resources for health, as well as donor funds to meet any gaps? Is there adequate investment in community-based initiatives and services for key populations?

This is one in a series of modules supporting a community response to the 2013 WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.*

Produced by the International HIV/AIDS Alliance, Global Network of People Living with HIV (GNP+) and STOP AIDS NOW!

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