Driving the HIV response

A community guide to the WHO 2013 Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection

About the Community Guide

The Global Network of People Living with HIV (GNP+), the International HIV/AIDS Alliance and STOP AIDS NOW! developed this Community Guide in response to the World Health Organization (WHO) 2013 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV*. It aims to assist community leaders and civil society organisations to:

- better understand the new WHO recommendations and guide country-level discussions on priorities (within civil society and between civil society and government)
- ensure the meaningful participation of communities most affected by HIV in national decision-making and planning
- advocate for any changes or further research necessary to adapt recommendations to suit their country context
- mobilise and prepare communities for the implementation of new recommendations.

The guide is designed to be updated regularly, and extra modules will be added as further guidelines are issued by WHO, such as those on key populations and adolescents.

We welcome your feedback on this guide, including ideas for future modules and how to make them more useful for your work. Please send your suggestions to Aditi Sharma at aditi.campaigns@gmail.com

The full set of modules that make up *Driving the HIV response: a community guide to the WHO 2013 Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* is available at:

- **www.gnpplus.net/community-guide**
- **www.aidsalliance.org/communityguide**
- **www.stopaidsnow.org/community-guide**

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Taking antiretroviral drugs, Malaysia © Alliance

Swazi woman reads information on HIV treatment as prevention © Adriaan Backer for STOP AIDS NOW!

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WHY DID THE WORLD HEALTH ORGANIZATION ISSUE **NEW ANTIRETROVIRAL GUIDELINES** AND WHY SHOULD COMMUNITIES CARE?

Introduction

Scientific developments and the scale up of effective programmes have meant that AIDS-related deaths and new HIV infection rates are falling. Despite this, 2.3 million people became newly infected with HIV in 2012 – substantially more than the increase in the number of people on treatment in the same year. The epidemic will continue to outpace the response unless the world accelerates the scale up of lifesaving HIV treatment and prevention.

Over the years, it is people living with HIV and communities at the heart of the epidemic who have raised their voices for better research, advocated for cheaper, more effective and safer antiretroviral (ARV) drugs, delivered services to the most marginalised, and campaigned relentlessly to end preventable HIV infections and deaths.

Although there is no vaccine or cure as yet, a research breakthrough confirming that antiretroviral therapy (ART) can effectively prevent HIV transmission has given a new impetus to the HIV response. It is in this context that the World Health Organization (WHO) issued the new *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* in June 2013; a significant new contribution to efforts to make universal access to high-quality services a reality.

For the first time, these 2013 Guidelines combine guidance on the use of ARV medication for HIV treatment and prevention across all age groups and populations. They reflect new evidence and research, and aspire to a universal standard of prevention, treatment, care and support for people living with HIV, regardless of where they live in the world.

Although there may now be greater consensus than two decades ago on what works and what needs to be done, communities affected by HIV will need to continue to lead the response and advocate for high standards of prevention, treatment and care for *all.*

Why this Community Guide?

There is widespread acknowledgement of the critical role that communities and people living with HIV play in helping to deliver more effective and equitable HIV programmes, and this guide aims to support that role. It provides information that will assist community leaders to better understand and advocate for the new ART recommendations in their countries.

The 2013 Guidelines are organised to cover the whole continuum of HIV care, including clinical (what to do), operational (how to do it) and policy (how to decide what to do where and when) issues. *Driving the HIV response: a community guide to the WHO 2013 Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* follows a similar overall structure, but aims to highlight the role of

Message

Since 2001, new HIV infections have dropped by 33%.

Forward

Links

The full set of modules that make up *Driving the HIV response: a community guide to the WHO 2013 Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* is available at:

- www.gnpplus.net/community-guide
- www.aidsalliance.org/communityguide
- www.stopaidsnow.org/community-guide

The WHO 2013 *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* is available at: www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html communities (e.g. as advocates, programme managers, peer educators and so on) and their perspectives on the key recommendations in the 2013 Guidelines.

At each step, this guide focuses on how we as communities can use the 2013 Guidelines to strengthen our continued struggle for the universal right to health in our countries. It does not aim to summarise all the debates around the new recommendations or provide definitive answers, as each country and epidemiological context is different and it is communities who can best lead these discussions.

The checklists at the end of each module serve as prompts to help communities and civil society organisations to discuss, prioritise and advocate to ensure that the new recommendations are used to further human rights and equity and are suited to our communities' specific needs. The final annex provides a list of useful resources that include best practice examples of community-led interventions delivering HIV and related services.

Community Guide modules

What are the key messages in the 2013 Guidelines?

One of the key reasons the 2013 Guidelines have been produced is to reflect advances in medicine and new research findings. In particular, there is now strong evidence showing the link between treatment and prevention. This means that people living with HIV who are on treatment are far less likely to pass on the virus. As a result, there is a stronger consensus towards offering people the option to start their treatment earlier.

The 2013 Guidelines also reflect the following advancements:

- Improvements in production have led to safer, simpler, cheaper and more effective drug regimens.
- Developments in testing for HIV mean that a wider range of health facilities and community-based services are able to offer testing services.
- More effective methods of monitoring people on ARVs are now available.

The new recommendations can be grouped into three main areas, and below are what we consider to be the key points in each:

New science reflected in improved medical guidance

- Diagnose HIV earlier through community-based HIV testing and counselling.
- Start treating adults, adolescents and older children earlier (CD4 count of 500 cells/mm^3 or less) while still priortising those who need it most (CD4 count of 350 cells/mm^3 or less).
- Provide a simpler, safer, once-daily, single pill treatment.
- Provide better monitoring of the success of ART and diagnosis of treatment failure through viral load testing.
- Provide greater focus on women's health by offering lifelong ART for pregnant and breastfeeding women in most settings, or at least for duration of risk.

Making services more effective and efficient

- Integrate services so those receiving treatment for HIV can be treated for other health issues at the same time (such as antenatal care or TB treatment).

Resources

Three simple graphics summing up the key new WHO recommendations are available on all the Community Guide websites listed on the previous page. Use them in your advocacy or treatment literacy work.

- Decentralise treatment and care – more HIV services, including testing, ART initiation and maintenance, should be available in the community at local health facilities.
- Introduce task shifting – trained clinicians, midwives and nurses can initiate and maintain first-line ART, and trained and supervised community health workers can dispense ART between regular clinical visits.

Ensuring accountability in national health policymaking and planning

- Meaningfully involve affected communities in a transparent, open and informed process for decision-making and national planning.
- Plan health programmes and policies based on evidence and data rather than ideology or politics.
- Uphold principles of ethics, equity and human rights, ensuring services meet the specific needs of key populations without coercion.

What does this mean for communities affected by HIV?

In order to ensure that the 2013 Guidelines change the lives of people affected by and living with HIV, together with their families and caregivers, communities need to take responsibility for making them a reality in their context wherever possible. The 2013 Guidelines themselves say, "Community involvement and peer outreach strategies are key to improve programme design, promote its sustainability and maximize coverage."

There are key areas where people living with HIV and civil society supporting community action can work towards the goal of universal access:

- **Advocate for the necessary changes** to national and local HIV laws, policies and programmes with programme managers, funders and policymakers.
- **Adapt community education** to better protect and empower people living with and affected by HIV.
- **Develop community-based services** for better adherence support, linkages to and retention in care.
- **Advocate for research** to strengthen the knowledge base in relation to the implementation of new science on the ground and its impact on universal access and standards of care.
- **Expose service delivery failings** where services are of poor quality, are not reaching those most in need, or are discriminating against some populations.

Getting started

Before you do anything, get to know the 2013 Guidelines. They are divided into clear sections. The next step is to discuss how the 2013 Guidelines apply to the reality on the ground in your country, and choose your priorities to take forward.

To have the maximum impact, all the key community stakeholders in your country, and all those dealing with HIV from a civil society perspective, should meet to discuss and form plans suited to the specific needs of your communities. It is important to ensure all the relevant people are involved, especially representatives of key populations and other marginalised groups.

Focus on rights

Many ethical concerns are highlighted by the 2013 Guidelines. For example, the proposals to offer lifelong treatment to pregnant mothers, children and people living with HIV in sero-discordant relationships require ethical consideration of voluntary and informed consent, prioritisation of some populations over others, coercive testing, privacy, etc. We, as communities, need to be involved in policy decisions about how to adapt the 2013 Guidelines to the local setting and ensure that they are implemented from a human rights perspective, with quality services tailored to different communities with different needs.

GIPA

It is essential that the GIPA principle – the greater and meaningful involvement of people living with HIV in decisions and services affecting their lives – is at the heart of any changes. All stakeholders in the process of change must take the necessary steps to guarantee this, including providing training programmes and support to increase the capacity, knowledge and skills of individuals living with HIV.

Respect!

Stand up for fundamental human rights and ensure that these are not sidelined as countries rush to adopt new recommendations or show results.

Begin advocacy

Engage with all the national processes governing HIV and health policies and service provision, and specifically with the national AIDS commission and the ministry of health. Highlight the priorities that you have identified as critical for your community, and present data to support your arguments where available. Remember, your government will have funding challenges and competing health priorities, particularly if money is to be found to finance wider and earlier access to ART. Be wary of programmes that seem to offer substandard care in order to reduce costs. You will need to campaign for greater resources for health and community-based initiatives.

Donors, United Nations agencies and wider civil society can be important allies in discussions with government. In order to ensure that programme changes move your country closer to equitable and universal access to prevention, treatment and care, call for continued decentralisation of testing, treatment and care to sites that best suit the needs of those living with and affected by HIV, including key populations.

Develop or adapt your community education programmes

The 2013 Guidelines place great emphasis on community-based and -delivered services. Communities will need to become more engaged in the creation and implementation of services that better meet their needs. There is much to do to guarantee that we strengthen and expand health systems, linking them with community-based services.

People living with HIV also need to understand fully the implications of earlier treatment with improved regimens. For many years, people living with HIV in resource-limited settings have been discouraged from beginning treatment until their CD4 count has become very low. But now, with evidence of the benefits of earlier treatment, communities, treatment advocates and civil society organisations will need to communicate and prepare people living with HIV for this new message.

Review and adapt your own work and programmes

- **Engage people living with and affected by HIV:** they should be involved in the design and delivery of services that the community needs and can deliver.
- **Learn the field:** work with partners in the health system and national HIV response to discover what sort of services the community can best deliver, what innovations can be implemented, what works well in different contexts, and how to better link communities with facilities.
- **Perform national and local needs assessments:** identify what services exist and where they are, what is working and should be continued and brought to scale, what is missing, and what is not working and should be discontinued.
- **Training and education:** adapt and roll out treatment and rights literacy tools within communities. Develop training resources for the kinds of services that are needed locally and within the community. Seek support and funds for training community healthcare workers.
- **Campaign for adequate resources for the community response:** community-based service delivery can expand health system capacity and reach but it needs to be adequately resourced. Learn how donors like PEPFAR, the Global Fund and others can support communities in implementing the 2013 Guidelines.
- **Monitor and evaluate:** just like any other health service, community-created and -delivered services need rigorous monitoring and evaluation to make sure they are meeting the community's needs effectively and efficiently.

✉ Message

AIDS-related deaths have decreased by 29% since 2005.

Forward

This is an introduction to 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!

HIV diagnosis

One of the biggest challenges in the HIV response is identifying people living with HIV who do not know their HIV status. These people are often identified late in the course of their disease or only once they have fallen ill, and therefore are not always linked to appropriate care. Late diagnosis leads to late initiation of treatment and care, which can result in unnecessarily high morbidity and mortality. Those who test negative are not always provided with appropriate prevention and other community-based support services, nor are they encouraged to retest at a later time.

WHO already recommends routinely offering HIV testing and counselling in health facilities (known as provider-initiated HIV testing and counselling) as an efficient and effective way to identify people with HIV who could benefit from treatment. However, many in our communities do not or cannot access or use healthcare services, in particular key populations (see below), men and adolescents.

While testing and counselling in clinical settings remain key, the 2013 Guidelines now recognise that "community-based testing approaches may reach people with HIV earlier in the course of HIV disease, … as well as reaching populations that may not normally attend health services." There are growing calls for a rapid increase in voluntary, confidential community-based HIV testing and counselling services for currently underserved key populations and adolescents.

Message

Globally, about half of all people living with HIV do not know their HIV status.

Forward

Key populations

Key populations are groups that are vulnerable to or affected by HIV. Their involvement is vital to an effective response. Key populations vary according to the local context, but are usually marginalised or stigmatised because of their HIV status or social identities. They include people living with HIV, their partners and families, people who sell or buy sex, men who have sex with men, transgender people, people who use drugs, children affected by HIV and AIDS, migrants, displaced people and prisoners.

What do the 2013 Guidelines say?

The 2013 Guidelines recommend **introducing community-based HIV testing and counselling with linkage to prevention, care and treatment services** in addition to provider-initiated HIV testing and counselling in three contexts:

- generalised epidemics
- to reach key populations in any epidemic setting
- to reach underserved adolescents (especially those in generalised epidemics and those who come from key populations).

Link

This module links to Chapter 5: Clinical guidelines across the continuum of care: HIV diagnosis and ARV drugs for HIV prevention, 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/clinical/en/

What does this mean for my country?

The 2013 Guidelines provide minimal operational guidance on how to scale up to achieve universal access to testing. Instead they refer readers back to a document on testing service delivery approaches,[1] published in 2012, that highlights four action points:

- Choose a strategic mix of service delivery models to achieve universal and equitable access to HIV testing and counselling.
- Expand community-based options and innovate to reach beyond facilities.
- Build strong linkages to guarantee prevention, care and treatment services after testing.
- Use the new HIV testing strategies for high and low prevalence epidemics to ensure correct test results (testing strategies involve confirmation of test results).

Crucially, your country will need to develop a testing framework, employing "a strategic mix of service delivery models" to achieve universal and equitable access to HIV testing and counselling. The framework must be based on the local context, the nature of the epidemic, cost-effectiveness and available resources. The mix should facilitate diagnosing as many people living with HIV as early as possible to enable timely linkage to antiretroviral therapy. Strategies should also enable you to reach the people who are most vulnerable, most at risk and marginalised.

The 2013 Guidelines also place great emphasis on making certain that there are good linkages so that people are not overlooked when moving from one service site to another. This begins with testing services that are only meaningful if those who test positive are linked to appropriate services afterwards and retained in care until eligible for treatment.

Evidence shows that community-based HIV testing helps reduce stigma and discrimination, encourages greater uptake of services and ensures greater protection of human rights. Community organisations are often better trusted by their peers to provide services that are ethical, convenient, acceptable and effective.

There are a variety of community-based HIV testing and counselling methodologies, some more appropriate than others in individual contexts or for reaching particular populations:

- **door-to-door testing** (systematically offering testing to homes in an area served by the local health facility)
- **index testing** (offering testing to household members of people living with HIV, including spouses and children, and other sexual partners who may have been exposed to HIV)
- **mobile testing** for the entire population in areas visited by the general public (e.g. shopping centres, transport hubs, roadside restaurants)
- **targeted mobile testing** for key populations and adolescents (e.g. at opioid substitution therapy sites, truck stops, youth centres)
- **workplace, church-based and school-based testing**
- **HIV self-testing**, a process whereby a person performs a test and interprets the test result in private. HIV self-testing does not provide a definitive diagnosis. It is a screening test and requires further testing. The current evidence on HIV self-testing is limited and no global guidelines or recommendations have been issued to date.[2]

Respect!

All forms of HIV testing and counselling should be voluntary and adhere to the 5 Cs: consent, confidentiality, counselling, correct test results and connection to prevention, care and treatment. No mandatory or coerced testing!

Engage!

Make sure your country's HIV testing and counselling plan builds strong linkages to prevention, treatment and care services, and includes a range of service delivery models to ensure access for all.

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[1] World Health Organization (2012). *Service delivery approaches to HIV testing and counselling (HCT): a strategic HCT programme framework.* Available at: www.who.int/hiv/pub/vct/htc_framework/en/

[2] For further information on HIV self testing see 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_chapter05.pdf?ua=1

As we focus on improving access to community-based HIV testing, it is also important to advocate for policymakers to address the existing gaps in facility-based testing. Many stand alone services targeting key populations, such as sites offering clean needles and syringes, or opioid substitution therapy, still do not offer testing services on site, but instead refer clients to other facilities (where key populations may not always be treated well). The 2013 Guidelines stress that HIV testing and counselling should also be offered to all key population members attending prevention services (such as drug dependence treatment facilities) in a socially acceptable and epidemiologically appropriate manner, with supportive social, policy and legal frameworks.

The limitations of facility-based testing in reaching communities may be due to a number of factors, such as resource constraints, delays in licensing rapid HIV tests or national regulations about who is qualified to administer the tests. These same constraints may also limit community-based testing. Weak referral systems, and a lack of strong linkages within the health system and between the health system and community systems, have also hindered effective retention in care and access to prevention, treatment and care services.

Review!

Review any community-based testing approaches used in your country and discuss adaptations or piloting new approaches, in particular to better reach key populations and adolescents.

Advocate!

Call for HIV testing and counselling services to be offered to key populations alongside other services, such as at drug dependence treatment sites.

Take stock! Take action!

- ☐ Is testing in your country voluntary for all? Do testing services adhere to the 5 Cs: consent, confidentiality, counselling (pre and post test), correct test results, and connections to prevention, care and treatment? Are healthcare workers and affected communities ensuring that people do not encounter undue pressure to test?
- ☐ What is the testing coverage rate in your country? Who has access and who doesn't? What is preventing access and uptake?
- ☐ What can we, as communities, do to improve access to voluntary and confidential testing and counselling for key populations and adolescents? Can we develop creative and effective models for reaching them?
- ☐ Who are the key stakeholders providing HIV testing and counselling services, including civil society and community-based organisations? Who coordinates this?
- ☐ Do current national laws and policies permit community-based testing in your country, or is there a need to align them to the new guidelines? Are rapid HIV test kits licensed in the country to facilitate community-based HIV testing and counselling?
- ☐ What community-based testing models are currently in place? Are these adequately funded? Is there operational research on models of community-based testing work in different regions and for different population groups in your country?
- ☐ Is there a plan and funding to provide training and support for community health workers and lay counsellors to offer counselling and perform rapid HIV tests as community-based testing is scaled up?
- ☐ What capacity exists within the community to ensure the quality of testing and monitor whether testing and counselling are conducted in an acceptable and effective manner (e.g. through community feedback mechanisms)?
- ☐ Is there a plan to ensure reliable supplies of testing materials, including rapid tests? Does the procurement and supply chain management of test kits need improving?
- ☐ What systems are currently in place to link people who have tested to further prevention, treatment or care services? What is working, and what it not working and needs to change? What role can we, as communities, play to improve the linkages?

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!

International HIV/AIDS Alliance
Together to end AIDS

GNP+ GLOBAL NETWORK OF PEOPLE LIVING WITH HIV

STOP AIDS NOW!

Using antiretroviral drugs to prevent HIV

It is not just people who are living with HIV who need to be linked to services. The 2013 Guidelines stress the importance of also linking people who are vulnerable to HIV to prevention services. Applying a combination prevention approach means that these prevention services should include the use of antiretroviral drugs (ARVs) by people who are uninfected to prevent them from acquiring HIV.

The 2013 Guidelines do not make new recommendations on the use of ARVs for prevention for people not living with HIV. However, they do reiterate a few points from recent WHO guidance on daily oral pre-exposure prophylaxis (PrEP), the use of ARVs to prevent HIV among serodiscordant couples (where one partner is living with HIV and the other is not) and post-exposure prophylaxis (PEP) for occupational and non-occupational exposure to HIV.

Pre-exposure prophylaxis (PrEP) is the daily use of ARVs by HIV-uninfected people to prevent HIV acquisition.

Post-exposure prophylaxis (PEP) is short-term antiretroviral treatment to reduce the likelihood of acquiring HIV infection after potential exposure, either occupationally or through sexual intercourse.

What do the 2013 Guidelines say?

The 2013 Guidelines restate recent WHO guidance regarding PrEP and PEP:

- **Provide oral pre-exposure prophylaxis (PrEP)** in the context of demonstration projects for partners in serodiscordant relationships and for men and transgender women who have sex with men.[1] (2007)
- **Consider post-exposure prophylaxis (PEP) for women presenting within 72 hours of sexual assault**, using shared decision-making with the survivor to determine if this is appropriate.[2] (2013)

WHO also stresses that although ARVs play a key role in HIV prevention, they should be used in combination with an appropriate mix of other biomedical, behavioural and structural interventions (e.g. condoms, voluntary safe medical male circumcision, risk reduction counselling, reduction of stigma and gender-based violence, opioid substitution therapy).

Message

When taken daily as directed, PrEP can reduce the risk of HIV infection by more than 90%.

Forward

Link

This module links to Chapter 5: Clinical guidelines across the continuum of care: HIV diagnosis and ARV drugs for HIV prevention, 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/clinical/en/

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[1] WHO (2012). *Guidance on oral pre-exposure prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV.* Available at: www.who.int/hiv/pub/guidance_prep/en/index.html

[2] WHO (2013). *Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines.* Available at: www.who.int/reproductivehealth/publications/violence/9789241548595/en/

What does this mean for my country?

Oral pre-exposure prophylaxis

Respondents in a community consultation[3] raised concerns regarding costs, stigma and discrimination (particularly when PrEP is used by key populations), and side effects. These were seen as barriers that must be addressed for PrEP to be effective. There is also some debate about what effects PrEP has for prevention messages and counselling (e.g. in relation to risk reduction and condom use). Community organisations have a critical role to play in ensuring acceptance of PrEP and in increasing demand for and linking communities to these kind of interventions.[4]

In controlled clinical trial settings, when people take PrEP as directed, it works. It is another question entirely whether people will want to take PrEP beyond these settings and whether or how programmes should construct prevention services that deliver PrEP to these target populations. Experience with PrEP beyond clinical trial settings remains very limited to date.

Given this uncertainty, WHO recommends that national programmes interested in PrEP perform small pilots to verify whether scale-up is worthwhile and what needs to be in place to make it effective. For example, WHO recommends that countries carry out implementation science studies with serodiscordant couples, and men and transgender women who have sex with men, to see how PrEP use impacts on these key populations.

Currently, PrEP recommendations do not extend to other populations at higher risk of HIV (e.g. sex workers, people who inject drugs). Interest in PrEP as a preventive measure may differ greatly among these populations in different epidemic settings.

Post-exposure prophylaxis

In light of recommendations to set up pilot projects to explore long-term PrEP among these populations, it seems a missed opportunity not to make similar recommendations about providing PEP to individuals who have experienced a sexual exposure that places them at high risk of HIV (e.g. after sex with someone known to have HIV, or with someone with a high risk of HIV). Providing PEP in these cases could be an identical process to providing PEP in cases of sexual assault: that is an initial supply of PEP followed by counselling to see whether the exposure warrants a month's supply of ARVs. Key populations such as female sex workers should not be forced to claim sexual assault because currently people with "chronic exposure" to HIV are not eligible to access PEP under WHO guidelines. Also, men and transgender people should have access to PEP after being sexually assaulted – not only women, as the current recommendations state.

Advocate!

There is a need for better global guidance on PEP that addresses the issues raised by communities. At a national level, PEP should become more readily available, and healthcare workers should be educated on providing it in a non-judgmental way.

Engage!

Promote and support research or pilot studies on the acceptability of PrEP among relevant communities in your country. Engage in future guidance, implementation and evaluation of follow up demonstration projects.

Research!

Further studies are needed on where and how to provide access to PrEP, support adherence, prevent stock-outs and monitor its success or failure.

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[3] International HIV/AIDS Alliance and GNP+ (2013). Community consultation to inform the 2013 WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*. Available at: www.aidsalliance.org/includes/Publication/1.%20Community%20Consultation%20Report.pdf

[4] To learn more about these technologies and the role communities can play, see resources available at www.avac.org

Take stock! Take action!

☐ Does your country have policies regarding PrEP and PEP? Who are offered PEP and PrEP, and does this match the needs of your country and your community?

☐ Is PEP readily available in your country and how is it being delivered? What needs to change to increase accessibility and effectiveness?

☐ Is your country considering PrEP demonstration projects, as recommended by WHO, or looking into other projects in your region? If conducting demonstration projects, will these include an analysis of project outcomes?

☐ Have communities groups, including key populations, been consulted for their views on PrEP? Have acceptability studies regarding PrEP been conducted?

☐ How would your communities or groups like PrEP to be delivered? Who should be able to prescribe and administer it? Will this require regulatory changes? How will adherence be supported? Who will monitor its success or failure, including observing side effects, preventing stock-outs and providing repeat testing and counselling services?

☐ Have your communities discussed WHO policies regarding PrEP? If so, has using PrEP to support the sexual and reproductive health rights of partners in serodiscordant relationships been considered? Also, has using PrEP among transgender men and women who have sex with men been considered?

☐ Is a multi-stakeholder group that includes funders, researchers, policymakers and advocates from countries where PrEP might be introduced collaborating to develop forward-looking strategy to fill specific gaps?

☐ Are advocates and policymakers having open conversations about how to ensure treatment access to those who need ARVs for their health, while finding a way to provide PrEP?

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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.

Message

Today, more than 4 million people are alive due to the scale up of HIV treatment.

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/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.

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 $\leq 500^3$

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.

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

Engage!

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

Advocate!

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

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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.

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.

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.

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]

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.

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[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!

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

Antiretroviral therapy for pregnant and breastfeeding women

D

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:[1]

- 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 ≤500 cells/mm^3) and need treatment for their own health should continue taking ART for life.

Message

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/arv2013/art/en/

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[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

- 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.

Review!

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

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.[2] 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.

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[2] See www.gnpplus.net/option-b-understanding-the-perspectivesexperiences-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:

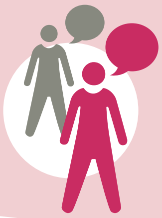
- community education, training for community health workers, and adequate funds to include providing lifelong treatment and care in services that previously only focused on providing ARV prophylaxis during pregnancy and delivery
- clearer guidance and support, including financial support and guidance 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?

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

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

E

Antiretroviral therapy for children

Infants and young children[1] living with HIV have a higher risk of falling ill and of dying than adults because their immune systems are not fully developed. Starting children living with HIV on antiretroviral therapy (ART) early has been shown to help them live longer and healthier lives. Early infant diagnosis (EID) is critical for this. But progress towards improving access to HIV testing and ART for children has been extremely slow.

While EID is expanding in many countries, in 2012 only 39% of children in low- and middle-income countries had access to HIV testing within the recommended two months from birth. In addition, programmes are failing to start treatment for infants diagnosed with HIV. In 2012, 34% of children received the life-saving ART they needed compared to 64% of adults.

To help simplify and expand treatment access for children, the 2013 Guidelines recommend immediate treatment without CD4 testing for all children aged under five. For children over five, the recommendation is the same as that for adults: to start treatment at CD4 cell count ≤500 cells/mm^3.

Research!

Investment is urgently needed to research the impact of earlier treatment of children on retention, adherence and potential drug resistance.

These recommendations are based on programmatic benefits as much as clinical evidence. Treating all children under five is expected to simplify paediatric treatment and facilitate significant expansion of ART coverage. Programmatic data suggests that children living with HIV are at greater risk of dying or being lost to follow up before starting ART than when enrolled in a treatment programme. Early treatment for children with HIV will help improve retention in care and may also facilitate treatment of other preventable diseases. This is because treatment programmes have a very active tracing system, including home visits and social support, as well as providing non-antiretroviral HIV care like cotrimoxazole prophylaxis and timely treatment of opportunistic infections.

There are serious concerns about the greater risks of drug resistance with early treatment if adherence is poor or supplies of medicines are unreliable. Many also point to the continued lack of child-friendly formulations that do not require refrigeration as a major challenge. There are further concerns regarding the toxicity of drugs used over a sustained period when treatment is initiated early in children who may otherwise be long-term non-progressors (individuals living with HIV who remain well for many years without ART, before developing symptoms of opportunistic infections or AIDS).

✉ **Message**

Without diagnosis and treatment, half of all children living with HIV die before their second birthday.

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/arv2013/art/en/

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[1] The 2013 Guidelines define infants as children under one year of age. They make separate recommendations for children under five and older children (five to ten years). Separate guidelines for adolescents are covered in Module H.

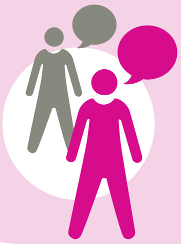
What do the 2013 Guidelines say?

Antiretroviral therapy should be initiated:

- in all children living with HIV aged below five, regardless of WHO clinical stage or CD4 count, with priority given to children under two
- in all children living with HIV aged five and older with CD4 cell count ≤500 cells/mm^3, with priority given to those with CD4 count ≤350 cells/mm^3
- in all children living with HIV with severe or advanced symptomatic disease (WHO clinical stage 3 or 4) regardless of age and CD4 count
- in any child younger than 18 months who has been given a presumptive clinical diagnosis (based on existing symptoms and a positive antibody test, where virological testing is unavailable) of HIV infection.

Advocate!

Communities need to advocate for training and support to prepare nurses and other healthcare workers to use improved point-of-care infant diagnostic tests, bringing programmes closer to communities.



What antiretroviral therapy regimens?

Choosing the best antiretrovirals (ARVs) for children is complex due to limited availability of child-friendly formulations, the long-term toxicities of ARVs and the difficulty of ensuring adherence in children. In addition, many children with HIV may have viral resistance to a class of ARVs called non-nucleoside reverse transcriptase inhibitors (NNRTIs) because they were exposed to these medications as prophylaxis given to mothers and infants to prevent vertical transmission of HIV.

The 2013 Guidelines recommend that infants and young children aged up to three who test positive should be started on a ritonavir-boosted lopinavir-containing (LPV/r) regimen. Despite concerns about storage, price, potential long-term toxicity and administration difficulties, many respondents in a community consultation[2] accepted LPV/r syrup because of its greater effectiveness. In some resource-limited settings, where providing a LPV/r-based regimen is not feasible or affordable, the 2013 Guidelines recommend providing a nevirapine-containing (NVP) regimen as an effective alternative, especially given the availability of two- and three-drug fixed-dose combinations. However, if the infant has or develops tuberculosis (TB) they will need access to an abacavir-containing (ABC) regimen because of the interactions between NVP and some TB medications. After reaching the age of three, the 2013 Guidelines recommend that children be switched over to the same first-line regimen that adults use (see Module C or 2013 Guidelines, Chapter 7).

Since 2010, WHO has recommended phasing out the use of stavudine (d4T) among adults and children because of its known long-term toxicity. However, considering the limited availability of age-appropriate nucleoside reverse transcriptase inhibitor (NRTI) formulations, d4T may be used in certain circumstances. These include when using zidovudine (AZT) may not be advisable due to the high risk of anaemia; where formulations of ABC are not available for children; or in a situation in which toxicity to AZT is suspected and ABC cannot be used.

What does this mean for my country?

There are many technical, social and psychological challenges to improving access to treatment for children living with HIV. The first challenge is the low coverage of EID, which is the entry point for treatment for most children. Links between diagnosis and treatment need to be improved as they are frequently offered at different facilities. An algorithm for EID (Annex 2.1) and best practices for EID implementation (Box 2.3) are presented in the supplementary section to the 2013 Guidelines.3 In the coming years, point-of-care virological tests for EID should become available, and this could enable more timely diagnosis of HIV in infants and promote more rapid linkage to treatment and care. There is also a need to identify opportunities to better integrate EID within other services, such as antenatal care, maternal and child health settings, and nutrition programmes.

Given the evidence gaps on the clinical benefits of initiating early treatment in all children aged under five diagnosed with HIV (regardless of WHO clinical stage

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2. International HIV/AIDS Alliance and GNP+ (2013). Community consultation to inform the 2013 WHO *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.*

3. See Annex 2.1, and Box 2.3 in 'Section 1: HIV self-testing' 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_chapter05.pdf?ua=1

or CD4 cell count), national programme mangers and affected communities will need to determine how best to implement this recommendation in their country. They will have to choose whether to recommend universal treatment for all children aged under five, or focus on universal treatment for infants younger than one and apply clinical and immunological criteria for children aged one to five until stronger evidence is available.

Respect!

High-quality, affordable, child-friendly ARVs should be available to all children in need.

Yet another challenge is the limited availability of child friendly formulations of ARVs and substantial difficulties in harmonising regimens with adults. Infants who are too young to swallow tablets ideally need to be provided with medications that are more child friendly, such as syrups, powders and sprinkles. However, these formulations are only slowly becoming available and are expensive. Unfortunately, a lot of HIV medicine has an unpleasant taste, especially in syrups and powder form. This can make it difficult for children to take their ARVs daily. Also certain formulations require refrigeration, which is not always feasible. The preferred first-line for young children (LPV/r) is not child friendly and has a particularly poor taste. A better generic sprinkles formulation that is heat stable has been developed, but issues regarding patents are hampering licensing of the formulations for use in middle-income countries such as South Africa.

In countries where there is a lack of affordable paediatric ARV formulations, clinicians often divide adult fixed-dose combinations into measures appropriate for children. The good news is that various fixed-dose regimens for children are now increasingly available. However, these paediatric formulations are often unaffordable for developing country governments to procure for the settings where they are most needed. Country programmes are urged to limit the procurement of ARVs for children to formulations included in the list of optimal and limited-use ARV formulations for children published by the Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children.[4]

Communities and governments should advocate strongly for development of better medications for children. However, while the use of better regimens is important, expanding ART coverage among children is the priority. We need to have a better understanding of the challenges experienced by affected communities, and they must be consulted and involved in addressing these challenges that may go beyond the availability of child-friendly formulations.

One of the major challenges is the lack of knowledge and training on how to provide adequate psychosocial support both to children affected by HIV and their parents and or caregivers. This includes challenges around testing older children, disclosure of HIV status within families, lack of child-sensitive counselling, and inadequate documentation of children's needs and priorities, including ways to address the stigma and discrimination they face. Another issue is the lack of differentiation in health services or guidance for children of varying ages, from infancy to adolescence.

The role of communities is critical in providing family-centred care strategies, psychosocial and nutritional support, disclosure and adherence support, and in reducing stigma and discrimination faced by children living with HIV.

The paediatric ART recommendations are slightly more complicated than those for other populations, with different recommendations on when to start and what to start with depending on the age of the child. This makes it harder for nurses and community healthcare workers to provide paediatric care. However, the hope is that better technologies, more effective regimens and simplified guidance will help bring services closer to communities.

Engage!

Communities need to be fully engaged in research and guideline development to ensure the best possible outcomes for children and uphold their rights.

Advocate!

Invest in community-based initiatives and strategies to deliver comprehensive care for children living with HIV and their families, including ways to engage them and respond to their own expressed priorities.

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[4] See Annex 10.1 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, Annex 10.1

Take stock! Take action!

☐ What are the barriers to EID in my country and what plans are there to address these? What is the current ART coverage among children in my country? What are the barriers to linking children diagnosed with HIV to treatment and care, and what plans are there to address these?

☐ What are the current initiatives to provide children affected by HIV, their families and caregivers with the psychosocial care, nutritional support and social protection they need? How can this be improved?

☐ Is ART for children available at the same facilities where adults go for ART or other relevant services such as maternal and child health? How can we improve the links between testing, diagnosis and treatment? What strategies should be used to improve retention and treatment adherence among children?

☐ Is my country moving towards the guideline of initiating immediate treatment for infants and children aged under five? Are we as communities discussing possible opportunities within and concerns about the new recommendations? Are community voices being heard and taken into account by policymakers?

☐ Are women living with HIV and community organisations engaged and able to influence discussions about which approach is most suitable for our country? Is consideration being given to how treatment for children will impact on their mothers and other family members?

☐ Is there enough consideration being given to ethical and human rights issues in initiating lifelong ART for all children living with HIV?

☐ Are there plans to switch to better regimens for children and to phase out medications like d4T? If not, what are the obstacles and what are the plans to overcome these?

☐ Are stock-outs for paediatric ARVs 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? If not, what needs to change?

☐ What is the role of civil society and communities in paediatric care for children living with HIV? What services do, or should, we provide? Are we undertaking advocacy for child-friendly formulations, affordable and quality ARVs for children, and child-friendly health services that consider children's evolving capabilities?

☐ What operational research is being undertaken to identify the best strategies, including family-based care, to improve uptake and retention in paediatric care and promote and support adherence? What has worked and should be scaled up? What hasn't worked and should be stopped? What new models should be piloted?

☐ Is there adequate funding for treatment and care for children living with HIV in the national budget? What are the gaps? How can these gaps be sustainably filled?

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Developing programmes and delivering services

Although HIV programmes have dramatically scaled up over the past decades, many challenges remain. Access to care for everyone eligible for antiretroviral therapy (ART), especially those disproportionately affected by HIV, has still not been achieved. Overall, we need to make the shift from a primarily biomedical approach to a holistic response that meets the needs of people living with HIV, their families and caregivers in their communities. Healthcare programmes need to be adapted to more efficiently use resources, promote an enabling environment that will reduce the likelihood of new HIV infections, and ensure better health and social outcomes for people living with HIV and their families. In particular, the many systemic barriers that communities face in accessing and taking up the best possible healthcare services must be addressed.

The 2013 Guidelines provide operational guidance to help countries develop programmes and services that support the new clinical recommendations, such as earlier treatment and provision of better drugs. The key new operational recommendations are around **integration and decentralisation of health services and task shifting**. These inter-linked strategies, adapted to local contexts, could directly address some of the most common barriers to care, such as the distance and cost of travel to health facilities and long waiting times at clinics.

Integrating and linking HIV services with other health services (including sexual and reproductive health, maternal and child health, tuberculosis (TB) and drug dependence) aims to provide more comprehensive care. It can take the form of providing related services in a single health facility, sharing information or making referrals across facilities. Integration of services is critical in different settings, including in concentrated epidemics and for key populations.

Decentralisation, a particularly important strategy in generalised epidemics, means moving HIV care and treatment from a limited number of specialised ART sites (often in urban areas) to sites in the community closer to where people live.

Task shifting refers to trained nurses, midwives and community healthcare workers taking on tasks that were traditionally carried out by doctors. In many countries there are not enough doctors to provide HIV treatment to all who need it, especially at primary care sites. With training and support, other healthcare workers can initiate or maintain people on ART.

The 2013 Guidelines call for people living with HIV, key populations and community-based organisations to be actively engaged in the development and delivery of many services. This is due to a growing recognition that

Message

People who inject drugs accounted for 62% of reported HIV cases in 19 countries in Europe and central Asia in 2010, but represented only 22% of the people receiving ART.

Forward

Link

This module links to Chapter 9: Guidance on operations and service delivery, 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/download/en/index.html people living with and affected by HIV play a key role in delivery of HIV services at the community level, including acting as role models to others in need of treatment, providing peer support and reducing stigma associated with seeking and using HIV services. These interventions are often critical to providing non-discriminatory and responsive care, particularly for population groups who are marginalised or even criminalised.

What do the 2013 Guidelines say?

Integrating and linking services

- In generalised epidemic settings, ART should be initiated and maintained for eligible pregnant and postpartum women and for infants at maternal and child healthcare settings, with linkage and referral to ongoing HIV care and ART where appropriate.
- In settings with a high burden of HIV and TB, ART should be initiated for an individual living with HIV in TB treatment settings, with linkage to ongoing HIV care and ART. TB treatment may be provided for an individual living with HIV in HIV care settings where a TB diagnosis has also been made.
- ART should be initiated and maintained in eligible people living with HIV in care settings where opioid substitution therapy is provided.

Decentralisation of HIV treatment and care

The following options for decentralisation of ART initiation and maintenance should be considered:

- Initiation of ART in hospitals, with maintenance of ART in peripheral health facilities.
- Initiation and maintenance of ART in peripheral health facilities.
- Initiation of ART in peripheral health facilities, with maintenance at the community level (that is, outside of health facilities in settings such as outreach sites, mobile and fixed syringe exchange sites, health posts, home-based services or community-based organisations) between regular clinical visits.

Task shifting

- Trained non-physician clinicians, midwives and nurses can initiate first-line ART and maintain ART.
- Trained and supervised community health workers can dispense ART between regular clinical visits.

What does this mean for my country?

Task shifting, decentralisation and integration of HIV care, support and treatment will require better understanding of local context – epidemiological, political, legal, socio-cultural, economic and best practices. A well-coordinated and appropriately funded multi-sector effort involving a wide range of organisations and stakeholders is also required to sustain and scale up services. Innovative strategies may need to be developed to overcome barriers, and careful planning, implementation, monitoring and evaluation are essential. If task shifting, decentralisation and integration are to achieve better health outcomes, they must be integrated into the existing national plan of action.

The aim of linkages and referrals must be to make it easier for individuals living with HIV to navigate the system and support them to remain engaged in care. As long as the legal environment supports cross-sector collaboration, multi-disciplinary disease and client management approaches can bridge gaps between sectors and disciplines (e.g. through the use of unique identifier codes protecting client confidentiality while allowing tracing of referrals and service uptake).

Linkages and referral systems must exist between community-based and other healthcare services in order to provide holistic care. Care should be rights-

Advocate!

People living with HIV and key populations must be actively involved in developing, delivering and monitoring services. We, as communities, make varied and critical contributions to health systems. These need to be better recognised and invested in.

Message

In sub-Saharan Africa, 32% of people living with HIV who were eligible for ART were lost before initiating treatment.

Forward

based, non-judgmental, and responsive to gender, age, sexual orientation, and individual risks and vulnerabilities. Communities must ensure that integration of services in one facility, for example, does not lead to further stigma or denial of choice to people living with HIV.

While the 2013 Guidelines focus on the integration of health services within healthcare facilities, integration can also be important within the framework of community-based services. Integration could occur, for instance, between HIV and sexual and reproductive health services in a drop-in centre for a key population run by a community-based organisation, with bidirectional referrals to public and private healthcare providers for additional health services. Another example would be the integration of peer-driven psychosocial and economic support services into healthcare facilities.

The 2013 Guidelines highlight some key implementation considerations:

- *Programme managers and communities should jointly consider options for decentralisation to see which are feasible and best fit local needs.*
- *Programme managers should consider human resources capacities and task shifting, and develop policies to recruit and retain staff particularly in remote rural settings. Adequate training and supervision, including for community health workers, is important to ensure high quality care.*
- *Programme managers and communities should strengthen linkages and referral systems.*
- *Programme managers should agree on the division of labour and responsibilities among levels of the health system (national, provincial or regional) and with community-based service providers, including networks of people living with HIV.*

Programme managers and communities need to communicate the new guidelines and their implications to build trust in the new service delivery models and standards of care. Communities must strengthen their treatment literacy and human rights programmes, thus empowering people living with HIV to make informed decisions regarding lifelong prevention, treatment and care.

It is widely recognised that people living with HIV have been at the forefront of efforts to ensure that *all* people living with HIV get the services they need. The Positive Health, Dignity and Prevention (PHDP) operational guidelines[1] offer further guidance on meaningfully involving people living with HIV and ensuring that HIV programmes meet their needs. For instance, assessment checklists can guide communities and programme managers in planning, implementing and evaluating the recommended service delivery models. Communities can also ensure that the comprehensive package of services and support for people living with HIV, described in the PHDP guidelines, is integrated into the national strategic plan and other national-level strategies (e.g. health system strengthening). National networks of people living with HIV need the support of donors and United Nations agencies to use the PHDP guidelines to improve national HIV programmes.

In order to achieve rapid scale up and acceptance of new standards of care and service delivery in affected communities, it is crucial to ensure the leadership and engagement of communities and people living with HIV in all their diversities.

Community-led services[2] need to continue to support and complement the health system. There is increasing evidence of the benefits of community-based ART delivery models to offer treatment, support adherence, maintain people in high-quality care, and improve the quality of life of people living with HIV. More research is needed on how community models can support underserved populations who often have difficulties accessing ART. Depending on context, these may include vulnerable men, women, children, adolescents, people in rural areas, prisoners, refugees, mobile populations, sex workers, men who have sex with men, transgender people and people who use drugs. Communities need to be clear about the costs of these models so they can advocate for them to be included in national budgets.

Advocate!

Governments and other stakeholders should use the Positive Health, Dignity and Prevention framework to ensure that national HIV programmes are responsive to and meet the needs of people living with HIV.

Research!

Further studies are needed on how community models can better serve populations who are often last to benefit from HIV services, and promote their human rights.

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[1] See Module G. PHDP operational guidelines are available at: www.gnpplus.net/assets/positive_health_dignity_and_prevention_operational_guidelines_-_unaids_gnp_2013.pdf

[2] See examples of models of community ART delivery in Annex 11.1. of 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/arvs2013upplement_march2014/en/

Simple, integrated systems to monitor and evaluate community-based models of care are necessary to ensure reliable drug supply, support programme efficiency and effectiveness, and ensure programme transparency and accountability. Similarly, services delivered by communities need to be regularly monitored and evaluated using an agreed set of indicators, and integrated into national monitoring and evaluation (M&E) systems. The PHDP framework provides guidelines for measuring the impact of national programmes and references to other useful M&E resources. Community-based organisations delivering services and advocating for change also need to feed back to the communities they serve, and put in place ongoing consultation and feedback mechanisms.

Take stock! Take action!

☐ Has there been an assessment of the strengths and weaknesses of current programmes and delivery of services, including identification of gaps? Have there been discussions in your country on how to adapt and improve both health and community systems and the linkages between them to better support adoption of the 2013 Guidelines?

☐ Is your community engaged in plans to help deliver ART (e.g. via home-based care or adherence clubs for stable patients)? Have the different models of community-based services been evaluated to determine which should be scaled up to support the 2013 Guidelines?

☐ Do national laws and policies need to be updated to allow for community-based models of prevention, care and support?

☐ Are networks of people living with HIV, community-based organisations, healthcare workers and programme managers aware of and using PHDP operational guidelines?

☐ Have the new recommendations been discussed with other relevant programmes, such as maternal and child health, TB and drug dependence, to ensure delivery of integrated services? Are current linkage/referral systems adequate and functioning, including between health facilities and community-based services? What are the changes needed to support the new recommendations?

☐ Where and what services need to be decentralised to better support the 2013 Guidelines? Have different options or models of decentralisation of services been analysed?

☐ Are nurses and community health workers engaged in discussions around the adoption of the 2013 Guidelines and prepared to take on additional roles recommended for task shifting?

☐ Has there been an assessment of how many additional healthcare workers are needed to implement the new recommendations? What cadres (doctors, nurses, midwives, community health workers, laboratory assistants) are needed, and how can they be recruited and retained?

☐ Is there a plan to update training curricula for healthcare workers and provide ongoing and systematic training, including for community health workers? Will there be an established system to ensure ongoing organisational support and quality assurance of services provided at periphery and community levels?

☐ Are targeted communication strategies, along with updated treatment and rights literacy initiatives, in place to ensure that people living with HIV, their families, caregivers and communities are adequately informed about the new recommendations?

☐ Have the health system costs of implementing the new recommendations been estimated and budgeted for? Are there adequate national resources or have donor funds been mobilised, including for community models?

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International HIV/AIDS Alliance
Together to end AIDS

GNP+ GLOBAL NETWORK OF PEOPLE LIVING WITH HIV

STOP AIDS NOW!

Making decisions and designing policies

The 2013 Guidelines emphasise the need to base decisions on and design policies to address the current national context. This includes promoting and fulfilling the human rights of underserved populations and reviewing punitive laws and practices.

Throughout the world, including in sub-Saharan Africa, HIV prevalence is substantially higher among key populations.[1] Yet in many countries key populations, including men who have sex with men, transgender people, sex workers and people who use drugs, are not receiving essential health services. And despite the evidence that punitive laws hamper an effective HIV response by denying services to people in greatest need, many countries continue to criminalise HIV transmission, sex work, drug use and homosexuality.

The 2013 Guidelines also recognise that different countries face different constraints, and that their respective HIV responses have strengths and weaknesses. Each country will need to decide on their priorities and the steps they must take in order for their HIV programme to reach the standard of care that the guidelines recommend. The 2013 Guidelines for the first time offer countries guidance on the decision-making process needed to prioritise the recommendations and design effective policies. There is also guidance on programme implementation and how to make efficient use of resources and monitor the outcomes of HIV programmes.

Most importantly, the 2013 Guidelines highlight the critical need of people living with HIV and HIV-affected communities, including key populations, to be meaningfully engaged and to have a say in the decisions that will affect their lives. Communities also need to advocate for key recommendations to be adopted into national programmes, and to hold the government and its partners accountable for their implementation.

What do the 2013 Guidelines say?

- Decisions regarding the implementation of the 2013 Guidelines should be made through a **transparent, open and informed process with broad stakeholder engagement, including meaningful participation from affected communities**, in policy, design, implementation, monitoring and evaluation.
- Decisions on how to adapt and implement the 2013 Guidelines should be based on an analysis of **epidemiological dynamics, programme performance, and the socioeconomic, policy and legal context**.
- Global and national commitments require providing HIV treatment and prevention to everyone in need, following the **human rights principles of non-discrimination, accountability and participation**. Key **ethical principles of fairness, equity and urgency** should also be observed in the process of reviewing and adapting the 2013 Guidelines.

Message

In 78 countries, either adult same-sex sexual conduct is criminalised or lesbian, gay bisexual or transgender people have been criminally prosecuted under other laws on the basis of their sexual orientation.

Forward

Link

This module links to Chapter 10: Guidance for programme managers, 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/progmanager/en/

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[1] See Module A for a definition of key populations.

Engage!

People living with HIV and affected communities must actively engage in decision-making and priority setting to secure the most benefit from the 2013 Guidelines.

Advocate!

Advocate! Say no to laws and policies that criminalise key populations. Ensure the rights of all people living with HIV are respected.

What does this mean for my country?

Setting priorities

The 2013 Guidelines come at a time when many countries are still to adapt their national guidelines and deliver care that is up to the standards recommended by the previous version of the guidelines. Given the realities of treatment programmes on the ground, with funding challenges, stock-outs and competing health priorities, providing wider and earlier access to a higher standard of treatment and prevention could seem particularly challenging. Some policymakers may argue they cannot afford to upgrade and further expand their programmes, while others may try to move forward by offering sub-standard care. Communities need to be vigilant throughout the decision-making process, gather evidence on the risks of such strategies, and put forward reasoned arguments to counter them.

In addition, programmes need to have a plan to *guarantee* that treatment of the most sick patients (those who are symptomatic or with a CD4 cell count of 350 or below) is prioritised. It is critical that the offer of treatment to healthier patients does not jeopardise the continued decentralisation and scale up of antiretroviral therapy (ART) to all areas, including remote, peripheral primary healthcare settings and to anyone for whom immediate access to ART could be life-saving.

Consulting widely

The 2013 Guidelines recommend setting up, if not already in place, a multidisciplinary working group, including people living with HIV and civil society, to consider and advise policymakers who are updating and implementing national guidelines. The role of this group would include reviewing the current context of the HIV and tuberculosis (TB) epidemics and the policy environment; assessing evidence related to the new recommendations and providing advice on how best to interpret them within the local context; identifying implementation issues such as costs, human resource and infrastructure needs; and providing advice on how to address these issues. Other effective mechanisms to influence policies, such as community advisory groups, should also be considered.

The 2013 Guidelines recommend an open, informed and transparent process so that all stakeholders are meaningfully involved. Networks of people living with HIV and community based organisations need to be aware of and engage with all available decision-making spaces and opportunities, including technical working groups, national AIDS councils, and Global Fund platforms such as the Country Coordinating Mechanism and country dialogues. As representatives of communities engage in these policymaking forums, they must consult, feed back and be accountable to the constituencies they speak on behalf of.

Following evidence

Communities will need to ensure that decisions are based on widely available evidence – not just about the nature of the epidemic, but also programme performance, gaps in coverage and the political, socioeconomic, legal and policy context. There is a need to generate and share better evidence on effective community-led services. We particularly need to highlight examples of initiatives that work to address the structural barriers that affect the ability and willingness of certain groups, including key populations, to access health services. There is also a need to advocate against the laws that criminalise key populations particularly sex workers, lesbian, gay and transgender people, and people who use drugs recently enacted in many countries.

Finally, while cost-effectiveness and impact of the new recommendations should guide decision-making and priority setting, communities will need to take a stronger stand to ensure that all decisions are based on the key principles of ethics, equity and human rights. For example, communities with allies such as human rights organisations or lawyers will need to monitor and respond to any moves to use the new recommendations as an excuse to coerce key populations in accepting early treatment, particularly in the context of concentrated epidemics. Evidence collected by communities that already monitor and report on human rights violations on a regular basis should be used to support advocacy efforts.

What is Positive Health Dignity and Prevention?[2]

Positive Health, Dignity and Prevention (PHDP) encompasses the full range of health and social justice issues for people living with HIV. It espouses the fundamental principles that responsibility for HIV prevention should be shared, and that policies and programmes for people living with HIV should be designed and implemented with the meaningful involvement of people living with HIV themselves.

Communities can use the PHDP framework to advocate for the key principles of creating a supportive and protective legal and policy environment; improving and maintaining the health and well-being of people living with HIV; promoting holistic health and wellness; addressing factors that undermine health and dignity; and responding to the needs of key populations. In contexts where advocating for human rights is risky and where key populations are criminalised, HIV and public health programmes can offer a platform to promote the universal right to health.

Operationalising PHDP does not involve creating new programmes, unless basic programmes do not currently exist. Rather, it focuses on creating linkages between existing programmes and improving their efficiency and responsiveness in meeting the needs of people living with HIV and their families in their communities. Individual programmatic elements will inevitably differ from setting to setting according to local contexts.

Programmatic components of PHDP fall under the following eight thematic areas:

1. Empowerment of people living with HIV and networks of people living with HIV
2. Health promotion and access
3. Gender equality
4. Human rights
5. Prevention of new infections
6. Sexual and reproductive health and rights
7. Social and economic support
8. Measuring impact.

Review!

Be vigilant! Make sure that human rights and the quality of treatment and care are not compromised in the rush to adapt guidelines or meet global goals.

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[2] UNAIDS, GNP+ (2013). *Positive Health, Dignity and Prevention: operational guidelines*. Available at: www.gnpplus.net/resources/positive-health-dignity-and-prevention-operational-guidelines/

Take stock! Take action!

☐ How close is your national programme to meeting the recommendations in the 2013 Guidelines? Where are the greatest gaps? What should be prioritised to improve access to the quality of care that people living with HIV receive and to save the most lives in your epidemic setting?

☐ Are the processes for discussing and making decisions related to the 2013 Guidelines transparent and open? Do all participants, including community representatives, have access to the evidence and information needed to inform their decision-making?

☐ Have representatives from all relevant stakeholders been involved? Do they include people living with HIV, women and youth groups, and representatives of key populations?

☐ Is the participation of people living with HIV and other key populations meaningful? What policy, legal or technical support can they be given so they can influence decision-making? Who can provide the support required?

☐ Are the decision-making criteria and rationale transparent? Are decisions made on the basis of scientific evidence, comparative cost-effectiveness of interventions, and principles of equity and human rights?

☐ Are the promotion, protection and fulfillment of human rights included in the national guidelines, and are the programmes rights based? Are Positive Health, Dignity and Prevention values being followed? Are there mechanisms at community and national levels to address, monitor and report violations of human rights?

☐ Has the decision-making taken into consideration:

- HIV incidence and prevalence in specific population groups and regions
- current coverage of programmes (e.g. testing, treatment, prevention of mother-to-child transmission) and their impact, such as viral suppression, drug resistance or mortality among people receiving treatment or new HIV infections in children
- poverty, gender inequality, stigma and other factors affecting HIV vulnerability, access to services and the quality of life of people living with HIV
- how punitive laws and practices related to HIV transmission, sex work, drug use and homosexuality may hinder access to services
- ways to promote greater access to treatment and other services for people with least access, including key populations.

☐ Is there a risk mitigation strategy in place to ensure continued and assured service delivery, especially for those most in need?

☐ Is there a monitoring and evaluation plan with clear responsibilities for different stakeholders? Does it include the roles of communities as watchdogs to ensure effective implementation and promote equitable access and human rights? Are there mechanisms for community representatives involved in policymaking to consult and feed back to their constituencies?

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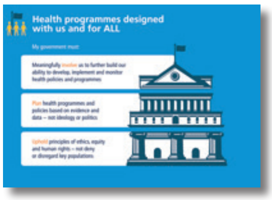
Resources

Following the same order as the Community Guide, this module highlights some useful resources, in particular from civil society and community organisations.

- Three simple graphics summing up the key new WHO recommendations are available on the Community Guide websites listed under *Links*. Use them in your advocacy or treatment literacy work.



- The WHO 2013 Guidelines and a range of other useful United Nations, Global Fund and PEPFAR resources are available at:

WHO	www.who.int/hiv/pub/guidelines/en/
PEPFAR	www.pepfar.gov/reports/guidance/index.htm
UNAIDS	www.unaids.org/en/resources/documents/2014/
UNICEF	www.unicef.org/aids/index_documents.html
UNDP	www.undp.org/content/undp/en/home/librarypage/hiv-aids.html
Global Fund	www.theglobalfund.org/en/documents/operational/

- For convincing evidence that communities achieve results, see: *Investing in communities achieves results: findings from an evaluation of community responses to HIV and AIDS*. World Bank. Available at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/213936/Investing-communities-achieve-results.pdf
- If you are looking for an extensive collection of tools and resources to build healthy and prosperous communities, see: www.ctb.ku.edu/en
- For a wide range of HIV and AIDS support and technical resources, see: www.aidstar-one.com/resources
- For community-specific HIV and AIDS tools, see: www.aidsalliance.org (for example, International HIV/AIDS Alliance (2006). *All together now! Community mobilisation for HIV/AIDS*, available at www.aidsalliance.org/includes/Publication/All_Together_Now_2009.pdf; and the Alliance Good Practice Guides, at www.aidsalliance.org/Publicationsdetails.aspx?Id=480).

Links

The full set of modules that make up *Driving the HIV response: a community guide to the WHO 2013 Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection* is available at:

- www.gnpplus.net/community-guide
- www.aidsalliance.org/communityguide
- www.stopaidsnow.org/community-guide

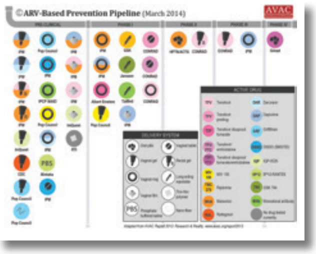
On these websites you can also see the results of the community consultations that informed the 2013 Guidelines and a briefing paper summarising some of the key issues arising from the 2013 Guidelines from a community and civil society perspective.

Module A: HIV diagnosis

1. WHO has issued a strategic HIV testing and counselling programme framework: http://apps.who.int/iris/bitstream/10665/75206/1/9789241593877_eng.pdf
2. For an HIV testing and counselling update, see the "must read" literature at: www.aidstar-one.com/focus_areas/hiv_testing_and_counseling/resources/htc_update
3. If you want to know what works for women in HIV testing and counselling, see: www.whatworksforwomen.org/chapters/11-HIV-Testing-and-Counseling-for-Women/sections/27-HIV-Testing-and-Counseling-for-Women/evidence
4. The Global Forum on MSM & HIV (MSMGF) regularly issues technical bulletins, including one on HIV testing and counselling: www.msmgf.org/files/msmgf/documents/TechBulletins/EN/Sec7MSMGF_TechBulletins2012.1.pdf
5. If you want to know what works in resource-limited settings when you plan to scale up HIV testing and counselling towards universal access, see: www.aidsmap.com/Scaling-up-HIV-testing-and-counselling-towards-universal-access-what-works-in-resource-limited-settings/page/1330557

Module B: Using antiretroviral drugs to prevent HIV

1. The AVAC website (www.avac.org) provides community-friendly information on HIV prevention research and new prevention options. Frequent updates on PrEP research and roll out are posted on www.avac.org/prevention-option/prep You can check the state of antiretroviral-based research at: www.avac.org/infographic/arv-based-prevention-pipeline AVAC's Resource Database (www.avac.org/resources-search) contains a wide range of materials covering the full spectrum of issues and interventions related to biomedical HIV prevention research and implementation.

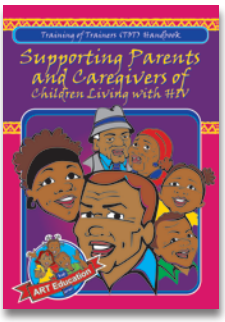


2. The PrEP Watch website (www.prepwatch.org) is a clearinghouse for information on PrEP for HIV prevention. It includes information on data, additional research, cost, access and advocacy efforts.
3. My PrEP experience (http://myprepexperience.blogspot.com) features real stories from people who have chosen to use PrEP as one way to protect themselves from HIV.
4. *PrEP: a new option for women for safer loving* (www.avac.org/sites/default/files/resource-files/PrEP-%20A%20new%20option%20for%20women%20for%20safer%20loving.pdf) is a brochure designed for women who want information on whether PrEP is the right prevention option for them (Project Inform, 2014).
5. For national guidelines on PrEP, see: www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf
6. If you plan to conduct a study on the acceptability of PrEP in your country, you may find the following useful: 'Attitudes and acceptance of oral and parenteral HIV preexposure prophylaxis among potential user groups: a multinational study', *PLoS ONE* 7(1): e28238. Available at: www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0028238&representation=PDF
7. For a good discussion on combination HIV prevention, see: www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2010/JC2007_Combination_Prevention_paper_en.pdf

Module C: Antiretroviral therapy for adults

1. WHO has produced a range of treatment-related documents, such as the *Global update on HIV treatment 2013* (www.who.int/hiv/pub/progressreports/update2013/en/), *The treatment 2.0 framework for action* (http://whqlibdoc.who.int/publications/2011/9789241501934_eng.pdf), and *Antiretroviral medicines in low- and middle-income countries: forecasts of global and regional demand for 2013–2016* (http://apps.who.int/iris/bitstream/10665/111626/1/9789241507004_eng.pdf?ua=1).

2. MSMGF published an interesting policy brief in 2013 on the access challenges of people living with HIV and key populations: www.msmgf.org/files/msmgf/Publications/Access_Challenges_for_HIV_treatment_KAPs.pdf
3. The International Conference on HIV Treatment and Prevention Adherence provides useful presentations and guidelines on adherence and retention in care, including the latest evidence and discussions: www.iapac.org/AdherenceConference/Adherence_2013.html
4. If you are interested in a new format of HIV treatment materials, see: www.aidsmap.com/page/1444485/
5. SAfAIDS has produced a children's treatment literacy toolkit that shares knowledge, facts and a series of creative and fun activities: www.safaids.net/content/kids-art-education-series-childrens-treatment-literacy-toolkit

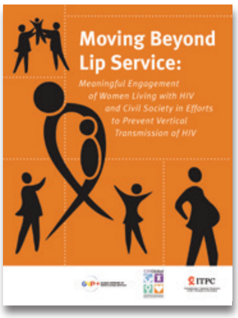


6. UNITAID issued a progress report in 2012 on the HIV, tuberculosis and malaria medicines landscape, looking at emerging issues and potential opportunities to improve access: www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/unitaid_hiv_tuberculosis_and_malaria_medicines_landscape_2012.pdf
7. PEPFAR has set up a community centre looking at supply chain management: http://scms.pfscm.org/scms/communitycenter/tools

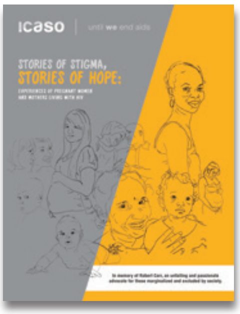
8. STRIVE partners investigate how social factors drive vulnerability to HIV and what programmes work to tackle them: http://strive.lshtm.ac.uk/
9. Treatment activists can learn more from TAC in South Africa: www.tac.org.za and from ITPC: www.itpcglobal.org
10. MaxART is an implementation study in Swaziland looking to bring HIV services closer to people: www.stopaidsnow.org/maxart-bringing-services-closer-people

Module D: Antiretroviral therapy for pregnant and breastfeeding women

1. Check out the Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping their Mothers Alive that was launched in 2011: www.zero-hiv.org
2. To help inform your discussions at country level, see feedback from community consultations (www.gnpplus.net/evidence/pvt-consultations/), as well as a case study from Uganda and Malawi on Option B+ (www.gnpplus.net/option-b-understanding-the-perspectivesexperiences-of-women-living-with-hiv-in-uganda-and-malawi/) and a toolkit that is looking at managing the transition to Option B/B+ (http://emtct-iatt-v2.org.php54-1.dfw1-2.websitetestlink.com/wp-content/uploads/2013/03/Toolkit-Section-7.pdf).



3. If you plan to assess sexual and reproductive health and rights (SRHR) in your country, the following tools may be useful: GNP+ SRHR country assessments (www.gnpplus.net/evidence/srhr-country-assessments/) and IPPF, UNFPA, WHO, UNAIDS, GNP+, ICW and Young Positives SRHR rapid assessment tool (www.mhtf.org/wp-content/uploads/sites/17/2013/12/rapid_assesment_2009.pdf)
4. The International HIV/AIDS Alliance brief looks at addressing low uptake of antiretroviral drugs for prevention of mother-to-child transmission of HIV in sub-Saharan Africa: www.aidsalliance.org/includes/Publication/WEBbrief_PMTCT.pdf
5. For other useful resources and personal stories, see ITPC and ICASO resources: www.itpcglobal.org/prevention_of_vertical_transmission and www.icaso.org/files/stories-of-stigma-stories-of-hope-experiences-of-pregnant-women-and-mothers-living-with-hiv



Module E: Antiretroviral therapy for children

1. The Interagency Task Team's Laboratory & Child Survival Working Group has published an important background paper on early infant diagnosis: www.zero-hiv.org/wp-content/uploads/2013/03/EID-TaskTeam-background-paper.pdf
2. New progress and guidance on HIV diagnosis and treatment for infants and children can be found at: www.who.int/hiv/pub/paediatric/Paediatricfactsheet/en/ See also the country experiences of Zambia (www.who.int/bulletin/volumes/90/5/11-100032/en/), Nigeria (www.who.int/reproductivehealth/publications/mhealth/infant_diagnosis_hiv_nigeria/en/) and Malawi (www.who.int/bulletin/volumes/90/9/11-100776-ab/en/).
3. The Coalition for Children Affected by AIDS has issued ethical decision-making guidance for care workers: www.ccaba.org/our-projects/policy/care-worker-guidance/
4. For more on ethical research involving children, see: http://childethics.com
5. STOP AIDS NOW! has mapped African networks for children affected by AIDS and/or orphans and vulnerable children: www.stopaidsnow.org/sites/stopaidsnow.org/files/mapping-africannetworks-for-caba.pdf

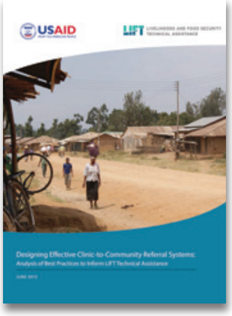
Module F: Developing programmes and delivering services

GNP+ has produced a range of useful guidance on positive health, dignity and prevention (PHDP):

- PHDP policy framework, at www.gnpplus.net/resources/positive-health-dignity-and-prevention-a-policy-framework/

- PHDP operational guidance, at www.gnpplus.net/assets/positive_health_dignity_and_prevention_operational_guidelines_-_unaids_gnp_2013.pdf
- PHDP operational research, at www.gnpplus.net/evidence/phdp-operational-research/
- Positive Development manual, focusing on the self empowerment of people living with HIV and strengthening their ability to build and maintain networks, at www.gnpplus.net/resources/positive-development-2/

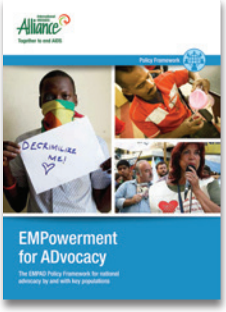
1. If you plan to set up a community advisory group, you may find the following guidelines useful: http://research.ukzn.ac.za/Files/National%20Guidelines%20for%20Community%20Advisory%20Groups%20for%20Research%20(2012).pdf
2. For more information about integrating HIV with other health services, see: www.msh.org/our-work/health-areas/hiv-aids/integration-of-hiv-and-other-health-services
3. For a systematic review of task-shifting for HIV treatment and care in Africa, see: www.who.int/workforcealliance/knowledge/resources/taskshifting_hivtreatment/en/ For country experiences, see: www.msfaccess.org/content/swaziland-community-takes-part-treatment and www.msfaccess.org/content/malawi-reducing-pressure-health-services-task-shifting
4. Médecins Sans Frontières' Access Campaign, Speed Up Scale-Up, is providing useful strategies, tools and policies to get the best HIV treatment to more people sooner: www.msfaccess.org/content/speed-scale-strategies-tools-and-policies-get-best-hiv-treatment-more-people-sooner



5. If you want to design effective clinic-to-community referral systems and are looking for best practices, see: http://theliftproject.org/wp-content/uploads/2013/12/Referral-Literature-Review-and-Technical-Brief-FINAL.pdf
6. If you are not familiar with individual identifiers and want to learn more, see: www.unaids.org/en/media/unaids/contentassets/documents/dataanalysis/20110520_Unique_Identifiers_Meeting_Report_Montreux.pdf
7. To find out more about standards for HIV and AIDS case management look here: www.health.ny.gov/diseases/aids/providers/standards/casemanagement/docs/casemanagementstandards.pdf
8. The HIV NGO Code of Good Practice provides useful checklists for standardised approaches to HIV: www.hivcode.org

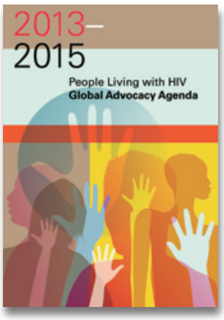
Module G: Making decisions and designing policies

1. Key population networks have advocacy pages full of useful resources and tools on their websites. Check out, for example, the MSMGF advocacy centre (www.msmgf.org/index.cfm/id/65/themeID/71/ma/1) and NSWP's advocacy page (www.nswp.org/category/tags/advocacy).
2. The International HIV/AIDS Alliance has a range of advocacy resources:
   - *Advocacy in action: a toolkit to support NGOs and CBOs responding to HIV/AIDS* (2003). Available at: www.aidsalliance.org/includes/Publication/adv0602_Advocacy_toolkit_eng.pdf
   - *EMPowerment for Advocacy: the EMPAD Policy Framework for national advocacy by and with key populations* (2014). Available at: www.aidsalliance.org/includes/Publication/EMPAD.pdf
   - *Making it work: lessons learnt from three regional workshops to integrate human rights into national HIV strategic plans* (2012). Available at: http://issuu.com/aids_alliance/docs/makingitwork



Check out GNP+'s tools on criminalisation, GIPA, human rights, stigma and related issues:

- Criminalisation Scan, at www.gnpplus.net/evidence/criminalisation-scan/
- GIPA Report Card, at www.gnpplus.net/evidence/gipa-report-card/
- Human Rights Count!, at www.gnpplus.net/evidence/human-rights-count/
- People Living with HIV Stigma Index, at www.gnpplus.net/evidence/plhiv-stigma-index/



3. For more about the People Living with HIV Global Advocacy Agenda look here: www.hivadvocacynow.org
4. The Global Fund has issued practical tips to ensure its new funding model delivers the impact communities need: www.theglobalfund.org/en/publications/2014-04-24_Engage_Civil_Society/
5. UNAIDS has published case studies on country progress towards efficient and sustainable HIV responses: www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/JC2450_case-studies-country-progress_en.pdf
6. If you would like to design an HIV discrimination monitoring, reporting and referral system, check out international best practices, and current policy, practice and opportunities in Ukraine: www.healthpolicyproject.com/pubs/80_UkraineDiscriminationSystem.pdf

7. The Treatment Action Campaign (TAC) has a great newsletter entitled *Equal Treatment*. For more and to subscribe, go to: www.tac.org.za/equal-treatment/subscribe
8. ARASA has published a range of helpful advocacy training manuals. Check them out at: www.arasa.info/info/training-manuals/

This is one is 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!

About us

The **Global Network of People Living with HIV (GNP+)** is a network for and by people living with HIV. GNP+ advocates to improve the quality of life of people living with HIV and is driven by the needs of people living with HIV worldwide.

The **International HIV/AIDS Alliance** is an innovative alliance of nationally based, independent, civil society organisations united by a vision of a world without AIDS. It is committed to joint action, working with communities through local, national and global action on HIV, health and human rights.

STOP AIDS NOW! aims to expand and enhance the quality of the Dutch contribution to the AIDS response in countries hardest hit by the epidemic. In STOP AIDS NOW! five organisations, Aids Fonds, Cordaid, Hivos, ICCO and Oxfam-Novib, have joined forces.

International HIV/AIDS Alliance
Together to end AIDS

GNP+ GLOBAL NETWORK OF PEOPLE LIVING WITH HIV

STOP AIDS NOW!

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