# SPEED UP SCALE-UP

Strategies, tools and policies to get the best HIV treatment to more people, sooner


UNAIDS

MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

# Contents




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# Where are we now?

**For over a decade, people living with HIV, treatment advocates, clinicians, and health ministries have been grappling with how to ensure increased access to quality antiretroviral therapy in resource-limited settings.**

**Although there have been enormous strides over the past decade, constrained budgets and sub-optimal policies that are only slowly changing are impeding the effort to reach all people in need. In addition, too many people are still dying because they do not know they are living with HIV. And many people are being diagnosed with HIV late or fall out of care before starting treatment.**

This report outlines some of the strategies, tools and policies that have supported the scaling up of treatment during the past decade as well as those that can address persistent or new challenges. The results are presented from a 23-country survey of how consistently these strategies are being implemented. (See **Annex 1**) The findings demonstrate encouraging progress by some health ministries in adopting many of the enabling policies needed to facilitate scale-up and improve care. Nevertheless, the adoption and implementation of these strategies, tools and policies are lagging in some countries.

The survey results provide a mixed picture: 11 of 23 countries have reached antiretroviral therapy coverage of 60% or more. Some countries have already made or are making strides towards their own national targets of reaching 80% of people in need with antiretroviral therapy. On the other side of the spectrum, six countries are still only reaching one third of the people in need or less. As the international norms for HIV move towards better and earlier treatment and technological advancements in diagnostics are becoming available, it is important to shore up and strengthen the remaining key success factors that risk being compromised: political and financial support dedicated to addressing and reversing the epidemic.

The last 12 years of antiretroviral therapy in resource-limited settings have shown that, when treatment is offered close to home and before people get sick, their chances of survival increase.[1,2] In many countries, health facilities are often overburdened and difficult to reach. In response, several treatment strategies were developed to provide care within communities, and these have shown promising results. Such efforts to simplify and decentralize treatment need to accelerate to reach even more people with durable, high-quality care.

To continue to make meaningful progress, affected and donor countries will have to fulfil commitments made at the 2011 United Nations High Level Meeting on HIV/AIDS, when governments pledged to reach 15 million people with treatment by 2015.[3] This target may well need to be revised upwards if earlier initiation of antiretroviral therapy for clinical benefit or for reduction of transmission becomes a global goal. Nevertheless, current antiretroviral therapy coverage is only halfway there: meeting the goal means getting an additional seven million people onto life-saving treatment in the next three years and helping them remain in care. Rapidly increasing the number of people living with HIV receiving antiretroviral therapy and supporting retention in care are major challenges, but the potential to start reversing the epidemic by scaling up treatment provides new motivation and represents an opportunity that must be seized.


Teboho Haborone started antiretroviral treatment when his CD4 count was 25. He now works at the clinic in Motsekuoa, Lesotho, as an HIV/TB lay counsellor helping nurses with clinic tasks.

# 2 Methods and results

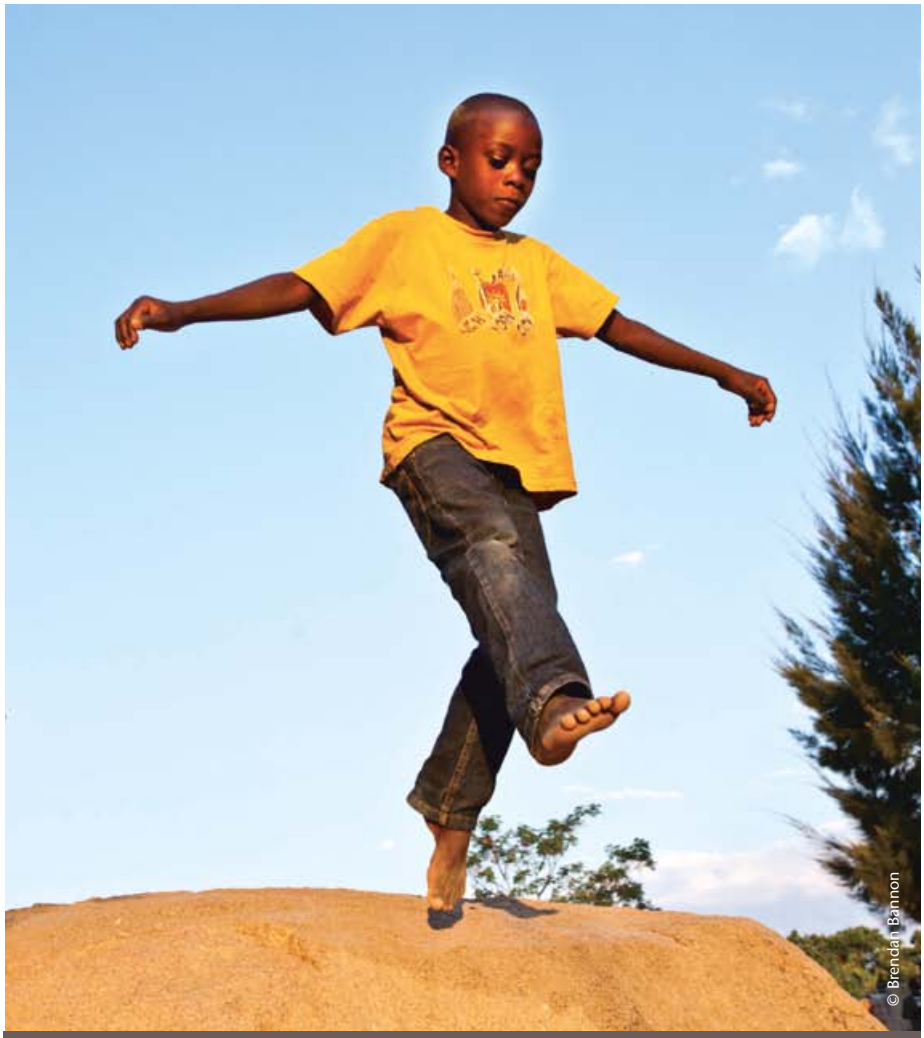
**This survey examined 25 HIV indicators in 23 countries, 18 of which are in sub-Saharan Africa.**

## STUDY DESCRIPTION AND METHODS

The data for this study were collected from March to June 2012 with the objective of assessing the status of key policies and operational practices relevant to HIV and tuberculosis (TB) treatment programmes in 23 countries.

Médecins San Frontières (MSF) is an emergency medical humanitarian organization that works in more than 60 countries worldwide and that currently provides HIV treatment to 220,000 people in more than 20 countries. Of the countries included in this survey, MSF has HIV projects in 16. MSF field teams collected data for the countries where MSF has HIV projects. Data for the remaining seven countries were collected from similar national and international sources with the support of UNAIDS.

In 2011, MSF published "Getting Ahead Of The Wave: Lessons for the Next Decade of the AIDS Response"[4], providing facts and figures on the implementation and progress of HIV treatment policies in 16 countries. The present report is an attempt to enlarge the scope of the above-mentioned publication. The 25 indicators included in the study were assembled with input from MSF and UNAIDS. Data were collected mostly from national government sources, primarily the health ministry and HIV programme coordinating bodies. Documents included national HIV and TB guidelines as well as national programme updates from departments responsible for the programmes related to HIV, TB, preventing mother-to-child transmission or human resources for health. Alternatively, where reliable data were not obtained from national documents, MSF teams conducted interviews with national authorities and/or used verifiable information sourced locally.




Brian, seven years old, is enrolled in the HIV/AIDS programme in Epworth, an urban settlement outside Harare, Zimbabwe.

For countries where MSF does not have HIV operations, UNAIDS was asked to assist in the process of information collection and validation. The main international source was the Global HIV/AIDS response: epidemic update and health sector progress towards universal access, Progress report 2011.[5] Citations for the sources of survey results as well as a more detailed methodology can be found at www.msfaccess.org.

The information presented is thus largely reported by governments and published in reliable national and international sources. In some cases there is a delay between the establishment of normative best practices and adopting and adapting them into revised national guidelines. Similarly, even when national guidelines reflect new normative standards, implementation may lag.

As an emergency medical humanitarian organization, it is not within MSF's purview to validate officially reported figures or data.

UNAIDS, the Joint United Nations Programme on HIV/AIDS, has endorsed robust goals for continuing the rapid expansion of antiretroviral therapy to achieve universal access by 2015 and, as well, to eliminating new HIV infections among children and keep their mothers alive. Achieving these goals depends on several factors, including mobilizing sufficient resources from domestic and international sources, adopting national policy frameworks that are consistent with international best practices and normative guidelines and innovating service delivery to facilitate greatly expanded HIV care and treatment in low- and middle-income countries.

UNAIDS, as well as other partners, is continuing to support the mobilization of resources and the innovations that are embedded in Treatment 2.0, the WHO/UNAIDS programmatic approach, structured on five pillars: optimizing drug regimens; developing point-of-care and simplified laboratory platforms; innovating service delivery; reducing costs; and mobilizing communities. These activities are occurring in many venues, including research and development, international forums and support for and the dissemination of innovative best practices.

UNAIDS therefore supported MSF in surveying 23 countries facing high-burden HIV epidemics, focusing on the status of implementation of national policies that facilitate the implementation of Treatment 2.0 and eliminating new HIV infections among children. The outcomes of the current publication provide a clear picture of the national policy framework and implementation status of the domains important to monitor and advocate for policy and programme change and growth. We hope that it serves as a powerful tool for policy-makers and programme managers to inspire them in scaling up antiretroviral therapy (ART).

## KEY RESULTS

- Of the 23 countries surveyed, nine have antiretroviral therapy coverage below 50%. The coverage rates of services for preventing mother-to-child transmission of HIV are greater than 80% in six of the countries surveyed, but eight are still below 50% coverage. Only eight of the 20 countries for which data was available provide antiretroviral therapy in 30% or more of public-sector facilities.
- Almost all countries are in accordance with WHO-recommended protocols for antiretroviral therapy initiation and first-line drug regimens, although implementation in some countries has faltered due to funding gaps.
- Of the 18 countries surveyed in sub-Saharan Africa, 11 allow nurses to initiate antiretroviral therapy. Six of these countries changed their policies to allow nurses to initiate antiretroviral therapy in the past two years. Only 13 of the 23 countries have policies allowing nurses to prescribe and provide TB treatment.
- In many countries, policies are still not in place to support the provision of basic HIV-related tasks by lay workers: only 14 of 23 countries allow lay workers to provide HIV counselling and testing and adherence counselling.
- Only eight countries' guidelines allow for multiple (two or three) month refills, rather than monthly, for people in stable condition.
- Of the 23 countries surveyed, four require viral load before switching to second-line or further regimens, but the technology is only widely available in four countries.

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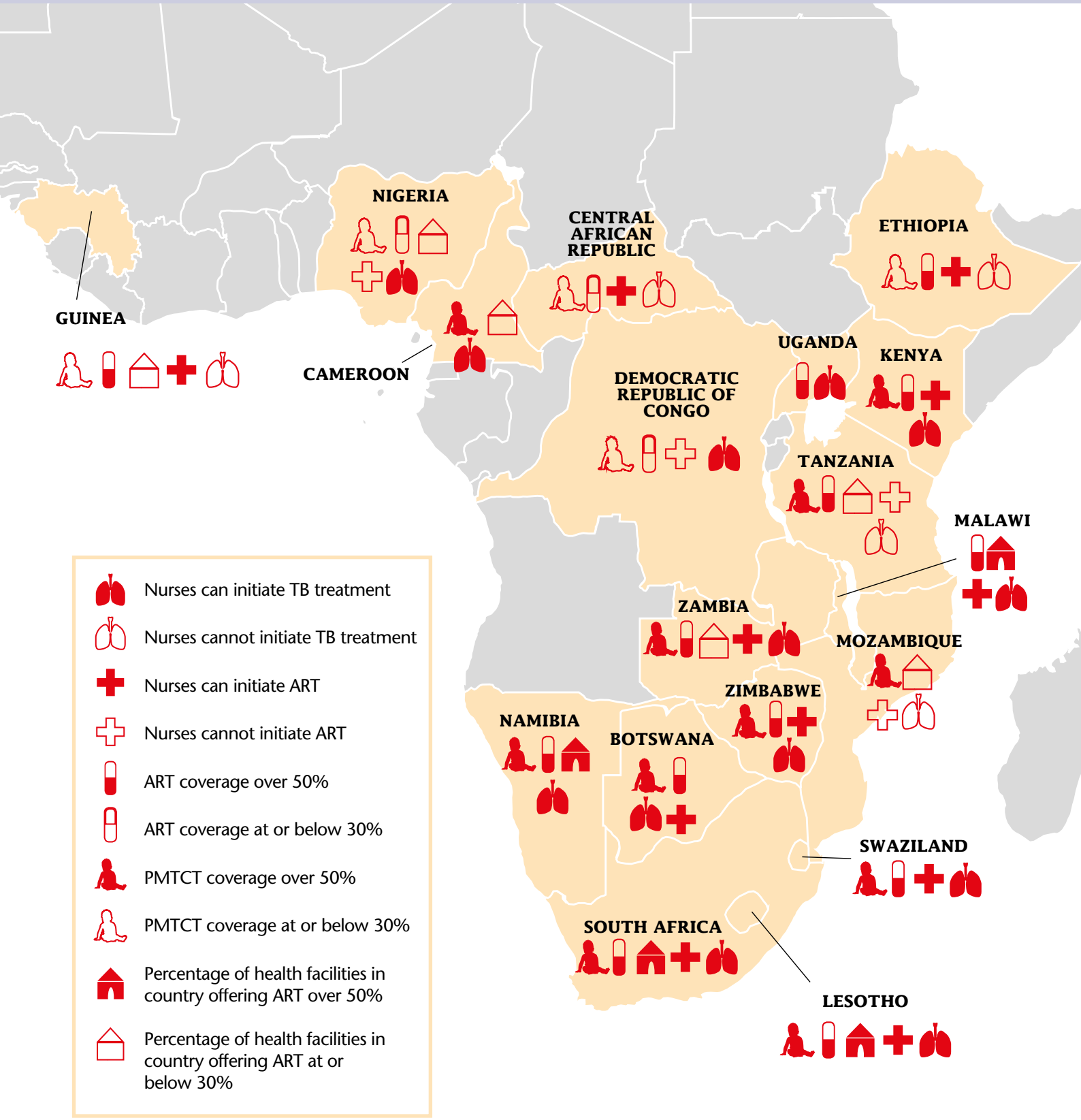
# Policies and Progress in 18 Sub-Saharan African Countries



# 3 Timing is everything

**Recent scientific findings confirm that in addition to prolonging the lives of individuals, HIV treatment is itself a key component of HIV prevention. The landmark HPTN 052 study showed that providing HIV treatment earlier helps to stave off opportunistic infections and reduces the risk of sexual transmission to HIV-negative partners by 96%.[2]**

**Time is a critical factor: getting treatment to people before their disease progresses is important both for their own health and for preventing further infections.**

HIV treatment policy is quickly responding to this new evidence. In April 2012, the World Health Organization (WHO) issued two critical new pieces of guidance on HIV treatment. Firstly, its April 2012 programmatic update *Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants*[6] points to the benefits and momentum behind offering lifelong antiretroviral therapy to all pregnant women living with HIV for preventing mother-to-child transmission and for their own health. This protocol, known as option B+, is easier to manage in many settings than the current practice for preventing mother-to-child transmission of starting and stopping antiretroviral therapy with each pregnancy. It is also better for mothers and babies, especially in places where women have multiple pregnancies but may not be accessing services for preventing mother-to-child transmission of HIV early enough.

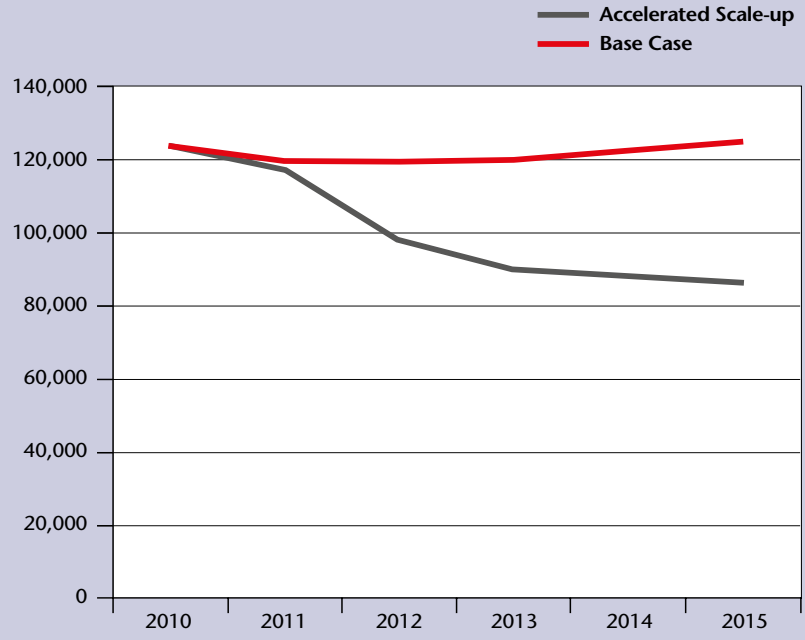
Second, WHO's *Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples*[7] recommends treatment for everyone living with HIV who has an HIV-negative partner (serodiscordant couples), regardless of their CD4 count, to help prevent the sexual transmission of HIV.

These two interventions targeting specific populations, when considered in addition to efforts based on growing evidence of clinical benefit to reach others earlier in their disease progression, collectively constitute a care package referred to as accelerated antiretroviral therapy (**see box**).

## ACCELERATED ANTIRETROVIRAL THERAPY INCLUDES:

- initiating antiretroviral therapy at an early stage of disease (at CD4 count of 350 per $mm^3$ or higher);
- immediate initiation of antiretroviral therapy for people living with HIV who have active TB;
- early initiation of treatment for people living with HIV who have HIV-negative partners (treatment as prevention) which reduces the risk of transmission by 96% for serodiscordant couples; and
- lifelong treatment for pregnant women and breastfeeding mothers living with HIV, regardless of CD4 count.

## ACCELERATED TREATMENT CAN RESULT IN A DECLINE IN NEW HIV INFECTIONS




Under the scenario of today's scale-up pace and treatment access rates, incident HIV infections in Kenya are expected to remain relatively constant at or above 120,000 new cases per year. With accelerated treatment scale-up, new HIV infections could be driven down to around 86,500 by 2015. *Source: John Blandford, PhD, CDC*

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## SCALING UP ANTIRETROVIRAL THERAPY NOW WOULD HAVE SIGNIFICANT BENEFITS BOTH FOR INDIVIDUALS AND COMMUNITIES:

- Scaling up treatment to meet the "15 by 15" commitment would, according to United Nations estimates, prevent seven million people from dying and 12 million people from acquiring HIV by 2020.[8]
- Every 1,000 people given treatment per year averts 228 people dying, 61 people becoming newly infected with HIV through sexual transmission and 26 infants from acquiring infection.[9]
- Accelerated treatment is expected to have a community-level impact and provoke an even steeper drop in the incidence of new HIV infections. The United States Centers for Disease Control and Prevention used data from Kenya to model treatment acceleration and demonstrated that extending HIV treatment to an additional 323,000 Kenyans by 2015, above the current pace, would reduce the number of people newly infected with HIV by 31% by 2015 (**see graph**).[9]
- In northern KwaZulu-Natal, South African researchers found that every percentage point increase in antiretroviral therapy coverage among adults living with HIV was associated with a 1.7% decline in the risk of an HIV-negative adult acquiring HIV. People living in areas with higher antiretroviral therapy coverage (30 – 40%) were 38% less likely to acquire HIV than people in low-coverage areas (coverage less than 10%).[10]

## PROGRESS IN SCALING UP AND IMPLEMENTING WHO-RECOMMENDED IMPROVED TREATMENT PROTOCOLS FOR EARLIER INITIATION VARIED ACROSS THE 23 COUNTRIES SURVEYED:

- Of the 23 countries surveyed, nine have antiretroviral therapy coverage below 50%. Botswana and Swaziland provide antiretroviral therapy to 80% or more of those who need treatment.
- All but one country surveyed have adopted WHO recommendations to start treatment at CD4 count of 350 per $mm^3$ or lower and for all people coinfected with HIV and TB, irrespective of CD4. Zambia has moved to provide early antiretroviral therapy in cases of serodiscordant partners regardless of CD4 count; additional countries are considering such a policy change.
- The coverage rates of services for preventing mother-to-child transmission of HIV are greater than 80% in six of the countries surveyed, but eight are still below 50% coverage.
- All countries surveyed have adopted protocols for services for preventing mother-to-child transmission of HIV as recommended by WHO:[1] 12 countries implement option A; six countries implement option B; two countries allow either protocol; some of these countries are considering a change to from option A to B or B+; only two countries have option B+ as policy – as recommended by WHO in its April 2012 update,[6] plus Kenya, where it is offered as an option among all three protocols for facilities to decide.
- Although limited data were available, the median CD4 count when antiretroviral therapy was initiated was less than 170 per $mm^3$ in the six countries with available data.
- Reaching children with treatment continues to lag across many of the countries surveyed. Children represent an average of 7% of the people receiving treatment in the 23 countries.


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Charles Sako, 41, started ARV treatment in 2005 and now lives with his partner and three-year old daughter in Kibera, Nairobi.

# 4 Strategies: reaching more people with treatment

## 1) MAKING TESTING AND TREATMENT ACCESSIBLE

A major challenge in increasing access to care is that most people with HIV do not know their HIV status.[11] Of the 23 countries in the study, 21 offer provider-initiated testing and counselling, which is mostly still conducted at the health facility level. Implementation, however, lags behind. A recent study from Malawi of clinic-based HIV counselling and testing[12] showed that only 13% of clinic attendances included HIV counselling and testing. A growing number of countries[16] now allow lay health workers to administer HIV testing, although not all of these 16 have implemented this policy to the point of being standard practice.

Ensuring that treatment is available free of charge is also essential. And although user fees and other charges passed down to service users are a documented barrier to access,[13] there is a risk that treatment free of user charges might be reversed if funding levels are not increased. According to the survey results, all 23 countries have policies providing antiretroviral drugs for free, but this policy is not being consistently followed everywhere. For example, in the Democratic Republic of the Congo, Central African Republic and Zimbabwe, people are being charged according to MSF teams on the ground. In two countries (Cameroon and Myanmar), the policy of providing drugs free of user charges does not include the diagnostic and monitoring tests required with care, and in three countries (China, Kenya, and Myanmar), the policy does not include drugs needed to treat opportunistic infections. In Mozambique, a nominal fee is charged to all outpatients for prescriptions and consultations. In Zimbabwe, the government is proposing charging people for antiretroviral therapy to make up for funding shortfalls, since international donors have reduced support.

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*"I train nurses who work in local health clinics and are able to start patients on antiretroviral treatment and also TB treatment. In many clinics where the nurses work, there is no doctor available so task-shifting allows patients to be seen every day."*

**Nolitha Mabandlela,** Nurse mentor, Khayelitsha, South Africa

## 2) SCALING-UP FACILITY-BASED TREATMENT

### GETTING TREATMENT INTO EVERY CLINIC

Decentralization – getting care out of centralized hospitals and into community clinics and local health posts – has been the cornerstone of expanding access to antiretroviral therapy. Nevertheless, only eight of the 20 countries for which data were available provide antiretroviral therapy in 30% or more public-sector facilities. Five of the 16 countries with an adult prevalence of HIV infection above 2% have decentralized treatment and care to the extent that at least 40% of public-sector health facilities offer antiretroviral therapy. Making treatment available in more health facilities has allowed more people to be reached in countries like Lesotho, Malawi and South Africa, where facility coverage is more than 60% and antiretroviral therapy coverage is more than 50%.

### SHIFTING HEALTH CARE TASKS

One of the key obstacles to decentralized treatment has been reluctance on the part of some policy-makers to shift health care tasks from doctors to nurses and nurses to lay health workers. Nevertheless, this has changed in some countries.

In Malawi, an estimated one million people are living with HIV, but there are just 1.2 doctors and 28 nurses for every 100,000 people. To cope with this critical shortage, the government started shifting tasks such as initiating treatment from physicians to non-physicians, including nurses. The results are positive. In Chiradzulu district, three-year treatment outcomes for people whose treatment was initiated by nurses were comparable to those initiated by clinical officers and medical assistants; in fact, people started on treatment by non-physicians were more likely to remain in care.[14] A randomized trial in South Africa[15] found task-shifting of HIV treatment from doctors to nurses to be safe and effective.

Of the 18 countries surveyed in sub-Saharan Africa, 11 allow nurses to initiate antiretroviral therapy. During the past two years, six of these countries have changed their policies to allow nurse-led initiation: Kenya, South Africa, Swaziland, Uganda, Zambia and Zimbabwe. Three of the seven African countries that do not allow nurses to initiate antiretroviral therapy do allow them to provide follow-up

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for people on antiretroviral therapy. Of the countries surveyed, Mozambique is the one with the highest HIV prevalence that has yet to allow nurses to initiate and manage antiretroviral therapy, even though it suffers from a severe human resources crisis and nurses comprise 70% of the health workforce. Medical technicians (tecnicos de medicina) are the only non-physicians permitted to perform these tasks but are not often found at the primary care level.

Similarly to policies that allow the task-shifting of treatment initiation, policies that allow lay workers to dispense antiretroviral drugs support scale-out by easing the strain on the health system. A study in western Kenya showed that lay workers living with HIV successfully provided adherence screening and antiretroviral drug refills to people in the community, and the government is considering replicating this strategy throughout the country.[16] A randomized trial, also done in Kenya, showed that outcomes were equivalent under lay worker surveillance and clinic-based care but required half the number of clinic visits, easing the burden on both the people living with HIV and the system. In many countries, however, policies still do not support lay workers providing basic HIV-related tasks: only 14 of the 23 countries allow lay workers to provide HIV testing and antiretroviral therapy adherence counselling. Seven of the 23 do not allow lay workers to provide HIV testing.

## INTEGRATING ANTIRETROVIRAL THERAPY WITH OTHER HEALTH SERVICES

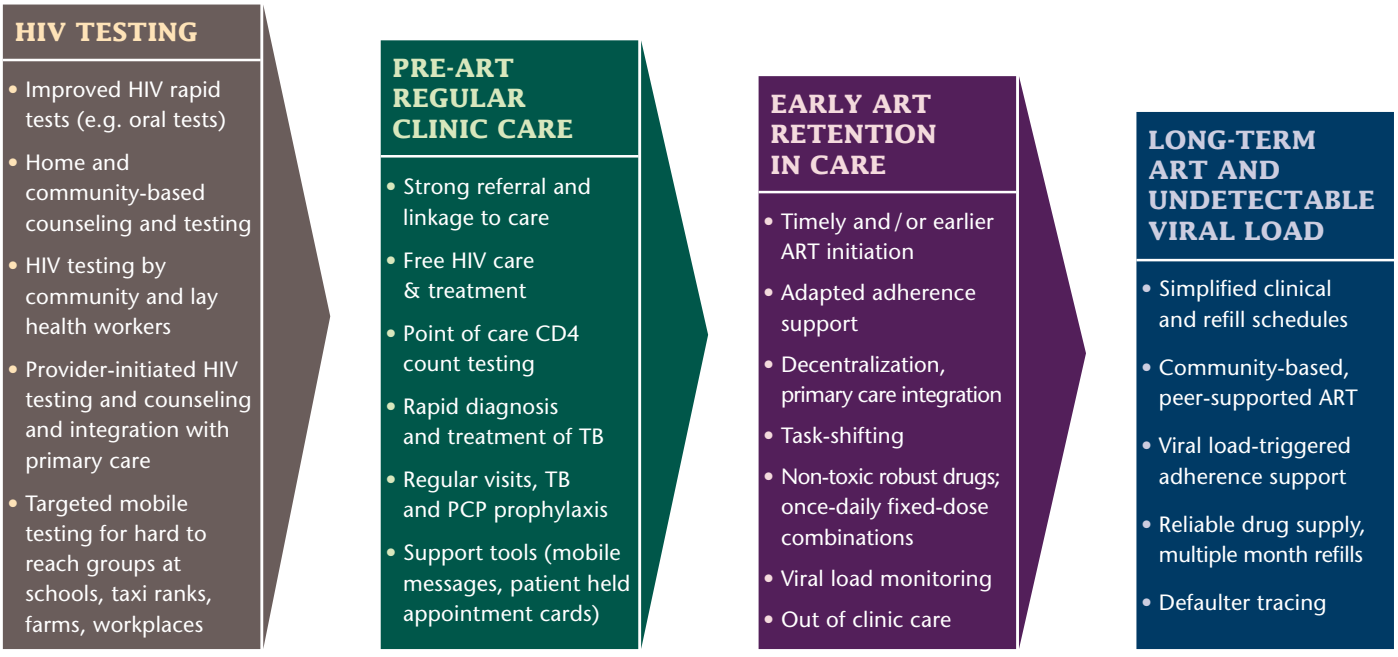
Optimizing antiretroviral therapy delivery also requires providing treatment within settings where people can have their broader health care needs addressed at the same time, in one location, and from the same health worker. This means addressing health needs beyond HIV.

**Integration with TB care.** In Lesotho and South Africa, integrating HIV and TB at the primary health care level has shown improved case-finding and better outcomes[17] as well as reducing half the delay in starting antiretroviral therapy for people newly diagnosed with TB.[18] Despite growing recognition that HIV and TB integration is the preferred approach to tackling the twin epidemics in settings with a high burden of HIV infection and TB disease, and despite resulting policy changes, integration is lagging in practice across many of the countries surveyed, and full one-stop care remains rare.

In several of the countries surveyed, the policies that establish where antiretroviral therapy and TB treatment can be provided and by whom make decentralization and integration difficult. Of the 16 countries in which MSF provides HIV treatment, only six were free from policy barriers that prevent the same primary health care worker from providing HIV and TB treatment. In Cameroon, for example, nurses can initiate TB treatment but not antiretroviral therapy. In Lesotho, although more than 90% of public-sector facilities are reported to be providing antiretroviral therapy and nurses can provide both antiretroviral therapy and TB treatment, the initiation of TB treatment is not decentralized to the primary care health centres. In Uganda, the reverse situation – nurses are not allowed to provide antiretroviral therapy and TB treatment is more decentralized than antiretroviral therapy – gives the same result: integrating decentralized HIV and TB care is more difficult. Of the 23 countries, only 13 have policies allowing nurses to prescribe and provide TB treatment.

**Integration with prenatal and infant care.** New WHO guidance on option B+ for services for preventing mother-to-child transmission of HIV – in which all pregnant women living with HIV are to be offered continuous antiretroviral therapy, instead of starting and stopping antiretroviral therapy with each pregnancy – can greatly simplify the provision of prenatal and infant care. This applies especially to regions with high fertility, since it should reduce attrition between pregnancies. An MSF study from Thyolo, Malawi showed that, during the expansion and integration of HIV services with prenatal and infant care, the use of reproductive health services increased, and the outcomes of infants born to mothers living with HIV improved. Of the countries surveyed, only Malawi and Uganda have option B+ as policy, and Uganda only plans to implement the policy if it is successful in securing additional funds from international sources. Other countries such as Mozambique are also considering switching to this protocol.

## STRATEGIES TO ADDRESS THE HIV CARE CASCADE



# 3) MANAGING TREATMENT AT THE COMMUNITY LEVEL

With the continuing shift away from specialised clinic HIV care, antiretroviral therapy programmes are increasingly looking towards newer models for chronic disease management, whereby the community manages people living with HIV with a stable condition and interventions to support treatment adherence. This further decentralization and task-shifting involves strategies such as peer antiretroviral therapy groups, which can boost adherence and relieve the burden on people living with HIV and health systems. Other policies can help reduce the number of required clinic visits, simplify clinical appointments and/or reduce burdens by providing people with several months of medicines in one refill visit.[19, 20]

In the Democratic Republic of the Congo, community organizations of people living with HIV run antiretroviral drug distribution points throughout Kinshasa, providing refills, adherence counselling and basic health follow-up. People spent an average of 12 minutes to pick up their refills at these points, compared with 85 minutes at the hospital.[21]

MSF has piloted community-based programmes in several high-prevalence settings. For example, in Tete, Mozambique, community antiretroviral therapy groups of six people on antiretroviral therapy take turns going to the clinic every month to pick up medicine refills for the whole group. This peer management also helps people to motivate one another to adhere to treatment and helps prevent loss to follow-up.[22] This was rolled out in 20 health facilities in Tete Province, and only 0.1% of the 4,410 people enrolled in 1,023 groups between February 2008 and December 2011 have been lost to follow-up.

In response to this success, the Government of Mozambique is scaling up the strategy nationwide, and health ministry delegations from Malawi, Swaziland and Zimbabwe have visited the project to assess whether the model could be replicated in their contexts. Malawi's health ministry has started a pilot project. A similar strategy in Khayelitsha, South Africa offers streamlined health visits for people in stable condition in adherence groups, who receive check-ups as a group and get refills within two hours. A lay adherence counsellor leads the group, providing support to long-term service users who sometimes experience adherence fatigue. Retention in care was significantly higher for group members compared with people not in groups (97% versus 85%).[23] Among the 23 countries surveyed, only Mozambique has an explicit policy allowing antiretroviral drugs to be dispensed outside facilities and mobile clinics.

Routine multiple-month refills and simplified clinical appointments have been implemented in many programmes and settings. Such practices are showing good outcomes for people in their first year of antiretroviral therapy in Zimbabwe.[24] In Chiradzulu, Malawi, 97% of those in a programme offering clinician appointments every six months for people in stable condition, and antiretroviral drug refills every three months from health surveillance assistants, remained in care after one year.[25] Of the 23 countries surveyed, eight explicitly allow in the treatment guidelines for multiple (two or three) month refills for people in stable condition, a policy that is also accepted standard practice, although not reflected in the guidelines, in three additional countries. Drug supply problems, however, can be a barrier to implementing such strategies.

## HIV TREATMENT IN CONFLICT SETTINGS AND AMONG MOBILE POPULATIONS

Access to treatment has increased in stable environments but is less available in conflict or post-conflict settings.[26] Given competing medical priorities, severe human resource and funding constraints and a lack of priority given to HIV-related health needs in countries in conflict, the international community has been reluctant to engage. One major concern is that treatment will be interrupted in an unstable environment, leading to possible drug resistance. In these contexts, simplified recommendations and implementation procedures that anticipate the possibility of sudden population movements are essential, as is the integration of HIV with other health services. MSF's experience in treating HIV in post-conflict settings, such as in Bukavu, Democratic Republic of the Congo, has shown results comparable to those in stable settings, with programmes rarely disrupted by conflict.[26]

Providing antiretroviral therapy for mobile populations requires adapted operational strategies to deliver treatment. Migrants (especially those who are undocumented) can be reluctant to seek care for fear of deportation, and likewise, clinics can be reluctant to deliver care for migrants out of fear that they will not adhere to treatment or be able to access refills. Through a weekly mobile HIV and TB clinic service, MSF provides HIV care to Zimbabwean migrant farm workers in South Africa in Musina. They receive a three-month supply of antiretroviral drugs if they plan to return home for a period, as well as a health "passport" that serves as a record of their care if they need to transfer to another antiretroviral therapy provider. Models that account for population mobility could benefit other HIV treatment programmes.[27]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*"I've found so many advantages to belonging to the community group. Firstly we all support one another like a family and if someone in the group is sick we help them – maybe we fetch water or we clean or cook for them. Then another good thing is that we only need to send one person in the group each month to the clinic to collect the medicine refills for everyone else in the group. Now we only have to go individually to the clinic once every six months. That means for me that I can stay home, getting essential things done around the house and my shop."*

**Carmen Jose-Panti,** 32 years old, HIV positive, Tete, Mozambique

# 5 Tools: improving quality of care

**Getting the best possible treatment to the most people possible – and retaining them in care – requires securing access to the best medicines and tools needed to monitor HIV treatment and properly and timely diagnose TB. These must be affordable. But limited budgets should not stand in the way of ensuring the best possible treatment and monitoring options are available.**

## BETTER DRUGS

In 2006, WHO recommended a shift away from stavudine; WHO's 2010 guidelines recommended that it be phased out entirely and be replaced in first-line treatment by either zidovudine or tenofovir. The current best option for first-line therapy is the combination of tenofovir + lamivudine + efavirenz, which is available as an adherence-friendly one-pill-once-a-day formulation.

Of the countries surveyed, all had adopted alternatives to stavudine into policy, be it tenofovir (eleven countries) or zidovudine (seven countries) or either of the two options (five countries). However, in several countries, funding constraints have resulted in decisions to delay the implementation of improved treatment whether for people initiating therapy, or people already receiving antiretroviral therapy, or to roll it out on a partial basis only.

As more people are placed on treatment, providing robust and potent antiretroviral drugs with as few side effects as possible will help long-term adherence, which delays the need to switch to more costly second-line regimens. New treatments will need to be easy to take and should be offered in fixed-dose, once-daily combinations. They also must not be counterindicated with other medicines routinely taken for coinfections and should be safe for use in pregnancy.

> *"To make sure my treatment is effective, the clinic takes a blood sample to check my CD4 count and viral load. My latest viral load count, taken in June 2011, was undetectable. Antiretroviral treatment is life-long so it's encouraging to be told that the treatment is working well for me.*
>
> *It helps to know that whatever the difficulties, I am controlling the virus. I am proud that my viral load is undetectable, and I tell others about it. It helps me plan for tomorrow and I am confident I will live a normal life in the future."*
>
> **Fanelwa Gwashu**, 40, HIV positive, Khayelitsha, South Africa

Given the development of new drug classes and new generations of well-tolerated and easy-to-use drugs, first-line regimens are expected to improve further. Second-line regimens should also be revised to include more powerful protease inhibitors and integrase inhibitors.

## VIRAL LOAD MONITORING

Treatment failure, where HIV develops drug resistance, goes mostly underdetected and underdiagnosed in low- and middle-income countries; according to WHO,[28] only 3% of the people receiving antiretroviral therapy are receiving second-line treatment, although the need is greater given the rate of failure:[29] one study of almost 20,000 people in South Africa found that 10% needed second-line treatment after five years on antiretroviral therapy[30]. This compromises people's care and reduces the impact of antiretroviral therapy at the community level because of increased illness and transmission.

Viral load monitoring can improve treatment by indicating when a person may need to switch regimens. Viral load monitoring also helps preventively, as it can identify people who need targeted adherence support to stave off the emergence of drug resistance and treatment failure, so that they can continue on the same regimen. In Khayelitsha, South Africa, where routine viral load testing identified detectable viral load in clinic attendees, all were given targeted adherence support. Of that group, 71% had an undetectable viral load at the next check three months later.[31]

Nevertheless, most programmes in Africa do not have access to viral load testing – primarily because of its high cost and because the complexity of the technologies make them ill-suited for resource-limited settings. At best, viral load monitoring is reserved for confirming treatment failure once people already show clinical or immunological signs of failure – not to guide targeted adherence counselling that can prevent the emergence of resistance in the first place. Of the 23 countries surveyed, nearly all recommend using viral load testing to confirm treatment failure. Six of the countries' guidelines require viral load testing before switching regimens, and routine monitoring of viral load is recommended in some countries and required in four of them. Nevertheless, of the countries surveyed, the tools necessary for viral load are only widely available in four countries.

There is an urgent need for simple and affordable viral load technologies that are adapted to resource-limited settings and that could be used in district laboratories, clinics and at the community level.[32,33] A number of point-of-care tests are expected to become available starting in 2013,[34] and several laboratory-based tests in the pipeline could also be simple enough for use at the district level.[35] Although cost currently limits the use of viral load testing, donors and national governments should support its implementation, since this will draw multiple producers to the market, fostering price-reducing competition. Similarly, additional simplified tools could help in overcoming existing human resource constraints towards greater implementation of viral load monitoring.

## TB DIAGNOSTICS

TB continues to be the main killer of people living with HIV,[36] with at least 350,000 people dying from HIV-associated TB each year. A key factor behind this persistently high death rate is the difficulty of accurately diagnosing TB among people living with HIV. The most commonly used test, sputum smear microscopy, detects only half of all TB cases among people living with HIV.[37]

There is still an urgent need for affordable and easy-to-use tests that can detect TB without referral for more specialized testing. Many people living with HIV are harder to diagnose with the usual sputum test. Developing a new test or technology to diagnose TB that does not rely on sputum but on other samples such as urine or blood offers the best solution.

*"When my TB treatment was completed, I felt as if I had got a new life. I could now live for my children and do some work. Now I stitch blouses, dresses, alteration work. People of my neighbourhood support me a lot. They give me work and I am able to earn good money from my work."*

**Veena Panchal,** HIV positive and previously co-infected with MDR TB, Mumbai

### NEW TB MOLECULAR TESTING

A new rapid molecular test, Xpert MTB/RIF, represents an important advance. Not only does it speed up diagnosis (giving results in two hours versus up to two months with other methods) and therefore significantly shortens the time from TB test to initiating TB treatment, improving chances of survival for people living with HIV who have TB, it also screens for drug-resistant TB and improves TB detection among people who have falsely tested negative through sputum smear (prominent among people living with HIV who have TB).

A study by MSF in Zimbabwe[38] showed that, of 1,672 sputum samples, 184 were positive for TB using sputum smear microscopy, but of the remaining negative 1,488 samples, Xpert MTB/RIF detected TB in a further 116, which had been missed by microscopy. After implementing Xpert MTB/RIF, the median time from diagnosis of smear-negative TB among people living with HIV who have TB to the initiation of treatment was reduced from 18.5 days to seven days[38].

Although Xpert offers new potential in TB diagnosis, it has a number of drawbacks including its relatively high price (120 countries will be soon eligible for a new price of US$ 9.98 per cartridge) and its reliance on a stable electricity supply and controlled temperature.

# 6 Policies: enabling affordable and rapid scale-up

**Bringing to scale the strategies outlined in this report could help dramatically accelerate the scaling up of antiretroviral therapy. Countries hard hit by the epidemic have a responsibility to implement health policies that serve the needs of people living with HIV, even in an environment of tight budgets. But these efforts must be backed up by sustained international donor commitment and policies that promote access to affordable antiretroviral drugs.**

## DONORS MUST RE-ENGAGE

Funding for global HIV treatment has been lagging during the past several years. Although there has been some renewed political commitment to support the scaling up of HIV treatment and care, such as the AIDS-free generation policy of the United States Government, many international donors continue to leave their financial commitments unfulfilled. An estimated US$ 22 – 24 billion will be needed each year to reach the goal of reaching 15 million people with antiretroviral therapy by 2015, but donors are falling short of this, by half.[3]

One consequence of reduced global donor funding was the unprecedented cancellation of a funding round in late 2011 by the Global Fund to Fight AIDS, Tuberculosis and Malaria.[39] Some donor countries' bilateral programmes have also reduced funding. Both of these leave countries more vulnerable and less equipped to scale up antiretroviral therapy.

Although low- and middle-income countries cannot pay for the response on their own,[40] national governments do need to increase domestic HIV and health funding. Some countries are considering innovative strategies to identify new revenue streams. But these have limitations: an assessment in Malawi concluded that a combination of new strategies such as an airline and telecommunication levy would cover only 17% of the HIV funding gap.[41] Further, extra revenue should not come at the expense of people: although Zimbabwe is raising an AIDS levy, it is still considering a change to its policy of providing HIV treatment free of charge and may introduce user fees.

Nevertheless, innovative funding mechanisms, if applied in multiple countries, could add up to a substantial amount to supplement national and donor governments' contributions. UNITAID, an international organization that generates funds for HIV, TB and malaria through an airline tax, is an important example of how a small tax can have an ongoing and important impact on health. Mechanisms able to generate long-term, predictable revenue, such as through a financial transaction tax, could raise substantial revenue and should be implemented. Although the feasibility of a financial transaction tax is now largely accepted in many government circles, especially in Europe, whether or to what extent the revenue raised from such a tax will be dedicated to global health remains an unanswered question.

## ANTIRETROVIRALS MUST BE AFFORDABLE

Sustained access to the best treatment options at affordable prices is essential so that money goes as far as possible. The most powerful tool to bring medicine prices down is market competition among multiple producers.[42] However, patent barriers and restrictive licensing agreements often prevent many low- and middle-income countries from accessing the most affordable prices for medicines (**see box, page 14**).

Competition among multiple generic pharmaceutical manufacturers in countries in which medicines were not patented, especially India, is what has reduced the cost of HIV treatment by 99% since 2000. The lack of pharmaceutical patents in India until 2005 additionally allowed for the production of fixed-dose combinations, which both support adherence and are crucial to the simplification of treatment that has been central to the global scaling up of treatment. India has thus been called the pharmacy of the developing world: more than 80% of donor-funded purchases of antiretroviral drugs for use in low- and middle-income countries from 2003 to 2008 were manufactured in India, and more than 80% of the antiretroviral drugs MSF uses are sourced from India.[43]

When India did introduce pharmaceutical patents, it designed a patent law that is strict about what merits a patent, reserving these only for medicines that show therapeutic benefit over products that already exist. India has also put in place a system that allows patents to be opposed before and after they are granted. This measure has led to several antiretroviral drug patents being rejected in India, keeping the door open for price-reducing generic competition. Other countries should consider designing patent laws that have similar clauses.

But increased drug patenting in key production countries, especially India, is starting to block price-reducing generic competition for newer antiretroviral drugs. If increased patenting and other intellectual property measures mean that generic competition cannot catalyse reductions in the prices of medicines, tomorrow's battle for access to affordable antiretroviral drugs will require more systematic use of compulsory licences and other policies to bring prices down or through voluntary licensing arrangements that respond to public health needs.

When drugs are patented, generic competition can only happen through compulsory licences or voluntary licences. Compulsory licences can open up the market to competition by overriding patents to lower prices and increase access. Several countries have issued compulsory licences for antiretroviral drugs, which have led to significant cost savings and have set an important precedent for access to medicines that have been priced out of reach. Low- and middle-income countries should ensure that they have the ability to issue such licences in their legislation.

In issuing a voluntary licence, a patent holder authorizes a generic manufacturer to produce and export a generic version of a medicine, often in exchange for royalty payments. Several antiretroviral drugs are now being produced under different forms of licensing agreements between originator and generic producers. However, the terms of these licences are critical: they often exclude many low- and middle-income countries with sizeable burdens of HIV; they often contain clauses that limit competition by restricting where licensees can produce and the sources of the active pharmaceutical ingredient; and they often are a de facto way of preventing compulsory licences by preventing licensees from supplying a country if it issues a compulsory licence. Further, the terms and conditions of voluntary licences are not publicly available, meaning that their potential contribution or threat to public health benefit cannot be scrutinized. Mechanisms that encourage transparent licensing, such as the Medicines Patent Pool, should be supported. The Medicines Patent Pool manages intellectual property collectively in the interest of public health rather than through secret bilateral agreements between companies.

Other policies also threaten affordable medicines. Bilateral free-trade agreements and poorly drafted anti-counterfeiting legislation often seek levels of intellectual property protection that exceed requirements in international trade rules.[43] Examples include the European Union–India free-trade agreement currently being negotiated, the Anti-Counterfeiting Trade Agreement and

*"Affordable ARVs made in India have played a vital role in scaling up ART to eight million people in developing countries over the last decade. But this 'safe haven' for the production of low-cost, quality generic medicines is under threat: local generic production of a number of newer antiretroviral medicines is being blocked because of patents and new threats are emerging.*

*If we want to scale up treatment to those in need, we must keep these sources of affordable medicines open."*

**Leena Menghaney,** MSF Access Campaign, Delhi


Demonstrators against the India-EU FTA on the streets of New Delhi.

*Continued overleaf*

the Trans-Pacific Partnership Agreement that the United States is negotiating with Pacific Rim countries. The leaked Trans-Pacific Partnership Agreement text has shown that the United States is seeking to impose intellectual property provisions at levels yet unseen that would restrict access to life-saving medicines.

Ensuring that more affordable generic versions of newer-generation antiretroviral drugs can be produced and accessed is therefore critical. Low- and middle-income countries should enact and use all the public health flexibilities allowed in international trade rules. Ensuring that excessive intellectual property provisions are kept out of both free-trade agreements and anti-counterfeiting agreements will also be essential to sustaining long-term access.[44] Low- and middle-income countries should refrain from pushing measures that impose even greater intellectual property protection than international trade rules require.

## ANTIRETROVIRAL DRUG PRICES AND THE 23 COUNTRIES

Annex 2 illustrates how quality-assured generic manufacturers charge significantly less for the key fixed-dose combination (tenofovir + lamivudine + efavirenz) recommended for first-line treatment in comparison with the price charged by the originator.

Matrix/Mylan sells tenofovir + lamivudine + efavirenz for US$ 172 per person per year. In contrast, Merck charges certain low- and middle-income countries US$ 613 per person per year for the therapeutically equivalent regimen tenofovir + lamivudine + efavirenz and US$ 1033 per person per year in other low- and middle-income countries. Two additional generic sources of quality-assured tenofovir + lamivudine + efavirenz are expected to reach the market within the next 12 months, which should lower the generic price even further.

Annex 2 also shows that certain per person per year countries are excluded from originators' discount pricing schemes and/or are unable to access medicines manufactured under voluntary licence because of territorial restrictions. India, for example, is not eligible for Merck's discounted price, although it may purchase from both current generic suppliers. In contrast, Brazil and China are excluded from both the discount prices offered by Merck and from purchase from Mylan because of voluntary licence restrictions.

## SPOTLIGHT: LOW HIV TREATMENT COVERAGE

### DEMOCRATIC REPUBLIC OF THE CONGO

The vast majority of people living with HIV in the Democratic Republic of the Congo do not have access to antiretroviral therapy. This is because of a lack of political commitment on the part of the government, compounded by the withdrawal of international donors. An estimated one million people are living with HIV and 435,000 need antiretroviral therapy, with only 12% of those in need receiving treatment. In 2011 funding shortfalls led to a cap on the number of new treatment slots. Nationally, only 6% of mothers living with HIV have access to antiretroviral therapy to prevent transmission of HIV to their child; the country's Global Fund Round 11 proposal aimed to increase the coverage of services for preventing mother-to-child transmission of HIV, but the funding round was subsequently cancelled. In 2013, the Global Fund will be, again, the main ARV purchaser in the country. The PMTCT program supported by PEPFAR purchases ARV treatment for mothers that are eligible for lifelong treatment, up to 18 months only. By 2015 the ART coverage is forecast to be 22%, a best-case scenario.

### MYANMAR

Myanmar is the least developed country in South-East Asia. Although there are expectations of an increase to the health budget, it will be years before the country has a fully comprehensive health care system. A total of 40,000 people receive antiretroviral therapy, less than a quarter of the estimated 125,000 who urgently need it.[45] Between 15,000 and 20,000 people living with HIV die every year in Myanmar because of the lack of access to life-saving antiretroviral therapy. Despite 9,300 new cases of drug-resistant TB every year, by the end of 2011, only 300 people had been started on treatment.[46] Life-saving treatment for both HIV and drug-resistant TB urgently needs to be scaled up. Political reform in the country has led to greater international engagement, providing an opportunity to give priority to access to treatment for people living with HIV and TB.

# 7 Conclusion

**Recent research results along with novel treatment models provide a genuine possibility to both reduce the number of people acquiring HIV infection and ensure long-term survival for people already living with HIV. National governments, donors, and other key actors must seize this opportunity to turn around the epidemic.**

Research results presented in this report show that critical progress has been made in ensuring policies are put in place that allow more people to be reached with treatment. Antiretroviral therapy is getting decentralized further and further into communities, people are being reached with treatment earlier in their disease progression, and more individuals are being provided with better-tolerated drugs that allow them to stay on their regimens longer.

At the same time, much more needs to be done to reach even more people with treatment and care: several countries are still resisting policies to allow the task-shifting necessary to decentralize treatment further into the community, offer integrated HIV at the lowest-level facilities and offer simplified treatment outside of facilities. It is crucial to move treatment to the community level to reduce the burden of multiple clinic visits on people with HIV and decrease the workload at over-stretched health facilities. This approach also allows people with HIV greater autonomy and responsibility for managing their own care.

The experience of the past decade has shown that treatment costs can and will decrease when tools are simplified, treatment is decentralized and measures are supported to reduce medicine prices.

Nevertheless, the right policies must be in place. Policies should be promoted that support the production of affordable medicines and the development of medical tools that enable massive scale-up and sustainable long-term treatment provision. Further, international donors must re-engage and recommit to HIV globally. If they continue to withdraw support, the progress achieved over the last decade of investing in global HIV treatment risks being unravelled.

***Governments and donors:***
***"Pay now, or pay forever."***[47]

*"When I first found out I was HIV positive, I didn't believe for a minute that I would be here today. Everyone in my family was upset and crying. But now I am on treatment and working again. In the future I would like to have a sewing machine to make clothes for my husband, my kids and my neighbours."*

**Ivone Culimbica,**
HIV positive, Mozambique

# Annex 1. Survey results: strategies, tools and policies

MSF field teams provided data for the first 16 countries shown here where MSF has HIV projects. Data for the remaining seven countries were collected from national and international sources with the support of UNAIDS.

| | Cameroon | CAR† | DRC‡ | Ethiopia |
|---|---|---|---|---|
| Population (millions) | 20.1 | 5.10 | 73.6 | 93.8 |
| Prevalence of HIV infection among adults (%) | 4.3 | 4.9* | 2.6 | 1.5 |
| **ANTIRETROVIRAL THERAPY COVERAGE AND AVAILABILITY** | | | | |
| % of pregnant women living with HIV receiving services for preventing mother-to-child transmission | 53*[a] | 24*[a] | 5.6[b] | 24[b] |
| % of people in need who receive antiretroviral therapy | 46.4 | 26.1 | 12.3 | 86[h] |
| Number (%) of public-sector facilities offering antiretroviral therapy | 108 (4.4%) | 76 | 222[l] | 743 |
| Children (<15 years) as a % of people receiving antiretroviral therapy | 4.2 | 5.4* | 11.6 | 6 |
| **BEST PRACTICES AND WHO PROTOCOLS AS NATIONAL POLICIES** | | | | |
| Provider-initiated testing and counselling is national policy | Yes | Yes | Yes | Yes |
| Antiretroviral therapy offerred free of charge in outpatient public facilities | Yes, but not labs | Yes, but not in practice | Yes, but not in practice | Yes |
| WHO-recommended protocol for services for preventing mother-to-child transmission is national policy | A | A | A | A |
| WHO-recommended protocol for initiating ART is national policy | Yes | Yes | Yes | No[w] |
| TDF or AZT is part of the preferred adult first-line regimen | AZT or TDF | AZT | AZT | AZT or TDF |
| % of people on ART on a d4t-containing regimen | 0◊ | N/A | N/A | 59* |
| % of pregnant women receiving single-dose NVP | 13.4 | N/A | 43.4 | N/A |
| Protocol includes third-line antiretroviral therapy or salvage treatment | Yes | No | No | No |
| TB prophylaxis (isoniazid preventive therapy) for all people living with HIV is national policy | Yes (LTD) | No | No | Yes |
| **VIRAL LOAD (VL) TESTING IN NATIONAL PROTOCOLS** | | | | |
| VL testing to confirm treatment failure | Optional | Optional | Optional | No |
| Routine VL testing of people on antiretroviral therapy | Optional | No | No | No |
| VL testing is available for this purpose | LTD | LTD | LTD | LTD |
| **TASK-SHIFTING ALLOWED AS NATIONAL POLICY** | | | | |
| Nurses can initiate antiretroviral therapy | Follow-up only | Yes | No | Yes |
| Nurses can initiate TB treatment (drug-sensitive) | Yes | No[kk] | Yes[ll] | No |
| Same health worker can provide TB and HIV treatment at PHC level | No[mm] | N/A | No[ll] | No[mm] |
| Lay workers can provide HIV testing and antiretroviral therapy adherence counselling | Adherence | Adherence | Yes | No |
| **SIMPLIFIED ANTIRETROVIRAL DRUG DISPENSING ALLOWED AS NATIONAL POLICY** | | | | |
| 2- to 3-month routine antiretroviral drug refills for people in stable condition | No | No | No | 2 |
| Antiretroviral drug refill dispensing at the community level | No | No | No | No |
| **FUNDING FOR HIV & HEALTH** | | | | |
| % of government expenditure on health as % of general government expenditure | 8.5* | 8.5* | 9.1* | 13.5* |

# supporting the scaling up of treatment in 23 countries

| | Guinea | India | Kenya | Lesotho | Malawi | Mozambique | Myanmar | South Africa | Swaziland | Uganda |
|---|---|---|---|---|---|---|---|---|---|---|
| | 10.9 | 1,210.2 | 43 | 1.9 | 16.3 | 23.5 | 54.6 | 48.8 | 1.4 | 35.9 |
| | 1.5 | 0.3** | 6.2 | 23** | 10.6* | 11.5** | 0.5 | 16.6 | 26◊ | 6.7 |
| | | | | | | | | | | |
| | 40.5[c] | 27.8[d] | 69.2[b] | 78[c] | 48[b,e] | 52*[c] | 54.3*[c] | 87.1[c] | 87.5[c] | 46.1[b] |
| | 59.9 | N/A[l] | 72.1◊ | 61 | 57.7 | 45.5 | 33.4 | 52 | 80 | 54.3 |
| | 41 (9%) | 1,297 (3%) | 1,242 (34.8%) | 197 (94%)* | 487 (80.4%)[m] | 261 (22%) | 100 (3.4%)* | 2,552 (68%) | 110 (42%) | 1,424[n] |
| | 4.8 | 5.8◊ | 9◊ | 7.3 | 8.9 | 8.4 | 7.5 | 8.5 | 9.1 | 7.9 |
| | | | | | | | | | | |
| | Yes | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes |
| | Yes | Yes | Yes, but not some opportunistic infections[p] | Yes | Yes | Yes, with restrictions[q] | Antiretroviral drugs, not opportunistic infections/labs[r] | Yes | Yes | Yes |
| | B | B | A, B, or B+ | A | B+ | A | A or B | A | A | B+[u] |
| | Yes | Yes | Yes | Yes | Yes | Yes | Yes[x] | Yes | Yes | Yes |
| | AZT | AZT | TDF | TDF | TDF[y] | AZT | AZT or TDF | TDF | TDF | TDF |
| | N/A | t | 24.9◊ | N/A | 81 | 7* | N/A[z] | 40* | 0◊ | 2 |
| | N/A | 27.8 | 4.2 | 0* | 14[bb] | 28 | 0 | 0* | 0* | 7.3 |
| | Yes | No | Yes | Yes | No | No | Yes | Yes | No | No |
| | No | No | Yes (LTD) | Yes | Yes (LTD) | Yes (LTD) | Yes (LTD)[ee] | Yes (LTD) | Yes | Yes (LTD) |
| | | | | | | | | | | |
| | Optional | Required | Optional | Optional | Required | Optional | Optional | Required | Optional | Optional |
| | No | No | No | No | No[cc] | Required[dd] | No | Required | No | Optional |
| | LTD | LTD | Yes | LTD | LTD | No | LTD | Yes | LTD | LTD |
| | | | | | | | | | | |
| | Yes[ff] | No | Yes | Yes | Yes | No[gg] | No | Yes | Yes | Follow-up only[hh] |
| | No | No | Yes | Yes | Yes | No | No | Yes | Yes | Yes |
| | No[nn] | No[nn] | No[oo] | Yes[pp] | Yes | No[qq] | No[rr] | Yes | Yes | No[ss] |
| | HIV | Yes | Yes | Yes | Yes | HIV | No | Yes | Yes | Yes |
| | | | | | | | | | | |
| | No | 2 | 2-3 | No | 2-3 | No | No | 3 | 3 | No (Yes in practice) |
| | No | No | No | No | No | Yes[tt] | No | No[uu] | No | No |
| | | | | | | | | | | |
| | 1.8* | 3.6* | 7.3* | 13.4* | 14.2* | 12.2* | 1* | 11.9* | 10.1* | 12.1* |

| | Zambia | Zimbabwe | Botswana | Brazil | China | Namibia | Nigeria | Tanzania | Ukraine |
|---|---|---|---|---|---|---|---|---|---|
| | 14.3 | 12.6 | 2.9 | 205.7 | 1,343.2 | 2.2 | 170.1 | 43.6 | 44.9 |
| | 14.6** | 13.1 | 25 | 0.6 | 05-0.07 | 13.5 | 3.4* | 5.6** | 1 |
| | | | | | | | | | |
| | 84.5[b] | 84*[b] | 93.98[c] | 50.23[c] | N/A[f] | 89.5[c] | 15.9[c] | 71.53[b] | 68[g] |
| | 77.6 | 79.7 | 96.1[h] | 71.9 | 46.8%[j] | 74 | 29.8 | 76.2 | 13.4*[k] |
| | 1784 (25.4%)* | 590 (36%)[o] | (32.2%) | 737 (0.3%) | 3.142 (0.3%) | 181 (52.8%) | (2.9%)* | (17.4%)* | 127 (16.7%) |
| | 7.3 | 8.4 | 6.2* | 2.7 | 1.84 | 10.2 | 5.7* | 7.7* | 8.5 |
| | | | | | | | | | |
| | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| | Yes | Yes, not in practice consistently | Yes, with restrictions[s] | Yes | Yes, but not opportunistic infections | Yes | Yes, with restrictions[t] | Yes | Yes |
| | A | A | B | B | B | A | A or B[v] | A | B |
| | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| | TDF | TDF | TDF | AZT | TDF | TDF | AZT or TDF | AZT | TDF |
| | N/A | 75.8◊ | N/A | N/A | 36.3 | N/A | N/A | 63*[aa] | 4.6 |
| | 11.4 | 8.6 | 0* | N/A | N/A | 3.7 | 24.8* | 18.2 | 4.3 |
| | Yes | No | Yes | Yes | No | Yes | Yes | No | Yes |
| | Yes (LTD) | Yes (LTD) | Yes (LTD) | Yes | No | Yes | Yes (LTD) | Yes (LTD) | Yes |
| | | | | | | | | | |
| | Optional | Optional | Required | Required | Optional | Optional | Optional | Optional | Required |
| | Optional | No | Required | Required | Optional | Optional | Optional | Optional | Optional |
| | LTD | LTD | Yes | Yes | LTD | LTD | LTD | LTD | LTD |
| | | | | | | | | | |
| | Yes | Yes[ii] | Yes[jj] | No | No | Follow-up only | No | No | No |
| | Yes | Yes[ll] | Yes | No | No | Yes | Yes | No | No |
| | Yes | Yes | No | No | N/A | N/A | No | No | No |
| | Yes | Yes | Yes | Adherence | Yes | Yes | Adherence | Yes | Adherence |
| | | | | | | | | | |
| | 3 | No (Yes in practice) | No | No (Yes in practice) | No (Yes in practice) | No | No | 2 or more | No (Yes in practice) |
| | Yes[vv] | No | No | No | No | No | No | No | No |
| | | | | | | | | | |
| | 15.6* | N/A[ww] | 17* | 7.1* | 12.1* | 12.1* | 4.4* | 13.8* | 9.4* |

*Legend and Footnotes continued overleaf*

# Annex 1: Legend and Footnotes

## LEGEND

**HIV programme and policy data are from 2011 except where indicated:**

**2009 data; *2010 data, ◊2012 data. †Central African Republic. ‡Democratic Republic of Congo Adult population means 15–49 years old. TDF: tenofovir. AZT: zidovudine. NVP: nevirapine. NA: not available. LTD: limited availability or implementation. Adherence: Antiretroviral treatment adherence counseling.

PMTCT and ART coverage: As reported by governments or sources such as WHO, these figures are based on the numbers of pregnant women living with HIV receiving intervention for PMTCT out of national estimates of need.

PMTCT protocols include: option A (zidovudine from week 14, single-dose nevirapine at birth, zidovudine + lamivudine during labour and delivery and zidovudine + lamivudine one week postpartum); option B (triple-course antiretroviral therapy from week 14 of pregnancy through to one week after breastfeeding); and option B+ (lifelong antiretroviral therapy for all pregnant women living with HIV).

WHO recommended ART initiation protocol includes CD4<350 per $mm^3$, HIV/TB coinfection and/or Stage 3 or 4.

## FOOTNOTES

**a.** Based on women receiving ARV drugs, excluding single-dose NVP.

**b.** Includes pregnant HIV-positive women who received a partial PMTCT protocol (e.g. single-dose NVP).

**c.** Does not delineate specific protocols for preventing mother-to-child transmission delivered.

**d.** Based on percentage of estimated 43,000 HIV poslitive pregnant women in 2010–2011, of whom 11,962 mother-baby pairs received intervention for preventing mother-to-child transmission.

**e.** Data from last quarter of 2011 only, following change in PMTCT eligibility protocol in mid-2011.

**f.** National estimate for the number of HIV positive pregnant women not available. Government-reported PMTCT coverage figure (74.1%) is based instead on the number of pregnant women who tested positive for HIV at ANC clinics received intervention for preventing mother-to-child transmission.

**g.** Ministry of Health reports 95.5% coverage, based on the number of pregnant women who tested positive rather than on national estimates of HIV positive pregnant women.

**h.** Based on CD4<200.

**i.** National estimate for the number of HIV+ people in need of ART is not available. The government-reported ART coverage figure (33.8%) is based on the number of people registered to be in need, a subset of the overall population in need.

**j.** Based on 2010 WHO estimates of national ART need. The government-reported coverage figure (76.1%) is based on the actual reported number of people in need of ART (such as those registered in the HIV program) at the end of 2011.

**k.** MOH reports 53% coverage, which is based on the total number of people needing ART and registered and enrolled in the MOH health care system.

**l.** Government target is for 4,017 public and private ART facilities. In 2011, 444 public and private sites were operational, so current coverage based on the government target is 11%.

**m.** Includes some Christian Health Association of Malawi facilities, partly supported by the MOH to provide ART.

**n.** Includes non-MOH facilities.

**o.** Number of facilities offering ART follow-up. Initiation is provided at 141 facilities.

**p.** Free ART policy includes diagnostics and treatment only for certain OI's.

**q.** Patients pay a nominal fee for prescriptions (not including TB treatment and ART) and consultations.

**r.** Patients pay under a cost-sharing model for labs and OI treatment. TB diagnosis and treatment is free.

**s.** For citizens only.

**t.** Includes CD4 monitoring but not other lab tests and also not consistently offered free in practice.

**u.** Option B+ adopted as national policy, but roll-out deferred until early 2013 due to funding shortfalls.

**v.** MOH recommends Option B for "facilities with capacity to provide and monitor triple ARV medication" and Option A for "facilities with limited capacity (on–site or by referral) to provide and monitor triple ARV medication."

**w.** Pregnant women or people at clinical Stage 3 can start ART with a CD4<350. Otherwise, ART initiation threshold for adults is CD4<200.

**x.** Latest guidelines include CD4<350 but haven't been implemented in parts of the country.

**y.** Full implementation delayed due to funding shortfalls. The first phase of implementation prioritizes HIV positive pregnant women, people with TB/HIV co-infections, and patients with severe d4T side effects (e.g., advanced lipodystrophy). Other adults start on a d4t-containing regimen.

**z.** The majority of people on ART in Myanmar are on d4t as the new guidelines stipulating TDF-containing regimens for preferred first-line treatment for adults are not in full effect yet.

**aa.** Estimates of people on ART are on a d4t-containing regimen in 2011 are between 10-20%.

**bb.** For the last quarter of 2011.

**cc.** VL monitoring for patients on ART is included in Malawi's ART guidelines, but rollout deferred due to funding shortfalls.

**dd.** National protocol requires VL testing at six months on ART, but this testing is not generally available.

**ee.** Policy is in place, but implementation is still at pilot stage.

**ff.** Only under doctor's supervision.

**gg.** Only medical technicians (Tecnicos de medicina) can initiate and manage ART. A 2011 pilot program to train agents of medicine (agentes de medicina), general nurses (Nurses Geral Medio) and general and PMTCT middle nurses (Nurses Medio) to initiate and manage ART is undergoing an evaluation by the MOH. Basic nurses, who represent more than half the health workforce are not being considered to initiate ART or provide follow-up.

**hh.** Nurses can start ART for HIV+ positive pregnant women and provide ART follow-up.

**ii.** Registered General Nurses who received training and mentorship can initiate ART with verbal authorization from district health officials, although formal policies not yet adopted. Primary Care Nurses cannot initiate but can provide follow-up.

**jj.** Nurses can start ART for asymptomatic adults with CD4>150 and not yet exposed to ARVs.

**kk.** No official policy adopted, but in practice nurses can prescribe TB treatment.

**ll.** Nurses can start TB treatment only for smear-positive patients.

**mm.** Nurses cannot initiate ART, but they can start patients on TB treatment.

**nn.** HIV and TB treatment provided in separate facilities or at different levels of care.

**oo.** TB treatment initiated at lower-level health centers (II and III) than ART (mainly level IV and above), although the latter is changing. Thus, TB and ART may soon be initiated by the same PHC health worker.

**pp.** Policy supports task-shifting of ART and TB treatment to nurses, but ART is being more rapidly decentralized to PHC. Most health centers still lack drugs and/or capacity to initiate TB treatment.

**qq.** Nurses cannot initiate ART and TB treatment but are the only medical staff present in many PHC clinics. Cadres allowed to initiate both treatments are not widely available at PHC level.

**rr.** ART not available at MOH-supported PHC facilities but new HIV/TB policies in development are expected to support integrated HIV/TB care.

**ss.** TB treatment is decentralized further than ART. Nurses can initiate ART only in pregnant women.

**tt.** Peers in community ART groups (CAGs) can deliver ARV refills to other CAG members.

**uu.** MSF is piloting pre-packed ARVs dispensed by lay counselors to CAGs in Khayelitsha.

**vv.** Mobile ART clinics are part of national HIV strategy.

**ww.** The Government of Zimbabwe allocated 9.3% of its 2011 budget to health. Health expenditure data is not available.

# Annex 2. TDF-containing first-line regimen: pricing eligibility in 23 countries

| COUNTRY | First-line treatment option of TDF/3TC/EFV 300/300/600 mg or TDF/FTC/EFV 300/200/600 mg | | | | |
|---|---|---|---|---|---|
| | Quality-assured* generic options for TDF/3TC/EFV 300/300/600 mg | Quality-assured* generic options for TDF/FTC/EFV 300/200/600 mg | | Quality-assured* originator option for TDF/FTC/EFV 300/200/600 mg | |
| | Matrix (Mylan) US$ 172 | Matrix (Mylan) US$ 197 | Cipla US$ 207[a] | Merck | |
| | | | | Category 1 countries US$ 613[b] | Category 2 countries US$ 1033[c] |
| Botswana | Eligible | Eligible[d] | Eligible for supply if patent barriers overcome**[d] | Eligible[d] | N/A |
| Brazil[e] | Not eligible[f] | Not eligible[f] | Eligible for supply but price unknown | Not eligible | Not eligible |
| Cameroon | Eligible | Eligible | Eligible for supply but patent status unknown*** | Eligible | N/A |
| CAR, DRC, Ethiopia, Guinea, Lesotho, Malawi, Mozambique, Myanmar, Tanzania, Uganda, Zambia[g] | Eligible | Eligible | Eligible | Eligible | N/A |
| China | Not eligible[f] | Not eligible[f] | Eligible for supply if patent barriers overcome | Not eligible | Not eligible |
| India | Eligible | Eligible | Eligible | Not eligible | Not eligible |
| Kenya | Eligible | Eligible | Eligible for supply if patent barriers overcome[d] | Eligible[d] | N/A |
| Namibia | Eligible | Eligible[d] | Eligible for supply if patent barriers overcome[d] | Eligible[d] | N/A |
| Nigeria | Eligible | Eligible | Eligible for supply but patent status unknown | Eligible | N/A |
| South Africa | Eligible | Eligible | Eligible for supply if patent barriers overcome | Eligible | N/A |
| Swaziland | Eligible | Eligible[d] | Eligible for supply if patent barriers overcome[d] | Eligible[d] | N/A |
| Ukraine | Not eligible[f] | Not eligible[f] | Eligible for supply if patent barriers overcome | Eligible | N/A |
| Zimbabwe | Eligible | Eligible[d] | Eligible for supply if patent barriers overcome[d] | Eligible[d] | N/A |


## LEGEND

All prices displayed in US$ per patient per year, as quoted by companies.

*Quality-assured: The term quality assured is used here to refer to products assured by US FDA or WHO prequalification (as of June 2012). Currently Mylan is the only quality assured source of this combination, but additional manufacturers in India are in the process of submitting their products for quality assurance. Prices should decrease further as this competition is introduced.

**Eligible for supply if patent barriers overcome: Countries identified as 'eligible for supply if patent barriers overcome' are those territories where a patent on one of the drugs or drug combinations has been granted. Patent status information taken from the Medicines Patent Pool Patent Status database available at http://www.medicinespatentpool.org/table/. [Last accessed 18/06/12].

***Eligible for supply but patent status is unknown: The patent status for TDF and TDF combinations is unknown. Source: http://www.medicinespatentpool.org/table/. [Last accessed 18/06/12].

## FOOTNOTES

**a.** Cipla does not manufacture TDF under voluntary licence from Gilead, and are therefore free to sell in any territory. However, where patents on TDF or TDF combinations with FTC or EFV have been granted, importation barriers may occur. Cipla has negotiated higher prices separately for 10 Latin American countries.

**b.** The following list of category 1 countries was provided by Merck for TDF/FTC/EFV 300/200/600mg: Afghanistan; Angola; Antigua and Barbuda; Bangladesh; Belize; Benin; Bhutan; Botswana; Burkina Faso; Burundi; Cambodia; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo; Congo (DRC); Côte d'Ivoire; Djibouti; Dominica; Dominican Rep.; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Grenada; Guatemala; Guinea-Bissau; Guinea; Guyana; Haiti; Honduras; Jamaica; Kenya; Kiribati; Laos; Lesotho; Liberia; Madagascar; Malawi; Maldives; Mali; Mauritania; Moldova; Mozambique; Myanmar; Namibia; Nepal; Niger; Nigeria; Pakistan; Panama; Papua New Guinea; Rwanda; São Tomé and Principe; Senegal; Sierra Leone; Solomon Islands; Somalia; South Africa; St Kitts and Nevis; St Lucia; St Vincent and the Grenadines; Samoa; Sudan; Suriname; Swaziland; Tanzania; Timor-Leste; Togo; Trinidad and Tobago; Tuvalu; Uganda; Ukraine; Vanuatu; Yemen; Zambia; Zimbabwe.

**c.** The following list of category 2 countries was provided by Merck for TDF/FTC/EFV 300/200/600mg: Bolivia; Indonesia; Kyrgyzstan; Mauritius; Mongolia; Nicaragua; Seychelles; Syria; Tajikistan; Uzbekistan; Vietnam.

**d.** The Medicines Patent Pool patent status database shows that a TDF combination with FTC patent was granted (AP2089) in the ARIPO region. Non LDC ARIPO countries could technically see combination patents on TDF with FTC enforced. Source: http://www.medicinespatentpool.org/table/. Last updated November 2011. [Last accessed 18/06/12].

**e.** There are several combination patents on TDF filed in Brazil, but none are currently granted. Source: http://www.medicinespatentpool.org/table/. Last updated January 2012. [Last accessed 18/06/12].

**f.** Matrix manufactures TDF under voluntary licence from Gilead. Those countries marked as 'non eligible' are countries not included in the geographic scope for sale.

**g.** The World Trade Organization (WTO) Doha Declaration, paragraph 7 states that least-developed members do not have to implement or enforce pharmaceutical patent protection until January 1, 2016. List of 48 LDCs Source: http://www.unohrlls.org/en/ldc/25/. [Last accessed 18/06/12].

## METHODOLOGY

The latest pricing data supplied by ARV producers to MSF for the 15th edition of 'Untangling the web of antiretroviral price reductions' utw.msfaccess.org was cross checked with the stated eligibility criteria of these companies in order to determine which of the 23 countries were eligible for supply from each producer. Where generic companies had not included their own eligibility restrictions through, for example, specifying a list of eligible countries under the terms of a voluntary licence, we used the Medicines Patent Pool Patent Status database http://www.medicinespatentpool.org/patent-data/patent-status-of-arvs/ to identify where patents on these ARVs had been filed or granted. Where we identified patent barriers we noted them. Such barriers may be overcome, but the importing country will need to take specific action in this case.

# References


**1.** Pinto AD et al. A cost-effectiveness analysis of centralized care versus decentralized care for HIV/AIDS in Malawi. XVIII International AIDS Conference, Vienna, Austria, 18–23 July 2010 (http://www.iasociety.org/Abstracts/A200741271, accessed 2 July 2012).

**2.** Cohen M et al. Prevention of HIV-1 infection with early antiretroviral therapy. New England Journal of Medicine, 2011, 365:493–505.

**3.** Secretary-General of the United Nations. United to end AIDS: achieving the targets of the 2011 Political Declaration. Report of the Secretary-General. New York, United Nations, 2012.

**4.** Getting ahead of the wave: lessons for the next decade of the AIDS response. Geneva, Médecins Sans Frontières, 2011.

**5.** WHO, UNAIDS and UNICEF. Global HIV/AIDS response: epidemic update and health sector progress towards universal access. Progress report 2011. Geneva, World Health Organization, 2011 (http://www.who.int/hiv/pub/progress_report2011/en/index.html, accessed 2 July 2012).

**6.** Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants. Programmatic update. Geneva, World Health Organization, 2012 (http://www.who.int/hiv/pub/mtct/programmatic_update2012/en/index.html, accessed 2 July 2012).

**7.** Guidance on couples HIV testing and counselling including antiretroviral therapy for treatment and prevention in serodiscordant couples. Recommendations for a public health approach. Geneva, World Health Organization, 2012 (http://www.who.int/hiv/pub/guidelines/9789241501972/en, accessed 2 July 2012).

**8.** Schwartländer B et al. Towards an improved investment approach for an effective response to HIV/AIDS. Lancet, 2011, 377:2031–2041.

**9.** Blandford J. Estimating health impact and costs of treatment in PEPFAR-supported programs. Washington, DC, PEPFAR Scientific Advisory Board, 2011.

**10.** Tanser F. Effect of ART coverage on rate of new HIV infections in a hyper-endemic, rural population: South Africa. 19th Conference on Retroviruses and Opportunistic Infections, Seattle, WA, USA, 5–8 March 2012 (Abstract 136LB; http://www.retroconference.org/2012b/Abstracts/45379.htm, accessed 2 July 2012).

**11.** WorldAIDSDayreport2011.Geneva,UNAIDS, 2011 (http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2216_WorldAIDSday_report_2011_en.pdf, accessed 2 July 2012).

**12.** MacPherson P et al. Suboptimal patterns of provider initiated HIV testing and counselling, antiretroviral therapy eligibility assessment and referral in primary health clinic attendees in Blantyre, Malawi. Tropical Medicine and International Health, 2012, [Epub ahead of print].

**13.** Boyer S et al. Financial barriers to HIV treatment in Yaoundé, Cameroon: first results of a national cross-sectional survey. Bulletin of the World Health Organization, 2009, 87:279–287.

**14.** McGuire M et al. Task-shifting of HIV care and ART initiation: three year evaluation of a mixed-care provider model for ART delivery. XVIII International AIDS Conference, Vienna, Austria, 18–23 July 2010 (Abstract MOPDD0104; http://pag.ias2011.org/Abstracts.aspx?SID=51&AID=2379, accessed 2 July 2012).

**15.** Sanne I et al. Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRA-SA): a randomised noninferiority trial. Lancet, 2010, 376:33-40.

**16.** Selke H et al. Task-shifting of antiretroviral delivery from health care workers to persons living with HIV/AIDS: clinical outcomes of a community-based program in Kenya. Journal of Acquired Immune Deficiency Syndromes, 2010, 55:483–490.

**17.** Bygrave H, Trivino L, Makakole L. TB/HIV integration: lessons learned from implementation of a TB/HIV "one stop shop" at primary health care clinics in rural Lesotho. XVIII International AIDS Conference, Vienna, Austria, 18–23 July 2010 (Abstract MOAB0301; http://www.iasociety.org/Abstracts/A200740348.aspx, accessed 2 July 2012).

**18.** Médecins Sans Frontières, Western Cape Province Department of Health, City of Cape Town Department of Health, University of Cape Town, Centre for Infectious Disease Epidemiology and Research. Khayelitsha activity report 2001–2011: ten years of HIV/TB care at primary health care level. Cape Town, South Africa, Médecins Sans Frontières, 2011 (http://www.msf.org.za/publication/khayelitsha-activity-report-2001-2011-10-years-hivtb-care-primary-health-care-level, accessed 2 July 2012).

**19.** Decroo T et al. Are expert patients an untapped resource for ART provision in sub-Saharan Africa? AIDS Research and Treatment, 2012, 749718.

**20.** Delivering antiretroviral therapy in the community: experience from four countries in southern Africa. Washington, DC, Médecins Sans Frontières, 2012.

**21.** Economic evaluation of HIV/AIDS primary/community care in 4 selected MSF project settings (patient & health care provider perspective). Brussels, Médecins Sans Frontières, 2011.

**22.** Decroo T et al. Distribution of antiretroviral treatment through self-forming groups of patients in Tete province, Mozambique. Journal of Acquired Immune Deficiency Syndromes, 2011, 56:39–44.

**23.** Luque-Fernández MÀ. Patient adherence clubs: a new model of care to reinforce long-term retention on antiretroviral therapy in Khayelitsha, Cape Town. 19th Conference on Retroviruses and Opportunistic Infections, Seattle, WA, USA, 5–8 March 2012 (http://www.retroconference.org/2012b/PDFs/1150.pdf, accessed 2 July 2012).

**24.** Kuwenyi K et al. Antiretroviral treatment outcomes from a decentralized ART programme in rural Zimbabwe: impact of targeted adherence strategies and extended ART supply. 6th IAS Conference on HIV Pathogenesis and Treatment, Rome, Italy, 17–20 July 2011 (Abstract MOPE429; http://www.iasociety.org/Abstract/A200742071.aspx, accessed 2 July 2012).

**25.** McGuire M et al. Optimizing patient monitoring after the first year of ART: three years of implementing 6-monthly clinical appointments in rural Malawi. 6th IAS Conference on HIV Pathogenesis and Treatment, Rome, Italy, 17–20 July 2011 (Abstract MOPE436; http://www.iasociety.org/Abstract/A200742498.aspx, accessed 2 July 2012).

**26.** Culbert H et al. HIV treatment in a conflict setting: outcomes and experiences from Bukavu, Democratic Republic of the Congo. PLoS Medicine, 2007, 4:e129.

**27.** Matambo T et al. Targeted adherence strategies for provision of cross border antiretroviral therapy (ART) to migrant farm workers in Musina, South Africa. XIX International AIDS Conference, Washington, DC, 22–27 July 2012 (Abstract No. TUPE752).

**28.** WHO and UNAIDS. Joint WHO/UNAIDS annual consultation with pharmaceutical companies. Global forecasts of antiretroviral demand 2012–2013. Geneva, World Health Organization, 2011:1–23 (http://www.who.int/hiv/meetingreports/consultation_pharmaceutical_companies/en/index.html, accessed 2 July 2012).

**29.** Bertagnolio S et al. Surveillance of transmitted and acquired HIV drug resistance using WHO surveys in resource-limited settings. 18th Conference on Retroviruses and Opportunistic Infections, 22 February – 2 March 2011, Boston, MA, USA (Paper 52; http://www.retroconference.org/2011/Abstracts/41940.htm, accessed 28 June 2012).

**30.** Fox MP et al. Rates and predictors of failure of first-line antiretroviral therapy and switch to second-line ART in South Africa. Journal of Acquired Immune Deficiency Syndromes, 2012 [Epub ahead of print].

**31.** Van Cutsem G. Why we need a better first line, access to viral load and alternative drugs for treatment failure. MSF satellite: The Emergency Is Not Over: Access to Treatment and the Challenges of Long-term Survival on Antiretrovirals, Cape Town, South Africa, 19 July 2009.

**32.** Calmy A et al. HIV viral load monitoring in resource-limited regions: optional or necessary? Clinical Infectious Diseases, 2007, 44:128–134.

**33.** Gupta RK et al. Virological monitoring and resistance to first-line highly active antiretroviral therapy in adults infected with HIV-1 treated under WHO guidelines: a systematic review and meta-analysis. Lancet Infectious Diseases, 2009, 9:409–417.

**34.** HIV/AIDS diagnostic technology landscape. 2nd edn. Paris, UNITAID, 2012.

**35.** Wang S, Xu F, Demirci U. Advances in developing HIV-1 viral load assays for resource-limited settings. Biotechnology Advances, 2010, 28:770–781.

**36.** Lawn S, Churchyard G. Epidemiology of HIV associated tuberculosis. Current Opinion in HIV/AIDS, 2009, 4:325–333.

**37.** Cattamanchi A et al. Sensitivity of direct versus concentrated sputum smear microscopy in HIV-infected patients suspected of having pulmonary tuberculosis. BMC Infectious Diseases, 2009, 9:53.

**38.** Bygrave H et al. Implementing Xpert® MTB/RIF in rural Zimbabwe: impact on diagnosis of smear-negative TB and time-to-initiation of TB treatment in smear-negative patients co-infected with HIV. XIX International AIDS Conference, Washington, DC, 22–27 July 2012 (Abstract No. THAB0105).

**39.** Losing ground: how funding shortfalls and the cancellation of the Global Fund's Round 11 are jeopardizing the fight against HIV and TB. Geneva, Médecins Sans Frontières, 2012.

**40.** Hecht R et al. Financing of HIV/AIDS programme scale-up in low-income and middle-income countries, 2009–31. Lancet, 2010, 376:1254–1260.

**41.** Sustainable financing for HIV/AIDS in Malawi. Oxford, Oxford Policy Management, 2012.

**42.** Untangling the web of antiretroviral price reductions. 15th edn. Geneva, Médecins Sans Frontières, 2012.

**43.** Waning B et al. A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. J Int AIDS Soc. 2010;13:35.

**44.** DOHA+10 TRIPS flexibilities and access to antiretroviral therapy: lessons from the past, opportunities for the future. Geneva, UNAIDS, 2011 (http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA10TRIPS_en.pdf, accessed 2 July 2012).

**45.** HIV estimates and projections: Asian epidemiological model, Myanmar 2010–2015. Yangon, Strategic Information and M&E Working Group: Technical and Strategy Group on AIDS, 2010.

**46.** Global tuberculosis control 2011. Geneva, World Health Organization, 2011 (http://www.who.int/tb/publications/global_report/2011/gtbr11_a2.pdf, accessed 2 July 2012).

**47.** Sidibe M, Executive Director UNAIDS. Remarks to the UN General Assembly High Level Meeting on HIV/AIDS. New York, 8 June 2011.

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