

GETTING AHEAD OF THE WAVE:

Lessons for the Next Decade of the AIDS Response

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MAY 2011

Patongo, Pader District, Uganda

**ARVs REDUCE
FROM MULTIPLE**

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CONTENTS



INTRODUCTION	03
THE IMPACT OF ART	04
GETTING AHEAD OF THE WAVE OF NEW INFECTIONS	05
LESSONS FROM THE FIRST DECADE	06
1. BETTER TREATMENT, EARLIER	08
Treat people before they get sick	08
Give people better drugs	09
Prevent HIV transmission to babies	10
2. TREATMENT AVAILABLE IN EVERY CLINIC	11
Decentralise and provide ARVs to clinic level	11
Integrate HIV and TB care	12
Shift medical tasks to support ART 'scale-out'	13
INNOVATIONS: LOOKING TO THE PIPELINE	14
Better drugs at lower prices	15
A promising pipeline of new drugs, delivered in new ways	15
Simpler diagnostic and monitoring tests in development	16
THE IMPACT OF DWINDLING DONOR SUPPORT	18
Malawi: A success story under threat	19
Zimbabwe: Told to go slow	19
Uganda: Treatment retreat	19
DRC: Treatment scale down	19
PUTTING THE RIGHT POLICIES IN PLACE	20
Support global HIV/AIDS treatment targets and scale up best possible care	21
Increase funding for HIV/AIDS treatment and explore innovative new financing mechanism	21
Rein in drug costs	22
Support research and development for tools	23
CONCLUSION	24
ANNEXES	26
Survey results	26
Putting the right policies in place	28
Intellectual property barriers to key ARVs	29

Mother and child enter MSF's HIV/
TB 'Blue House' clinic in Mathare,
Nairobi, Kenya



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“
Antiretroviral drugs have changed my life from
negative to positive. I frequently used to get
sick, and lost a lot of weight. Without these
drugs I would not be on this planet. I have
not had a single major health problem since I
started taking them. They have saved my life.

”

Luis Júnior Mariquele, Mozambique.

INTRODUCTION

Médecins Sans Frontières (MSF) began providing antiretroviral treatment (ART) for HIV/AIDS in 2000 in Thailand, Cameroon, and South Africa, to a limited number of people in urgent need of treatment. At the time, doctors and nurses faced very sick patients in over-crowded waiting rooms. Initially providing treatment in dedicated HIV/AIDS projects, MSF has increasingly decentralised HIV services, including prevention, treatment and care, into primary health care facilities and partnered with health ministries to deliver care.

Over the past decade, we have witnessed time and again how treatment dramatically reduces illness and deaths in the communities in which we work. Today, MSF treats more than 170,000 people in 19 countries, and some MSF projects have been able to reach and maintain so-called 'universal access' to treatment in their districts.¹

Looking beyond MSF, the past ten years have seen considerable progress. The major mobilisation of donors triggered by UN Secretary-General Kofi Annan's call for a "war chest" to fight the epidemic ushered in an unprecedented international effort to provide care and treatment in some of the most impoverished and hardest-hit countries in the world. The Global Fund to Fight AIDS, Tuberculosis and Malaria was created in 2002, followed by the US Government-led President's Emergency Plan for AIDS Relief in 2003. Together, they provide treatment to 81% of the more than six million people who are alive today because of antiretroviral therapy (ART).¹

This is important progress – but the treatment gap endures. An additional ten million people are today still in urgent need of treatment and many will die within just a few years if left untreated. Recognising this, UN Secretary-General Ban Ki-Moon recently called for at least 13 million people to be on treatment by 2015. Others have asked for treatment targets to be set at 15 million.^{2,3}

MSF and other providers of care have learned important lessons about how to reach more people with treatment without compromising quality of care. By scaling up ART to more people in need, illness, deaths, and new HIV infections can be reduced. And by scaling up intelligently, and with the right policies, the costs associated with HIV care can be reduced, allowing more people to be reached. Today, the latest evidence is beginning to show that ART not only

saves lives, but also can prevent transmission of the virus from one person to another. HIV treatment is therefore also HIV prevention, and can help slow the pace of the epidemic.

This report will detail MSF's experience implementing treatment strategies to improve care and reduce costs for patients and health systems. It presents results of a survey conducted by MSF teams in 16 countries where MSF works.¹¹ The 16 countries represent a mix of low, general and hyper-endemic countries, and together account for 52.5% of the global HIV/AIDS burden.

The progress they have achieved in implementing WHO treatment guidelines as well as other important strategies to increase access to treatment, provides an important window into the current strengths and weaknesses of the international response to HIV/AIDS. Most countries have policies to better manage the co-epidemics of HIV and TB; to integrate HIV and maternal services; and to bring care closer to where people live, using existing facilities and health care workers. But most HIV-prevalent countries are still struggling to reach more than 50% of people in need of ART or provide ART in more than 50% of existing facilities.

The progress thus far would not have been possible without external financial support, but it will take more mobilisation of domestic and external resources so that the population benefits of ART in reducing infections, deaths, and illness can be fully realised. With more than six million lives saved there is a lot to show for the last ten years of effort. But with new evidence of ART as prevention, even more can be done in the next decade.

As governments meet to draw up the blueprint for the next decade of the global HIV/AIDS response at a UN High-Level Meeting in New York in June 2011, they must recommit to their past promises to bring life-saving treatment to all in need, support an ambitious treatment target, and ensure the policies are in place to improve the quality of care, reduce the burden on patients and on health systems, support lowering the costs of drugs, and foster the needed medical innovation.

¹ Defined as reaching 80% of people in need of HIV/AIDS treatment

¹¹ Cameroon, CAR, DRC, Ethiopia, Guinea, India, Kenya, Lesotho, Malawi, Mozambique, Myanmar, South Africa, Swaziland, Uganda, Zambia, Zimbabwe

THE IMPACT OF ART

"I remember when I first started treating people with antiretrovirals in Mozambique, people were so ill and weak as a result of their illness that they sometimes weighed so little they were often carried into the clinics by their grandmothers. But one year later, after starting ART, those same people were just walking into the clinic to ask for their pills themselves. It was amazing."

Dr. Gilles Van Cutsem, MSF, South Africa

- **Fewer Deaths:** Globally, HIV-related deaths dropped by 19% from 2004 to 2009 as ART access increased.⁴ In Thyolo district, Malawi, MSF estimates that over 10,000 lives were saved between 2000-2007 because of scale-up of HIV/AIDS care and ART.⁵
- **Fewer AIDS Orphans:** According to a recent study, ART could avert a total of more than four million children being orphaned by AIDS in 10 African countries by 2020.¹³
- **Less Illness:** ART decreases the risk of developing TB by 67% and reduces the risk of death from TB by up to 95%.⁶ In Malawi, MSF documented a 42% decrease of new cases of TB between 2005-2010, a time during which ART was scaled up and high levels of treatment coverage were maintained.⁷ The availability of ART also reduces incidence of other infections: in a Ugandan study, provision of ART and cotrimoxazole antibiotic was associated with a 64% fall in malaria incidence.⁸
- **Fewer Babies Dying:** Providing ART to expectant mothers and prophylaxis to babies reduces infant mortality by reducing HIV – and therefore also HIV/AIDS-related infections – in babies. In Thyolo, Malawi, scaling up HIV testing and providing ART to pregnant women, the proportion of infants who tested HIV-positive decreased from 13.3% in 2007 to 6.1% in 2010.
- **Fewer HIV Infections:** A study in seven African countries found that ART reduced transmission of the virus by 92% among couples where one person was HIV-positive and on ART and the other was HIV-negative.⁹ According to UNAIDS, scaling up treatment and prevention strategies could allow new infections to be cut by half, thus averting more than one million new infections each year.¹⁰ In the MSF-supported programme in Khayelitsha, South Africa, ART is associated with a reduced proportion of pregnant women testing HIV positive, which fell from 31% in 2008 to 26% in 2010.
- **Reduced Cost:** There is clear evidence of the economic benefits of ART at the household level,¹⁴ and models suggests that universal access to treatment is cost-effective in the mid- and long-term.¹⁵ Studies have found that initiating ART earlier is cost-effective as it reduces mortality, illness, and hospitalisation.¹⁶ Delaying the provision of treatment to save costs today will likely cost more in the medium term.¹⁷
- **Fewer Pregnant Mothers Dying:** ART helps prevent pregnant women from dying of HIV.¹¹ HIV is a main driver of maternal deaths in countries with high prevalence and a factor in an estimated 20% of all maternal deaths. In Lesotho, which has the world's third highest HIV prevalence, an estimated 58.9% of maternal deaths are linked to HIV.¹² MSF is launching a new project in Lesotho to reduce maternal mortality by providing comprehensive HIV and TB care as part of antenatal services.
- **Stronger health systems:** HIV programmes have been found to strengthen health systems by strengthening service delivery, human resources, information systems, finances, and leadership.^{18,19} ART has also shown to reduce hospitalisation and ease burden on overstretched health systems. MSF programme reports have found that HIV care contributes to improving the overall uptake and delivery of primary care services.^{20,21,22}

A child co-infected with HIV/TB sits with his grandfather. Since starting ART his health has improved significantly. Myanmar



New scientific evidence shows that treating people with HIV not only fights their own illness but also stops the HIV virus spreading – in fact, the evidence is that people on antiretroviral treatment are 90% less infectious than those not on treatment. This opens up a whole new world where we not only treat the individual with ARVs but we can aim to reduce new infections at the community level too.



Dr. Isabelle Andrieux-Meyer,
HIV advisor, MSF Access Campaign

This ten-year old child from Myanmar was orphaned when his parents both died from AIDS. He was also sick - infected with the HIV virus - and was abandoned in a market. The woman who found him took care of him and eventually reunited him with his 79-year-old grandfather. He started antiretroviral treatment in 2008.

"I could not sleep well when I was seriously ill," the boy explains. "I woke up in the middle of the night. I could not eat anything. I just drank water but always vomited. I had diarrhea all the time. I am happier after taking ARV treatment. I can eat and sleep well and I want to play and stay happy."

"After taking ART, his skin complexion looks better," his grandfather says. "He eats more and plays a lot. Before taking ART, he looked so gloomy. But now he plays like a monkey and he is even told off for playing too much. He has been taking ART for 3 months and his health condition is significantly improved."

"I remember my daughter - his mother - who was also sick with HIV and think if only she had known about treatment and come to this clinic, she would not now be dead."



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BEFORE AND AFTER...

Dr. Fiona Fisher who works for MSF in Manipur, India tells Vanlalsiam's story.

Vanlalsiam is currently 11 years old. His parents and two siblings have all died (we assume due to HIV/AIDS) and so he is cared for by his grandmother. He had been attending MSF's Singngat clinic in Manipur since 2008, having started antiretroviral and anti-tuberculosis treatment with the Ministry of Health but was not getting any better. The first photo of Vanlalsiam was taken in November 2009 in Shalom, and I honestly thought he would not survive. He was very unwell with chronic diarrhea, poor appetite and severe pulmonary tuberculosis (he had an appalling chest x-ray.) It was hard for MSF to decide whether he was ill with multidrug-resistant TB or whether it was resistant HIV. Finally, after a viral load test showed extremely high levels of the HIV virus present in his blood, we decided to put him on treatment for

resistant HIV. The second photo was taken at a follow-up appointment at MSF's town clinic in Churachandpur in April 2010, and I could barely believe it was the same child. His grandmother is so grateful, and clearly spoils him rotten (he was eating a big bag of crisps!). She now walks him several kilometres to school each day and waits there until after class to walk him home again. When I last saw him, he was happily playing with his classmates like an average healthy 11 year-old boy.

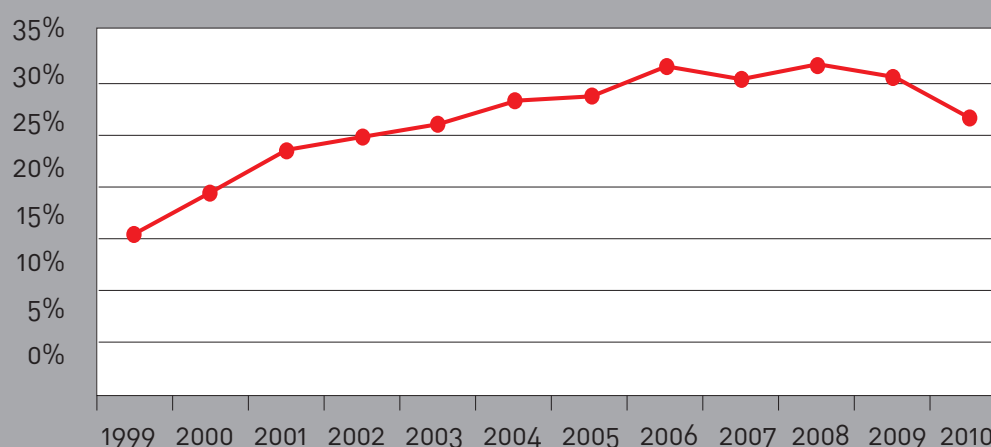
In the north-eastern Indian state of Manipur, MSF staff in 2010 provided counselling, testing and treatment for HIV-positive patients as part of the basic healthcare programme.

Khayelitsha



GETTING AHEAD OF THE WAVE OF NEW INFECTIONS

Decreasing HIV prevalence among pregnant women in Khayelitsha



Khayelitsha is a large township on the outskirts of Cape Town, South Africa with a population of over 500,000 and one of the highest burdens of both HIV and TB in the world. An estimated 16% of the adult population is HIV-positive. MSF began providing ART in Khayelitsha in May 2001, and today supports ART provision to more than 17,000 people.

There are indications that as treatment has been scaled up in Khayelitsha, new HIV infections have decreased. An analysis of HIV prevalence data among pregnant women shows that the proportion of HIV-positive pregnant women attending antenatal care had risen from 15.4% in 1999 to 31.4% in 2008. By 2010, that percentage had fallen to 26.3%. While other factors including deaths, out-migration, and behaviour change may have played a role in this reduction, ART scale up is considered to be the strongest contributing factor in reducing new infections.

In 2011, MSF will open a pilot programme in South Africa with the goal of reducing new HIV *incidence* – that is, the number of new HIV infections. The project will be situated in a rural and peri-urban area in KwaZulu-Natal province. Since 1990, KwaZulu-Natal has consistently had the highest-recorded rates of HIV in the country, with HIV prevalence among pregnant women at an alarming 39.5%,²³ and overall adult prevalence at 25%.²⁴ Acting on the latest scientific evidence^{III} that ART can decrease HIV incidence – as well as offering established benefits such as reduced mortality and reduced incidence of other infections, in particular tuberculosis – MSF will work closely with the community and local health authorities to show the feasibility of massively increasing uptake and coverage of HIV testing, ART coverage, and treatment adherence.

^{III} Antiretroviral (ARV) drugs reduce transmission of the virus from mother to child. (Garcia et al. N Engl J Med 1999) Studies have shown that viral load is the main predictor of HIV transmission (Quinn et al. N Engl J Med 2000) and that treatment can reduce the risk of heterosexual transmission by 92% (Donnell et al. Lancet 2010). In Taiwan a 53% reduction in new infection rates followed the scale-up of ART (Fang et al. Infect Dis 2004), and more recently, a study showed a strong association between increased ART coverage, decreased viral load, and decreased new HIV diagnoses per year among injecting drug users in Vancouver, British Columbia (Montaner et al. Lancet 2010).

LESSONS FROM THE FIRST DECADE

Over the past ten years, a number of key strategies have been identified to support scale up of treatment, improve quality of care, and reduce costs. These are outlined below, with an analysis of progress on implementing these strategies in the 16 countries surveyed.

1. BETTER TREATMENT, EARLIER

“

Years ago, we would wait until the patient's immune system would be very low to start treatment. And very often people were already very sick at that point. We know today that it is much safer and makes much more sense to start treatment earlier before people get sick.”

Nich Oucho, MSF Clinical Officer, Kenya

Treat people before they get sick

Until recently, people in developing countries had to wait until their CD4 cell count, an indicator of the immune system, dropped to 200 cells/mm³ or lower, before being considered eligible for treatment. This meant that many were already ill or at risk of opportunistic infections before starting treatment. Following evidence from research from both developed and developing countries, the latest WHO guidelines for HIV treatment recommend initiating patients at an earlier stage in their disease, when their CD4 level drops to 350. MSF's experience in Lesotho, where people were started on treatment at CD4 350, showed major benefits of doing so: people started between CD4 200-350 were 68% less likely to die, 63% less likely to need hospitalisation, and 39% less likely to drop out of care, compared to people who began treatment at CD4 200 or lower.²⁶

MSF staff from the HIV/AIDS team in Arua, Uganda.



→ In the sixteen countries surveyed for the purpose of this report, twelve have adopted earlier treatment according to WHO guidelines, or are in the process of doing so. However, Uganda and South Africa limit early initiation to “pregnant women only” because of financial constraints and concerns about expanding the pool of patients that would qualify for treatment given limited treatment slots. India's National AIDS Control Organisation recommends the country upgrade its initiation protocol from CD4 250 to 350, but the government is still weighing the cost implications. Ethiopia has not adopted the guideline.

Progress providing earlier treatment in the 16 countries surveyed is encouraging on a whole. However, given the clear reductions in mortality and diseases like TB associated with early initiation, it is worrying that several countries have had to put plans on hold.



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Give people better drugs

Side effects are one of the main reasons why people on ART stop taking their medicines.²⁷ The most commonly used first-line drug regimen in developing countries today contains the drug stavudine (d4T), which can cause intolerable side effects from cumulative use. Latest WHO guidelines recommend starting patients on ART regimens with safer drugs such as zidovudine (AZT) or tenofovir (TDF). Data from MSF's programmes show that TDF is the preferable of the two alternatives: people on TDF were six times less likely to experience side-effects compared to patients on d4T; the risk of side-effects on TDF was halved compared with patients on AZT.²⁸ A recent study in India found that given the costs of managing side effects from d4T, TDF is cost-effective.²⁹ TDF is also cheaper than AZT, at \$76 per patient per year (ppy), compared to \$88 ppy.³⁰

Giving people better drugs also means giving people simple treatment – one pill, once a day. People are also more likely to stick to their treatment if it is easier for them to take and multiple medicines are combined into a single pill – a 'fixed-dose combination,' or FDC.³¹ Adherence to treatment further improves if treatment is given once a day compared to twice a day.³² This gives further support to the switch to TDF-based treatment, which is available as a one pill, once daily treatment.

- ➔ Of the 16 countries surveyed, eight have upgraded or are in the process of upgrading their guidelines to use TDF in preferred first-line regimen. Six other countries are using a regimen containing AZT. Malawi and Zimbabwe had changed their protocols or were in the process of doing so but had to reverse course because of financial constraints. Malawi reserves TDF only for certain groups (TB/HIV co-infected, pregnant women, patients experiencing severe side effects). In Zimbabwe, a TDF-containing regimen is provided only to pregnant women, with the rest of adults remaining or starting on d4T. The Ministry of Health notified facilities that if funding improves, TDF will be phased in over the course of three years.

The majority of countries surveyed have moved away from d4T. However, it is unfortunate that some countries have adopted AZT as the new first-line therapy instead of TDF which is more affordable, associated with fewer side-effects, and available as a once-daily fixed-dose combination.

“Before patients were on put on the newer drug, tenofovir, they were struggling, complaining of peripheral neuropathy (acute pains in arms and legs). They were also getting large fat deposits on their body, changing the way they looked. I like giving patients the ARV regimen with tenofovir because it is taken only once per day. Patients adhere more to treatment now.”

Magerard Mochesane, Nurse, Lesotho



We know how to stop the vast majority of babies from acquiring the HIV virus. It's easily done - these babies don't need to get infected and it's painful and frustrating to see children's lives hit like this when they are just starting out in life and the problem is entirely preventable.



Dr. Marianne Gale, MSF paediatrician

Prevent HIV transmission to babies

In wealthy countries, using HIV treatment to prevent mother-to-child transmission (PMTCT) has reduced transmission to below two percent. But in countries where MSF works, such as Uganda and Mozambique, mother-to-child transmission accounts for a significant portion of new HIV infections because of poor access to PMTCT services and less than optimal PMTCT prophylaxis.³³ WHO has recommended improved PMTCT protocols, which need to be implemented, and access to PMTCT services in general needs to be improved. Providing comprehensive HIV services under the same roof as antenatal care and maternity services is essential for preventing mother-to-child transmission of HIV and reaching more women in need of ART for their own health.

- ➔ Of the countries surveyed, 11 have adopted one of the WHO-recommended options for prevention of mother-to-child transmission, and three countries are in the process of doing so. In Malawi, where the fertility rate is high, the Ministry of Health will provide ART to all HIV-positive pregnant and lactating women for life, and in Uganda, MSF's project, with the support of the government, will serve as a pilot site to implement full ART for HIV-positive pregnant women, for life. All 16 countries support policies for integration of HIV services into maternal health care, but full implementation lags behind.

Progress adopting better PMTCT protocols is promising, although the choice of protocol is likely driven by cost considerations. It is urgent that governments are supported in increasing access to improved PMTCT as soon as possible.



© Judy Waguma

"I decided I was going to live and not die"

Geoffrey Ochieng is 22 from Mathare, a deprived area of the Kenyan capital Nairobi. He's the second child in a family of three and his parents died when he was only seven years old. Geoffrey discovered he was HIV positive in 2005 and started on medication in 2008. He lives alone and does tutoring jobs for both high school and primary school children to sustain his day-to-day life. Here he explains how treatment has turned around his life.

I wasn't very shocked when I learned that I was HIV positive. I was always sick, and I was tired of my classmates always mocking me each time I fell ill. But I did wish for one moment that my parents were still alive.

My aunts sent me packing when I told them of my status. With no one to talk to, I decided to start treatment. Since then I have been on ARVs. Taking medication has never been easy. Among my siblings, I am the only one who has the virus. It's a mystery because I am the middle child. Sometimes I ask, why me?

There were days when I felt like ending it all. My sight is far from good. I stumble when I walk, and I hate it when people treat me as though I were a corpse. Some days I wouldn't take my medication, but after a strong debate with myself, I decided I was going to live and not die. Today I take my drugs religiously; there are joys to adhering to the HIV treatment.

My CD4 count is increasing, and with that my sight is getting better. I am happy about that. I am working hard too; I want to go back to school. I know that the sky is the limit, and I will not stop at anything.

I am only 22, but I will not stop, I have to go the extra mile, and make sure that I have the life that I have always wanted. Blue House, MSF's clinic in Mathare, has given me a family, and I always go there whenever I feel low, and I get counselled. I have a great support group. I wouldn't make it without them.

2. TREATMENT AVAILABLE IN EVERY CLINIC

In high HIV-endemic countries, the following strategies have proven instrumental in getting more people on ART.



We need to bring care and services much closer to where people actually live. That way we'll reach all those people who normally wouldn't get treated because they couldn't afford the transport to a health clinic or couldn't afford the time away from home and work. We've seen here in Hlatikhulu, in Shiselweni region, that more people in the district now know about the services on offer and people have seen how family members, friends, and colleagues get better. This motivates them to come to the clinics, get tested and start treatment. Also, we have been able to start people on treatment much earlier, before they get ill and when the immune system still works relatively well.



Dr. Marcella Tomassi, MSF, Swaziland

Decentralise and provide ARVs at the clinic level

Particularly in HIV-endemic countries, moving care from central hospitals to health centres and from health centres to clinics and community health posts has enabled MSF teams to reach many more people in need of treatment and bring care closer to people's homes.^{34,35} Decentralising care reduces transport costs that have been a limiting factor in patient access to care.³⁶ Studies that have compared outcomes in hospitals and health centres have found no difference in the quality of care provided, while it improved adherence.^{37,38,39} In order to scale up treatment in endemic settings to even more people in need, ART should be provided by existing primary health care facilities where feasible.

Moving beyond the primary health care clinic and into the community is necessary. HIV testing and dispensing of ARVs and other essential HIV medicines at the community level can also further reduce the costs to patients and congestion at facilities.^{40,41} MSF's HIV/AIDS programmes in Malawi, Mozambique, and South Africa have been implementing strategies to limit the number of times people need to attend clinics by providing medicine refills to stable patients in the community.^{42,43}

Studies have shown that user fees are an important barrier to access to care, and providing HIV care free of charge to patients improves patient adherence and survival,⁴⁴ whereas user fees and other out-of-pocket costs hinder treatment and adherence.^{45,46} This applies not only to ARVs, but also the cost of consultations, laboratory testing, and associated medicines.

→ In only six out of the 13 countries with a generalised-epidemic, for which there was data, is ART available in over 30% of public facilities. In Kenya,⁴⁷ Zimbabwe⁴⁸ and Guinea,⁴⁹ decentralisation of ART to community clinics is occurring at a slow pace, primarily because of a delay or reluctance to allow nurses to start patients on ART. This results in fewer facilities offering ART and fewer people having access.

There is major room for improvement across the board in the high-endemic countries surveyed. The low level of facility coverage in some countries most likely relates to a lack of support for task-shifting or is caused by health system deficiencies or resource concerns.



© Sebastien Le Clezio



A woman with HIV receives treatment for multiple-drug resistant TB in Mathare, Kenya



It is easy to see how integrating treatment of HIV and TB makes sense for both patients and healthcare staff: patients avoid having to travel between services as they can get hold of their medicines for both illnesses at the same time at a one-stop service, and health resources are saved as a single health worker can check how well the treatment is working for both diseases, and monitor for side-effects and other potential problems.



Dr. Eric Goemaere, MSF, South Africa

Integrate HIV and TB care

It is crucial that comprehensive HIV care be integrated with TB care.^{iv} By integrating HIV and TB services in Khayelitsha, South Africa, MSF has been able to cut in half the time it takes to get people co-infected with both HIV and TB on to ART. Proper diagnosis of TB has also increased.⁵¹ In MSF's programme in Shiselweni, southern Swaziland, TB detection almost doubled within a year once HIV/TB services were integrated.⁵² For countries with growing numbers of multidrug-resistant TB cases, integration is crucial. Integration of HIV/TB services is key to meeting the global target of reducing by half the number of people living with HIV that die of TB by 2015.⁵³

→ Although all 16 countries surveyed have national policies that are in support of HIV/TB integration, in 10 of the countries, the policies have yet to be fully implemented. Even in countries where HIV and TB integration are the official policy of governments, such as in Malawi, Kenya, Mozambique, and Swaziland, patients are either seen by different staff within the same facilities, or TB patients must go to separate facilities for their HIV care and medicine refills.

Integration of TB and HIV services is slow and incomplete. Until full integration is realised, countries are missing opportunities to prevent TB and TB-related deaths, and initiate ART at a greater pace.

^{iv} Components of TB care include: TB diagnosis, prevention and treatment care involving systematic access to provider initiated HIV testing and counselling and early ART initiation for co-infected TB patients; TB intensified case finding (ICF) and isoniazid preventive therapy (IPT) for HIV patients; with TB infection control (IC) measures in health facilities and household level

Shift medical tasks to support ART 'scale-out'

'Task-shifting' has been recommended by WHO as a way to overcome the lack of health care workers and bring treatment closer to patients in HIV-endemic settings. In many MSF HIV programmes and in an increasing number of national programmes, nurses and clinical workers initiate patients on treatment and lay counsellors provide HIV testing and adherence counselling in community primary health care clinics. Programme outcomes from such projects have been reported from Malawi, Lesotho and South Africa are found to be equivalent to programmes run by doctors.^{54,55,56,57}

→ In only five of the countries surveyed were nurses allowed to initiate patients on ART. Swaziland, although a hyper-endemic country, is like Uganda, Cameroon and Myanmar in that nurses do not initiate or manage patients already on ART. Out of the 16 countries Uganda, DRC, Guinea, and Mozambique do not have policies allowing lay health workers to provide HIV testing and adherence counselling.

Task-shifting has helped many countries scale-up ART, but slow implementation of task-shifting in some countries is creating bottlenecks for offering ART to more people in more facilities, particularly in countries where policies supporting nurse initiation of ART are inadequate or lacking.

How to reduce the burden on patients and on the health system? Lessons learnt in MSF programmes

With regard to treatment strategies aimed at reaching more people, reducing the burden on health systems and patients, much still needs to be accomplished among countries surveyed where the epidemic is generalised. Governments must be urged and supported to implement policies that not only will reduce illness, deaths and new infections, but also reduce costs. Here are some of the strategies seen to work in MSF programmes run in collaboration with ministries of health.

Margarida Smith was diagnosed with HIV in 2006 and is the leader of two patient groups.

"I live in a village outside the city of Tete. My role is to collect medication at the health centre and distribute it to the others in the group. The people in the group appreciate this, because many don't have enough money to travel to the health centre every month. It's great to be able to help others to take care of their illness."

In **Tete, Mozambique**, ART is distributed and adherence is monitored through self-formed and patient-led 'community ARV groups.' Members take turns getting ARV refills for the group, allowing each member to have a clinical consultation every six months.^v Patient outcomes have improved while the workload at under-resourced facilities has decreased four-fold. Out of 1,301 patients, 97.5% were retained in care and only 0.2% were lost to follow up.⁵⁹ The Mozambican Health Ministry plans to pilot this strategy in three health structures in each of the 11 provinces.

In **Khayelitsha, South Africa**, over 17,000 people are on ART and over 4,000 new patients are started on ART each year. Treatment outcomes are good, with 80% remaining alive and in care at two years on ART and less than 14% with treatment failure at five years on ART. To help encourage people to stay on treatment for life, MSF established 'adherence clubs' for adults who are doing well on ART. A lay health worker visits these clubs every other month to stimulate support-group discussions, provide health and adherence screening, and dispense pre-packed ARVs,

all within two hours. The club members report that the convenience, fast-tracking, and support has made a difference to their relationship to treatment.

In **Chiradzulu district, Malawi**, MSF has initiated over 26,000 people on treatment since 2001. In order to decongest services, people who have been on ART for at least one year receive their drug refills from lay health workers every three months and only need to see a nurse every six months. After one year, 97% of patients remain in care.⁶⁰ MSF plans to expand this strategy to half the patients in the programme next year. And in neighbouring **Thyolo** district, patients can receive ART refills as well as chronic care in "improved" health posts staffed by lay health workers and regularly visited by community nurses.



© Niklas Bergstrand

^v Listen to a member of a community ARV group explain how it works: <http://aids2010.msf.org/2010/a-new-model-for-decentralized-care-in-mozambique/>

INNOVATIONS: LOOKING TO THE PIPELINE

Children near MSF's HIV/AIDS project in Busia, western Kenya



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“
I want to be able to reach all those people who are in urgent need of treatment or who will need treatment but who live in very remote and rural areas, currently beyond the reach of medical care. To do this, we need to find radically simpler and better ways to test, treat and monitor AIDS treatment. That means tests that can measure viral load on the spot without relying on electricity, it means medicines that can be given at much longer intervals, say monthly instead of daily, it means drugs that have fewer side effects so patients stick to their treatment – and this all has to be at an affordable price for the places where we work.”

Dr. Ali Ouattara, MSF, Kenya

In addition to the previously outlined strategies that are already making a difference in many places, a number of important innovations are in the pipeline that could further influence the epidemic trajectory of HIV by speeding up access to care, reducing illness and death, and lowering costs.

Better drugs at lower prices

Over the past ten years, thanks to competition from generic manufacturers, the price of the most commonly used ARV combination fell by 99%, from more than \$10,000 per patient per year to \$67 today. A number of approaches are being implemented to further reduce manufacturing costs. These include:

- New, efficient ways of producing 'active pharmaceutical ingredients' (API) which can account for 55-99% of direct manufacturing costs.⁶¹ Recent price reductions for e.g. efavirenz and TDF are largely the result of reducing API production costs.
- Reducing the amount of API, which has the advantage of both lowering costs and reducing side-effects. Studies are underway to assess the efficacy of a number of key ARVs at lower dose, including AZT and efavirenz. Estimates suggest that if the dose of efavirenz could be reduced by one third (from 600mg to 400mg), then one third of the price can be shaved off the cost of the drug per patient per year.⁶²
- Improving the absorption of drugs through new formulations. This is being explored with tenofovir and some protease inhibitors and is a way to reduce the necessary amount of needed API, and therefore costs.

Wanted :

Medicines that are adapted to scaling-up and decentralising treatment. They must be potent, very well tolerated, easy to take, robust, have limited drug interactions especially with TB drugs, have a low pill burden, few side effects and be compatible for special populations, such as children and women of childbearing age, and be safe during pregnancy.

A promising pipeline of new drugs, delivered in new ways

The pipeline for ARVs contains multiple drugs that are promising for the future, including new classes of drugs that have new ways of preventing the virus from replicating. Some could be administered as long-acting formulations that would allow once-weekly or once-monthly dosing. And some of the drugs could be potentially cheaper than the ARVs most commonly used today, provided patent barriers are surmounted.

- Rilpivirine can be produced for as little as \$10 per patient per year, and also has the potential for use in long-acting formulations – an injectable 'nano-suspension' of rilpivirine has been developed and showed potential for monthly dosing.⁶³
- Dolutegravir, from the new integrase inhibitor class, has shown to be very potent at low doses, which suggests it could be produced at a low price.⁶⁴
- S/GSK1265744, also an integrase inhibitor, has been developed as a long-acting injectable. Other drugs that hold the same potential for long-acting formulation are elvucitabine and CMX157. However, elvucitabine remains stuck in the development pipeline.

Mechanisms must be in place to ensure people in developing countries can benefit from these therapeutic advances and not have them be priced out of reach.

Simpler diagnostic and monitoring tests in development

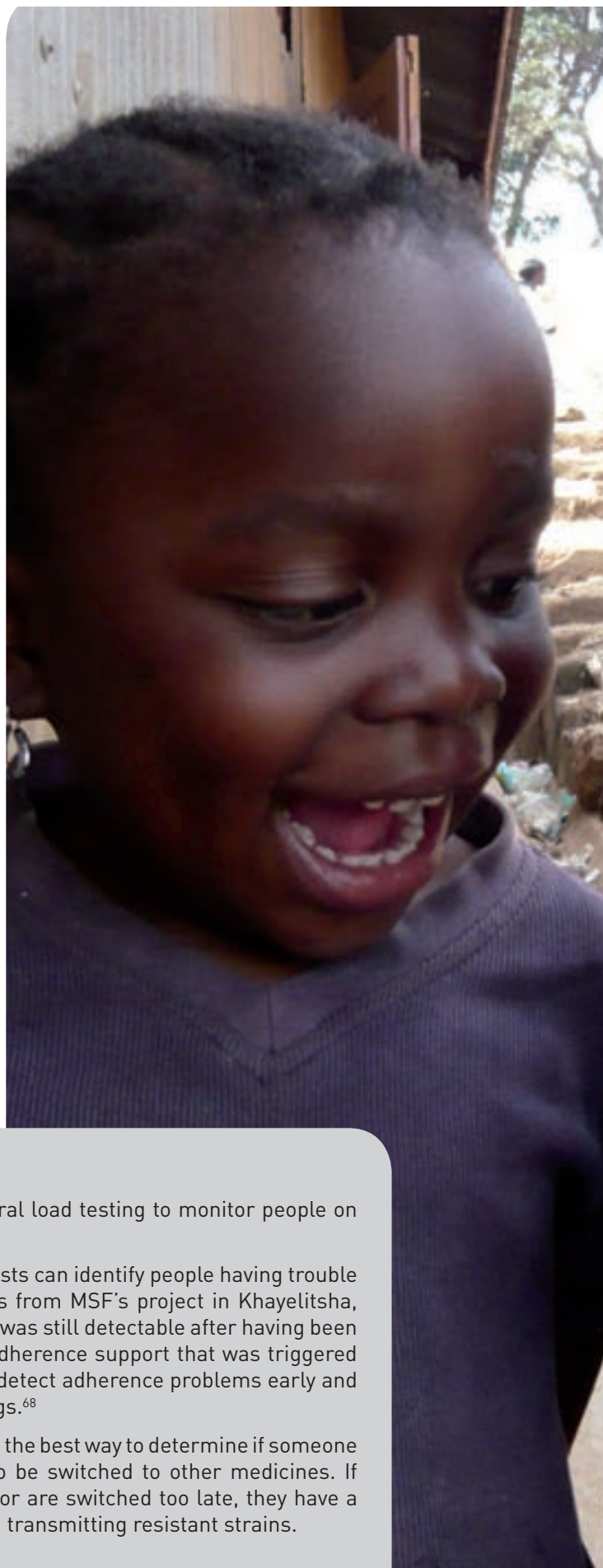
To monitor patients as recommended, and to support decentralised treatment and task shifting, new simplified tests are needed. Such tests need to be designed to work without electricity, and be easily performed by minimally-trained health workers. They must also be designed for use with a sample that is easy to take, such as a cheek-swab or blood sample from a finger prick.

Existing pipeline:

- **CD4 Level:** Technologies in the pipeline measure CD4 in a more affordable and simplified way. Smaller devices the size of an alarm clock are due to be released in 2012, and disposable 'dipstick'-type CD4 tests in 2013.^{vi}
- **Viral Load:** Current tests are complex and expensive, limiting availability. Smaller, fully-automated versions of the current molecular tests will be available in 2012, and even simpler, more compact and more affordable technologies will be available from 2013 onwards.^{vii}
- **TB:** A new molecular TB test endorsed by WHO can reduce the time it takes to diagnose drug-resistant TB from up to three months down to less than two hours. It can also detect TB much more easily among people who are also infected with HIV, in whom diagnosing TB is much more difficult. MSF is rolling out this new test in 16 countries in 2011. But still a simple and affordable rapid 'point-of-care' version is needed.

It is essential that provisions are put in place to ensure that these and other promising innovations are made accessible and affordable for patients in developing countries. Governments must support an innovation agenda that systematically aims to further simplify treatment and reduce costs so that even more people can be reached with even better treatment.

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The Benefits of Viral Load Testing

The new WHO treatment guidelines recommend scaling up viral load testing to monitor people on treatment. The benefits include:

- **Detecting adherence problems early:** Access to viral load tests can identify people having trouble adhering to treatment so they can receive support. Studies from MSF's project in Khayelitsha, South Africa, showed that 71% of people whose level of virus was still detectable after having been on treatment for six months became 'undetectable' after adherence support that was triggered by testing their viral load. In this way, viral load testing can detect adherence problems early and avoid the need to switch to more expensive second-line drugs.⁶⁸
- **Detecting treatment failure on time:** Testing viral load is also the best way to determine if someone might be resistant to their drug combination and needs to be switched to other medicines. If people are not switched when they start failing treatment, or are switched too late, they have a much greater risk of developing even further resistance and transmitting resistant strains.



Children in Mathare, a deprived area of Nairobi, Kenya where the AIDS epidemic is rife

Children with HIV: Still an afterthought

In wealthy countries, prevention of mother-to-child transmission of HIV has been so successful that nearly no child is born with HIV any longer. With no market in wealthy countries, pharmaceutical companies see little incentive to develop appropriate and adapted ARVs for children. Yet every day in developing countries, 1,000 children are newly infected with HIV. While there has been important progress in scaling-up paediatric AIDS treatment over the past ten years, children continue to be neglected when it comes to treatment – only 28% of children in need of treatment have access, compared to 37% of adults.

Treatment options in particular are lacking. Of the 22 antiretrovirals approved by the US FDA today, five are not approved for use in children, and six do not come in any paediatric formulations. When drugs for children do exist, they often come in formulations such as powders or syrups that are not adapted for use in resource-poor settings as they are difficult to store and administer, requiring clean water or refrigeration or involving complex dosage calculation. Some are extremely unpalatable.

The impact on the quality of care children receive is evident. Recent data from a European trial shows that within five years of starting treatment, 12% of children have grown resistant to the three main classes of drugs, illustrating the need for more robust treatment options.⁶⁵ Yet the neglect of children living with HIV threatens to persist, as the majority of promising pipeline drugs continue to be tested only in adults.

^{vi} Benchtop tests include Pima, Pointcare NOW and Partec CD4 miniPOC.; Smaller devices include Daktari, mBio; and dipstick tests include Zyomyx, Burnet

^{vii} Tests available in 2012 include Alere, Liat; tests available from 2013 onwards include SAMBA, NW Uni VL, Wave 80, GeneXpert VL, Micronics, ALL, Biohelix

THE IMPACT OF DWINDLING DONOR SUPPORT

© Sophia Apostolia



MSF's project in Luwingu, Zambia

For the first time in a decade, overall funding for HIV decreased in 2009.^{69 70}

The Global Fund is facing a several billion dollar shortfall because of insufficient donor pledges at its 2010 replenishment conference. As a result, new funding rounds have been delayed and, for the first time in its history, no new funding round will be approved for 2011. In 2010, more than half of the HIV proposals were rejected. These countries will now have to wait until 2012 for decisions on proposals, with funding likely to be available only in 2013. Some countries with high HIV burdens are thus reducing ambitions to scale up treatment and putting on hold plans to implement new improved WHO recommendations for better and earlier treatment. Also, more demand is being put on the Global Fund to fill in as other funders, such as World Bank and UNITAID, end their programmes.

PEPFAR is also facing funding reductions and policy changes that translate into a withdrawal of support for ART on the ground. As of October 2010, PEPFAR reports that it supports 3.2 million people on ART.

Although funding has been flat-lined for the past three years, PEPFAR added 700,000 people on ART in 2010, the highest number of people in a year yet, using previously unspent funds. But now, PEPFAR is showing signs of slowing down and reducing its budget for ART according to country operational plans. In some countries, PEPFAR is prematurely handing over responsibility and funding for HIV treatment programmes to governments that are not yet able to cope with the caseload or cost. In South Africa, where PEPFAR is abruptly terminating some programmes, patients on ART were referred to government clinics that could not cope with the additional ART patient load.

The funding squeeze for these two agencies, which together provide treatment for eight out of every ten people on ART, has translated in overall reduced availability for HIV programmes in low-income countries with high HIV burdens. These countries will be unable to fund the necessary HIV interventions on domestic funds only, even with increased allocation for health budgets.⁷¹

The following four countries among the 16 surveyed are experiencing concrete consequences of stagnating or shrinking funding levels:

Malawi: A success story under threat

MSF has worked for over ten years in Malawi, supporting comprehensive HIV/AIDS services with the health ministry in two districts, with 36,910 patients alive on ART. Malawi has been cited as a success story for its rapid ART scale up in a very poor setting with severe health workforce shortages, having achieved ART coverage of 63% of people in need. The country has a high dependence on Global Fund support, but its last two grant proposals were rejected. A lack of funding has led to the decision to reserve better drugs such as TDF for certain patient groups, while plans to decentralise ART and PMTCT services to all its 760 public health facilities over the next three years are at risk.

Zimbabwe: Told to go slow

In Murumbina district in Zimbabwe, MSF provides ART for over 13,000 patients and in Bulawayo the MSF project has around 4,500 children under ART. Zimbabwe is still in the early stages of the process of decentralising ART: only 8% of public health facilities can initiate ART and 21% can provide follow up services including medicine refills. New WHO recommendations were adopted in Zimbabwe in 2010 but because of funding constraints, implementation will take place in a phased approach over three years. Because its last proposal to the Global Fund was rejected, Zimbabwe will have to wait and try again, hoping for funding for scale-up to be approved in 2012 and received in 2013.

Uganda: Treatment retreat

In 2002, MSF now counts 5,000 people on ART in Uganda, a country where 300,000 people are in need of treatment. PEPFAR limited the number of HIV treatment slots in its Ugandan programmes in 2009, allowing a new patient to be given treatment only once another patient had died or been lost to care.^{72,73} Global outrage over this policy led to it being lifted several months later,⁷⁴ but PEPFAR still has not offered new funding that would come with a Partnership Framework Agreement, and the government has not done enough to scale-out ART. Uganda planned to implement WHO recommendations but in 2010 the country's Global Fund proposal was rejected. Now only pregnant women can start ART at the WHO-recommended earlier treatment threshold. Implementation of full ART for all HIV-positive pregnant women was also put on hold. Instead, Uganda will settle for a more affordable, but more complicated protocol that requires mothers to start and stop treatment with each pregnancy.

DRC: Treatment scale down

MSF has run an ART project in Kinshasa since 2001. As funding cuts take their toll on access to treatment, MSF is receiving more and more patients at its clinics, who often arrive too sick to be saved. With three important funding sources drying up, the future for HIV/AIDS treatment scale-up in DRC looks increasingly bleak. PEPFAR ended its grant for medical items in 2010, and the World Bank Program and UNITAID funding for paediatric care will both end their support in 2011. The DRC's Global Fund proposals were rejected in both 2009 and 2010. Already, DRC is behind the curve, with only 17% of people in need of ART currently receiving it and only 2% of pregnant women receiving PMTCT services.⁷⁵ The ART treatment initiation rate fell 18% from 2009 to 2010⁷⁶ and now caps have been placed on the number of new patients that can be started on treatment. Facilities that have reached their quota can only start a new patient on treatment once a slot is freed up through death or loss of another patient on ART. Further, ART is already rationed through the costs passed to patients, who are required to pay up to \$15 for CD4 testing, and \$60 for viral load testing, on top of consultation fees.

MSF and other care providers are deeply concerned that people living with HIV/AIDS in these countries will not be able to benefit from the latest treatment recommendations and science on the benefits of high ART coverage. Further, the continuity of medicine supply is threatened, which carries a risk of dangerous treatment interruption for patients. In some cases patients are required to cover more of the costs of their own care.

“

If there is reduced funding, it will mean more people will die, and we will have more orphans. The ones that are HIV positive often need to assist others, like their children. People will lose hope and die. It will be the end. If there are no drugs there is no future.”

Catherine Mango,
person living with HIV/AIDS, Kenya

PUTTING THE RIGHT POLICIES IN PLACE

© Lewis



"In the past few years, we have been losing more and more teachers because of HIV/AIDS. This photo in front of the school was taken just before two of the teachers died."

A teacher in Malawi

“

Ten years after we started treating people for AIDS in developing countries, governments now need to reavow their commitment to providing life-saving treatment to all those in need. To do this will mean supporting policies that enable us to scale up treatment, including promoting medical innovation to develop better tools, making drugs more affordable, and delivering sustainable funding for treatment programmes. It is a matter of political choice with millions of lives hanging in the balance.

”

Dr. Tido von Schoen-Angerer,
Executive Director, MSF Access Campaign

In order to achieve the call by UN Secretary-General Ban Ki-Moon to put 80% of the 18 million people in need on treatment by 2015, governments will have to put in place policies that create an enabling political and economic environment for treatment scale-up; policies that support lowering the costs of drugs; and policies that foster the innovations that can help triple the number of people without tripling the costs.

1. Support global HIV/AIDS treatment targets and scale up best possible care

Donors and developing countries should support explicit global HIV/AIDS treatment and prevention targets that can be monitored. Continued scale-up of ART is needed in order to save lives and capitalise on new evidence that treatment itself is a prevention tool that reduces the risk of HIV transmission.

The new WHO recommendations for treatment initiation, improved drug regimens, monitoring, and PMTCT and need to be fully implemented by endemic countries, with support from donors and civil society. Implementation of these recommendations will reduce illness and deaths of people with HIV, reduce the burden on health systems, and help prevent new infections. Additional improved treatment strategies include integrating HIV and TB care, task-shifting to allow for decentralisation of HIV care, and greater patient autonomy such as through the community medicine dispensing strategies.



Joseph Ramokoatsi is a HIV/TB counsellor in Lesotho

2. Increase funding for HIV/AIDS treatment and explore innovative new financing mechanisms

Increased funding of the HIV/AIDS response is essential and both donor and developing country governments must share this responsibility according to their capacity to contribute. Donor governments must reaffirm the commitments made at the G8 in 2001 and 2006 to support access to HIV prevention, care, and treatment for those in need.⁷⁷ Developing country governments must respect funding commitments, such as the Abuja Declaration on allocating at least 15% of African country GDP to health. Additional funders are also needed.

According to UNAIDS, a \$10 billion gap exists out of an overall \$25.9 billion needed to meet treatment and prevention commitments.⁷⁸ The Global Fund to Fight AIDS, TB and Malaria estimates that \$20 billion would allow another 7.5 million people to be put on treatment by 2015. However, pledges have stagnated at \$11.7 billion for the coming three years and have yet to materialise into concrete contributions. PEPFAR also needs to be fully funded to help meet the challenge of treating 15 million people by 2015.

In addition, innovative and additional funding streams should be explored and promoted with the goal of securing regular, predictable and sufficient revenue to fund global health in the long term. Models such as UNITAID, which relies on a small tax on airline tickets in participating countries, have shown to be successful in generating predictable funding. There are proposals for applying a similar tax to financial transactions of the banking sector, which could lead to millions in revenue for just a 0.05% levy on international bankers' transactions. While several countries are supporting financial transaction taxes, governments have yet to take the step to turn discussions into reality.



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3. Rein in drug costs

More affordable medicines means more people can be put on treatment. Competition among generic manufacturers – in particular in countries like Brazil, India and Thailand where medicines were not patented and more affordable versions could be produced – helped prices fall 99% from over \$10,000 per patient per year in 2000. PEPFAR has reported that the use of generics has resulted in a cost savings over \$300 million over four years.⁷⁹

Affordable medicines produced primarily in India have been instrumental in scaling up HIV treatment to more than six million people in developing countries. This was possible because the country did not grant patents on medicines until 2005. More than 80% of donor-funded purchases of ARVs for use in developing countries from 2001 to 2008 were manufactured in India, and more than 80% of the ARVs MSF uses are sourced from India.⁸⁰ But newer drugs are protected by patents in India, preventing price-busting competition. This includes more robust drugs with the potential to be used in first-line regimens, and drugs that people with life-long HIV will need as future treatment options.

The lowest price for the WHO-recommended TDF-based, first-line one pill once a day ARV combination is \$155 per patient per year.⁸¹ The price for 'second-line' medicines, needed when someone fails their first-line combination, is nearly three times that. It is estimated that the need for 'second-line' medicines will nearly double to almost half a million people in 2012.⁸² Today, further treatment options for people failing treatment cost up to \$3,200 per year.⁸³

“The availability of affordable treatment through generic medicines has meant that for patients in South Africa and millions of others living with the HIV virus in developing countries, AIDS is not an automatic death sentence.”

Dr. Eric Goemaere, MSF, South Africa

Supporting the policies needed to contain the cost of drugs is a political choice. Ensuring newer medicines are made affordable for people in developing countries depends on:

- Least-developed countries using their right not to grant or enforce medicine patents until 2016, and members of the World Trade Organization extending this deadline.
- Developing countries exercising their right to issue compulsory licenses to allow for production of more affordable generics, like Thailand in 2007, in a move which brought the price of the drug lopinavir/ritonavir down by 75%, or Brazil, which overcame a patent on efavirenz, thereby enabling the government to import a generic version from India at one third of the originator company price.
- Developing countries designing flexible patent laws. India's patent law contains key public health safeguards, reserving monopoly status only for those drugs that show a therapeutic benefit over ones that already exist – this restricts frivolous patenting. The law also allows any interested party to oppose a patent before or after it is granted ('pre-grant' and 'post-grant' oppositions) so undeserved patents can be challenged.
- Developed countries refraining from pushing measures that go beyond TRIPS in trade agreements, such as the current demands by the European Union and the European Free Trade Association countries for 'TRIPS-plus' policies to be included in trade deals with India that will damage access to affordable medicines. By attacking the "pharmacy of the developing world," such policies also directly undermine any effort by donor governments to finance and support treatment scale up.
- All countries refraining from introducing intellectual property enforcement measures that limit the production, export, transit and importation of generic medicines.



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- Pharmaceutical companies pursuing voluntary methods that meet the needs of people in developing countries and keep costs down. The Medicines Patent Pool is a new mechanism whereby patent holders are asked, in exchange for an agreed royalty payment, to make their patents available so that generic companies can produce more affordable versions. The Patent Pool would allow for much easier production of needed three-in-one fixed-dose combination pills that otherwise would require lengthy negotiations with numerous different patent holders. The Patent Pool received its first license in September 2010 from the US National Institutes of Health for the drug darunavir. Yet the license itself does not allow for the production of the drug, as further patents are held by Johnson & Johnson. Significantly, the licence terms offered by the NIH include middle-income countries. Many of these have large numbers of people on HIV treatment, but are not eligible for the price discounts offered by drug companies, making access to patented medicines extremely difficult. A number of companies are currently in negotiations with the Patent Pool, but MSF is urging all entities that hold patents on HIV drugs to share their patents with the Patent Pool. The Pool could help overcome intellectual property hurdles, but only if the licences cover all developing countries.

4. Supporting research and development for better tools

The needs of people in developing countries must be systematically taken into account in medical research and development (R&D) for HIV/AIDS. Improving HIV/AIDS care will require governments to support HIV innovations that simplify treatment through new, better-tolerated medicines that can be dosed less frequently, as well as crucial point-of-care tests for measuring CD4 and viral load, and TB diagnostic tests that can deliver results quickly.

Furthermore, the fruits of HIV/AIDS innovation must be affordable for people in developing countries. As currently discussed at the WHO⁸⁴ and other fora, new global norms for medical R&D must be explored and promoted, including innovation models that de-link the cost of R&D from the end price of products, as well as global R&D treaties.

In March 2011, nearly four thousand people marched in Delhi for access to affordable medicines.

CONCLUSION

Governments made a commitment ten years ago to provide life-saving treatment to people living with HIV/AIDS. This commitment must be upheld, in particular now that we know HIV treatment not only saves lives and reduces illness, but can also dramatically reduce further infections.

Ten years into providing HIV/AIDS treatment, MSF is encouraged by the successes achieved in bringing treatment to some of the most remote populations, where we have witnessed treatment outcomes as good as in developed countries. Treatment has been simplified to ease the burden on patients and treatment providers, and strategies have been developed to reach more people in need. The benefits of providing better treatment to people earlier, before they become very ill, are now widely known, and beyond saving lives, the preventative effect of treatment provides even further incentive to scale up now.

But there is a limit to what can be done with today's strategies and medical tools. Looking to the challenges in the decade ahead, there needs to be aggressive innovation to develop even more effective treatment strategies and even simpler and better medicines and tools, while ensuring they are affordable enough to reach people who need them.

The survey MSF conducted in 16 countries shows that important progress has been achieved on many levels, but also that this progress is volatile. Many strategies to reach more people with treatment are still not being implemented, despite having shown to be successful in multiple contexts.

For MSF's work and that of others to continue, there is a need for sustained political commitment. Policies that support scale up of the best available HIV/AIDS treatment must go hand in hand with policies that support the development of medicines and medical tools that address the needs of people living with HIV/AIDS in developing countries. Policies that support the production of affordable medicines must prevail over agendas to push trade agreements and other rules that restrict it. And policies that look at sufficient and sustained funding mechanisms must be implemented to ensure that additional, predictable resources are available for HIV/AIDS and global health.

HIV/AIDS has claimed more than 25 million lives over the last thirty years. The world is in a position to halt further deaths, but today, only one third of the people who need treatment receive it. The decision to extend life-saving treatment is a political one, but one with immense human consequences. And while global treatment scale up will bring challenges, these are not insurmountable and we must fiercely reject a double standard in care and a complacency of doing less.

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Nondumiso has HIV and multidrug-resistant tuberculosis. She works as a peer educator in Khayelitsha township, Cape Town, South Africa

ANNEXES

SURVEY RESULTS : PROGRESS IN 16 COUNTRIES

National Policies	Cameroon	CAR	DRC	Ethiopia	Guinea
Early initiation of ART (CD4↓350 and Stage III and IV)?	Yes	Yes	Pending ¹	No	Yes
Better-tolerated drugs (TDF in first-line regimen)?	Yes	No ³	No ³	Yes	No ³
Is PMTCT protocol in line with WHO recs – Option A, B, or B+?	Yes (A)	Yes (A)	Pending (A) ¹	No	Pending (B) ¹
What % of public sector facilities provide ART according to the latest information?	31%	13%	46.4%	59%	8%
Is TB/HIV integration a matter of policy?	Partial	Partial	Yes	Partial	Partial
Does government policy support integrating HIV and maternal health services?	Yes	Yes	Partial	Yes	Partial
Does government policy support nurses or non-physicians initiating ART and providing follow up (FU)?	No	FU only	FU only	Yes	FU only
Task-shifting of HIV testing & adherence counseling to lay health workers?	Yes	Yes	No	Yes	No
Percentage of people in need receiving ART (according to WHO recommendations of CD4 ↓350)?	35%	30%	17%	52.5%	40% ⁶
Endemicity (hyper, generalised, low)	Gen	Gen	Gen	Gen	Gen

LEGEND

(A): OPTION A prophylaxis: Mother gets daily AZT from 14 weeks of pregnancy, single dose NVP at onset of labour, AZT+3TC during labour/delivery, AZT+3TC for seven day tail protection. Infant gets single dose NVP at birth and then daily NVP from birth until one week after all exposure to breast milk has ended. Non-breastfeeding infants get single dose NVP at birth and then daily NVP or AZT from birth until 4 to 6 weeks of age.

(B) OPTION B prophylaxis: Mother gets triple ART starting from 14 weeks of pregnancy until one week after all exposure to breast milk has ended. Infant gets daily administration of AZT or NVP from birth until 4 to 6 weeks of age.

(B+) OPTION B+: All HIV+ pregnant women receive life-long ART. Infant gets same as above.

PARTIAL: Policy, but not systematically implemented

¹ Guidelines not yet updated

² Only for TB/HIV co-infected, pregnant women and patients with severe side effects

FU only=Initiation by MDs only, nurses do FU

India	Kenya	Lesotho	Malawi	Mozambique	Myanmar	South Africa	Swaziland	Uganda	Zambia	Zimbabwe
No	Yes	Yes	Yes	Yes	Pending ¹	No	Yes	No	Yes	Yes
No ³	Yes	Yes	No ²	No ³	Pending ¹	Yes	Yes	No ³	Yes	No ²
Yes ³ (A)	Yes (A)	Yes (A)	Yes (B+)	Yes (A)	Pending (A) ¹	Yes (A)	Yes (A)	Yes (A)	Yes (A)	Yes (A)
⁵	14%	69%	55%	18%	9.4% ⁴	44%	31%	7.4%	29%	21.4%
Partial	Yes	Yes	Yes	Yes	Partial	Partial	Partial	Partial	Yes	Partial
Partial	Yes	Partial	Yes	Yes	Yes	Yes	Partial	Partial	Yes	Partial
FU only	FU only	Yes	Yes	Yes	No	Yes	No	CO	CO	CO
Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Partial
39%	52%	48% ⁶	46% ⁶	32%	25%	37% ⁶	70%	44%	68%	43%
Low	Gen	Hyper	Gen	Gen	Low	Hyper	Hyper	Gen	Gen	Gen

CO=Initiation by MDs and clinical officers only, nurses do FU

³ Using AZT

⁴ Myanmar: 30 sites for 320 townships (which is 9.4%)

⁵ India has 293 ART centers and more than 300 "link or satellite" centers where treatment is followed but not initiated, parallel structures . not known as not integrated services are offered

⁶ FROM WHO: "Estimated antiretroviral therapy coverage based on WHO 2010 guidelines, 2009"

GEN= Generalized epidemic country: where adult HIV prevalence is between 1-15% and HIV is "firmly established in the general population"

Low= Lower-level epidemic country: adult HIV prevalence rate is below 1%

Hyper= Hyper-epidemic country : the adult prevalence is over 15%

PUTTING THE RIGHT POLICIES IN PLACE

Developing Countries	Donors and Developed Countries	Pharmaceutical Companies
TREATMENT TARGETS		
Support ambitious treatment coverage targets to provide treatment to 13-15 million people by 2015		
TREATMENT GUIDELINES		
Implement WHO guidelines and optimal treatment strategies	Support implementation of WHO guidelines and optimal treatment strategies	
FUNDING		
Allocate adequate funding for health, including HIV/AIDS programmes and explore innovative and additional financing mechanisms	Fully fund the Global Fund and bilateral HIV programmes and explore innovative and additional financing mechanisms	
ACCESS TO MEDICINES		
Use flexibilities included in the TRIPS Agreement, such as: • right for least-developed countries not to grant or enforce patents on pharmaceuticals until 2016; propose an extension beyond 2016 at WTO • use compulsory licenses and other provisions to overcome patent barriers to access • design patent laws that are favorable to access to medicines including strict patentability criteria, and pre- and post-grant patent oppositions	Respect developing country use of TRIPS flexibilities and refrain from threatening trade sanctions against countries that use public health flexibilities Evaluate the nature and content of the technical assistance provided to developing country on intellectual property issues Refrain from imposing TRIPS Plus provisions (including data exclusivity, patent linkage and patent extensions) in developing countries	Respect developing country rights to use TRIPS flexibilities Refrain from exerting legal, economic or political pressure against countries using public health flexibilities
Revise the 2003 WTO August 30 Decision to ensure an expeditious solution for countries with no or insufficient manufacturing capacity		
	Implement strategies to ensure affordable access to patented medicines for patients living in developing countries License relevant intellectual property to the Medicines Patent Pool	
Refrain from introducing intellectual property enforcement measures that limit the production, export, transit and importation of generic medicines		
RESEARCH AND DEVELOPMENT		
Support the creation of public-health driven global research & development (R&D) norms, including the establishment of incentive mechanisms that ensure access by separating [de-linking] R&D costs from the price of final products, and an exploration of a biomedical R&D treaty		

DID YOU KNOW ?

Intellectual Property Barriers to Key ARVs
The effects of the TRIPS Agreement are becoming apparent

FIRST LINE	COUNTRIES WHERE PRODUCT IS KNOWN TO BE PATENTED ¹
Rilpivirine (TMC 278) (under development)	Benin, Botswana, Burkina Faso, Cameroon, Central African Republic, Chad, China, Congo, Gabon, Equatorial Guinea, Gambia, Ghana, Guinea, Guinea Bissau, India, Ivory Coast, Kenya, Lesotho, Malawi, Mali, Mauritania, Mexico, Mozambique, Namibia, Niger, Senegal, South Africa, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe. Patents pending in Argentina, Brazil, Chile, Egypt, Jordan, Malaysia, Panama, Philippines, Vietnam.
TREATMENT FAILURE	
Raltegravir (RAL)	Colombia, India, Mexico, Philippines, South Africa, Ukraine, Uzbekistan, Vietnam. Patents pending in Argentina, Brazil, Chile, China, Malaysia, Nicaragua, Thailand.
Etravirine (ETV)	Argentina, Armenia, Azerbaijan, Belarus, Cameroon, Central African Republic, Chad, Chile, China, Congo, Benin, Botswana, Burkina Faso, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, India, Gambia, Ghana, Ivory Coast, Kenya, Kazakhstan, Kyrgyzstan, Lesotho, Malawi, Malaysia, Mali, Mauritania, Mexico, Moldova, Mozambique, Namibia, Niger, Philippines, Russia, Senegal, Sierra Leone, South Africa, Somalia, Sudan, Swaziland, Tanzania, Tajikistan, Togo, Turkmenistan, Uganda, Ukraine, Vietnam, Zambia, Zimbabwe. Patents pending in Brazil, Indonesia.

¹ The information reflects data available on the "Patent Status Database for Selected HIV Medicines" provided by the Medicines Patent Pool as of April 30, 2011. Patent information may be subject to changes and confirmation with relevant patent authorities is highly recommended. 'Patents pending' indicates that a patent application has been filed and is awaiting a decision from the patent office as to whether it will be granted or not.

The Medicines Patent Pool	
Patent Holder	Status of negotiations
Abbott Laboratories	Not currently in negotiations
Boehringer Ingelheim	Not currently in negotiations
Bristol-Myers Squibb	Not currently in negotiations
F. Hoffman-La Roche	Preparing negotiations
Gilead Sciences	In negotiations
Merck & Co.	Not currently in negotiations
Sequoia Pharmaceuticals	In negotiations
Tibotec/Johnson & Johnson	Not currently in negotiations
US National Institutes of Health	First license issued/ In negotiations
ViiV Healthcare	In negotiations

“
At the moment second-line AIDS drugs are much more expensive than first-line drugs....we're talking about over three times more expensive and we are having patients in our clinic again who have become now resistant to the drugs that are available at affordable prices and we're back into a situation for certain patients, we have to tell them, "look, there are drugs in the private sector, or in rich countries that could treat you, but we cannot afford them."
”

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Monica Juma receives HIV treatment through MSF's clinic in Mathare, Kenya. She also survived multidrug-resistant tuberculosis, which required arduous two-year treatment.



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