The Ten Consequences of AIDS Treatment Delayed, Deferred, or Denied

July 2010

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The MSF Access Campaign editorial team wishes to acknowledge **Sheila Shettle**'s substantial contributions in writing and finalising this document.

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"I don't think donors really understand what is at stake. If they saw the problem from HIV-positive people's perspective, maybe then they would think of a way to sustain HIV/AIDS funding, and to keep giving additional resources for pressing health care needs. When donors withdraw funding and commitment for treatment, no matter how slowly, in the end, life for a lot of people in Africa will be either miserable or nonexistent." – Jimmi Gideyi, PLWHA, Kenya

Over the last decade, antiretroviral treatment (ART) scale-up to millions of people living with HIV/AIDS in developing countries has been possible thanks to a massive mobilisation of resources and political will, the simplification of ART, and the competition among drug manufacturers that has pushed prices for AIDS medicines down by more than 99% since 2000. More than four million people are alive today who without treatment would not be, and epidemiological trends show crucial progress in the battle against the epidemic. MSF currently provides ART to more than 162,000 people in 25 countries.

The World Health Organization (WHO) has recently made important changes to treatment guidelines, and now recommends that people be provided with treatment earlier, before the disease is allowed to progress. This would bring clinical practice in developing countries closer to standards long adhered to in wealthy ones. In addition, new evidence shows that wide-scale and early treatment may be an effective way to curb transmission of the virus at population level.[1]

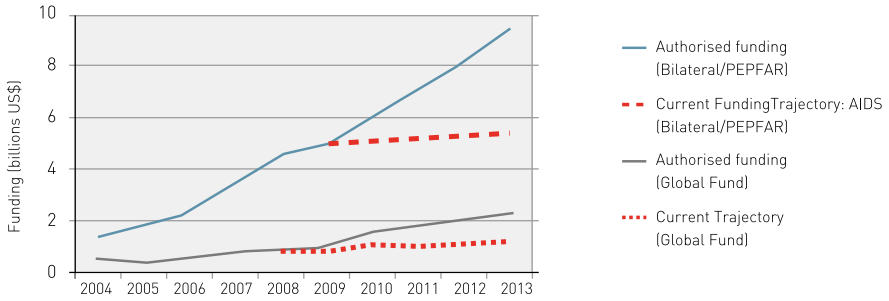
But despite evidence of the broad benefits of ART, we are witnessing alarming backtracking just as efforts should be ramped up. Donors have started to shift their support away from HIV/AIDS, and funding is not keeping up with the need. MSF has seen the negative impact this is already having in some countries: care is being rationed because of limited treatment slots, slowing treatment scale-up for those in urgent need, and threatening the lifeline of those fortunate enough to be on treatment. Today, ten million people are in immediate need of treatment [2] – if nothing is done, most of these people will die within the next few years.

2010 brings us to a critical crossroads that will determine the size and pace of the AIDS response for the coming years. Donors will make the political choice to either fulfil their commitment to universal access to ART as promised in 2005, or to continue down the path of disengagement.

This document illustrates ten consequences of the funding retreat for people living with HIV/AIDS in developing countries, drawing upon data from MSF field research released at the XVIII International AIDS Conference (IAC) 2010 in Vienna, and experience providing ART over the last ten years.

Donors Suffering From AIDS Fatigue

UNAIDS estimated in 2007 that addressing the AIDS epidemic in low- and middle-income countries would require US$25 billion in 2010 [i], but donors have only given roughly half that amount so far.[9] With the economic downturn and shifting, rather than increasing, funding to other health issues such as maternal and child health, donors have begun to downsize their contributions to HIV/AIDS:



US government global HIV/AIDS contributions: 2004 - 2013.

Source: Health GAP Policy Analysis: Making a Mistake on Treatment – PEPFAR's New Five-Year AIDS Strategy by Brook K. Baker, Feb. 5, 2010; accessible at: http://www.healthgap.org/waiting-in-line-baker-paper.htm and the Lantos and Hyde 2008 act for re-authorisation of second phase of PEPFAR; accessible at: http://www.pepfar.gov/about/index.htm

• The US government's PEPFAR programme, initiated in 2003, pays for treatment for more than half the people receiving ART in developing countries. In May 2009, US President Obama launched the Global Health Initiative (GHI), which aims to spend $63 billion over six years (2009-2014) on global health programmes, of which PEPFAR is the largest.[10] But PEPFAR's budget is being flat-lined – the budget for 2011 marks the third year in a row. And while PEPFAR support put 2.4 million people on treatment by September 2009, the programme only plans to initiate an additional 1.6 million people on ART from 2009-2014. This means a slowing of yearly enrolment of new patients by an average of 56% as compared to 2006-2008.[11] PEPFAR has already told some implementers to stop enrolling new patients on ART unless slots become vacant through deaths or defaulters.[12] At the same time, the White House is decreasing the contribution to the Global Fund to Fight AIDS, TB and Malaria (GFATM).[13]

• GFATM provides support for one quarter of all people on ART in developing countries. However, it is facing an unprecedented funding gap and risks not being able to fund the treatment proposals submitted by developing countries. GFATM needs at least $20 billion for the next three years, but donors are reneging on commitments, and are requesting that GFATM lower its financial ambitions in the lead up to a replenishment conference in October 2010.[14]

• UNITAID, the international finance facility funded primarily by an airline tax, has been providing support for second-line and paediatric antiretrovirals (ARVs) through its partner on HIV/AIDS, the Clinton Health Access Initiative (CHAI). UNITAID currently pays for ARVs for three in four children on treatment in developing countries.[15] As with all UNITAID projects, the idea has been to hand over to other funders once supply of quality products and reduced prices have been achieved. However, given current difficulties to hand over to GFATM or PEPFAR, funding for second-line and paediatric ARVs, which runs out in 2011 and 2012 [16] respectively, may need further extension. This will limit UNITAID's capacity to take on new important projects, such as building viral load testing capacity.

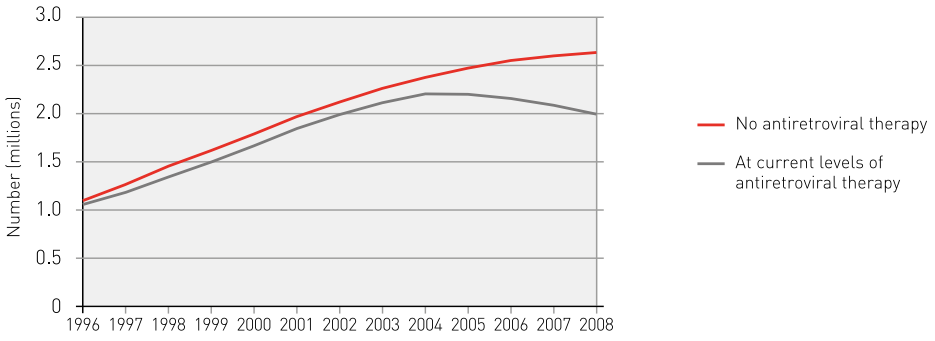
• The World Bank's Multi-country HIV/AIDS Programme (MAP) has distributed $1.5 billion in more than 30 countries since it began in 2000, and has supported ART provision in 26 countries. The programme has been phased out in three African countries over the last four years, and will end in a further three by the end of 2011.[17]

• Other donors such as the UK government and other European Union countries who collectively provide nearly half of the GFATM's contributions, are either shifting support to maternal and child health and health systems strengthening, or are cutting back development and health funding.[18]

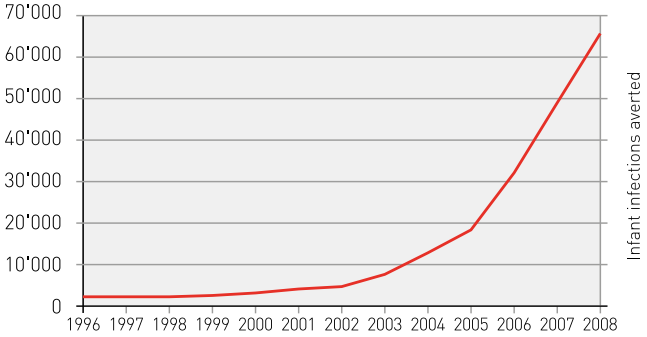
i This estimate is based on old WHO treatment initiation criteria, which underestimates the number of people in need. The amount of funding needed to address the AIDS epidemic would therefore, according to latest clinical evidence, be even higher.

Living Proof: The Positive Impact of AIDS Treatment

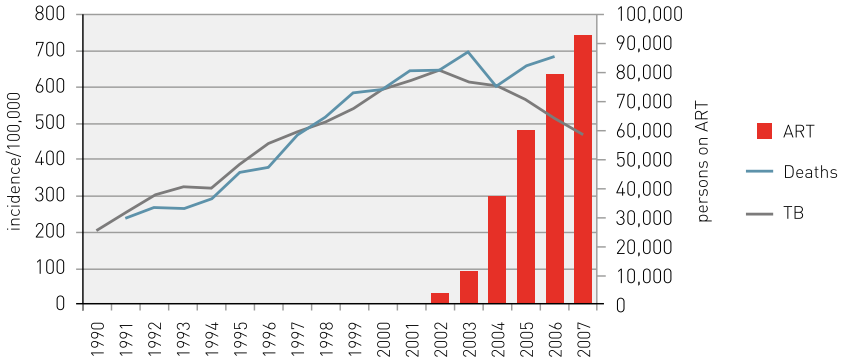
"People's lives have been improved, their quality of life has been maintained. There are fewer people dying of HIV-related complications. There are fewer hospital admissions, fewer people coming to seek help for treatment of opportunistic infections. It has reduced the workload and the burden of what we are doing." – David Some, Clinical Officer, MSF, Kenya



Estimated number of AIDS-related deaths with and without ART, globally, 1996 - 2008 (UNAIDS, 2009 AIDS epidemic update)



Estimate of the annual number of infant infections averted through the provision of ARV prophylaxis to HIV-positive pregnant women, globally, 1996 - 2008 (UNAIDS, 2009 AIDS epidemic update)



Source: Botswana MOH TB control program report to the Global Fund; mortality Central Statistical Office; ART, MOH; WHO, Botswana Triangulation 2005-6.

Reported TB incidence, all cause mortality and ART uptake Botswana, 1990 - 2007.

ART bends the epidemiological curves associated with HIV: AIDS deaths have begun to decline worldwide[3] and there have been decreases in overall adult mortality, as well as infant and under-five mortality.[4] ART has also led to fewer children being born with HIV and fewer AIDS-related orphans.[5] Further, ART helps decrease the emergence of opportunistic infections such as tuberculosis (TB), with a 60% reduction in TB incidence among people receiving ART documented in some ART programmes as well as steep declines in malaria.[6,7] People are less sick and thus less likely to require hospitalisation. And new research shows that treatment is prevention: one recent study published in the Lancet found a 92% reduction in HIV transmission in Africa among couples in which one partner was HIV-positive and on ART.[8]

Rationing Treatment is Irrational in a Growing Epidemic.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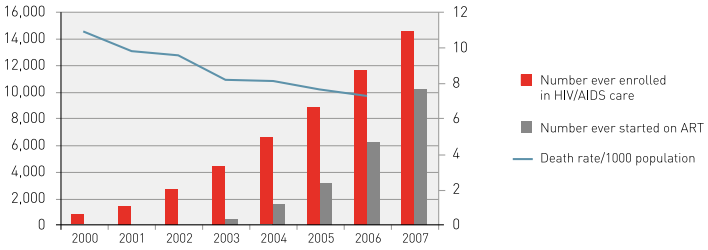

Source: Mwagomba B. et al. PLosOne. Available at: http://dx.plos.org/10.1371/journal.pone.0010452

Registered deaths at five traditional authorities and relationship to enrolment in HIV/AIDS care and ART, 2000 - 2007, Thyolo District, Malawi

1. Limiting Treatment Slots Means Choosing Who Lives and Who Dies.

"We were told we couldn't put more patients on ARVs because the funding was insufficient. It's really hard seeing a patient come here to be told 'we can't help you.' We don't know how many of them died or what happened to them, unfortunately."
– Dr. Margie Hardman, physician in PEPFAR-funded clinic, South Africa.

ART has had a dramatic positive impact on reducing mortality, measurable at the community level. At the 2010 IAC in Vienna, MSF presented data from rural Thyolo, a district of Malawi, where MSF works with the Ministry of Health to provide HIV services at the primary health care level. In Thyolo district, universal access to treatment and care has been reached – meaning at least eight out of ten people in need receive ART – and between 2000 and 2007, a 37% reduction in the district's death rate was measured through death registers, coffin sales and church funerals. Death rates decreased over time as ART coverage increased. An estimated 10,156 deaths were averted in the district[ii] over an eight-year period.[19]

But decreased funding for ART is resulting in fewer treatment slots being available for an increasing number of people in need. Clinicians and nurses in some instances are faced with the agonising decision that comes with rationing care: choosing who gets to live and who doesn't. An example of this in Uganda serves as an alarm bell for what MSF is witnessing in several countries across sub-Saharan Africa.[20] A letter from the US Centers for Disease Control received by PEPFAR implementers in Uganda in October 2009 states that there will be no funding increases despite rising needs. And therefore, treatment providers should only enroll new patients on ART if people in the treatment programme die or are lost to follow-up. The letter outlines an "equitable system of triage" for ART slots, reserved only for the sickest patients, pregnant women, children, patients co-infected with TB and family members of those on ART. Rationing care will result in the waiting line for treatment getting longer as people paradoxically are forced to first become sick enough to be eligible for treatment. And many people may be lost to follow-up in the meantime.

Treatment Reserved for Those Who are Almost Dead

2. Delaying or Deferring Treatment Leads to Transmission, Illness and Death.

"Most of the people are still healthy when they initiate [treatment] now. It is easier for them to pick up faster, to get on ARVs. Before, they had to delay taking ARVs as they first had to treat TB or other opportunistic infections."
– Magerard Mochesane, Nurse, MSF Lesotho

Providing people with ART earlier, when their CD4 cell count [iii] is higher, keeps them healthier and out of hospitals, allowing them to live more productive lives, while improving their chances

ii Thyolo district population: 592,630 in 2007.
iii The CD4 cell count is a measure of the immune system's robustness.


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of survival. Earlier initiation at higher CD4 levels also supports earlier viral suppression, and thus reduces the likelihood of transmitting the virus to other people.[21] Further, an MSF study presented at the IAC found that people starting treatment at lower CD4 levels have higher rates of treatment failure, thus needing to switch to newer, more expensive drug regimens.[22] Early treatment thus makes clinical, social and economic sense.

In wealthy countries, people are initiated on treatment when their CD4 count drops to 350 cells/mm^3, or earlier. In developing countries, in contrast, people have typically only been started on treatment when the disease has progressed significantly, at a CD4 count of 200 cells/mm^3, or below. In late 2009, WHO revised its guidelines for initiation, moving the recommended threshold for developing countries from 200 to 350 cells/mm^3, in line with wealthy countries.[23]

Earlier initiation is feasible in HIV-endemic countries. Data presented at the IAC from MSF's ART project in Lesotho supports earlier initiation: patients initiated earlier were less likely to die and/or be lost to follow-up; hospitalisation rates were higher for patients initiated at a CD4 count below 200.[24] Providing treatment earlier thus frees up beds and limited staff time for other patients.

However, such a policy change, while clinically sound as well as cost effective,[25] is politically problematic: changing the eligibility criteria for treatment initiation also means that more people – 14 million instead of 10 million – are eligible for treatment, of whom only four million receive it. Addressing the ten-million-person treatment gap will demand vastly increased resources for ART scale-up.

With ART, Sharing Isn't Caring.


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3. Failing to Ensure a Stable Drug Supply Means Viral Load Shoots Through the Roof.

"If the drug is continuous dose, then you can't miss it. But when they tell you that the drugs are not there, you have to come back and it creates a lot of worries."
– Catherine Mango, PLWHA, Kenya

For ART to work, people must adhere to their treatment as much as possible – this means taking the right drugs at the right time. People on ART in endemic countries are as adherent to their treatment regimens as those in wealthy countries.[26] But if treatment is interrupted or not taken correctly, the virus is no longer adequately suppressed and thus allowed to multiply and weaken the immune system. People rapidly become sick again, and infections such as TB emerge and spread in the community. Additionally in such scenarios, drug-resistant strains of the virus can develop and be transmitted to others.

A commitment to adherence presupposes that there is a steady supply of ARVs available to patients. But with unstable funding come unstable drug supplies and even stock-outs. As a result, people may share ARVs, with devastating effects. Health workers manage supply shortages in various ways, either by switching

patients to other medicines that may have more side effects, by providing different dosages, or by giving patients ARVs for shorter time periods. The latter increases the burden on overworked health staff as well as on patients, who often have to travel long distances to reach clinics.[27]

MSF has witnessed an increasing number of supply disruptions in sub-Saharan Africa since 2009. In 2009 and 2010, MSF has had to regularly provide emergency supplies to public clinics in Mozambique, Malawi, Uganda and the DRC that previously relied on international donors for ARVs.[28] After the Malawian national treatment programme began experiencing stock-outs in 2009, MSF purchased ARVs for €375,000 to avoid treatment interruptions for its patients in Chiradzulu district, covering the needs for nine months.[29] Beyond MSF clinics, the organisation has been approached to provide emergency buffer stock to ministries of health and international and local NGOs in Malawi, Zimbabwe, the DRC, Kenya, Uganda, Guinea, and the Central African Republic.[30]

The Vicious Circle Returns


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4. Breaking the Promise of ART Means People Won't Come Forward to Get Tested.

"I would call it a moral betrayal because we will have failed our patients, who were told to get tested. And all the ones who tested positive, we promised them we'd provide treatment."
– Dr. Eric Goemaere, MSF South Africa

Despite persistent social stigma, people have come forward to get tested for HIV because of the increasing awareness that life-prolonging treatment is available to those who test positive. This promise of ART has been the cornerstone of reaching those in need through voluntary counselling and testing.

But if people are turned away from clinics that are forced to ration care, and unstable ARV supplies and stock-outs become commonplace, the promise of ART availability will have been broken. As this news spreads through communities, there will be little incentive for people to get tested. It has taken PLWHA groups and health workers years to establish a sense of trust in communities and to encourage people to know their HIV status. It may take even longer to re-establish the promise of ART if it is lost.

The Next Generation of AIDS Babies?


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5. Slowing AIDS Efforts Means Kids With AIDS Become Even More of an Afterthought.

"Children were the last to come onto the radar when it comes to treating HIV/AIDS, and they will be the first to fall off. We need to make sure that the response to AIDS for children becomes mainstreamed."

– Dr. Myrto Schaefer, Paediatric HIV Advisor, MSF

Children in developing countries have consistently lagged behind adults when it comes to HIV/AIDS treatment and care. First, child infections are almost entirely avoidable: successful measures to prevent mother-to-child transmission of the virus (PMTCT) have virtually eliminated paediatric AIDS in wealthy countries, where it is estimated that there were fewer than 200 new child infections in 2008.[31] Although there has been an improvement in access to PMTCT interventions for women in poor countries,[32] nearly half a million children were still newly infected in 2008.[33] WHO now recommends improved PMTCT protocols with HIV-positive pregnant women receiving full ART prophylaxis throughout the pregnancy and breastfeeding period. But without funding to increase outreach to expectant mothers and implement such new protocols, it is unlikely the number of babies born infected will decrease.

Second, because the market for paediatric AIDS treatment and diagnostics is concentrated in countries with limited ability to pay, the pharmaceutical industry does not prioritise the development of improved and adapted paediatric medicines and tests – there are far fewer options for children than for adults. Such a small and fragile market will be particularly vulnerable to funding instability, with a number of priority paediatric formulations identified by WHO likely not to be developed unless there is increased funding, or other incentives are created. And much less priority will be placed on developing urgently-needed diagnostic tests that would allow treatment providers to immediately see whether the virus has been passed from the mother to the newborn or not. Without such a tool, treatment providers must continue to perform testing that requires samples to be sent away to laboratories, with the risk that babies are lost to follow-up in the meantime. Decreased funding for AIDS will send a signal that paediatric AIDS is even less of a priority, which will have devastating effects on the effort to improve treatment and care for the youngest patients.

Why Quit When Things Were Just Taking Off?


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6. Limiting the Number of Facilities Offering ART Means it's Harder to Reach People in Urgent Need.

"People have to come more often to the clinics. Some of them are not from around here. They use vehicles to come to the clinic. If you don't have the transport you will have to put a lot of effort into how to get the fare. If you are told to go home and come back, then it will force you to look for another fare to come back to clinic. If you're working, it will make you lose some of the days that could be used for getting food for your children for example. So it makes you uncomfortable."
– Catherine Mango, PLWHA, Kenya

Bringing AIDS treatment close to where people live facilitates treatment scale-up to those in need and reduces the risk of losing patients to follow-up. It removes the need for patients to travel longer distances, which can be both expensive and disruptive to their lives, especially for the very sick. In Lesotho, more than 80% of primary health care facilities offer ART, and in Tete, Mozambique, care has been decentralised further to the community,[34] with significant benefits in terms of improved retention in care.

Further, medical tasks are 'shifted', allowing nurses to perform duties previously reserved for doctors, and lay health workers with specific training to perform functions otherwise reserved for nurses. In one of MSF's longest-running treatment programmes, in Khayelitsha, South Africa, 400 patients were initiated on ART in 2003, whereas after decentralisation and task shifting to nurses, 4,000 patients were initiated in 2009. Data presented at the IAC from MSF's treatment project in Malawi shows that nurse-delivered, decentralised care is leading to treatment outcomes as good as those of centralised care.[35]

Further data presented at the IAC shows that a new, simplified approach to decentralised care is being implemented by MSF in Malawi and Mozambique: stable patients who have been on ART for more than one year, are 95% adherent, have CD4 counts above 350 and show no signs of opportunistic infections go for medical checkups only once every six months.[36] They are provided with ARV refills in the interim and are followed for clinical evaluations every two to three months by health surveillance assistants – health workers who have received training for six weeks. This approach has reduced stable patient consultations by 25%, freeing up medical staff time for cases requiring more attentive care and follow-up, or for new patients. It has thus far shown good outcomes, and could be a way to reduce the number of people lost to follow-up.[37]

With external resources, Lesotho was able to make ART available in more than 80% of primary health care clinics.[38] Kenya and Malawi both have national plans to achieve universal access by 2012 through increasing the number of facilities offering ART. Kenya plans to increase the number of public sector facilities offering ART from 15% to 40%.[39] Malawi started with nine sites providing ART in 2003, jumped to 224 in 2009, and now plans to capacitate 65% of existing facilities to provide ART.[40] However, both countries are facing funding shortfalls, with little more than half of

the funding needed. Whether ART will be decentralised depends on the success of proposals to the GFATM and how well the GFATM is funded.

But putting a stop to ART scale-up by reducing funding will mean that fewer facilities offer ART. This will freeze availability of treatment, in an effort to ration care by placing limits on the number of access points. In many countries, decentralisation has yet to happen, and ART is only initiated by doctors, only at centralised facilities, and only accessible to those lucky enough to live nearby, or those who can afford transport. Without decentralisation, no treatment or financial gains can be made in freeing up medical staff time, thereby reducing the number of patients that can be reached and slowing ART scale-up.

Shutting Down the HIV/TB One-stop Shop Before it Even Opened.

7. Slowing Down the Integration of HIV and TB Care Means Patients Will Slip Through the Cracks.

"HIV and TB treatment and care must go hand in hand. Unfortunately, in most places, HIV and TB are still treated separately, even though it's one and the same patient who suffers from both diseases."
– Dr. Frauke Jochims, MSF

Tuberculosis remains the primary killer of people living with HIV/AIDS: an estimated one quarter of the people who died of TB in 2007 were co-infected with HIV – nearly half a million people.[41] Providing a package of TB and HIV services together in one clinic is critical to tackling the dual epidemic, but today, this integration has only barely begun to be implemented.

Data presented at the IAC from two MSF programmes where TB and HIV treatment and care have been integrated shows good results. In Swaziland, where HIV prevalence among adults is 26%, eight out of ten HIV-positive people are also co-infected with TB, and drug-resistant strains of TB (DR-TB) are significantly on the rise, posing major challenges to communities. In the rural Shiselweni region, MSF provides integrated HIV/TB care in 17 clinics. Case detection for TB improved greatly, from 58% to 87% during 2009, and DR-TB detection and treatment initiation doubled from 2008 to 2009.[42] A similar approach was taken by MSF in Lesotho, where undiagnosed TB was the number one killer of people living with HIV. TB and HIV care is provided at primary health centre level by nurses trained in HIV/TB care, including ART initiation, and HIV/TB lay counsellors are trained to give adherence support for both therapies. Because of high rates of HIV/TB co-infection, an aggressive screening process was put in place. In 2008, 93% of TB cases were tested for HIV (78% positive), of whom 81% received ART. The TB treatment success rate in co-infected and non-co-infected patients respectively was 65% and 77% in 2007 and 70% and 79% in 2008.[43]

These data show that decentralised, integrated TB/HIV care at primary care level improves access to treatment and outcomes,

and is a successful way to reach people affected by the dual epidemic in rural high-prevalence settings. However, a reduction in funding means that all services may suffer, further decelerating efforts to integrate HIV and TB treatment and care, allowing cases to continue to go undetected and TB to spread, posing a strain on already overburdened health clinics.

It's the Same Patient

8. Choosing Between Maternal & Child Health or AIDS Means Making a Fatal Choice.

"Primary care clinics are the pillar of most public health services in Africa. Inevitably, when you support the clinic, you support it in all its aspects. At population level in areas such as Thyolo in Malawi, or Khayelitsha in South Africa, we measure not only an HIV/AIDS-related mortality, but in the whole area, we see the entire mortality going down, which includes of course the maternal mortality and the paediatric mortality."
– Dr. Eric Goemaere, MSF South Africa

There has recently been a major move among donors to focus more on maternal and child health, and this has been used as one of the explanations for reductions in support for HIV/AIDS interventions. But in Africa's AIDS-devastated countries, child and maternal mortality is inextricably linked to HIV/AIDS. The main cause of death in women of childbearing age is AIDS, and over 40% of deaths of children under five in Swaziland, Botswana, Lesotho, Zimbabwe, Namibia, and South Africa are because of HIV/AIDS.[44]

Addressing HIV/AIDS has measurable positive benefits in other health areas. [45, 46] In particular, PMTCT programmes can lead to more women receiving maternal care. In MSF's treatment project in Thyolo, Malawi, PMTCT services, along with support to reproductive health care, led to a near doubling of the proportion of women giving birth in health centres, from 22% in 2006 to 41% in 2008.[47] In South Africa's Western Cape province, there was a 54% reduction in under-five child mortality at population level after comprehensive HIV/AIDS services were introduced. And after the introduction of PMTCT services in Khayelitsha, South Africa, MSF observed reductions in infant mortality from 43 per 1000 live births in 2001 to 30 per 1000 in 2007.[48]

MSF began integrating HIV/AIDS treatment and care into primary health care in some projects in 2005, after having provided HIV treatment and care in vertical projects since 2000. Data presented at the IAC comparing treatment outcomes from 2003-2009 in integrated and vertical programmes across nine countries in sub-Saharan Africa shows that outcomes in integrated programmes are similar to those in vertical programmes,[49] thus reinforcing the feasibility of providing ART as part of the basic health care package.

Donors who now want to shift the focus away from supporting HIV/AIDS treatment and care to maternal and child health are creating false choices and perpetuating a futile and divisive debate: we are talking about the same people. More funding should be allocated to global health rather than withdrawing support from one area to fund another.

Second-Class Care for the Poor?

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9. Continuing to Use Drugs With Side Effects Means Relegating Patients to Second-Class Care.

"On d4T, patients were getting large fat depots on their body. People feel better with TDF now, complaining less of side effects. As they vomit less, they don't need to repeat doses of their medication."

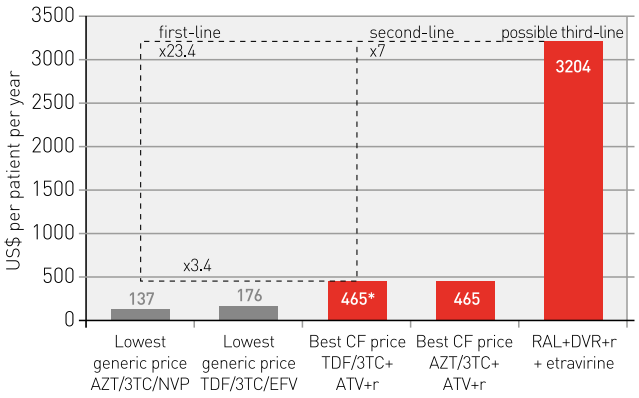
– Magerard Mochesane, Nurse, MSF Lesotho

People on AIDS treatment in developing countries should have access to newer, better treatment.[50] The drug stavudine (d4T), which is one component of the most-commonly-used ARV combination in developing countries, has significant side effects for patients. In MSF's project in Kigali, Rwanda, 16.6% of patients needed to be switched from stavudine after a median duration on treatment of 1.5 years because of side effects.[51] Increased toxicity-driven switches associated with stavudine have been documented in MSF programmes in South Africa[52] and Lesotho.[53] In place of stavudine, WHO now recommends patients ideally receive tenofovir (TDF)- or zidovudine (AZT)-based regimens. These are generally better tolerated, improving adherence and helping people stay on a first-line of treatment for as long as possible, before needing to be switched to more costly second-line drugs.

The most affordable generic TDF-based first-line regimen still costs $141 per patient per year (ppy). This is more than double the price of the older stavudine-based regimen ($67 ppy). History has shown that if the more expensive newer combinations are purchased in large volumes from multiple producers, prices will come down significantly.

Less-toxic drugs are not only better for people living with AIDS, they also cost less over time when one factors in the cost of managing side effects: fewer clinic visits, less need for testing and fewer hospitalisations. MSF's treatment project in Lesotho, which has the third highest HIV-prevalence rate in the world, has been providing TDF-based first-line ART since 2008. A cost-effectiveness analysis presented at the IAC of alternative first-line ART regimens based on primary clinic data from Lesotho showed that TDF would be cost-effective compared to d4T with anticipated price reductions.[54] These results are reassuring for countries considering introducing TDF in first-line ART.[55]

Failing treatment: a Return to Death Row?



*At the time of going to press, there is no TDF/3TC + ATV+r co-pack. The Clinton Foundation-negotiated price of the individual components of this package comes to $465. The Clinton Foundation (CF) expects the co-pack to be available by the end of 2010. At that stage its price is expected to drop to $425.

Price comparisons of first-lines, second-lines and possible third-lines.

10. Cutting Back on Funding for Treatment Means Sacrificing Long-term Survival.

"We have quite a lot of people who have prolonged their lives thanks to ARVs, and we need to keep them on ART for the rest of their lives."

– David Some, Clinical Officer, MSF Kenya

HIV/AIDS is a life-long disease and ensuring people's long-term survival on ART requires sustained commitment. Similar to other chronic diseases, people who have been on ART for several years inevitably need to switch treatment regimens to stay alive as drug resistance emerges. It is essential to switch people to a different drug combination at the right time – waiting until they become sick again may be too late.

In wealthy countries, a 20-year old starting ART can expect to live another 43 years on average.[56] But in HIV-endemic countries, there are two fundamental challenges to ensuring long-term survival: first, treatment failure is a hidden problem, because there are no point-of-care tests to determine a patient's viral load, which is the most important and sufficiently early measure of treatment failure. Today, viral load testing requires access to high-tech laboratory equipment that is often only found in countries' capitals. Further, viral load testing is expensive (up to $80 per test) in part because of company monopolies on the technology.[57] This means that treatment providers struggle with trying to diagnose when a patient is failing their treatment and may wait until clinical signs of illness recur.[58]

Second, switching people to newer drugs is very expensive, as these cost between three and seven times what a first-line regimen costs today.[59] And for patients who are already beginning to fail on their second-line regimen, options are extremely limited, with prices high and availability low – a third-line combination costs $3,200 per patient per year – seven times more than the cheapest second-line, and 48 times more than the cheapest first-line.[60]

Data presented at the IAC from 28 MSF-supported treatment sites in Africa and Asia underline the fact that these two difficulties combined mean delays in switching patients. Of 67,601 patients in the study, 18% met criteria used to define treatment failure after a median of 12 months on ART, but only 1.4% had switched regimens after nearly 26 months on treatment. Patients in rural areas in particular were less likely to switch regimens when they were failing, and had lower CD4 counts when switched.[61]

A commitment to providing universal access necessarily means providing people with the treatment they need to stay alive in the long run. Retreating from AIDS funding means shutting the door on treatment for life.

What needs to happen

The first decade of providing ART in resource-poor countries has shown that treatment is effective and has a dramatic impact on people's lives and communities. Now is not a time to throw away that progress. This means not only committing the funds needed to continue scaling up ART, but also to close the quality gaps that persist between AIDS treatment in rich and poor countries. It means adhering to WHO guidelines to start ART earlier, monitor patients' viral loads to ensure optimal treatment, and provide people with less-toxic drugs that improve treatment outcomes, as well as providing access to second- and third-line regimens and implementing PMTCT protocols. And it also means supporting models of care that have proven to work, and not pitting HIV/AIDS against other health priorities.

Although costs will increase in the short-term, these will be offset by the long-term payoff of healthier and more productive people. In light of the financial crisis, donors may be tempted to walk away from their commitments to provide universal access to AIDS treatment, turning their backs on clinically-sound interventions. But these policies are short-sighted and fail to take into account long-term payoffs, including savings in economic terms, as well as increased quality of life and quality outcomes. Donors must close the $20 billion funding gap at GFATM's October 2010 replenishment conference, and PEPFAR must put an end to flat-lining its budget.

With the number of people in need of ART projected to reach as many as 55 million by 2030,[62] we must ensure that donor funds are used to benefit the lives of as many people as possible – prices for newer ARVs must come down dramatically. Generic competition in countries where ARVs were not patented is what led to the cost of ARVs plummeting by more than 99% over the last decade, in large part making ART scale-up possible. But the World Trade Organization's TRIPS Agreement[63] is making the patenting of medicines more widespread in key production countries, such as Brazil and India, with all developing countries affected by 2016. Overcoming patent barriers for newer generations of AIDS drugs will require a range of different solutions: for example governments must make full use of TRIPS flexibilities, including routine use of compulsory licences and be supported by donor countries in doing so;[64] where possible, civil society and other groups must challenge inappropriate patents before or after they are granted; companies can increase access by putting their AIDS patents into the newly-established Medicines Patent Pool;[65] and wealthy countries should refrain from pressuring developing countries to include intellectual property measures that go beyond what the TRIPS Agreement requires, such as in the current free trade agreement under negotiation between India and the EU.[66]

In times of growing need, new and sustained sources of funding must be identified to help fill some of the funding gaps for HIV/AIDS, as well as other global health priorities. A number of innovative financing mechanisms are being discussed to recoup some of the losses governments experienced as a result of the economic contraction and the bank and industry bailouts. One such proposal is a financial transaction tax currently being promoted by the European Union. But a share of the funds raised by such a levy must be earmarked to global health issues such as nutrition, HIV/AIDS treatment and tuberculosis research. For HIV/AIDS specifically, there are compelling reasons to support such a tax: substantial and sustained funding is needed to scale up ART and end the AIDS epidemic, and AIDS can't be victim to changes in political and financial support.

HIV/AIDS continues to be a global emergency requiring an emergency response. But barely four years after promising to provide support to put all people on treatment, donors have begun questioning the affordability of universal access. The epidemic already claims more than two million lives each year, but a reduction in support will add many more lives to this glaring statistic. It is not too late for donors to re-engage.

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66 More info on the India/EU FTA available at: www.msfaccess.org/main/access-patents/free-trade-agreements/

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