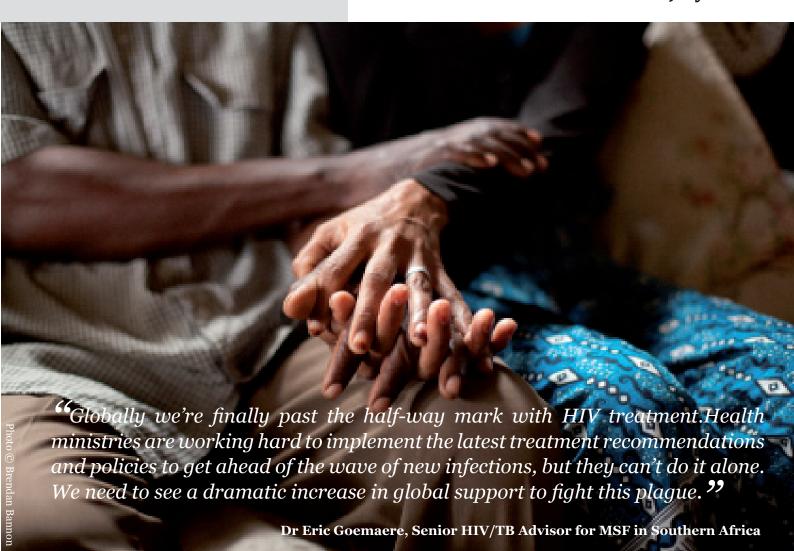


Progress under threat

Perspectives on the HIV treatment gap

Democratic Republic of Congo Guinea Malawi Mozambique Zimbabwe While significant gains made in the fight against HIV/AIDS in the past decade are encouraging, countries most affected by the pandemic continue to struggle to place enough people on treatment and to implement the best science and strategies to fight the disease. The current situation in these five affected countries reminds us that the HIV epidemic is still an emergency in many African countries.

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Democratic Republic of Congo: HIV treatment out of reach for majority

In Democratic Republic of Congo (DRC), the outlook for HIV treatment looks particularly grim. Both government and donors have abandoned patients in need, and are in danger of contributing to yet another crisis in an already troubled country.

The Global Fund to Fights AIDS, Tuberculosis and Malaria (GF), which remains the main antiretroviral (ARV) treatment funder in the country, faces not only a shortfall in funding availability, but also important management and disbursement issues that undermine the existing capacity to assure continued treatment and much-needed scale-up.

These funding problems have already undermined patients' access to free ARVs in DRC. While some of the issues at the GF are being addressed, there is a need for additional efforts by the government and by international donors.

However, donors such as US President's Emergency Plan for AIDS Relief (PEPFAR), the World Bank and UNITAID/Clinton Health Access Initiative (CHAI) are limiting or phasing out their financial support for ARV purchase. Meanwhile health donors such as the European Union, its member states and the World Bank have no concrete engagements for the coming years to invest in financial support of ARV treatment. Most have pushed the responsibility for improving ARV coverage onto the GF. However, in a country like DRC, where the context is fragile and the territory is vast, leaving a single donor with the responsibility for essential treatment supplies creates the additional risk that programmes, supply lines, testing and treatment will be interrupted.

DRC's civil society has mobilised to request the allocation of a fair share of domestic resources to effective and free HIV/AIDS treatment. The stakes are high, in particular because of conditions of counterpart financing required by several donors, such as the GF and PEPFAR. Initial reports on the 2012 budget indicate that approximately US\$7 million will be allocated to HIV/AIDS, which can be read as an encouraging signal.

- An estimated 1,000,000 people are living with HIV in DRC. However, because it is not classified as a high prevalence country for HIV, patients in DRC are perceived as less of a priority for HIV/ AIDS funding.
- 430,000 people are in urgent need of ARV treatment, but coverage is among the lowest worldwide at 12.3 percent (in sub-Saharan Africa, only Somalia and Sudan have similar rates).
- ARV treatment is available in only 444 health centres across the country, or 11% of the health centres targeted in the national plan.
- Fewer than six percent of HIV-positive mothers have access to ARV drugs to prevent their children from becoming infected.
- Providing care for patients on time is hampered by poor access to health services, a shortage of free diagnostic tests for HIV and CD4 counts, and by people having to pay for healthcare.
- Besides poor access to testing and treatment, efforts to prevent and treat HIV are jeopardised by regular shortages of condoms, laboratory tests, ARV drugs and medicines for treating opportunistic infections.

What is at stake?

- Without significant change, there will be further rationing of treatment initiation, increased risks of treatment interruption (bringing about the need for second-line treatment and hence more costs), and there will be a further decline in the operational capacity of non-governmental treatment providers.
- Because patients cannot access treatment in time, by the time that they arrive at MSF-supported clinics, it is often too late: many are terminally ill and struggling with serious medical complications a situation reminiscent of the pre-ARV era.
- As funds shrink, the Ministry of Health faces the almost impossible task of implementing the new WHO guidelines, which recommend starting treatment on time and with better drugs. Better suited prevention of mother-to-child transmission (PMTCT) options (B or B+) also remain out of reach.
- The lack of ARV treatment has led to HIV testing being slowed down. The 2010 plan to test more than four million people failed to reach even 300,000 people.
- Without additional engagement by international donors, ARV coverage will remain below 25% in 2015.
- UNITAID's commitment to provide paediatric ARVs will run out by the end of 2012.
- Continuity of treatment for eligible women in the PEPFAR-supported PMTCT programme remains fragile because of the lack of PEPFAR financing of the purchase of ARVs after 18 months. In practice these women need to switch to GF-supported ARV treatment sites in or outside their home areas.

- Financial barriers preventing people from accessing crucial care are likely to increase. Already NGOs that previously provided free ARVs are now asking patients to pay. Meanwhile people must pay US\$15 to US\$25 to have their CD4 count tested, and cannot start treatment before they find the money. In a country where more than 70 percent of people live on less than a dollar a day, these fees exclude the majority of people with HIV.
- If the GF remains the main and potentially only financial contributor to ARV treatment, programmes and treatment continuity will be extremely vulnerable to disruption.

It's something of a vicious circle because, to have access to ARVs, you've got to test. But testing isn't available for most Congolese. It should be elementary, whether for the general population or for pregnant women. That's not the case in DRC and, with most of the donors pulling out, I think we are just going to sink into despair.

Dr Maria Machako Centre Hospitalier de Kabinda, DRC

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Guinea:

Ignored HIV crisis and insufficient treatment for those in need

Guinea, a country whose income is among the lowest in the world, faces an HIV epidemic that remains largely ignored by the rest of the world. The current Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) grants cannot provide treatment in line with the existing needs. Initiation rates have been halved to even lower levels. The continuity of treatment for at least 11,000 patients is not assured, due to delays in disbursement that threaten interruption of antiretroviral (ARV) supplies. In the absence of other international donors investing in HIV treatment, patients arrive at health facilities in late and aggravated stages of the disease.

The government has been offering antiretroviral (ARV) treatment since 2003. While it is keen to lead the fight against HIV/AIDS − having increased its contributions with a disbursement of €1.2 million in 2011 and €1.3 million planned in 2012 − the government's financial resources for HIV treatment are limited.

Guinea has an external debt of up to US\$3.2 billion, and there are international constraints to keep public spending for the social sector low. As a result, funding for health – and specifically for HIV care – remains inadequate. The health budget for 2011 was 3.8% of the overall national budget – far below the 15% target of the Abuja Declaration.

Few international donors are willing to support HIV care. Guinea relies heavily on the GF, which funded up to 50% of the country's ARV drugs in 2011. However, as GF monies are restricted and cannot cover the existing needs, agencies such as Médecins Sans Frontières (MSF), the German Development Corporation (GIZ) and the NGO Dream have had to step in and fund the remaining half of ARV treatments provided today.

What is at stake?

■ The present GF grant (Round 6, phase II), which funds HIV treatment for 11,000 patients, will end in December 2012. Continued purchase of ARV drugs for these patients is foreseen under Round 10, but disbursements have been delayed and, without them, orders have been equally delayed. Taking into account a usual gap of six months between order and arrival, the current delays threaten to create a countrywide stock-out from January 2013, with subsequent interruption of treatment for 11,000 patients.

- HIV prevalence was estimated at 1.5% in 2005.
- An estimated 67,300 adults and 11,300 children are living with HIV/AIDS.
- Official figures estimate that 22,935 (or 57%) of the people who need it are receiving ARV treatment, but this is probably an overestimate.
- Children are neglected, with only 1,097 children receiving ARV treatment in 2011, out of 6,607 in need of ARVs.
- Only four out of 10 mothers access prevention of mother-to-child transmission (PMTCT) – again, this is probably an overestimate.
- Only one health facility in the entire country offers an early diagnosis service for testing infants.
- Guinea applied for and was granted funds through GF Round 10, but used a cautious approach, with the budget request only partially covering the existing needs. The intention was to apply again in Round 11.
- The number of ARV initiations in the Round 10 proposal is extremely limited, with fewer than 110 initiations per month in the entire country, about half of the average initiation rate during Round

- 6. To put this into perspective, MSF alone provides treatment initiation for 120 patients per month in not more than six health facilities in Conakry. As a consequence, the scale up of ARV treatment is being jeopardised.
- Faced with insufficient funding availability under Round 10, agencies such as GIZ, Dream and MSF cannot access ARVs funded by the Global Fund to alleviate the high financial burden they face of around half of the patients on treatment in Guinea. MSF and GIZ face immediate difficulties in continuing treatment for 4,000 patients from early 2013.
- The combined effect is that, without additional funding, the country's treatment target will be missed for 12,430 patients by 2013.
- Due to the limited number of initiations, patients eligible for ARV treatment are being turned away. Patients have to wait longer to start the treatment, and are thus likely to present with more complications and a greater risk of dying before receiving access to lifesaving medication. Apart from the medical consequences, this puts an additional burden on patients, staff and the health system.
- Guinea was not eligible to apply for an HIV grant under the GF's Transitional Funding Mechanism (TFM), and will have to wait until at least 2014 for a new funding opportunity with the GF.
- Despite the government's declaration in 2007 that ARVs, the treatment of opportunistic infections, CD4 count and viral load testing would be free of charge, access remains challenging due to the lack of funding and stock ruptures, and patients have had to pay to access treatment for opportunistic infections since September 2011.
- In 2011, Guinea adopted the latest WHO guidelines to provide timely ARV treatment at a

CD4 count of 350 instead of at a CD4 count of 250. However, today most patients are still initiated on a clinical basis at a late stage, as the coverage of CD4 count machines remains very low at only 28%.

- Due to cost reasons at the time, Guinea adopted zidovudine (AZT) as first-line treatment. The improved, tenofovir-based (TDF) regimens are not available in Guinea.
- Although implementing psychosocial care is part of the national strategic plan, it is still non-existent in Guinean health facilities, due to funding constraints and a lack of expertise.

Because of the limited availability of ARVs, I have had to refuse daily patients who come to me in need of treatment. This constitutes an immense ethical problem to me - as a medical doctor and as a human being.

Dr Bah Elhadj Mamadou MSF doctor, communal medical centre Matam, Conakry

Worrying. Due to the absence of biological monitoring and the dysfunctional supply chain, we fear the emergence of first-line treatment resistance. This resistance could lead to many treatment failures and increase significantly the cost of care, due to the high cost of second-line treatment.

Mamadou Sawadogo President of West African PLWHA network

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Malawi:

Pioneering progress in HIV treatment threatened by uncertain funding situation

Malawi, one of the world's least developed countries, is among the top ten countries with the highest HIV prevalence worldwide. It is also the first country worldwide to implement the progressive prevention of mother-to-child transmission option PMTCT B+. But with donors retreating from HIV funding, the country is at high risk of reversing the progress made.

With an ambitious national programme, and thanks to the country's public health approach to the epidemic, which includes simplified treatment protocols and task-shifting amongst healthcare workers, significant progress has been made in the fight against HIV over recent years. As a result, people's access to treatment has increased substantially, and HIV prevalence appears to be decreasing.

Yet the country is almost entirely dependent on external funding for its HIV response. While Malawi supports at least five percent of its HIV programme through staffing, infrastructure and other expenses, 100 percent of its antiretroviral (ARV) drugs come from the Global Fund to Fight AIDS, Malaria and Tuberculosis (GF). This almost exclusive reliance on a single donor makes Malawi extremely vulnerable to funding cuts or delays.

Malawi's existing GF grant, which pays for ARVs plus the majority of the country's HIV response

including lifesaving ARVs, expires in early 2014. TThe resources will need to be raised for an estimated 450,000 to 500,000 people anticipated to be on treatment by then, as well as to ensure new initiations are not halted, with an estimated bill of US\$500 million for five years for ARVs aloneonly. Funding will also be needed to ensure the switch from the old regimen d4T (stavudine) to the better tolerated and more easily administered tenofovir (TDF) for all peoplepatients on d4T today. willis also be needed.

Realistically, this almost exclusive dependence on a single donor is unlikely to change without some effort. Other major actors in the HIV response are hesitant to enter into ARV treatment provision. Even though involved in other areas in the HIV response, PEPFAR in Malawi does not support regular ARV procurement, nor does the pooled Sector Wide Approach (SWAp) fund. Meanwhile CHAI/UNITAID is planning to phase out its provision of paediatric ARVs by the end of 2012.

- An estimated 960,000 people (or 10.6% of the adult population) are living with HIV.
- By the end of March 2012, 347,983 people were receiving ARV treatment.
- While Malawi offers ARVs to all children under the age of two, only 19 to 24% of eligible children are receiving them.
- The country suffers from major shortages of health staff, with vacancy rates of 65 percent, on average, amongst key cadres of healthcare workers.
- Retaining current healthcare workers in the public health sector will soon become a major challenge, as the GF grant that supported them with a 52 percent salary top-up allowance has run out, and the economic situation in the country is highly unstable. There is no clear plan, nor any commitment by the government or any donor, to support phasing in regular salary structures.

What is at stake?

- Malawi has adopted the latest WHO guidelines to provide early ARV treatment (CD4 count <350) and has adopted tenofovir (TDF), the first-line drug recommended by the WHO. However, due to funding shortfalls, Malawi has had to make difficult choices, and now only offers TDF to selected patient groups: pregnant women; TB/HIV co-infected patients; and patients with severe side effects.
- In order to protect infants and benefit maternal health, Malawi has adopted new national guidelines to include lifelong treatment for all HIV-positive expectant and lactating mothers (B+) the first country to do so worldwide. Continued funding needs to be secured in order to ensure these plans are successful and can continue.
- Malawi has adopted viral load monitoring so as to be able to switch patients failing on treatment in a timely manner and avoid drug resistance; however, implementing and rolling this out is dependent on increased funding.
- Malawi failed to secure funding through GF Round 10, partly because its plans — which included full implementation of all WHO recommendations on HIV treatment, as well as prevention through

- male circumcision were deemed too ambitious. Despite this, and despite the cancellation of Round 11, it has still managed to start implementing at least part of these plans through reprogramming existing money.
- With donors' money hard to find, governments like Malawi's are being pushed to increase resources to pay for their own HIV response. However, the burden is still too high for the country to be able to move quickly enough. For 2011, ARVs alone cost about US\$60 million, compared to the country's total health budget of US\$90 million. This cost cannot be absorbed in the short term. This was also confirmed in a study commissioned by UNAIDS that concluded that, even if all innovative financing mechanisms (airline levies, private sector mainstreaming, etc) were implemented in Malawi, the money raised would only cover 17% of the total estimated HIV financing gap expected by 2020/21. By then, even with all these alternative sources in place, the financing gap is expected to reach US\$348 million. This translates to 4.5% of Malawi's GDP, or 16.4% of overall government annual expenditure (source: Sustainable Financing for HIV/AIDS in Malawi, Oxford Policy Management, March 2012).

We're committed to implementing programmes based on recent scientific progress. Yet just as success is within reach, we're up against a great financial squeeze. I truly believe that we can end AIDS. But we can't do it alone.

Stuart Chuka Ministry of Health

National ART Programme Officer from Malawi's Ministry of Health

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Mozambique:

Ambitions in HIV policy clash with challenges in implementation

Mozambique's HIV response has been slightly slower than other countries in the region, with just under 45 percent of those who need it currently on HIV treatment. However, robust efforts have been made recently to include in the national HIV programme constructive plans to bring ARV coverage up to 80 percent within the next few years. This includes introducing tenofovir (TDF) as the standard treatment regimen, initiating patients on treatment at an earlier stage (CD4 count <350), and providing lifelong treatment for all HIV-positive expectant and lactating mothers to prevent mother-to-child transmission (PMTCT B+). However, donor funding and support will be crucial to ensure that implementation can take place.

Moving HIV/AIDS care out of the clinic and managing patient within their communities is increasingly recognised by policymakers as an effective strategy. In Mozambique's Tete province, this can be seen in the successful pilot of Community ART Groups (CAGs), whereby a group of HIV-positive people share the burden of collecting their monthly supply of antiretrovirals (ARVs) from

distant clinics on a rotational basis. This model has had highly successful outcomes, with only 0.2% of 1,384 patients being lost to follow up. The Ministry of Health (MoH) has decided to roll out CAGs across the country, while the MoHs of neighbouring Malawi and Zimbabwe have visited the programme to assess its feasibility for their own settings.

Facts and figures

- An estimated 270,000 of the 615,000 people who need it are receiving ARV treatment (44% ARV coverage).
- 23,000 (or 19%) of the 119,000 children who need it are receiving ARV treatment.
- Government spending on health accounts for 7% of Mozambique's budget.
- 96% of Mozambique's HIV budget is donor-funded (the majority by the GF and PEPFAR).
- Mozambique's total budget needs for ARVs alone are US\$75 million for 2013 and US\$95 million for 2014.

What is at stake?

- The government has recently approved recommendations for, among others: Option B+; tenofovir in a simplified fixed-dosed combination as the first-line regimen; and viral load as the monitoring tool. However, implementing these will depend on the availability of funding.
- Mozambique is willing to increase its current ARV treatment coverage targets for 2015 to 80% coverage (close to 600,000 people) but, again, can only do so if money is made available. Allowing nurses to initiate ARVs will be a crucial element of the strategy to achieve this target. Mozambique is still the only country in the region where this form of task-shifting is not permitted.
- There are plans to further integrate HIV and TB care to alleviate the burden of HIV/TB co-infection.
- Because funding through Round 9 of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) was not released on time, Mozambique had to submit an emergency request of US\$16 million

for ARVs in September 2011, of which only US\$10 million has arrived. Its Round 10 grant proposal was rejected, and Mozambique was not eligible to apply either for Round 11 or for the Transitional Funding Mechanism (TFM) for its HIV programme, since it still had unspent funds in its Round 9 grant. Although the US President's Emergency Plan For AIDS Relief (PEPFAR) is continuing its support to Mozambique, funding by the World Bank and Clinton Health Access Initiative (CHAI) will run out next year. Unless other funding can be found or existing funding is increased, implementing the improved guidelines and expanding access to ARVs may be forced to be slowed down.

■ Mozambique's TB programme is also under threat, due to the cancellation of GF Round 11, as Mozambique was eligible for TB grants. The situation is now more critical, since Round 10 – which included plans on treatment and diagnosis expansion for multidrug-resistant TB (MDR-TB) – was rejected. The country is reliant on Round 7 for first and second-line drugs and reagents for its TB programme until June 2013. However, the reagents funding line was not approved, and Round 7 was disbursed only recently; Mozambique is hoping that this delay will not cause another stock-out, as happened at the beginning of this year. The World Bank recently agreed to finance part of the reagents for the TB programme for 2012 as the situation is so critical.

For mid-2013 onwards, Mozambique applied for the GF's Transitional Funding Mechanism (TFM) for its TB programme, hoping that it would be covered until mid-2015. Although Mozambique has now increased its capacity to diagnose MDR-TB, it will be difficult to guarantee the supply of vital MDR-TB drugs because the TFM does not allow for scaling up treatment. Besides the possibility of the government of Mozambique covering part of the cost for TB and MDR-TB treatment, there are no other donors foreseen as likely to contribute to the national TB programme from 2013 onwards.

I come from a country where, tragically, for every five children in need of HIV treatment, four are not receiving it. We want to see our government increasing its contribution for health, but at the same time donors cannot walk away from their commitments and abandon the thousands of men, women and children in Mozambique whose lives are at risk, as we cannot save them alone.

Linda Chongo (MONASO) Representative of Mozambique's Movimento de Advocacia da Sociedade Civil

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Zimbabwe:

Success story at risk as country scrambles to cover HIV treatment gap

Despite having the third-highest HIV burden in southern Africa, Zimbabwe has achieved positive results over recent years by taking purposeful steps to improve its HIV/AIDS programmes. However, the funding shortfall is likely to result in shortages of antiretroviral (ARV) drugs which threatens to affect almost 70,000 patients in 2012.

The immediate funding gaps in Zimbabwe are due to the transitioning out of a pooled donor fund (the Expanded Support Programme) by the end of 2011. Funding for ARVs was not part of the new basket fund initiative (Health Transition Fund/HTF), as the assumption was that providing ARVs for the supported ARV cohort would be done with domestic and Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) support. However, despite the fact that Zimbabwe's AIDS levy currently pays for over 25% of its ARVs, it has not yet been possible to close the treatment gap.

The critical treatment gap, together with the international push for African countries to find domestic solutions, has led to a public debate on introducing user fees for those patients who can afford to pay for their treatment. After continuous advocacy from civil society and other actors, donors such as US President's Emergency Fund for AIDS Relief (PEPFAR) and the Department for

International Development (DfID) are now trying to help close the HIV treatment gap; however, most of these efforts will not be felt until later this year or early next year.

In the meantime, national buffer stocks are currently being depleted to cover some of the shortages, while GF money allocated for later during the grant's time period (2014) has been requested in order to build up the buffer stocks again, only shifting the burden forwards to the future. The country currently receives approximately 50% of its ARVs (covering about 193,500 patients) through the GF's Round 8, which will run out at the end of 2014. By that time, the treatment gap will have increased to an estimated 428,068 people eligible for treatment who will be unable to access ARVs. The GF will need to address a significant part of this shortfall, while additional funds to continue initiating new patients on ARV treatment also need to be ensured.

- One million adults (or 14% of adults) are living with HIV.
- 150,000 children are living with HIV.
- ARV treatment coverage has grown from just 5% in 2006, to 77% among adults and 39% among children in May 2012, according to the Ministry of Health and Child Welfare, with 435,000 adults and 41,000 children under treatment.
- ARV treatment is now available in 616 of the country's public health facilities, up from only 32 in 2006.
- Expanded ARV coverage has reduced annual AIDS deaths by 42% since 2006.

What is at stake?

- Zimbabwe has adopted the latest World Health Organization (WHO) guidelines to provide early ARV treatment (at a CD4 count of 350) and to provide short-course ARVs during pregnancy to reduce the transmission of HIV from mother to child (PMCTC)
- Zimbabwe has expanded HIV paediatric testing by increasing early infant diagnosis sites from only four in 2008 to 900 by the end of 2011. It hopes to continue expanding it to all the 1,560 facilities in the country in order to increase the percentage of infants diagnosed and treated.
- Zimbabwe has plans for ARV treatment to be available to 85% of those in need by the end of 2012. This would mean reducing annual deaths by a further 27%. However, this will require ARVs; lab commodities; support to upgrade rural health facilities into static start-up sites; and progress in the task-shifting policy that will authorise nurses to initiate adults and children on treatment.
- Targets were set to circumcise 1.2 million men by 2015, resulting in an estimated 25-35% reduction in HIV transmission. With the cancellation of Round

- 11, targets have been revised to cover just 15% of the male population by 2015.
- Zimbabwe wants to implement the WHO-recommended first-line treatment tenofovir (TDF) for all patients, but so far only a limited subgroup of patients (HIV-positive pregnant women and patients co-infected with TB) have been initiated on the better-tolerated drug. The phased approach aims to have 50% of patients on TDF and 50% on the old regimen d4T (stavudine) by the end of 2012, and to have 100% of patients on TDF by the end of 2013.
- Whereas no gap is foreseen in paediatric HIV treatment in 2012, about 12,800 children eligible for ARV treatment are at risk of not receiving it by 2013.
- Depletion of buffer stocks has led to patients needing to return to clinics on a more frequent basis (weekly or fortnightly), instead of once every two months. This has increased the burden on patients in terms of travel costs and time, which is known to be a key barrier for patients' adherence to treatment. It is also a burden on the health system, as more staff are needed to attend to more patient visits. This situation will continue for the coming months.

We have been supporting Zimbabwe's national HIV response for more than 10 years and have seen remarkable progress over that time. There is a genuine commitment on national level in the fight against HIV/AIDS. Domestic resources are mobilised through a special AIDS levy, new WHO recommendations have been adapted into national policy, and incredible headway has been made in access to treatment. But external funding is still needed to continue on the path taken, and it's tragic to see the progress made risked being stopped in its tracks, or worse, reversed.

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