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MSF Issue Brief : Threats to HIV treatment scale-up

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ur toolkit for fighting HIV/AIDS has improved drastically from the start of the global HIV epidemic. With new diagnostic tools and more effective drug regimens, the curve of this epidemic can and will be bent. World leaders have made ambitious political commitments, by adopting the Sustainable Development Goals (SDGs) in 2015 “to end the AIDS epidemic by 2030.” However, to achieve any further progress, action is required now.

The gains of the past decade must be accelerated and continue to evolve to produce flexible solutions to tackle new obstacles. There is an urgent need for countries to adopt new and more effective approaches: nearly half of all people living with HIV (PLHIV) are yet to be initiated on treatment and new research has found that progress in reducing new HIV infections has been slowing down. Over the past 10 years, 74 countries saw an increase in rates of new infections.¹ Undoubtedly, this epidemic continues to pose a threat to millions of people each year.

To stem the HIV epidemic, UNAIDS estimates that overall US\$ 26 billion annually will be needed by 2020, declining to US\$ 24 billion by 2030.² UN agencies and research institutes are thus calling for an additional US\$7 billion per year. Yet, while domestic investments in the HIV response have seen a steady increase globally, donor funding is decreasing, from US\$ 8.6 billion in 2014 to US\$7.5 billion in 2015.³

ADVANCES IN MEDICAL APPROACHES TO HIV

More immediate treatment initiation

New approaches have been developed in the past few years to more effectively treat people diagnosed with HIV. The “test and start” approach to treatment, recommended by the World Health Organisation (WHO), ensures that no people are lost between diagnosis and drug initiation by offering treatment immediately after they test positive. It is a simplified strategy to accelerate antiretroviral (ART) scale-up in particular in low ART-coverage countries, conflict/unstable settings, and hard-to-reach groups in high-prevalent settings. Early ART initiation reduces the risk of sexual transmission by 96%⁴ and reduces

AIDS, severe non-AIDS events and deaths by 57%.⁵ Additionally, ART reduces TB incidence by 65%, the most prevalent opportunistic infection in people living with HIV.⁶ New point-of-care early infant diagnosis (POC EID) technologies that can be used at the peripheral level have been shown to significantly reduce the time to deliver test results from several weeks to just one day.⁷ These tests are therefore crucial to reducing infant loss to follow-up along the cascade of care, and facilitating immediate ART initiation for infants.⁸



Exploring alternative drug regimens

ART regimens lead to uneven adherence because of a host of factors: dangerous side-effects, high cost, and poor monitoring of drug efficacy, among others. Countries must continue to adopt new technologies that are more effective in mitigating the negative effects of these barriers to adherence. Dolutegravir (DTG), a new ART drug with the potential to improve the daily treatment regimens of millions of patients, is recommended as an alternative first-line treatment to efavirenz (EFV) in the current WHO-consolidated ART guidelines.⁹ DTG-based treatment could lower the price of ART, since it is effective at only a 50mg dose. Once-daily DTG has a higher resistance barrier, stronger viral suppression and better tolerability than EFV. Further research is needed on DTG dosing and efficacy during pregnancy and breastfeeding, and in TB patients.¹⁰ By July 2017, there should be a large enough database of pregnant women treated with DTG for a first review of birth outcomes and congenital anomalies.¹¹ However, the current evidence for the safety and efficacy of DTG is not yet considered strong enough to justify its widespread introduction in Low and Middle Income Countries (LMICs).

More effective monitoring of disease progression

Viral load (VL) monitoring provides patients and clinicians with critical data to measure treatment efficacy and craft appropriate adherence support programmes before treatment failure due to drug resistance occurs. VL results can act as a powerful motivational tool that contributes to long-term retention in care and treatment adherence, as health improvements can be more easily measured.¹² Many countries have adopted VL testing as national policy, but coverage remains low, e.g. at the end of 2016, VL coverage rates in Malawi were estimated at 30-40%.¹³ Due to resource limitations, variations in both the frequency of testing and the threshold for action have been adapted across countries.¹⁴ Towards the end of 2016, PEPFAR released results for their population-based HIV Impact Assessment studies. Overall, their results show reduced HIV incidence with a treatment cascade of 72.7% diagnosed, 88.6% on treatment and 90.8% virally suppressed in Malawi; and 74.2% diagnosed, 86.8% on treatment and 86.5% virally suppressed in Zimbabwe.¹⁵ However, we see a lack of targeted interventions for those with high VLs, e.g. enhanced adherence counselling or timely switch to second or third line drugs. The decision-making process to switch high VL clients to second- or third-line treatment remains highly centralised and needs to be decentralised and task shifted.¹⁶



Better detection and treatment of opportunistic infections (OIs):

TB LAM is a point-of-care (POC) urine test with a quick turnaround time and considerable diagnostic potential. Unfortunately, the future supply is threatened; Alere's minimum volume to justify continued production is 35,000 tests per

month/420,000 per year. Treatment of cryptococcal meningitis (CM) with liposomal amphotericin (LAMB) is better tolerated than the conventional formulation, but largely unavailable across low and middle-income countries. It could potentially be used as a high-dose (10mg/kg) one-time injection, in combination with 14 days of high-dose fluconazole.¹⁷ This can reduce hospitalisation for treatment. MSF requests Gilead to make affordable quality-assured LAMB available for LMICs with a high burden of CM and consider technology transfer to generic producers. MSF recommends treatment of Kaposi sarcoma (KS) with pegylated liposomal doxorubicin (PLD), which is better tolerated than the treatment combinations most likely to be used in low-resource settings. Access to PLD in countries with high prevalence of KS is limited by price, lack of registration and worldwide shortage of product.

There is a lack of interest in CD4 monitoring at initiation and when PLHIV become severely ill. Yet, CD4 monitoring is the best predictor of mortality for PLWH and allows for quick identification of advanced disease and helps to development a guide for the management of the disease.

WEST AND CENTRAL AFRICA (WCA): EXAMPLE OF GLOBAL NEGLECT

The region of West and Central Africa has often been overlooked in international HIV efforts, yet this large population has 6.5 million people living with HIV (18% of the global HIV burden), and accounts for 22% of new HIV infections, 27% of deaths by HIV/AIDS and 43% of children born with HIV (UNAIDS 2014).¹⁸ Huge disparities exist in the treatment cascades for the WCA region (36% diagnosed, 28% on treatment and 12% confirmed as virally suppressed) compared to the Eastern and Southern African region (62%, 54% and 45%).¹⁹ There is a marked lack of access to ARTs in the region: only 28% of patients have access to the essential medicines they need, and this number drops to only 2 in 10 for children.²⁰ Access barriers include service failures such as weak supply chain, lack of trained staff, centralised and overmedicalised HIV care, stigma, patient fees/payments and weak involvement of CSOs.

For example, in MSF-supported hospitals in CAR, our teams report that 25-29% of hospitalised patients suffer HIV-related illness, while an



estimated 84% of all intra-hospital deaths are due to HIV. In the MSF-supported HIV ward in Kabinda hospital in Kinshasa, one in four HIV inpatients does not survive because they arrive very ill.²¹ We will not reach our global HIV goals without giving an urgent boost to this neglected region.

TRouBLING TRENDs IN THE DONOR AND GLOBAL HEALTH ACTOR LANDSCAPE

Shaky ground for HIV treatment scale-up as the US considers budget cuts

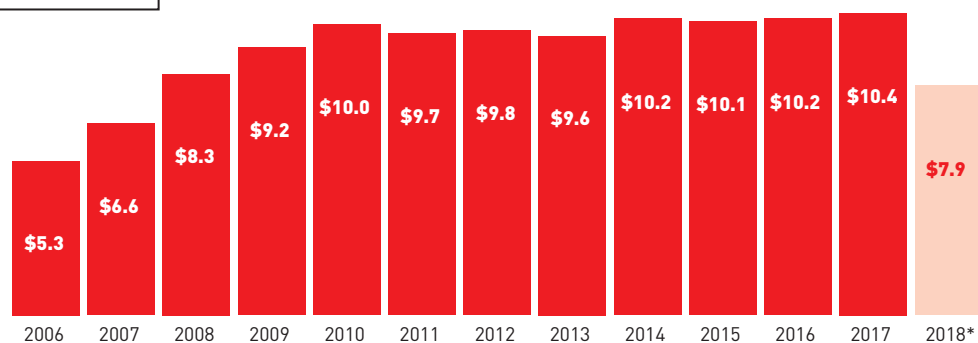
On May 22 2017, the federal budget proposed by the White House consisted of plans to cut US\$ 1 billion from global AIDS programmes, representing 17% cuts to the Global Fund to Fight AIDS, TB and Malaria (GFATM) and 11% cut to the President's Emergency Plan for AIDS Relief (PEPFAR). Currently, PEPFAR provides treatment to one in four people with HIV globally.²² The budget would prioritise 12 countries, none of which have been named yet.²³ Cuts to GFATM could mean nearly 300,000 additional lives lost per year, and a

potential 4.28 million new HIV, TB and malaria infections. Cuts to PEPFAR could lead to approximately 250,000 people experiencing disruptions in their treatment and 40,000 additional AIDS-related deaths.²⁴ Furthermore, the Global Gag Rule reinstated by President Trump will extend to PEPFAR and other global health programmes. The Global Gag Rule, a ban on providing US foreign aid to any health organisation that provides family planning or abortion services, has serious consequences for HIV prevention and treatment services.²⁵

Future expectations for the Global Fund

The pledges made by donors at the GFATM replenishment conference in September 2016 reached US\$12.9 billion, just short of the modest target of US\$ 13 billion set by GFATM.²⁶ With overall stagnating funding for country programs in the next funding cycle (2018-2020) and an allocation policy that increasingly focuses on poorest countries with highest disease burden, only a small sub-set of high prevalence countries will see a noticeable increase in funding compared to funds available in the previous cycle. However, in many of these countries, a significant portion of the grants will need to be used for purchase of commodities. For example, 70% of Zimbabwe's funding allocation goes to the purchase of commodities.²⁷ This often leaves significant funding gaps for critical areas such as community responses for targeted testing activities and for improving treatment adherence, and health system strengthening such as in-country supply chain, health workers and other human resources. For many of the countries classified as middle-income, such as Myanmar, and countries with lower disease burden, such as many countries in West and

U.S. Global Health Funding, FY 2006-FY 2018*
In Billions



* FY18 represents the budget request only.

Source : Kaiser Family Foundation analysis of data from the Office of Management and Budget, Agency Congressional Budget Justifications, Congressional Appropriations Bills, And U.S Foreign Assistance Dashboard.

Central Africa, the funding will be either flat lined or be reduced²⁸ - leaving little room for expanding access and improving quality. In Central African Republic (CAR), where the number on treatment has more than doubled from 2013 to 2016 despite significant challenges, the funding allocation is insufficient to ensure continued treatment even for those already on ART, let alone for those still waiting to start.

Donors are relying upon governments to do more with less

International donors refer to a “resource-constrained environment” when announcing cuts or restrictions to their future global health contributions. They instead raise their expectations for developing countries to more rapidly finance their own healthcare and in particular in countries with increasing Gross National Income (GNI) per capita. UNAIDS’ projections of annual HIV funding that expect a 450% increase in domestic funding by 2020 in LICs and 530% for LMICs appear highly unrealistic, given the political and economic context for many of these countries.²⁹

Many countries face important economic challenges, which are affecting existing public sector budgets and reduce the possibility of mobilising additional resources for health. In several African countries economic growth is stalling, linked to falling prices and of certain export commodities and the impact of extreme climate (e.g. El Niño) on agriculture.

- Cuts in health budgets in the Republic of Congo-Brazzaville have led to shortfalls in government purchase of ART and other essential medicines.³⁰
- In Zimbabwe the income generated through the “AIDS levy”, used to fund ARVs, has stagnated and shortfalls in the health budget have in recent years hampered purchase of essential medicines.³¹
- In Mozambique the public health budget suffered immensely from the country’s wider economic problems and from the cuts in international funding following the ‘secret loans’ scandal; as a consequence budgets are strained and the health services struggle to assure transport for drugs and referrals, food for inpatients and outreach activities.
- Since 2014, Malawi, one of the most donor dependent countries in the world (90% of funds for the HIV response come from donors), has experienced significant, rapid donor withdrawal. Under pressure to mobilise more domestic funds,

Malawi is considering expanding the use of paying wards in central and district hospitals and has already implemented other out-of-pocket strategies such as “by-pass fees.” A recent investigation into the feasibility of a National Health Insurance Scheme for the country has ruled that option out because of the extreme poverty of the bulk of the population and small number of people in the formal sector.

It is clear that in these circumstances in many countries, where health budgets and other social sectors are under severe strain, expectations for quick domestic resource mobilisation might be overoptimistic and possibly lead to reluctance or inability to expand or continue existing health programmes that are accessible and equitable, including for vulnerable, marginalised people or non-nationals. Several international institutions and donors cite the potential of “innovative financing” from the private and bank sectors as an alternative to public funds through grants, but without necessarily considering debt sustainability or the appropriateness and accessibility of such mechanisms for non-governmental actors.³²

The predicament of middle-income countries

Middle-income countries (MICs) face the triple bind of higher prices, trade-related intellectual property laws (TRIPS), and less donor support. GNI per capita is not an adequate indicator for assessing health needs and the need for international assistance. Middle-income countries are home to the majority of people affected by HIV (and TB) and access to health care is often limited and inequitable. However, most donors and donor agencies continue to rely on this blunt measure for aid allocations, leading to rapid disengagement while in particular programs for key populations and access to affordable medicines are not yet covered by domestic funding mechanisms.

For example, the Eastern Europe Central Asia (EECA) region is the only region where the HIV epidemic continued to rise rapidly, with a 57% increase in annual new HIV infections between 2010 and 2015. In 2015 in the region, only 67% of people living with HIV knew their status, 21% of people living with HIV were on ART, and 19% of people with HIV were confirmed as virally suppressed. In 2015, more than 80% of the region’s new HIV infections were in the Russian Federation, and an additional 15% in Belarus, Kazakhstan, the Republic of Moldova, Tajikistan and Ukraine.³³

WHAT IS AT STAKE: A CALL TO ACTION

Actions taken now by global leaders will be a test of their resolve to live up to their public commitments to “end the AIDS epidemic by 2030”. There are no shortcuts to curb this epidemic: to reach national and global goals, donor and affected governments must increase their financial commitments towards strategies that we know will work to combat the epidemic. Falling short on investments will not only seriously undermine progress, but also will be costly, both financially and in terms of human lives lost.

MSF calls for:

- **Science and evidence not to be ignored:** countries must implement Test and Start and viral load monitoring. Community service delivery and differentiated models of care must be scaled up and adherence counselling must become a minimum standard. Better ART regimens must become financially feasible and available at scale. Countries should develop innovative strategies to target and treat those currently being left behind, e.g. by combatting stigma and addressing financial barriers that block access for patients.
- **A donor commitment tailored to the urgent need to reduce treatment gaps and the spread of HIV.** The current trend of stagnation and decline in international funding for HIV and health is deeply worrying at this crucial period in the fight against HIV/AIDS. Domestic funds increases should bring additional funding and not be used to mitigate and compensate for reductions in international donor support. Specific international funding targets allowing global annual increases in people on treatment are needed, including for the next Global Fund replenishment in 2019. Reaching the global targets relies on accelerated scale-up of access to ARTs for all countries, and this will not be achieved with the current levels of funding.
- **World leaders to stay committed to fight the HIV epidemic, in every region and every country,** not allowing people in lower-prevalence and middle-income countries to fall behind.

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