THE GLOBAL FUND: PROGRESS AT RISK.

Opportunities and obstacles in the fight against TB and TB-HIV
The Global Fund to Fight AIDS, Tuberculosis and Malaria has had a profound effect on the tuberculosis (TB) epidemic, fundamentally transforming capacity to respond to a disease that takes the lives of 1.5 million people every year.

In order for the Global Fund to continue its progress in the fight against TB and TB-HIV, ACTION recommends:

- **Additional resources** – including a robust new replenishment in 2013 – are urgently needed from both current and new donors to ensure the Global Fund can achieve the targets in its new strategy.

- Governments should support **innovative financing mechanisms** to raise additional and sustainable resources to support global health priorities.

- A **new funding opportunity** is immediately needed to allow countries to scale-up TB-HIV services, MDR-TB treatment, quality DOTS² treatment, and to implement new technology.

- The Global Fund’s new funding model should ensure meaningful engagement by all country stakeholders in proposal development and implementation, be driven by quality expression of country demand (based on global best practices and standards taking into account investments by other donors and through national budgets), reward ambition and results, and leverage domestic investments.

- Affected country governments and their political leaders must lead the fight against TB and TB-HIV through financial and political commitments to accelerate the response.
The Global Fund: Progress at risk
Opportunities and obstacles in the fight against TB and TB-HIV

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Before the Global Fund, TB programs suffered from decades of neglect. In the last 10 years, Global Fund funding has made it possible for countries and implementing partners to detect and treat 9.3 million cases of TB. The Global Fund is also a leader in the fight against TB-HIV co-infection and has made it possible for 2.4 million people living with HIV to receive TB screening, treatment, and prevention services.

As the world’s largest external funder of TB care and control, the Global Fund’s continued and strengthened support remains critical to reducing and eventually eliminating TB as a leading killer.

Progress at risk

In November 2011, the Global Fund board cancelled Round 11, its 11th call for proposals to fight the three diseases. The sudden uncertainty of funding highlighted the fragility of efforts to fight TB, and the critical role that the Global Fund has played in the last decade. Without a process for submitting new applications to the Global Fund for ongoing work and scale-up, efforts to combat TB and TB-HIV co-infection are increasingly at risk.

To mitigate the impact of the cancellation and prevent disruption of some existing programs, the Global Fund established a Transitional Funding Mechanism (TFM) in late 2011. The TFM however, was not intended to serve as more than a temporary stop-gap measure, and did not include resources to treat new patients or scale-up critical new tools. Although final approval of TFM applications is pending, it is expected that only about 20 percent of the $616 million that countries applied for under the mechanism will go to TB, the leading killer of people living with HIV.

In May 2012, updates to Global Fund financial forecasts enabled by changes in Global Fund recipient countries and changes by U.S. and other donors in disbursing previous commitments allowed the Global Fund to commit to “turning the tap back on” by September 2012, with the goal of getting resources flowing to countries again by April 2013.

Getting resources flowing again will enable the Global Fund to accelerate the implementation of their bold new strategy to save 10 million lives by 2016. Uncertainty remains, however, and the improved funding forecast alone will not enable the Global Fund to capture critical opportunities now for major wins in fighting TB and TB-HIV. More resources are imperative.

COUNTRIES STILL FEELING IMPACT OF CANCELLATION OF ROUND 11

The World Health Organization estimates each person with untreated TB infects 10–15 people every year. The Stop TB Partnership estimates that if no immediate action is taken to increase funding for TB, as many as 3.4 million fewer TB patients will be treated over the next five years, which means an estimated 1.7 million people may die as a result.
Opportunities and risk: What’s at stake?

Several key opportunities exist to save lives and realize the ambitious Global Fund strategy, including increasing access to DOTS, treating more patients with multidrug-resistant TB (MDR-TB) – a dangerous form of TB that is resistant to two or more of the most powerful anti-TB drugs – and enrolling HIV co-infected TB patients on antiretroviral therapy (ART).

The Global Fund must be able to continue to work with countries to invest more strategically. This will enable countries to focus on high-impact interventions, implementation of new technology, and coordination of investments with other sectors. Better integrating TB and TB-HIV services with maternal and child health services for example, will enable more testing and treatment of women with TB and HIV, which remain leading killers of women worldwide.

Opportunity: Prevent TB deaths among people living with HIV

TB was declared an emergency in Africa seven years ago and remains one of the biggest public health threats of our time. Over the past decade, Global Fund resources have provided millions of people living with HIV access to ART, which suppresses the disease and enables people to live longer.

TB remains a major threat to people living with HIV, whose compromised immunity makes them more susceptible to developing active TB. The two diseases form a lethal combination, each speeding each other’s progression. TB is responsible for one in four HIV-related deaths, making TB the leading killer of people with HIV.

Fortunately, TB is curable and many of these deaths can be prevented. Modeling from the Stop TB Partnership shows that scaling up investments in proven TB-HIV interventions could reduce TB deaths in people living with HIV by 80 percent and save an additional one million lives by 2015.

The Global Fund has set explicit health targets in its new strategy, which will depend on support from current donors, new donors, and country stakeholders. Additional resources from a robust new replenishment and the development of innovative financing mechanisms are critical.

To ensure these resources are used as strategically as possible, the Global Fund board has mandated the development of a new funding model. This funding model must be driven by countries’ real needs, bold ambition, and interventions that will have demonstrable impact against the epidemics.

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Risk: Uncertainty stalling demand for scale-up

Many countries were planning to use financing from Round 11 to scale-up access to TB-HIV services. The cancellation of Round 11 and delays in accessing new funding has forced plans to scale-up TB treatment and prevention to be postponed.

- In Zambia, 65 percent of people with TB are HIV positive. Round 11 was seen as a critical opportunity to strengthen TB-HIV services. The Zambia hoped to improve case finding, scale-up TB diagnosis using mobile technology in remote areas, and increase the number of people on IPT. Failure to fund these services will threaten recent hard-won progress in reducing HIV-related deaths.

- The Malawian government has plans to expand TB treatment to 15,000 children over the next five years. These plans are now on hold.

- Africa’s newest country, South Sudan, hoped to use Round 11 to build its health system and strengthen national surveillance systems for TB and HIV. South Sudan continues to wait for a funding opportunity to support this work.

- To increase access to TB-HIV services, Swaziland sought funding from the Global Fund to increase the number of rural nurses and community health workers to help scale-up treatment. Without a new funding opportunity, strategies such as these will remain unfunded.

Opportunity: Fight drug-resistant TB

Over the last few years, innovative new technologies have emerged that could transform the fight against MDR-TB. In 2010, the World Health Organization approved a new TB diagnostic called GeneXpert. The Global Fund’s 11th round of funding would have been the first funding round since this approval and would have provided the first big opportunity for many countries to purchase GeneXpert.

A study in South Africa found that a national roll-out of GeneXpert would increase the number of MDR-TB cases diagnosed by as much as 71 percent.
Instead of waiting days or weeks for results, GeneXpert detects TB in less than ninety minutes, allowing people to be put on treatment that same day. Since, drug resistance occurs when medication is taken incorrectly or stopped prematurely, a fast, accurate diagnosis is critical to preventing drug resistance. A study in South Africa found that a national roll-out of GeneXpert would increase the number of MDR-TB cases diagnosed by as much as 71 percent.\textsuperscript{25}

GeneXpert can also more easily detect TB in people living with HIV, who are more vulnerable to the disease, preventing more dangerous cases of co-infection. Investing in improvements of TB programs broadly, and in particular, in scale-up of new diagnostics will allow more patients to receive appropriate treatment earlier and stop the spread of the disease.

To adequately fight the spread of TB and MDR-TB – airborne diseases without respect for political and economic borders – the Global Fund, affected countries, and implementing partners must be able to scale-up efforts everywhere.

**Risk: Drug resistant TB continues to grow**

Failure to adequately finance and manage TB programs has fueled the rise of MDR-TB, making it an entirely ‘man-made’ disease. Continued neglect of TB programs, including MDR-TB care and treatment, is leading to increasing numbers of MDR-TB as well as cases of extremely drug-resistant TB (XDR-TB), which is resistant to both first and second-line drugs. Cases of XDR-TB are exponentially more costly to treat, highly fatal, and threaten to take us back sixty years when TB was incurable. In January 2012, doctors in India identified twelve cases of drug resistant TB that may be totally resistant to all available drugs.\textsuperscript{27}

The number of MDR-TB cases increased to an estimated 650,000 in 2010.\textsuperscript{28} Eastern Europe and Central Asia are home to the highest rates of MDR-TB, and in Southern Africa MDR-TB and HIV have collided with devastating results. In the first reported outbreak of XDR-TB in a rural area of South Africa with high HIV

**Combating Multidrug-resistant TB**

Radu Stefan lives in Romania, which relies on the Global Fund to supply costly MDR-TB medication. In six months, the country’s grant will run out. Stefan fears the medicine will run out as well. In June 2011 Stefan became so sick with MDR-TB that he was forced to leave his job and delay his wedding. MDR-TB can require up to two years of difficult treatment including terrible side-effects from the medication. Stefan now worries his suffering may all have been in vain.

Without increased support from the Global Fund, Stefan worries patients like him will lose access to life saving TB treatment. “This will be a disaster. It will be like we went through torture for nothing. I will be TB positive again. In a few years I’ll die.”

Silvia Asandi, the head of Romanian Angel Appeal Foundation,\textsuperscript{29} believes poor and marginalized people in middle-income countries like Romania, will be some of the first casualties of the Round 11 cancellation and subsequent funding uncertainty. Without new funding, rates of MDR-TB will increase and Asandi estimates at least 1,000 Romanians with MDR-TB will go undiagnosed and continue to spread the disease. Asandi is unaware of other groups who could fill the gap. She notes, “no other donors apart from the Global Fund are providing financial support for our TB program.”

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Neichu Angami, Technical Specialist/Advisor for United Nations Development Program on MDR-TB Treatment and Prevention, Myanmar.\textsuperscript{26}
rates, 52 of the 53 patients died. Yet globally, only one in twenty TB cases is tested for drug resistance. Of the patients detected with MDR-TB, only 16 percent receive proper treatment. The rest go undiagnosed, are improperly treated, and continue to spread drug resistant strains of the disease.

The Global Fund is the largest external donor for MDR-TB programs, but a major funding gap remains. Many countries were hoping to use Round 11 to expand detection and treatment for MDR-TB to close the gaps mentioned above. New resources are immediately needed to halt and reverse the spread of MDR-TB.

Sierra Leone has a waiting list for patients with MDR-TB to enroll in treatment. The country was planning to use Round 11 financing to provide treatment to these patients.

Myanmar planned to use Round 11 to expand MDR-TB detection and treatment. Currently, only two percent of MDR-TB patients in Myanmar are receiving treatment. Myanmar plans included starting 10,000 new patients on treatment over the next five years. There is currently no funding for this treatment.

Fourteen percent of new TB cases in Uzbekistan are drug resistant. The country was relying on Round 11 to scale-up MDR-TB testing and treatment. Without a new funding opportunity, these plans risk being shelved.

In Belarus, 26 percent of new TB cases are drug resistant. Belarus planned to use Round 11 to purchase six GeneXpert machines, each of which can run up to 400 tests per day.

Opportunity: Implement new technology, support development of new tools and drugs

Investments in new TB technology are critical. Over the last few years, transformational new diagnostics have emerged that have the ability to alter the global response to TB. In 2010, less than one in twenty TB cases were tested for drug resistance. GeneXpert, if rolled out, could slash these numbers and by dramatically increasing accurate testing prevent the spread of MDR-TB.

Additional new tools and medicines, including new TB drugs and drug combinations, are also on the horizon. The current TB drug regimen was developed more than 40 years ago and requires at least six months of treatment – two years for MDR-TB. Shorter, simpler treatments are being developed and are currently in late stage clinical trials. These new drugs have the potential to reduce the suffering of people who have TB, reduce the burden on the health system, and reduce the economic impact of TB more broadly.

The current TB vaccine, BCG, is only partially effective and does not guard against the most common form of TB, which affects the lungs. Furthermore, children with HIV are unable to receive the BCG vaccine because it can make them sick. New TB vaccines are being developed that guard against all forms of TB and can be given to patients living with HIV, including one vaccine candidate currently being tested in South Africa. New funding must be secured to keep these innovations on track and ensure countries have the resources to roll out these new tools and technologies when they are complete.

Risk: Breakthroughs on hold, lives lost

Despite these breakthroughs and opportunities for new drugs and diagnostics, in most of the developing world, TB is still diagnosed using culture technology that is 130 years old. This old technology fails to detect the disease in 1.8 million people every year, many of whom are HIV-positive. Unlike the old TB test, GeneXpert not only identifies drug resistance, but also more accurately diagnoses TB in people living with HIV.

Many countries planned on using Round 11 to acquire GeneXpert. In Malawi, where 63 percent of TB cases occur in people living with HIV, making them more difficult to diagnose, the government planned to use Round 11 funding for 16 GeneXpert machines. Malawi is one of many countries that had to postpone purchasing this new technology. Delays in implementing new testing and treatment technology put thousands more lives at risk.

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The future of the Global Fund: A new funding model, accelerated progress

The Global Fund’s new strategy must have the resources behind it to capitalize on opportunities in TB-HIV, MDR-TB, and new technologies in addition to continuing and scaling-up existing TB and TB-HIV programs.

The Global Fund Board has mandated the development of a new funding model to replace the rounds system, and consultations will take place throughout June-August 2012.

The new funding model must reinforce and enhance current strengths of the Global Fund by allowing countries to analyze the latest critical innovations, identify gaps in services, and describe their full needs. The new funding model must reward ambition and results, involve all stakeholders, and leverage domestic investment. Done well, the new funding model will improve country strategies, meet country needs, and accelerate progress on all three diseases.

Suggested funding models which include pre-determined country funding ‘envelopes,’ or a set of interventions prioritized from the top-down, are counterproductive. These approaches would limit ambition and distort investments by leading countries to request what they think will be made available to them, rather than what they need to fight the epidemics in their particular context.

Despite the extreme challenges of poorer countries, 74 percent of new TB cases occur in middle-income countries. Strategic investments in middle-income countries should continue, particularly to address the needs of the most vulnerable and marginalized populations.

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Conclusions and Recommendations

Ten years ago, the Global Fund did not exist. TB programs suffered vast inattention. Millions lacked access to inexpensive drugs that would have saved their lives. Global Fund support has turned the tide on TB, AIDS, and malaria to the extent that experts and engaged policy-makers are now discussing and planning for the end of the three diseases.

End of AIDS
Zero TB Deaths
Elimination of Malaria

What was impossible has become possible, thanks to the Global Fund, its donors, supporters, and the work of affected countries.

THE REVOLUTIONARY PROGRESS OF THE GLOBAL FUND MUST CONTINUE.

#oneinfour  #endofaids  #fundthefund
IN ORDER FOR THE GLOBAL FUND TO CONTINUE ITS PROGRESS IN THE FIGHT AGAINST TB AND TB-HIV, ACTION RECOMMENDS:

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- Governments should support **innovative financing mechanisms** to raise additional and sustainable resources to support global health priorities.

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treatment, and to implement new technology.

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Endnotes


2. DOTS, which originally stood for directly observed treatment, short-course, is the WHO TB control strategy including: government commitment, case detection, standardized treatment, regular drug supply, and a standardized reporting system.


5. Domestic governments provide 86 percent of funding for TB programs. The rest comes from external sources, the largest of which is The Global Fund, which provides 82 percent of donor funding for TB. Global TB Control, 2011.


7. Some countries, including China, have offered to support domestic projects to free-up cash for more pressing needs elsewhere.


10. These figures do not take into account funding from the TFM.


19. Evidence from an unpublished survey conducted by the Stop TB Partnership suggests that Zambia will face a disruption to current TB services with the cancellation of round 11.


24. Also called Xpert MTB/RIF or Xpert.


26. Email conversation on May 1, 2012 with Neichu Angami, Technical Specialist/Advisor for UNDP and UNOPS on MDR-TB Treatment and Prevention in Myanmar.


33. Unpublished data from the Stop TB Partnership.


38. The benchmark for MDR-TB laboratory capacity is at least one laboratory capable of performing culture and drug susceptibility testing per five million people.


40. Bacille Calmette-Guérin.


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