



Investing in our future

The Global Fund

To Fight AIDS, Tuberculosis and Malaria

**Eighteenth Board Meeting
New Delhi, India, 7 – 8 November 2008**

**GF/B18/13
Decision**

**BUILDING AND SUSTAINING A TUBERCULOSIS RESPONSE TO ACHIEVE THE
MDG AND STOP TB PARTNERSHIP TARGETS.**

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This paper is a follow-up to the discussion the Board considered at its 16th Meeting on the issue of ensuring the Global Fund acts as a strategic and responsible investor and is focused on tuberculosis. The paper was prepared by the Stop TB Partnership at the request of the Chair and Vice-Chair of the Board. The decision point is offered by the Board Chair and Vice-Chair.

PART 1: INTRODUCTION

1. The World Health Organization (WHO) estimates that in 2006 there were 9.2 million new cases of active tuberculosis and 1.7 million deaths.¹ One-third of the world population is infected with *Mycobacterium tuberculosis* and, therefore, at risk of developing active disease. Although it is preventable and curable, Tuberculosis is a leading cause of adult mortality in low- and middle-income countries, ranking third after HIV and ischaemic heart disease as a cause of death among people aged 15-59 years.² Tuberculosis is a major killer of men, women, and children and its effect is greatest for the most poor and vulnerable, including migrating workers, ethnic minorities, refugees and prisoners. TB illness can initiate a cascade of ill effects for families including lost income, children taken out of school and social stigma.

2. Nearly half a million cases of tuberculosis are estimated to harbour multidrug-resistant strains of *M tuberculosis*, i.e., resistant to at least the two most powerful first-line drugs (isoniazid and rifampicin). Of those, 40,000 are estimated to be resistant to the most powerful second-line drugs; the resulting highly lethal form is named extensively drug-resistant tuberculosis or XDR-TB. At least 709,000 cases of tuberculosis are estimated to be co-infected with HIV, 85% of them in Sub-Saharan Africa. Tuberculosis is the leading killer of people living with HIV/AIDS.

3. The Stop TB Partnership is a global coalition of more than 700 partners worldwide strongly committed to fight and eliminate tuberculosis as a public health problem. The Partnership's Global Plan to Stop TB (The Global Plan) is a road map for policy makers and programme managers. Underpinned by the WHO's Stop TB Strategy,³ the Global Plan sets out the actions needed to control tuberculosis to achieve the MDG target of reversing TB incidence, and to halve mortality and prevalence rates by 2015. A World Bank study has estimated that the benefits of implementing the Global Plan exceed the cost by a factor of 15 in the 22 high-burden endemic countries.⁴

4. A great deal of progress has been achieved in the last few years. The average number of new smear-positive (infectious) cases of tuberculosis detected and reported under DOTS-based programmes globally has increased significantly from an annual average of 134 000 cases in the period 1995-2000 to over 243,000 cases in the period 2001-2006.¹ Treatment success has reached an impressive 85% globally. Major efforts on research & development for new tools against tuberculosis by Stop TB Partners have seen steady growth in the pipeline for new diagnostics, drugs, and vaccines.⁵ New diagnostics for tuberculosis, for instance those related to rapid detection of MDR-TB, are now becoming available and significant roll out should happen within the next two years.

¹ World Health Organization. Global tuberculosis control: surveillance, planning, financing. WHO Report 2008. WHO/HTM/TB/2008.393

² Lopez AD, et al. Global burden of disease and risk factors. New York: Oxford University Press and World Bank; 2006.

³ The Stop TB Strategy components: 1. pursue high-quality DOTS expansion and enhancement; 2. address TB/HIV, MDR-TB and other challenges; 3. contribute to health system strengthening; 4. engage all care providers; 5. empower people with TB and communities; 6. enable and promote research. From: Raviglione MC, Uplekar M. WHO's new StopTB Strategy. Lancet 2006; 367: 952-955.

⁴ Economic benefit of tuberculosis control. Policy Research Working Paper 4295. The World Bank, 2007.

⁵ Maher D, Dye C, Floyd K, Pantoja A, et al. Planning to improve global health: the next decade of tuberculosis control. Bull World Health Organ 2007; 85(5):341-7.

5. Several challenges threaten full achievement of 2015 targets (see below table). Drug-resistant tuberculosis including MDR/XDR-TB, HIV/AIDS, slowing progress in tuberculosis case detection in some of the highest burden countries, outdated tools,⁶ and weaknesses in health systems (e.g., access to services, human resources, fragile laboratory networks, weak reporting systems for tuberculosis cases and deaths, procurement bottlenecks,) are some of the most pressing challenges in-need of rapid and ambitious action.

MILLENNIUM DEVELOPMENT GOAL 6
"have halted by 2015 and
begun to reverse the incidence.."

Stop TB Partnership – Global Plan Targets

	Target for 2015	Targets for 2010	Status (as of 2007)
Prevalence	50% of ≈ 300/100K (1990)	187	219
Deaths	50% of ≈ 30/100K (1990)	20	25
Case detection (70%)*	84% for new smear- positive cases	78%	61%
Treatment success (85%)*	87%	86%	85%
MDR-TB (% of cases enrolled on treatment)	100%	100% (27 priority countries)	9%
TB/HIV (%of people with TB screened for HIV in Africa)	85%	81%	20%

* In 1991 the World Health Assembly set two targets for tuberculosis control to be achieved by 2005: to detect 70% of cases and to cure 85% of sputum-smear positive patients with pulmonary tuberculosis. It is estimated that these are the minimum outcome levels countries need to achieve and sustain in order to generate impact over the tuberculosis incidence, prevalence and mortality.

6. While this paper does not aim to detail all the available evidence on the aforementioned challenges, it is worth highlighting some critical areas. As of 2007, 38% of the estimated 9.2 million new cases of tuberculosis do not have access to proper diagnosis, prevention and care services as described in the DOTS approach, the main component of the Stop TB Strategy (table). More than two thirds (71%) of the missing cases are estimated to be living in Africa, India and China. This suggests the need for countries to scale up innovative interventions (e.g., laboratory strengthening, engagement of all providers, community involvement, advocacy and social mobilisation) to accelerate the finding of the missing cases.

7. MDR/XDR-TB and TB/HIV are the two greatest threats to tuberculosis control. Life-saving interventions are available but their implementation in countries is well behind Global Plan target. Current plans for 2008 suggest that only 9% of the estimated

⁶ Current diagnostic test is more than 100 years old; current vaccine is almost 100 years old and does not protect against the most common forms of the disease (pulmonary); and the last drug against tuberculosis was introduced almost 50 years ago. While the pipeline for new tools is steadily growing, it is not expected that new treatments and vaccines will be available for at least the next 3-8 years.

490,000 cases will be treated for MDR. At this pace the target for universal access for the 27 priority countries will not be met.

8. A similar situation exists for TB/HIV collaborative activities. The most challenging problem relating to TB/HIV collaborative activities is the scale up of interventions to reduce the burden of tuberculosis in people living with HIV. The Global Plan target for 2006 was to screen 11 million HIV-positive people for tuberculosis disease; the actual figure reported was 314,211. Only 27,000 HIV-positive people without active tuberculosis were started on isoniazid-preventive therapy, almost all of whom were in Botswana. From the tuberculosis programme side there has been greater progress but still well below targets. Preliminary data indicate that in 2007 in Africa 64,000 people with tuberculosis who tested positive for HIV were placed on antiretroviral treatment, a substantial increase with regard to 2006 but still short of the 157,000 targeted in the Global Plan. Similarly 75% of people with tuberculosis who tested positive for HIV were put under preventive treatment with cotrimoxazole, short of the targeted 90%. All this is a clear indication of the speed at which these important interventions should be rolled out if robust plans and budgets are forecasted.

PART 2: THE GLOBAL FUND AND TUBERCULOSIS

1. Funding for tuberculosis control from endemic and donor countries has substantially increased from US\$644 million in 2002 to US\$2.7 billion in 2008. Endemic countries continue to provide the bulk (two-thirds) of the funding for tuberculosis control. Yet the estimated annual financial gap (at least US\$ 1 billion)⁷, after endemic and donors funds are considered, to implement the Global Plan to Stop TB at country level is to be met. This gap is likely to increase substantially over the years if scale-up is undertaken by countries. This gap also suggests that country plans and assessments of funding requirements are not fully aligned with the Global Plan. Substantial collaboration, especially in Africa, to develop medium-term costed TB control plans that are ratcheted up to invest to achieve the 2010 and 2015 targets, and that can be used for future Global Fund project proposal, disease strategy proposals and to be embedded in national health plans/strategies.

2. The Global Fund is the largest single financier of tuberculosis control today, accounting for two thirds of all external development assistance for tuberculosis control. The Global Fund has recommended 2.2 US\$ billion upper ceiling for funding in seven rounds of funding. By mid-2008, Global Fund-supported programs detected and treated 3.9 million additional cases of infectious tuberculosis. In spite of this success, Global Fund financing is not sufficiently filling the gap in financing needed to achieve goals - and this links to demand as expressed in more ambitious project proposals - especially with regards to TB/HIV and MDR-TB interventions, as well as innovations to reduce the case detection gap. Also, only 14% of the total funding committed by the Global Fund goes to tuberculosis, as compared to 25% for malaria and 61% for HIV/AIDS.

⁷ The gap is estimated based on the latest data available to WHO and is likely to increase once all data from 2008 data collection process becomes available. The gap reported does not including funding gaps for technical assistance.

3. Recognizing that health systems weaknesses and gaps can impact the achievement of improved outcomes for the three diseases, the Global Fund has decided to allow the inclusion of health systems strengthening activities in the proposals through a disease-specific program approach or a cross-disease approach that benefits more than one of the three diseases. Several health systems areas of weakness in-need of dramatic scale-up relate to tuberculosis. These include: the strengthening and upgrading of laboratories with new diagnostic tools to detect drug resistant tuberculosis; b) improvement of surveillance systems for tuberculosis; c) speeding/addressing procurement processes and bottlenecks; and increasing novel recruitment, retention and distribution of health workers including community-based workers to increase case detection and ensure quality care.

4. Working with countries to encourage more comprehensive, bold Global Fund tuberculosis proposals and national strategy applications that address the most critical gaps in tuberculosis treatment scale-up could substantially help to mitigate the financial gap for tuberculosis control at country level and scale-up of Global Plan activities aimed at increasing case detection, TB/HIV collaborative activities, drug-resistant TB and health system core areas such as laboratory strengthening, procurement bottlenecks [to ensure high quality first- and second-line drugs and roll out of new diagnostics] for tuberculosis, human resources, and improved surveillance.

Stop TB Partnership support to the Global Fund

5. The Stop TB Partnership aims at supporting country implementation to maximize funding opportunities from the Global Fund through several mechanisms including the TB Technical Assistance Mechanism (TBTEAM), the Global Drug Facility (GDF), the Green Light Committee (GLC), and high-level advocacy. Equally important, the Partnership brings around the table an umbrella of partners fully ready to support countries.

TB Technical Assistance Mechanism (TBTEAM)

6. In November 2005 the Stop TB Partnership Coordinating Board created TBTEAM to help countries to access high quality well-coordinated technical assistance. TBTEAM facilitates, coordinates, aligns, and harmonizes the efforts of technical assistance partners at global, regional and country levels in order to optimize the use of resources and to reinforce and strengthen national programmes. This built on a history since before 2000 of technical assistance partners supporting countries to develop coherent medium-term national TB control plans and to implement them. Led and coordinated by WHO, within the Stop TB Partnership Working Group on DOTS-Expansion, TBTEAM provides strategic and technical assistance to countries for tuberculosis control management, including the preparation of mid-term national and strategic plans to reach the MDGs and of proposals for funding tuberculosis control, monitoring implementation, assessing gaps and results. It also builds technical assistance capacity among known partners and countries to maintain and expand available human resources. TBTEAM has supported countries to maximize funding opportunities within the Global Fund in the following areas:

i Development of GF proposals for tuberculosis grants

7. While technical assistance has been provided by Stop TB Partners since the Global Fund was created, the formalization of TBTEAM has contributed extensively to help countries to access Global Fund monies. Rounds 5-7 have seen a substantial increase in the approval rate of tuberculosis proposals (average = 54%), compared to rounds 1-4 (average = 38%). Similarly the 2-year funding for rounds 5-7 has increased (average = 457 million US\$) substantially with regard to rounds 1-4 (average = 214 million US\$) TBTEAM have assisted 200 countries for proposal preparation for rounds 5-8 including 16 global and regional workshops and 150 missions

ii Relieve of bottlenecks to implement GF tuberculosis grants

8. The United States government has provided a grant to the Stop TB Partnership for the provision of technical assistance by partners to countries to address implementation bottlenecks. 65 countries have received assistance during the first year of this grant through 109 short-term mission during the first year of this grant.

iii Grant negotiation, signature and implementation

9. TBTEAM has supported 75 countries with grant negotiation elements including diagnostic assessment, technical support needs, monitoring and evaluation plans, performance framework, procurement and supply chain plans for first- and second-line drugs and other components of the Stop TB Strategy.

10. Tuberculosis grants are the best performers of the three diseases. Of 215 grants evaluated for phase 2 review by the Global Fund,⁸ 32% of all tuberculosis grants were classified in category A, compared to 25% of all HIV/AIDS grants and 16% of all malaria grants respectively. A study published by the Global Fund has praised the role of the Stop TB Partnership in this endeavor.⁹

iv Country needs assessment

40 countries have requested assistance for proposal preparation for Round 9. TBTEAM is proactively targeting countries that have repeatedly failed to secure funding from the Global Fund. Several other countries in need of scaling-up case detection, TB/HIV collaborative activities, detection and management of drug-resistant tuberculosis have been targeted for needs assessment.

11. In support to the Global Fund, the Stop TB Partnership TBTEAM spends 5US\$ million per year which is not sufficient to attend the demand from countries. Costs for technical assistance to support the implementation of the Global Plan have been estimated at US\$2.9 billion (29 million per year) for the period 2006-2015.

⁸ The Global Fund. Partners in impact: results report. The Global Fund to Fight AIDS, tuberculosis and Malaria. Geneva, 2007

⁹ Low-Beer D, et al. Making Performance-Based Funding Work for Health. *PLoS Medicine*. August 2007. Volume 4. Issue 8. e219. 1308-1311.

Global Drug Facility

12. To date the GDF has supported >40 Principal Recipients (many via repeat annual orders) with first-line anti-TB drug and diagnostic supplies/technical support and >50 Principal Recipients with second-line anti-TB drug supplies, under the GLC mechanism. GDF has supplied 11 million patient treatments to more than 80 countries. GDF has negotiated the lowest prices for first-line drugs for tuberculosis. GDF collaboration with the Global Fund can be further strengthened in light of the rolling out of new diagnostics recently endorsed by the WHO and the establishment of the Voluntary Pooled Procurement and Capacity Building services by the Global Fund.

13. GDF and its partners can also offer expertise in capacity building and supply chain management to address challenges in the procurement and supply chain management systems of countries. Forecasting and quantification, procurement planning and inventory control, distribution and logistics management are some of the services principal recipients can benefit from via the GDF.

Green Light Committee

14. The GLC is the technical body that reviews and recommends approval for funding to the Global Fund for drug-resistant TB components of tuberculosis proposals submitted for funding. To date, the GLC has reviewed 151 applications from 63 countries of which 103 are supported by the Global Fund. The GLC has approved 126 applications representing 47,574 people with MDR-TB of which 39,409 are supported by the Global Fund. Ultimately the small number of people supported is a clear indication of the need to massively accelerate prevention, detection and care for drug-resistant TB including MDR-TB and XDR-TB. GLC is currently revising its modus operandi to ensure the increasing demand is properly addressed.

High Level Advocacy

15. The Stop TB Partnership is pleased to undertake efforts in support of resource mobilization for country needs and to support major institutions playing a leading role in TB prevention, care and control, including the Global Fund. Partners and prominent leaders, including the United Nations Secretary General's Special Envoy to Stop TB, Mr Jorge Sampaio, have participated in events/activities in support of the Global Fund. High visibility is also offered by the Partnership to Global Fund officials in activities related to tuberculosis.

Challenges with Global Fund Policies and changing Architecture to accelerate Global Plan Implementation

16. There are pressing challenges with some Global Fund policies that contribute to a slowing down in progressing towards the goal of universal access to life-saving interventions for tuberculosis. These include:

- i. Delays in access to funds

Access to Global Fund funds by countries following approval by the Board, has proven to be time consuming and sometimes 12-18 months lapses before interventions can be made available to the people in-need. Streamlining processes

to fast-track access to funding should be strongly considered for Rounds 9 and 10. The RCC and National Strategy Applications are positive developments that potentially could mitigate such a bottleneck.

ii. Procurement bottlenecks

Delays in delivery after grant approval do not help countries to implement properly. Products sometimes take more than a year to be delivered. While the collaboration between GDF and the Global Fund has improved in the last few years, this should be strengthened further particularly in light of the need to accelerate procurement of second-line drugs for MDR-TB and XDR-TB and new diagnostics for TB. It is envisioned that Round 9 applications will include scaling-up of these services. Moreover, with the establishment of the voluntary pooled procurement and capacity building services for Principal Recipients by the Global Fund, it is desirable that the Global Fund takes advantage of the value added of the Stop TB Partnership's GDF and formalizes further the collaboration.

iii. Commodity costs on grant applications

While tuberculosis treatment with first-line drugs can be as cheap as 25US\$ for the entire course of treatment through the GDF, this is not the case for second-line drugs or the new diagnostics that need to be rolled out. The next two years will see increasing requests to upgrade laboratories to introduce new diagnostics for tuberculosis and also second-line drugs, which may have an impact on the size of the grants requested.

iv. Application processes

The current application form is not helpful in catalysing acceleration of critical life-saving interventions for TB/HIV and MDR-TB. For instance people living in countries with high TB/HIV burden would greatly benefit if the current application forms require that HIV-proposals include robust tuberculosis components with specific budgets and targets and vice versa. To date, this has been only advised in the Global Fund proposal guidelines. Without required support (or assurance that that support is coming from another source), TB/HIV interventions may continue to be wrongly perceived as a low priority for many national efforts.

PART 3: STOP TB PARTNERSHIP RECOMMENDATIONS TO THE GLOBAL FUND BOARD

1. The Stop TB Partnership suggests the Global Fund urge countries to plan ambitiously for Round 9 and future rounds, National Application Strategies, and Rolling Continuation Channels (RCC) with the ultimate goal of scaling-up life-saving interventions in line with the Global Plan to Stop TB so that the 2010 and 2015 Global Plan targets are fully achieved.

Recommendation 1. Application forms

- i. The Global Fund should consider mandating all HIV proposals to include a significant and operationalized tuberculosis component. Likewise, all tuberculosis proposals should include a robust and operationalized component on HIV/AIDS.
- ii. The Global Fund should consider mandating all tuberculosis proposals to include a component on drug-resistant tuberculosis including prevention, detection and care.

Recommendation 2. Current grants

- i. The Global Fund Board should consider urging countries to reprogram budgets of existing grants/phase 2 to ensure that areas behind implementation in line with the Global Plan to Stop TB are properly addressed.
- ii. Front-loading from existing grants and RCC can be a helpful option to scale-up. The Secretariat of the Global Fund can place a critical role to ensure scale-up priorities are placed as priorities in grant agreement negotiations.

Recommendation 3. Encourage Submission of Ambitious, Comprehensive Proposals for Round 9

- i. The Global Fund should encourage countries to submit ambitious, robust, and well-articulated round 9 proposals to scale up the Global Plan activities and components of the Stop TB Strategy falling behind implementation especially innovation for case detection, laboratory strengthening, TB/HIV collaborative services, drug-resistant TB care, strengthening monitoring and evaluation, private providers, community engagement and social mobilisation.

Recommendation 4. National Strategy Application Proposals and Rolling Continuation Channels

- i. The Global Fund could urge countries to submit ambitious National Strategy Application proposals and RCC based on the six components of the Stop TB Strategy.
- ii. The Global Fund should consider making the Stop TB Partnership TBTEAM the independent review body to certify national strategy applications for tuberculosis. This will ensure the six components of the Stop TB Strategy and Global Plan main activities are fully mainstreamed.

Recommendation 5. Increasing the use of the Stop TB Partnership GDF

- i. The Global Fund should consider strengthening the collaboration with the GDF. GDF should be strongly linked to the upcoming Global Fund Voluntary Pooled Procurement Mechanism so that procurement support for principal recipients seeking assistance, on a voluntary basis, with first- and second-line anti-TB drug access and new diagnostic tools to be rolled out in 2009-10, can be leveraged with direct Global Fund facilitation.

- ii. The Global Fund could urge countries to use the GDF in light of the advantages offered by the GDF on prices, quality assurance and support for building supply chain capacity.

Recommendation 6. Technical Assistance

- i. The Global Fund could urge countries to submit technical assistance request through TBTEAM for proposal preparation (round channel, RCC, NSA channel) and grant monitoring (grant agreement preparation, phase one technical assessment, phase 2 evaluation), and for ad hoc grant bottleneck implementation.
- ii. The Global Fund should explore avenues to support and fund the necessary technical assistance for supporting development of quality proposals and implementation follow-up.

PART 4: CONCLUDING REMARKS

1. The Stop TB Partnership constituent members remain strongly committed to work with the Global Fund bodies and Countries to ensure rapid implementation of tuberculosis control especially in areas in urgent need of scale-up. There is enormous potential to expand access and move faster in reducing mortality and expanding access to life-saving treatment and improved prevention of TB through early case detection and preventive treatment. The Partnership is committed to help countries to address and prevent implementation bottlenecks. If the global community including the Global Fund does not move to dramatically address tuberculosis care and control dramatically, we will face a far more challenging foe in the years ahead.

2. The Board Chair and Vice-Chair propose the following decision point to accompany the session on TB:

Decision Point Proposed by the Chair and Vice Chair of the Board

Building and Sustaining a Response that Halves Tuberculosis Mortality and Prevalence

1. The Board acknowledges and commends the Stop TB Partnership's Global Plan to Stop TB 2006-2015 (the "Global Plan"), which aims to halve current TB prevalence and death rates by 2015. As the largest external financier of TB programs worldwide, the Global Fund is committed to ensuring that it is a key partner in supporting the implementation of the Global Plan.

2. The Board recognizes that almost 40% of the estimated 9.2 million new TB infections per year worldwide are not detected/diagnosed, posing a major risk to an increased transmission of TB. Therefore, the Board encourages applicants to the Global Fund and implementers of TB programs to develop innovative actions to accelerate case detection and effective treatment of these cases. This will require investment to: increase the speed and precision of TB diagnosis using new tools; strengthen in-country M&E and surveillance systems; build human

resource capacity, scale up engagement of private providers in TB control and increase community based responses.

3. The Board recognizes that the slow progress in implementing core TB-HIV collaborative services is a risk to achieving successful outcomes under current and future Global Fund TB and HIV grants. Given the large gap in TB screening in HIV settings and vice versa, the Board urges applicants to include and implement significant, robust TB interventions in their HIV/AIDS proposals and HIV/AIDS interventions in their TB proposals.

4. The Board also notes that the continuing crisis of MDR- and XDR-TB in many countries is of great risk to the Global Fund TB portfolio and the efforts to reach the MDG targets. The Board recognizes that a successful response will necessarily include a major scale up of drug susceptibility testing for all people suspected of having drug-resistant TB and people living with HIV/AIDS and effective treatment of these cases by expanding DOTS-Plus programs. As such, the Board urges applicants to massively scale up laboratory capacity and management of MDR- and XDR-TB cases.

5. Given the need for additional resources and increased implementation capacities at country level to achieve the Global Plan goals for 2015, the Board urges applicants to submit Round 9, Rolling Continuation Channel, and national strategy application proposals aimed at achieving rapid expansion of case-detection universal coverage of TB-HIV collaborative services, scaling up laboratory and care capacities to expand DOTS and to address MDR- and XDR-TB, and at strengthening M&E and surveillance systems. The Board also urges CCMs and Principal Recipients to take advantage of the flexibility offered in Global Fund financing and, if appropriate, to consider revising budgets for existing and new grants and for Phase 2 requests.

This decision does not have material budgetary implications.