



U.S. GOVERNMENT REPORT ON INTERNATIONAL FOREIGN ASSISTANCE IN TB FY 2010

LEADING AND LEVERAGING



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WHO/TBP GERRY HAMPTON

Cover photo: TB clinic in South Asia

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EXECUTIVE SUMMARY



TRISTAN BAYLY, KNCV TUBERCULOSIS FOUNDATION, NETHERLANDS, PHOTO TAKEN IN GHANA

Community empowerment through education is an essential element of TB outreach.

The U.S. Government's (USG) tuberculosis (TB) program is mainly implemented through USAID as the lead agency in international TB control, in close collaboration and coordination with U.S. Centers for Disease Control and Prevention (CDC), Department of State/ The Office of the Global AIDS Coordinator (OGAC), the National Institutes of Health (NIH), and Department of Defense (DoD). The U.S. Government continues to prioritize support to countries with high rates of TB and multi-drug resistant TB (MDR-TB), lagging case detection, poor program performance, and where the HIV epidemic is a driver of TB disease. This prioritization of countries led to investments in 20 "Tier 1" or focus countries, with funding levels of at least \$3 million per country; and in 21 "Tier 2" countries, with smaller but strategically targeted interventions.¹

Sustained and well-focused investments in fighting TB have begun to make their mark on the global TB burden. By 2010, death and prevalence rates in Tier 1 countries had decreased 29 percent and 14 percent, respectively, compared with 1990 levels. Detection of all forms of TB cases in U.S. Government TB programs reached 60 percent in 2010, and treatment success rates reached 85 percent, the global target, for the 2009 cohort of TB cases. Significant progress is being made to achieve the Global Health Initiative (GHI) targets for TB.

In 2010,² 3.8 million TB cases were detected in countries supported by the U.S. Government's TB control program, which is a 51 percent increase since 2000. In the past year, millions of lives were saved and tens of millions of additional cases of TB were averted. Of the almost \$249 million obligated by USAID

ACHIEVEMENTS

In 2010, 3.8 million TB cases were detected and 1.5 million smear-positive TB cases were successfully treated in USAID-supported countries

TB mortality and prevalence are decreasing in USAID's priority countries

The number of MDR-TB cases starting treatment increased 63% over the past year

for TB in 2010, 85 percent directly supported the country and regional level programming that enabled these gains. The remaining 15 percent supported global-level goods, such as surveillance, evolution of normative technical guidance, and research into shorter drug regimens.

The U.S. Government technical approach emphasizes support to innovative and quality-assured programs in TB endemic countries, progressive leadership internationally, and deliberate coordination with other stakeholders to ensure the most efficient use of funds. With its strong field presence, USAID works closely with disease endemic country governments to assess and respond to existing constraints in the health system and TB program that impede the provision of quality TB control services. With such in-depth country knowledge and presence in TB, the programs are uniquely positioned to share successful approaches between countries and to recognize common bottlenecks to implementation that may require a shift in the global policy, guided by operational research. Driven by evidence, innovative new approaches to care are promoted to make services more efficient and patient-centered, while improving quality.

Many of the flagship projects are making important contributions toward universal access to care. Two such initiatives aim to extend access to care beyond public sector health facilities, by a) engaging all care providers such as private sector practitioners, hospitals, pharmacists, prisons, social security, and health insurance organizations; and b) enabling community-based care. The contribution of these providers to case detection was notable. In Nigeria, for example, nearly 34 percent of the cases put on treatment came through private clinics and hospitals; in Cambodia, 17 percent of cases were identified through pharmacies and private providers. In Afghanistan, community health workers detected more than 30 percent of all cases detected nationally.

The U.S. Government demonstrated leadership in addressing the increased case load of MDR-TB as staff contributed to the development of new technical guidance and globally recognized policies. Country-based USAID programs launched some of the first diagnostic and treatment sites for MDR-TB in those settings. There were 19,121 persons initiated on MDR-TB treatment in 2010 in USAID supported sites—a 63 percent increase over 2009.

USAID TB resources leverage U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funding led by the Office of the U.S. Global AIDS Coordinator (OGAC) at the Department of State to strengthen country efforts to coordinate TB and HIV activities, increase early detection of TB and HIV, and expand access to integrated TB and HIV treatment. These TB resources have contributed significantly to country momentum in scaling up TB/HIV activities. HIV care to TB patients, especially HIV counseling and testing, cotrimoxazole preventive therapy, TB diagnosis, and anti-retroviral treatment in co-infected patients, has been scaled up in most USAID-supported TB/HIV high burden countries. By 2010, 58 percent of registered TB patients were tested for HIV in USAID-supported countries with TB/HIV activities compared to a global average of 26 percent.³

Exercising its comparative advantage in pivotal, late-stage research that stands to influence practice in high-endemic countries in the near term, the U.S. Government continued to invest in several areas of research. New short course regimens containing two new drug compounds that may shorten the duration of treatment have continued to progress through the development process. USAID is supporting a clinical trial of a drug regimen for MDR-TB that could cut treatment time in half. Operational research has also supported the rapid and appropriate roll-out of several new diagnostic technologies that are endorsed by the World Health Organization (WHO).

I. THE GLOBAL TUBERCULOSIS CONTEXT

Between 1995 and 2010, 41 million TB patients were treated successfully through TB control programs, saving up to 6 million lives. Globally, deaths due to TB have fallen by more than one-third since 1990. Still, there were an estimated 9.4 million new cases of TB and 1.7 million deaths in 2010. After HIV, TB is the leading infectious killer of adults worldwide.

Tuberculosis is caused by a bacillus and in its most common form, is transmitted by infectious droplets that easily travel through the air. Once infected with TB, a person does not necessarily become sick but can remain latently infected throughout his/her lifetime. Any weakening of the immune system, however, gives TB an opportunity to emerge in its disease form. Malnutrition, concomitant HIV infection, or other illness can trigger the progression from infection to disease. In conditions of poverty, TB thrives. TB is a disease that threatens the poorest and most marginalized groups, disrupts the social fabric of society, and slows or undermines gains in economic development.

Although TB infection is more common in men, once infected, women of reproductive age are more likely than men of the same age to develop active TB disease.⁴ The WHO estimates that 3.3 million women newly contracted TB in 2010, which is 35 percent of all cases.³ In addition to impacting the mother's well-being, evidence shows that TB can also lead to detrimental birth outcomes, including premature birth, low birth weight and obstetric mortality.⁵ TB is one of the top three killers of women worldwide: in 2010 it killed an estimated 580,000 women, many leaving children and families vulnerable.⁶ The WHO also estimates 9.7 million children cumulatively have been orphaned as a result of losing at least one of their parents to TB.

TB also has a significant economic impact on both families and societies. It is estimated that in some countries the loss of productivity attributable to TB is 4 to 7 percent of those countries' GDP.⁷ And, on a smaller scale, an estimated 75 percent of TB cases arise during people's most productive years, between ages 15 and 54. As a result, TB is a major economic stressor of poor families worldwide, as individuals may need to stop working in order to get treatment or to care for relatives. The economic costs of seeking treatment are also high—research shows that mean household spending on TB care for items such as transport to the health facilities as well as fees for medications for private sector care can be as much as 20 percent of total annual household income.⁸



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TB IN THE SLUMS

Poverty can affect patients' ability to complete their treatment. Here, a young woman lies on the floor of her mother's home in a neighborhood next to a garbage dump. Her son and mother sit behind her. The young woman and her husband came to the city to be closer to a treatment center so she could receive medicine, but they may soon return home, interrupting her treatment, so her husband can continue to work. She is currently so weak that she is often unable to sit up for more than 10 minutes at a time.

The TB epidemic has evolved into three distinct, but inter-related, epidemics that demand nuanced programmatic responses. First, the generalized TB epidemic occurring in HIV-negative people mainly related to ongoing transmission, delay in diagnosis and treatment, accounted for 88 percent of all TB cases in 2010. The majority of these cases can be found in Asia.

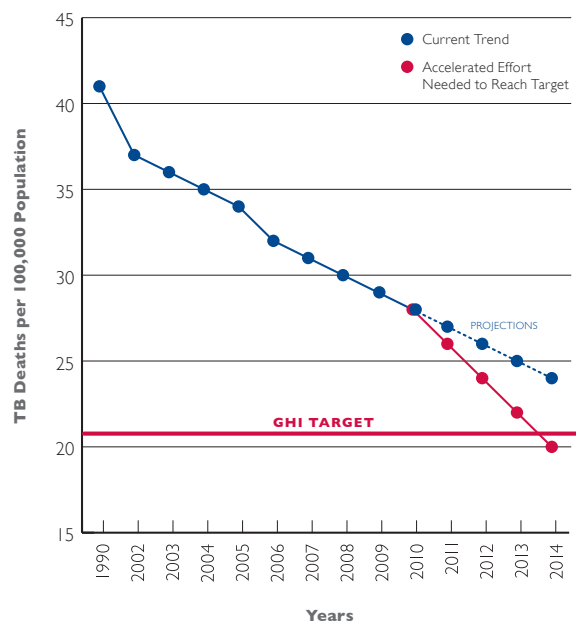
Second, the HIV epidemic is driving the spread of TB in selected countries and areas where the two diseases are prevalent. The African region is particularly the most affected by the HIV-related TB epidemic. In 2010, 37 percent of new TB cases in Africa were HIV positive. In addition, the interaction between TB and HIV is associated with high mortality in individuals who are TB/HIV co-infected. Therefore, collaborative approaches between TB and HIV are required to address this epidemic.

When TB is not appropriately managed and patients do not receive all of the drugs needed to cure them, drug resistance can emerge. MDR-TB, the third wave of the epidemic, has been detected in every region of the world, although it is most dramatically concentrated in countries of Eastern Europe and Central Asia. MDR-TB continues to be created through poor

quality programs and can be transmitted in its resistant form. When MDR-TB cases are then insufficiently managed, often in the same poor quality programs that created them, extensively drug-resistant TB (XDR-TB) can result. It is estimated that there were approximately 440,000 MDR-TB cases in 2008.⁹ MDR-TB is dramatically more expensive and complex to treat than drug sensitive TB, requiring up to two years of treatment with costly and toxic drugs (see sidebar). The drugs are 260 times more expensive than drugs for susceptible TB. Preventing MDR-TB and XDR-TB through quality management and successful treatment of all existing TB cases is a priority for USAID and the global TB community.

The Millennium Development Goals call for reducing the prevalence of TB and the number of TB deaths by 50 percent by 2015, against the 1990 baseline. The U.S. Government has committed to contributing to this global goal through the GHI by successfully treating at least 2.6 million new smear-positive TB patients and supporting the detection and initiation of treatment of at least 57,200 MDR-TB patients in 2014. By 2010, death and prevalence rates in USAID-supported countries had decreased 29 percent and 14 percent, respectively, compared with 1990 levels (see figures 1 and 2).

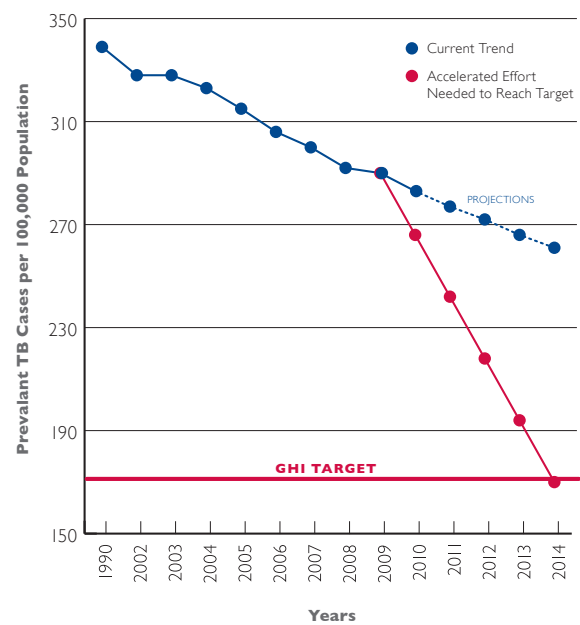
FIGURE 1. TB DEATHS REDUCED IN USAID-SUPPORTED COUNTRIES SINCE 1990



MDR-TB TREATMENT IN EASTERN EUROPE

Isoniazid and rifampicin will not cure MDR-TB, so a “cocktail” of medications is prescribed. Usually, the cocktail contains at least four medicines, including the first line medications that the bacteria are not resistant to and some second line medications. Treatment of MDR-TB can last up to two years or even longer. Treatment can be successful in MDR-TB cases yet side effects from the treatments can be severe, causing many people to stop their medications and thus eventually die of the disease. Even scarier, a new form of TB has emerged: **extensively drug-resistant TB (XDR-TB)**. XDR-TB is resistant to all of the first line medicines and at least one of three second line medicines. It is much more expensive to treat MDR-TB and XDR-TB.

FIGURE 2. TB PREVALENCE RATES IN USAID-SUPPORTED COUNTRIES DECLINED SINCE 1990



II. LEADING AND LEVERAGING: U.S. GOVERNMENT TB STRATEGIC APPROACH

Fostering Country Ownership

Central to sustainable progress is the commitment and capacity of disease endemic country governments to lead a national response to TB. The U.S. Government TB program promotes local government ownership. Drawing on the field presence of USAID Missions, the program partners closely with Ministries of Health to target critical gaps within the national strategic plans for health systems strengthening and TB control. Reflecting the close collaboration with governments, USAID supported the placement of technical experts in Ministries of Health in 10 countries and had TB experts in 41 countries in 2010, bolstering the countries' capacity to enhance TB control services and provide technical mentoring.

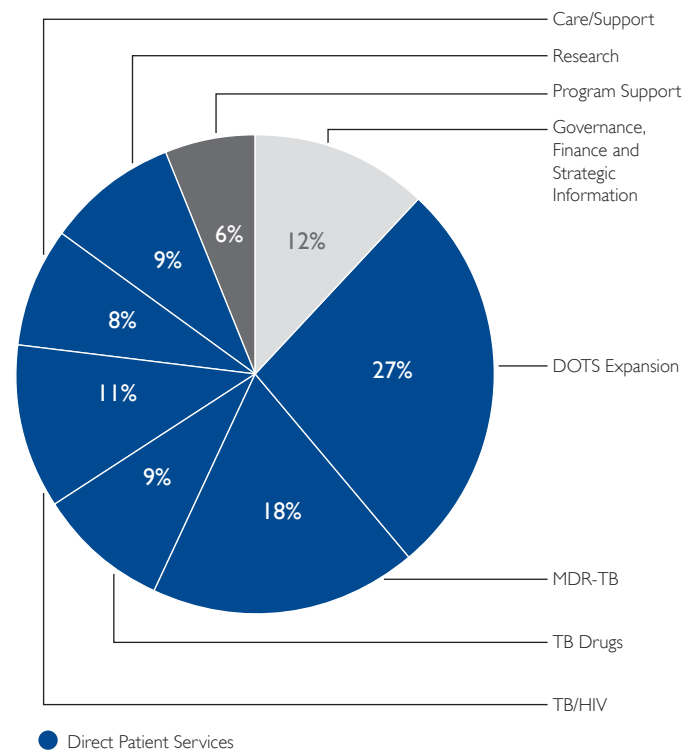
Funding Addresses Barriers to Progress at Country Level

In 2010, USAID obligated \$249 million for TB control. These investments were guided by a solid evidence base to strategically target key political, programmatic and operational barriers to progress. On 5-year cycles, the WHO-recommended Stop TB Strategy calls on National TB Programs to assess the state of TB control in their countries and develop prioritized strategic plans for the subsequent period. USAID, together with international partners and other donor stakeholders, contributed its human and financial resources to this process of in-depth programmatic review, evaluation and strategic planning. These opportunities are critical to help define programmatic priorities, and to define the comparative advantage of U.S. Government investments to lead pivotal change, within a broader, multi-stakeholder context. To further this effort to enable countries in data-driven planning, the support for TB prevalence surveys and drug resistance surveys will continue to be a priority investment.

Based on the gap analysis and prioritization process at country level, 82 percent of USAID resources were programmed to directly address the most critical local needs (figure 3). Wherever possible, USAID worked with Ministries of Health to invest in and through National TB control programs.

Other key investment areas in 2010 included: quality-assured laboratories, standardized treatment, patient support and supervision, drug management systems, quality-assured drugs, and monitoring and evaluation systems. Result highlights from 2010 are featured in the side bars of this report.

FIGURE 3. USAID TB EXPENDITURES IN 2010



Demonstrating Technical Leadership at the Global Level

By virtue of its technical proficiency and broad country experience, the U.S. Government is an influential leader in international TB. The U.S. Government prioritizes the development of global policy and technical standards as an output of its work as this extends the benefit of lessons learned and investments made to TB endemic countries. Collaboration with recognized normative agencies, such as WHO, facilitates this translation of our investments to global impact.

USAID invested in pivotal late-stage research that reflected global priorities, such as trials of new drug regimens and evaluation of operational modalities to maximize the impact of existing tools and technologies. A study is being supported by USAID to evaluate the efficacy of a 9 month (short course) regimen for the treatment of MDR-TB. If shown to be effective, this regimen can have a major impact on the course of the TB epidemic. Sites for these trials have been identified and are being prepared for the study initiation.

U.S. Government TB agencies help to support and galvanize partnerships around priority issues, using seed funding and its convening power. The U.S. Government has supported the development and recent revision of the strategic direction of a coordinated global response mechanism called TBTEAM, which is primarily funded through U.S. Government Global Fund technical assistance set aside resources. TBTEAM is housed within WHO and aims to strengthen the capacity of National TB Programs to better plan and coordinate their own technical assistance among relevant partners, particularly for Global Fund-supported activities. TBTEAM is building national capacity to produce comprehensive national technical assistance plans which are based on countries' five-year strategic plans and address needs, available human and financial resources, and gaps.

IN 2010, USAID PRIORITIES GENERATED:

Evidence for sound programming

- In-depth program evaluations and five-year strategic planning in 10 countries
- Prevalence surveys, to quantify the burden of disease, in 4 countries¹⁰
- Drug resistance surveys in 4 countries¹¹
- Annual global TB surveillance report including 198 countries
- Technical support to ensure quality programs in 41 countries
- 41 technical experts based at country level to support National TB Programs
- Technical support for planning and implementation of 15 Global Fund grants

Strengthened core health systems for sustainable progress

- Strengthened laboratory networks in 12 countries
- Reinforcement of 2 national laboratories in Africa to become supranational reference labs¹²
- Training of over 200 health staff to improve drug management
- Developed a web-based tool to integrate data for diagnosis, treatment, medicines, and outcomes in developing countries

IN 2010, USAID CONTRIBUTED TO:

Extending access to TB diagnosis and treatment

- 51% increase in the number of TB cases detected annually in USAID-supported countries, since 2000
- Treatment success rates averaged 85% in supported countries
- 94% of public sector clinics in 23 USAID-supported countries implemented quality-assured TB labs

Enabling care for MDR-TB

- 63% increase in the number of people who initiated MDR-TB treatment in USAID countries
- Innovative social support programs for MDR-TB patients piloted and/or scaled-up 6 countries

Ensuring co-management of TB and HIV

- By 2010, 58% of TB patients tested for HIV in USAID-supported countries **compared to a global average of 26%**³
- Over 200,000 TB patients with HIV received cotrimoxazole preventive therapy in Tier I USAID-supported countries

Investing in the future

- Furthered trials of new drugs that may shorten the treatment regimen by 30% or more
- Operational research to maximize the impact of the introduction of new diagnostic technologies

U.S. Government Resources Complement Financing From the Global Fund to Fight HIV/AIDS, TB and Malaria (Global Fund)

The Global Fund is the single most important source of external funding to countries for TB control, constituting 65 percent of external funding to the 22 highest burden countries.

In 2010, the U.S. Government contributed approximately \$791 million for Global Fund programs. The Global Fund TB grants support the implementation of the WHO Stop TB Strategy and can finance all components of it. The U.S. Government strives to support the successful implementation of Global Fund resources, playing a key role in many aspects of the Global Fund decision-making processes to improve program design and grant performance. At the country level, U.S. Government staff are often members of the Country Coordinating Mechanism that supports each grant.

The Global Fund grants and U.S. Government bilateral TB work plans were developed to complement one another in filling the financing gaps identified in the National TB Program strategic plan. The coordination of resources and activities have enabled the provision of direct technical assistance to the Global Fund grant Principal Recipients in implementing grants and removing bottlenecks to progress. In cases of delayed implementation of grants, the U.S. Government TB bilateral funds were reprogrammed to ensure that critical National TB Program activities continued without harm to the program. The National TB Programs recognize the importance of the U.S. Government bilateral funds and appreciate the flexibility to address this important need. In 2010, USAID funds were programmed to complement Global Fund resources in 30 countries. This approach ensured country ownership, promoted National TB Program management capacity, enabled coordination of external and national TB resources, and maximized outcomes from all funding sources. These investments have provided critical inputs for the evolution of global technical norms and standards, globally-relevant research, sharing of expertise and lessons learned between countries, and coordinated technical assistance to countries that benefit all Global Fund grant recipients beyond the USAID-supported TB countries.

Continued on page 14

CASE STUDY:

ETHIOPIA

Wrapping Bi-Lateral and Multi-Lateral Support Around Strong Government Commitment to TB

With an estimated 300,000 new TB cases in 2009, Ethiopia was among the 10 highest burden countries in the world. Detecting cases in Ethiopia has proven to be challenging as 85 percent of the population of more than 75 million people live in rural areas and 47 percent live below the poverty line. In 2010, there was only one physician per 35,493 people, disbursed across the vast country. This combination results in limited access to health care. In 1995, only around 20 percent of estimated TB cases reached a diagnosis and were started on treatment. Since that time, the government has strengthened its commitment to TB control and has adopted a decentralized approach to care that aims to reach cases in the most remote areas. In 2010, case detection climbed to 50 percent.

Expanding access to care for the remaining 50 percent of TB patients is a clear priority, and USAID has been collaborating closely with the government and other financing partners to do just that. In 2010, the National TB Program benefitted from various support from the U.S. Government including Global Fund resources (\$8 million disbursed), USAID's bi-lateral program (\$10 million), and PEPFAR funding for TB/HIV (\$8.5 million). This supplemented the estimated \$22.4 million invested by the government itself.³ Ensuring the complementarity of these resources has required continual assessment of the gaps and flexible programming by USAID.

Among the gaps identified by USAID was the need to enhance the diagnostic network to facilitate the detection of cases, particularly in remote areas. To build local capacity and promote



WHO/STOP TB PARTNERSHIP

Our commitment to collaboration helps promote innovative solutions.

a sustainable, quality-assured system, USAID employed a cascade approach with training of centralized supervisors and provision of support to enable them to provide on-site mentoring and quality control that reaches the periphery. In 2010, USAID provided on-site refresher training and quality supervision to over 450 laboratory technicians in 156 diagnostic centers across the country. Where lab infrastructure was lacking, USAID was able to respond, installing, for example, 75 new microscopes.

While the national, Global Fund and PEPFAR resources included programming for treatment of TB, TB/HIV collaborative activities and MDR-TB, USAID was able to bolster the technical excellence of all programming, by wrapping needed technical assistance around other activities, and by promoting innovative system solutions to address current

constraints to implementation of services. For example, USAID provided on-site training, supportive supervision and clinical mentoring in 84 health facilities, for both TB and TB/HIV collaborative activities, as well as direct training of 287 health care workers on TB/HIV collaborative activities and 100 health care workers on MDR-TB case management. Recognizing the potential to expand access to care through community-based care networks, USAID trained and supported 292 health extension workers in 2010. In addition private-sector TB related activities were expanded to four additional regions for a total of 93 sites that were providing TB and TB/HIV services. As a result, the private sector identified and referred to public health facilities a total of 9,759 TB cases.

USAID FLAGSHIP:



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Women in tailoring workshop in India being educated on TB issues.

TB is a disease of poverty. It disproportionately affects poor and marginalized populations as its transmission and degeneration to active disease is enabled by poor nutritional status, concomitant disease, and overcrowded living conditions. The availability of roads, infrastructure and public health facilities are inversely related to the needs of many of the marginalized people at risk for TB. It is often difficult to reach TB patients with the services they need.

USAID strives to support the capacities of governments to address TB, and notably the activities of Ministries of Health and their National TB Programs. Acknowledging, however, that the public health sector may not reach all patients and that patients may choose alternative care providers, USAID has

led global movements to engage *all* care providers in quality TB care and to extend services to communities through community-based care. These flagship areas support the global momentum toward universal access to TB care and treatment.

The evidence base in support of these interventions is now robust. Providing care and monitoring treatment through community-level structures reduces costs to the system and also to the patient, thereby enabling treatment completion in many cases. In Tanzania, for example, a study on community-based care reduced costs by 27 percent for the health system and 72 percent for patients.¹³ Other countries have reported similar efficiency gains through community-based care activities.

FIGURE 4. NON-GOVERNMENTAL PROVIDERS CONTRIBUTING TO CASE DETECTION³

Country	Coverage	Provider Type(s)	Contribution (number and % of total national cases detected)
Cambodia	Countrywide	Pharmacies, Private Providers	6,550 (17%)
Ghana	Countrywide	Diverse Public, Private	2,124 (15%)
Indonesia	Countrywide	Public, Private Hospitals	38,362 (13%)
Mexico	33 Million	Social Security Organization	3,438 (29%)
Nigeria	Countrywide	Private Hospitals	29,418 (34%)
Pakistan	Countrywide	Private Providers, non-governmental organizations (NGOs), Hospitals	43,162 (14%)

Linking all care providers who come into contact with TB suspects and patients can reduce diagnostic delays, promote standardized care practices, and enable access to quality-assured drugs. The contributions of these additional care providers to case detection in 2010 can be seen above.

The success of these initiatives to extend access to TB care reflect the effectiveness of USAID’s methodical and comprehensive approach to investing. A decade ago, evidence from country programs suggested that TB case detection was lagging, in part, because public sector services were not reaching all TB patients where they were able to access care. Policy barriers to engaging other providers existed in many countries, as dispensing medicines and monitoring treatment were limited to selected categories of providers. Demonstration of the potential for quality programs to be delivered by non-governmental partners, and particularly community-level partners, was needed to influence national and global policies.

In the last ten years, USAID has designed and invested in innovative approaches to engage communities and other providers in countries that were willing to explore this new model, carefully monitoring the impact and quality of care being provided. With successful experiences mounting, the focus turned to the sharing of experiences, building capacity in additional countries, and the formulation of global policy in support of these new practices. USAID helped shape WHO guidance, through engagement and support of the Public-Private Mix sub-working group of the Stop TB Partnership.

In 2010, USAID’s work in this area culminated in global policy guidance for all countries. With support from USAID, WHO and the Stop TB Partnership launched a Public-Private Mix toolkit that addresses country-level demand for guidance for establishing, monitoring the quality of, and sustaining engagement by non-National TB Program care providers. The toolkit consists of 14 individual tools, providing specific normative and strategic direction based on the types of providers who may be involved and the range of implementation strategies that may be most appropriate for different country contexts.

FIGURE 5. PROCESS FOR SCALING-UP APPROACHES



**IN 2010, USAID SUPPORTED:
ENGAGING ALL CARE PROVIDERS**

In Cambodia, private pharmacists were trained to detect TB, and linked to public providers. The number of cases referred increased 58 fold between 2005 and 2009

In the Philippines, 1,840 non-governmental treatment partners and 88 companies were supported to engage in serving TB patients through communities and workplaces

In Brazil, quality TB care network was expanded to 3 prisons with high burdens of TB

In Ethiopia, TB/HIV collaborative services were provided by private providers in 93 sites

In Indonesia, 172 hospitals in 10 provinces were trained in international standards and were linked to the National TB Program

In Senegal, 115 traditional healers were trained to refer TB suspects to health care facilities

**IN 2010, USAID SUPPORTED:
COMMUNITY-BASED CARE APPROACHES**

In Nigeria, community volunteers referred almost 5,000 people with TB symptoms for diagnosis

In Mozambique, community volunteers referred almost 19,000 people with TB symptoms for diagnosis

In Ethiopia, 1,105 community extension workers are engaged in referring people with TB symptoms for further evaluation

In Afghanistan, community health workers trained by USAID-supported programs detected more than 30% of all the cases detected nationally

In Cambodia, community-based DOTS covers 25% of population, reaching 3,441 villages and detecting over 10,000 TB cases

In Malawi, 268 volunteer-run community sputum collection points were established for hard-to-reach populations, referring more than 5,000 TB suspects for diagnosis




Diagnosis of TB in children is difficult and may require a chest radiograph.

CASE STUDY:

INDONESIA

Responding to country priorities for TB control in Indonesia



In 2002, only 39 percent of TB cases in Indonesia were being detected and of those 55 percent were successfully treated. By 2009, 68 percent of cases were detected and 91 percent were successfully treated. Contributing to this success, USAID supported the National TB Program to:

Engage all Care Providers in Increasing Case Detection and Improving Treatment Quality

Universal access—PPM: The country developed the Hospital Directly Observed Treatment, Short-course (DOTS) Linkage (HDL) approach, which enables people with TB to continue treatment close to home after being diagnosed and treated in a hospital DOTS clinic that has proven to increase adherence to treatment. Currently, 172 hospitals in 10 provinces are trained in International Standards of Tuberculosis Care (ISTC) and are linked to the National TB Program for drugs, monitoring and reporting. USAID also supports training of private providers, nongovernmental organizations, and prisons to improve earlier diagnosis and quality treatment in these facilities. The number of hospitals linked to the National TB Program doubled between 2007 and 2010.

Introduce Management of MDR-TB

MDR-TB: The country provided technical assistance for two hospitals to provide MDR-TB treatment. By the end of September 2010, 102 MDR-TB patients were undergoing treatment. USAID is supporting expansion of the MDR-TB management to three additional sites with the goal of treating 1,000 patients.

Enhance the Quality of Programming

Indonesia developed the National Strategic Plan for TB laboratories for 2011 to 2015, developed the Guideline of Culture and Drug Susceptibility Testing (DST) and provided financial and technical support to enable two provincial laboratories in West Papua province, a regional laboratory at Gadjah Mada University for a BSL 2-plus standard to be commissioned in 2010, and 27 other provincial laboratories to be assessed for Culture/DST.

Increase the Availability of Natural Resources

Universal access—education and advocacy: Indonesia designed a five-year plan for strengthening TB advocacy in selected provinces, including advocacy tools such as planning and budgeting tools. This advocacy succeeded in increasing the national government budget for TB from US \$18.3 million to US \$22.6 million in one year.

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Continued from page 8

An Integrated U.S. Government Response to the Global TB Epidemic

After disease-endemic countries themselves, the U.S. Government was the largest financial contributor to global TB control in 2010, providing support through its own agencies, international partnerships, and the Global Fund. U.S. Government support for global TB control efforts have evolved into an interagency model that is efficient and effective. As such, the U.S. Government agencies involved in global prevention and control of TB operate from a model of collaboration that draws on the strengths of each agency, limits duplication of efforts, and enables flexibility and innovation in interactions with multi-lateral partners and developing countries. The model, which is based on well-defined complementary roles and outcomes, has thrived over time without the addition of new layers of bureaucracy or management costs. As a result, the maximum amount of TB funds was directed to address gaps in country level plans and key research priorities.

The U.S. Federal TB Task Force is charged with facilitating translation of biomedical research findings into TB control strategies. Under this umbrella, the U.S. Government agencies involved in global TB prevention and care established an International Working Group, that meets monthly. The agencies represented on the international working group include USAID, OGAC, NIH, CDC, and DoD. The roles of the agencies, agreed upon by all respective agencies, are defined as follows:

A. USAID is the U.S. Government lead agency in international TB. USAID supports a comprehensive response to TB, TB/HIV and MDR-TB by strengthening national TB control programs and the general health systems in 41 countries. In addition, it is one of the major implementors (with CDC) of PEPFAR's TB/HIV programs. USAID also supports international normative and policy development for TB control in endemic countries, capacity building for TB program implementation, operational research to improve the effectiveness and efficiency of TB control programs, accelerated implementation of new diagnostic and treatment technologies and implementation methodologies, and improved prevention and care in developing countries.

- B. OGAC** coordinates the U.S. Government response to HIV/AIDS across U.S. Government agencies, and **leads the U.S. Government response to TB/HIV co-infection as part of PEPFAR.** Priorities include acceleration of TB/HIV collaborative activities, including diagnosis and treatment of co-infected individuals, prevention of TB in HIV positive individuals, as well as leveraging PEPFAR's HIV care, treatment and laboratory infrastructure.
- C. NIH** leads the way in improving the fundamental understanding of the science of TB and TB/HIV and supports and **conducts biomedical basic, applied, and clinical research** for both drug sensitive and drug resistant TB and is also heavily invested in the discovery and development of new drugs, vaccines and diagnostics. Within NIH, the National Heart, Lung and Blood Institute plays a critical role in global TB research; the National Institute of Allergy and Infectious Diseases (**NIAID**) is the **lead agency for TB research**; and the Fogarty International Center also is involved in TB research.
- D. CDC** leads domestic U.S. Government TB control efforts and provides critical technical support to international partners on epidemiology and surveillance (including drug resistant TB), **laboratory strengthening, and clinical/operational research** that evaluates promising diagnostic and treatment strategies, and informs the efficient use of new approaches to TB care. CDC is a major implementor (with USAID) of PEPFAR's TB/HIV programs. CDC also funds the TB Clinical Trials Consortium and the TB Epidemiologic Studies Consortium to fill current knowledge gaps in TB diagnostics, TB treatment regimens, case detection, and monitoring.
- E. DoD's** laboratories in numerous priority countries **monitor the quality of diagnostic services and conduct research.** In addition, mobile care units deployed in crisis and conflict settings are used in support of TB control efforts.

See figure 7 for some highlights of the complementary successes of the agencies.

**FIGURE 7. INTERNATIONAL WORKING GROUP OF THE FEDERAL TB TASK FORCE:
U.S. Government Agencies Involved in Global TB Control**

Agency	Leadership Role / Comparative Strengths	Key Achievements in 2010
Programmatic Implementation		
<p>Joint Common U.S. Government messages in global and domestic TB and TB/HIV forums; and USG international coordination working group; and USG working group to roll-out and evaluate impact of new diagnostics</p>		
U.S. Agency for International Development	Lead for international TB control including technical support in 41 countries including universal access, MDR-TB and laboratory strengthening; implementor for OGAC-funded TB/HIV programs	<p>3.8 million TB cases detected in USAID-supported countries</p> <p>Successfully treated 85 percent of detected TB cases</p> <p>Number of MDR-TB cases treated increased 63 percent over the past year</p>
Office of the Global AIDS Coordinator	Lead for control of TB/HIV co-infection	In almost half of the countries in Africa, more than 75 percent of TB cases know their HIV status. Anti-retroviral treatment for 40 percent of co-infected people in Africa
U.S. Centers for Disease Control and Prevention	Lead for domestic TB control and international lab support; implementor for OGAC-funded TB/HIV programs	Provided technical support to strengthen 8 country laboratories and developed 12 global guidelines to accelerate laboratory capacity in U.S. Government-supported countries
Research		
National Institutes of Health	Lead for biomedical research and research training	Critical contributor to development of Cepheid GeneXpert MTB/RIF. NIAID's investments in biomedical research have contributed to 5 diagnostics, 10 drug and 7 vaccine candidates that are, as part of the current global product pipeline, in clinical development
U.S. Centers for Disease Control and Prevention	Lead for operational research/reference laboratories	Developed method for screening people with HIV for TB, which more ably diagnoses patients while targeting limited resources to those at highest risk. This research changed international guidelines for TB screening
U.S. Department of Defense	Research laboratories and mobile care units	Engaged in the effort to prevent and control infectious diseases for many years. Building laboratory capacity to diagnose, monitor, and respond to infectious diseases, to strengthening public health systems with an emphasis on prevention and control, to emergency response in the face of disease outbreaks
U.S. Agency for International Development	Late-stage research, programmatic and operational research	Phase IIb and Phase III trials of 4 new drugs for TB

HIGHLIGHTS OF USAID TIER I COUNTRIES





- 1. Afghanistan** Through USAID-supported community-based care nearly 90,000 suspected TB cases were identified and screened for TB, of which more than 8,000 were confirmed as active TB cases.
- 2. Bangladesh** USAID-supported clinics reported high treatment success (92 percent), exceeding the WHO target of 85 percent.
- 3. Cambodia** Community-based DOTS continued to cover about one-fourth of the population, 10,961 TB cases (of all forms) were detected and enrolled in treatment under DOTS. In USAID-funded target areas, 93 percent of detected cases were successfully treated.
- 4. Democratic Republic of Congo (DRC)** USAID support for laboratory strengthening and MDR-TB treatment and care in DRC has resulted in the provision of MDR-TB treatment to 336 MDR-TB patients and a cure rate of 61 percent in 2010 compared to 47 percent in FY 2009.
- 5. Ethiopia** Private-sector TB-related activities were expanded to four additional regions for a total of 93 sites providing TB and TB/HIV services. The private sector identified and referred to public health facilities a total of 9,759 TB cases.
- 6. India** In 2010, the Government of India, through the Revised National Tuberculosis Control Program (RNTCP) treated 1.5 million cases of TB, including 1.3 million new cases. With technical assistance from USAID, India has met the global targets for TB control for the fourth straight year. In 2010, the country had a new smear-positive case detection rate of 71 percent and treatment success rate of 87 percent.
- 7. Indonesia** USAID developed the Hospital DOTS Linkage (HDL) approach, covering 172 hospitals in 10 provinces linked to the National TB Program for drugs, monitoring, and reporting. The country scaled up MDR-TB facilities and culture/DST labs from 0 to 5.
- 8. Kenya** With USAID support, the National TB Program ensured regular monitoring and supervision at all levels of the TB program, maintaining 80 percent coverage for supervision visits in 210 districts. With this support, Kenya continues to surpass the WHO targets for case detection and treatment success.
- 9. Mozambique** The engagement of the community in the early diagnosis of TB suspects has been important to improve the very low case detection rate in Mozambique. In 25 USAID supported districts, community volunteers referred 19,701 suspects to the health units, of which 2,470 people were diagnosed with TB (all forms).
- 10. Nigeria** USAID continued to strengthen integration of DOTS into general health services by supporting the National TB Program to train nearly 5,000 medical doctors, nurses, and community health personnel in 17 states, and procure light and LED microscopes, Global Drug Facility consumable kits, and sputum containers for health facilities.
- 11. Pakistan** USAID supported a national TB disease prevalence survey in order to estimate the prevalence of bacteriologically confirmed pulmonary TB. Despite the security situation and other difficulties in the country, the survey has been completed and the report is expected in spring 2012.
- 12. Philippines** USAID supported private sector participation in TB DOTS initiatives by engaging and linking to the National TB Program in 88 companies in the workplace TB program and an additional 33 private hospitals and clinics, 158 pharmacies, and 208 referring physicians.
- 13. Russia** In USAID pilots, 78 percent of released prisoners with TB successfully completed treatment in the civilian sector. Pilot projects in Russia also support home-based care, food and psychosocial support for most-at-risk patients; default rates are less than 2 percent compared to the national average of 10 percent.
- 14. South Africa** USAID assisted the National TB Program in developing guidelines piloting and scaling up decentralized and community-based MDR-TB and XDR-TB case management.
- 15. Tanzania** With USAID funds, TB/HIV services significantly expanded in Tanzania, reaching a total of 955 facilities in 35 districts in which 22,319 TB patients were notified. In addition, in these facilities 95 percent of all TB patients were tested for HIV.
- 16. Uganda** USAID leveraged PEPFAR funding for improved integration and implementation of TB/HIV activities, resulting in the screening of 30,866 TB patients for HIV, screening of 349,766 HIV-positive clients for TB, and the starting of 14,358 co-infected patients on TB treatment.
- 17. Ukraine** TB case detection rate of smear-positive cases in project sites has increased from 45 percent in 2009 to 55 percent in 2010.
- 18. Zambia** With USAID support, the case detection for all forms of TB significantly increased from 74 percent to 80 percent in the last year.
- 19. Zimbabwe** In USAID-supported Midlands Province, the treatment success rate increased from 53 percent to 81 percent and the default rate decreased from 19 percent to 5 percent from 2008 to 2010.

III. BUILDING ON SUCCESS

IN 2010, USAID SUPPORTED: Country Level Innovation and Success

Geo-mapping system developed in South Africa to help local governments identify and serve people with MDR-TB

Expanding TB/HIV collaborative care in Tanzania, with 95% of TB patients being tested for HIV in new sites

LED microscopy introduced nationwide in Bangladesh and Tanzania

Evaluated appropriate use of Line Probe Assay diagnostic testing for rapid screening of drug resistant TB in Brazil and South Africa



The U.S. Government is supporting the global effort to roll-out an exciting new diagnostic (Xpert) in priority countries and leading efforts in developing and implementing technical assistance to Ministries of Health. The Cepheid Xpert® MTB/RIF assay is a new molecular test that has the potential to transform how TB is detected. The assay can detect TB and mutations associated with rifampicin resistance in less than two hours with far greater accuracy than smear microscopy.

Successful interventions will be continued and expanded, including:

- Strengthened detection and treatment through:
 - Developing tools to address service delivery barriers, referral linkages, and screening for all levels
 - Implementing activities that increase capacity and willingness of communities and service providers to identify patients and provide care
 - Introducing and expanding use of Cepheid Xpert (MTB)/(RIF) to expand case detection
 - Implementing MDR-TB programs in the private sector
 - Improving the TB regulatory framework for the non-ministry of health sector
- Expanded access to first and second line drugs, including funding to the Global TB Drug Facility for financing and technical assistance to avoid drug stock-outs
- Increased investment in local pharmaceutical firms producing second line drugs to obtain certification by the WHO prequalification program to ensure there are at least two manufacturers producing an adequate supply of each second line drug within the next three years
- Testing of diagnostic tools and development of global laboratory norms and guidance
- Increased health system strengthening to accelerate scale-up of MDR-TB activities, surveillance for drug resistance, develop infection control policies and apply evidence-based programming
- Increased investments in operational research on access and service delivery to sustain the momentum in the decline of mortality due to TB to achieve the Millennium Development Goals in a timely manner
- Integration of TB program activities into GHI efforts in order to catalyze programmatic efficiencies within population and reproductive health, maternal and child health, HIV/AIDS, and nutrition and to reinvigorate local solutions to universal access and comprehensive care

CONCLUSION



MARY LINEHAN, ZANZIBAR 2006

Infants and young children are at special risk of having severe, often fatal forms of TB, such as TB meningitis, which can leave them blind, deaf, paralyzed, or mentally disabled.

Taking stock of the impact of the U.S. Government's sustained and strategic investments in global TB control reveals millions of lives saved every year as death rates in USAID-supported countries decreased by 29 percent since 1990. The U.S. Government's approach is responsive to country-level needs and priorities, ensures efficiency in the use of multiple funding sources, and promotes evidence-based and innovative solutions to persistent constraints to progress. In 2010, the results of its work toward increasing

access to care through community, private sector and other non-traditional providers bore fruit in country after country, with millions of additional cases being detected and provided quality-assured treatment. The work culminated in new global policy guidance, in collaboration with WHO and the Stop TB Department. With an estimated 1.7 million TB deaths in 2010, there is still work to be done and the U.S. Government's role in promoting technical excellence is as important as ever.

ENDNOTES

1. **Tier 1** Countries: Afghanistan, Bangladesh, Brazil, Cambodia, Democratic Republic of Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Nigeria, Pakistan, The Philippines, Russia, South Africa, Tanzania, Uganda, Ukraine, Zambia, Zimbabwe; **Tier 2** Countries: Armenia, Azerbaijan, Belarus, Bolivia, Djibouti, Dominican Republic, Georgia, Ghana, Haiti, Kazakhstan, Kyrgyzstan, Liberia, Malawi, Mexico, Namibia, Peru, Senegal, South Sudan, Tajikistan, Turkmenistan, Uzbekistan
2. 2010 refers to fiscal year 2010 results
3. WHO Global Tuberculosis Control Report, 2010
4. <http://www.who.int/tb/challenges/hiv/faq/en/>
5. Lin, H.C. and Chen, S.F. (2010). Increased Risk of Low Birth Weight and Small for Gestational Age Infants Among Women With Tuberculosis. *BJOG: An International Journal of Obstetrics and Gynaecology* 117(5): 585
6. WHO Global Tuberculosis Control Report, 2011
7. Tuberculosis disease report (The Global Fund to Fight AIDS, TB and Malaria), Geneva, 2006
8. Laxminarayan, R., Klein, E., Dye, C., Floyd, K., Darley, S., Adeyi, O. Economic Benefit of Tuberculosis Control. The World Bank, Human Development Network, Health Nutrition and Population Team. August 2007, p 1
9. Multi-Drug and Extensively Drug Resistant TB: 2010 Global Report on Surveillance and Response
10. Cambodia, Ethiopia, Pakistan, Indonesia
11. Bangladesh, Malawi, Namibia, Nigeria
12. Uganda and Benin
13. Wandwalo E., Robberstad B. and Morkve O. (2005). Cost and cost-effectiveness of community based and health facility based directly observed treatment of tuberculosis in Dar es Salaam, Tanzania. *Cost Effectiveness and Resource Allocation* 3: 6

U.S. Agency for International Development

1300 Pennsylvania Avenue, NW

Washington, DC 20523

Tel: (202) 712-0000

Fax: (202) 216-3524

www.usaid.gov