THE EXPAND-TB PROJECT
PROGRESS AND IMPACT BRIEF

REACHING PEOPLE WITH MDR-TB

PROGRESS IN DIAGNOSIS: A KEY STEP IN OVERCOMING THE MDR-TB CRISIS

The theme for World TB Day 2014 is “Reach the missed 3 million”. Every year 3 million people who fall ill with TB are ‘missed’ by health systems and do not always get the TB services that they need and deserve. One key element in reaching the unreached is improved access to quality TB diagnostic services. Capacity has been especially weak for diagnosing multidrug-resistant tuberculosis (MDR-TB), which is one of the critical elements in the overall response to end the MDR-TB crisis. Matching diagnosis with improved access to quality treatment and care is another key step in the response.

This brief presents results from a collaborative multi-country project that is a pathfinder in expanding access to diagnosis for people with MDR-TB, enabling them to get the care they need.

The EXPAND-TB (Expanding Access to New Diagnostics for TB) Project was initiated in 2009 to accelerate access to diagnostics for patients at risk of MDR-TB in 27 low- and middle-income countries. The project received US$ 87 million in financing from UNITAID. The project partners are, the World Health Organization (WHO) and the Global Laboratory Initiative (GLI), the Stop TB Partnership’s Global Drug Facility (GDF), and the Foundation for Innovative New Diagnostics (FIND).

BACKGROUND

THE MDR-TB CRISIS

In 2013, the World Health Organization (WHO) called for multidrug-resistant tuberculosis (MDR-TB) to be addressed as a **public health crisis**. MDR-TB is a global health security risk and carries grave consequences for those affected.

Globally in 2012, WHO estimates that 450 000 people fell ill with MDR-TB and there were 170 000 MDR-TB deaths.

The public health crisis of MDR-TB has three main elements which need to be addressed urgently.

1. Access to diagnostic services:

In 2012, only as few as 94 000 people (one in four) who were estimated to have MDR-TB were detected. This includes 84 000 people with confirmed MDR-TB plus 10 000 with rifampicin resistance. While this number represents nearly a 50% increase in MDR-TB detection as compared to 2011, progress towards reaching all people with MDR-TB remains far off-track.

2. Treatment coverage:

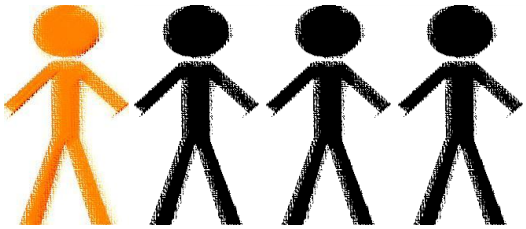
Beyond expanding access to diagnostic services, a key challenge is treatment coverage for people with MDR-TB. Just over 77 000 people with MDR-TB were started on second-line treatment in 2012, leaving at least 16 000 detected patients without treatment. Treatment coverage gaps for detected cases were much larger in some countries, especially in the African Region (51% enrolled in treatment), and widened in China, Pakistan and South Africa.

3. Quality of care:

Intensified efforts are also needed to improve quality of care for drug-resistant TB. The treatment success rate for MDR-TB patients is currently low at 48%. This suggests that most countries are not achieving high treatment success due to high mortality rates and a large number of patients being lost to follow up.

This brief focusses on the importance of expanding access to diagnostic services for people with MDR-TB as one of the crucial elements in overcoming the MDR-TB crisis. Results from the EXPAND-TB project illustrate how this can help make a difference in enabling people to access the care they need and deserve.

DIAGNOSING DRUG-RESISTANT TB: WHY IT MATTERS



Worldwide, less than one in four of the people estimated to have fallen ill with MDR-TB were detected in 2012.

Overcoming the MDR-TB crisis hinges on the scaling up of diagnostic capacity in countries to detect drug-resistant TB. Matching this with improved access to quality treatment and care completes the chain to enable people with MDR-TB to get the care they need.

BOTTLENECKS IN REACHING PEOPLE WITH MDR-TB

Limited access

Diagnostic services for MDR-TB are generally not easily accessible to patients. This is because many countries only have a central lab situated in big cities with limited or no capacity to diagnose MDR-TB, leading to patient samples being referred out of the country for diagnosis. For example, before 2008, Lesotho had limited laboratory capacity and some samples of patients were referred to South Africa for diagnosis. The high prices of some new diagnostic tests also pose financial barriers for access.

Lack of functional laboratories capable of providing quality assured TB diagnostic services

Modern diagnostics available through a network of appropriate and quality-assured laboratories will have a sustainable impact on MDR-TB control. However, laboratory capacity currently varies widely among resource-constrained countries, with generally few having reference laboratories capable of performing the recommended tests for MDR-TB including TB culture and drug susceptibility testing (DST).

Most countries still use outdated techniques which miss many people with TB and MDR-TB. The high price of new diagnostic equipment, together with the costs of training of staff and establishing new procedures inhibits countries from taking first steps towards modernizing their laboratories.

Shortage of well-trained staff

The tests for diagnosis of MDR-TB require skilled operators. Human resources at country level often don't have the skills required to use new diagnostic technologies.

BENEFITS OF EARLY DIAGNOSIS OF MDR-TB

Better treatment outcomes, including higher chances of survival

Cut risk of spread

THE EXPAND-TB PROJECT

EXPANDING ACCESS TO NEW DIAGNOSTICS FOR PEOPLE AT RISK OF MDR-TB

To enable people at risk of MDR-TB to be reached with diagnosis and care in a timely manner, the UNITAID Board approved US$ 87 million to finance a project in 2008 covering 27 low- and middle-income countries. These countries carry 40% of the estimated global burden of MDR-TB.

ABOUT

The EXPAND-TB (Expanding Access to New Diagnostics for TB) Project began operations in 2009. This project is being coordinated by the World Health Organization (WHO) and the Global Laboratory Initiative (GLI) in collaboration with the Foundation for Innovative New Diagnostics (FIND) and the Stop TB Partnership's Global Drug Facility (GDF).

AIM AND OBJECTIVES

The aim of the project is to diagnose more than 100 000 patients with MDR-TB through:

Improved control of MDR-TB	• by introducing rapid, quality-assured WHO-endorsed tests
Improved market dynamics	• by increasing market size and decreasing test price
Integrated tools in TB control programmes	• by supporting 100 TB laboratories in 27 countries

ROLES

UNITAID is the main funding partner and provides support for technical assistance and to procure equipment, reagents and consumables.

WHO hosts the secretariat of the Global Laboratory Initiative (GLI), and provides overall strategic guidance to the project. WHO also works closely with FIND and GDF to monitor project indicators and assess impact.

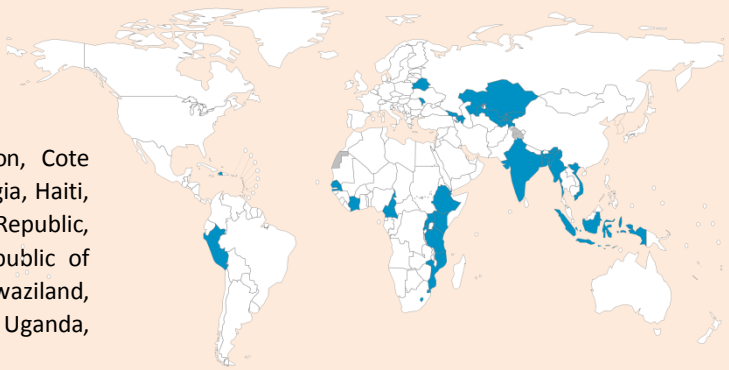
FIND is the main implementing agency. It is responsible for project management, including support for procurement and logistics, as well as training as part of technology transfer.

Stop TB Partnership's GDF coordinates and manages procurement and delivery of diagnostic equipment and supplies to eligible countries.

Other collaborators: EXPAND-TB complements resources provided in countries for laboratory strengthening, from the Global Fund, the World Bank, the US Government and others.

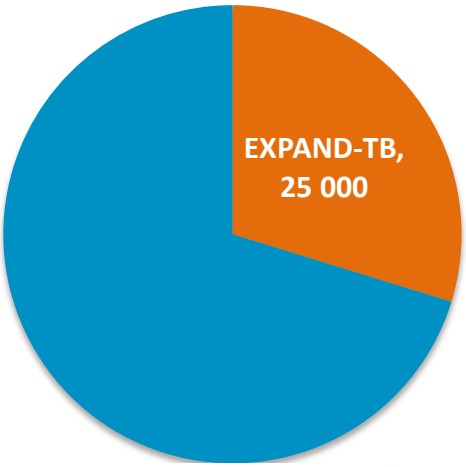
EXPAND-TB PROJECT COUNTRIES CARRY 40% OF THE GLOBAL MDR-TB BURDEN

Azerbaijan, Bangladesh, Belarus, Cameroon, Cote d'Ivoire, Djibouti, Ethiopia, Indonesia, Georgia, Haiti, India, Kazakhstan, Kenya, the Kyrgyz Republic, Mozambique, Myanmar, Lesotho, the Republic of Moldova, Peru, Rwanda, Senegal, Swaziland, Tajikistan, the United Republic of Tanzania, Uganda, Uzbekistan and Viet Nam.



KEY ACHIEVEMENTS

GLOBALLY IN 2012, NEARLY ONE THIRD OF THE NOTIFIED MDR-TB CASES WERE DETECTED THROUGH EXPAND-TB



84 000 people with confirmed MDR-TB detected globally in 2012

In 2012, nearly 30% of the confirmed MDR-TB cases globally, were diagnosed with EXPAND-TB project support.

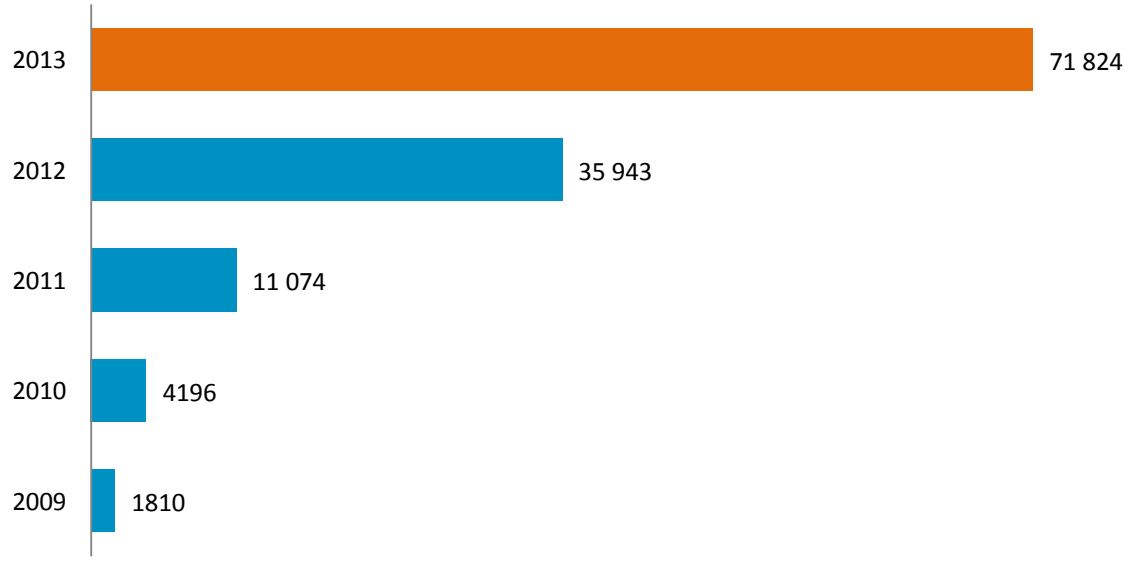
Between 2011 and 2012, the number of MDR-TB cases detected globally increased by almost half. This is attributable in large part to the EXPAND-TB project.

In India, 16 000 people with MDR-TB were detected in 2012 through EXPAND-TB. This represents 90% of the MDR-TB cases reported that year by the country.

IN 27 COUNTRIES NEARLY 72 000 PEOPLE WITH MDR-TB DIAGNOSED BETWEEN 2009-2013

Between 2009 and 2013, nearly 72 000 people with MDR-TB were detected through EXPAND-TB in 27 low- and middle-income countries.

CUMULATIVE NUMBER OF MDR-TB CASES DETECTED BETWEEN 2009-2013



MDR-TB DETECTION TRIPLED IN 27 COUNTRIES

In 2008, prior to the start of the project, the 27 countries reported 10 000 MDR-TB cases. In 2012, the number of MDR-TB cases being notified had tripled to more than 36 000 cases in the same countries. Around 70% of these cases were detected with EXPAND-TB support.

CAPACITY OF 92 LABORATORIES STRENGTHENED

LABORATORY CAPACITY

By the end of 2013, 92 of the 100 targeted laboratories were fully operational and reporting cases using quality-assured new and rapid TB diagnostics. A majority of them did not have the capacity to diagnose MDR-TB before the project.

Several new tests and diagnostic approaches endorsed by WHO have been rolled out through these laboratories. These include:

- Liquid culture and DST with rapid speciation as the reference standard for bacteriological confirmation;
- Molecular line probe assays for rapid detection of MDR-TB; and
- Xpert MTB/RIF for the rapid diagnosis of TB and rifampicin-resistant TB in under two hours.

HUMAN RESOURCE CAPACITY

Since the project's inception, over 450 laboratory staff, managers and other medical personnel have been trained by the EXPAND-TB implementation teams and manufacturers on new diagnostic methods. In addition, as part of technology transfer, expertise and tools were shared to assist with the introduction of new diagnostics and facilitate their proper use.

UNITAID/Gerhard Jörén

SHAPING THE MARKET

NEW DIAGNOSTICS

Increasing demand and decreasing price

The project has increased the market for new and rapid TB diagnostics through 92 newly established or upgraded laboratories and 24 decentralized GeneXpert sites. Over 620 000 line probe assays, 696 000 tests using liquid culture, 118 000 liquid culture tests for drug susceptibility testing, and 160 000 Xpert MTB/Rif tests were procured for EXPAND-TB since the start of the project. This has contributed to achieving decreases in prices for laboratory commodities and creating potential for competition. FIND has also facilitated negotiations with manufacturers to decrease prices for new diagnostic tools.

EXPAND-TB has benefited from the recent reduction in the cost of Xpert MTB/Rif cartridges in 145 low-and middle income countries. An agreement, reached by UNITAID, the United States Government and the Bill & Melinda Gates Foundation, significantly reduced the price of diagnostic cartridges from $17 in 2012 to less than $10.

Facilitating better country planning

Improved diagnostic capacity has also increased the information available on people diagnosed with MDR-TB. This has helped countries better plan for procurement of quality-assured drugs for people ill with MDR-TB, and ensure they are provided with quality treatment and care.

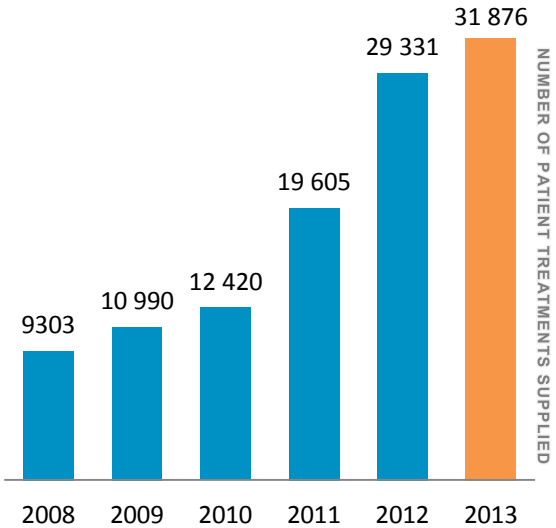
SECOND-LINE DRUGS

Increasing demand and decreasing price

EXPAND-TB has enabled more patients to be treated with quality-assured second-line drugs, and therefore contributed to increased demand for drugs provided by the Global Drug Facility. There has been an increase in procurement of second-line drugs with the greatest demand from India, Ethiopia, Uganda.

The project has contributed to stabilizing the market for second-line drugs through increased demand and helped the Global Drug Facility further secure significant drops in price of individual medicines and MDR-TB treatment regimens (up to 32% reduction).

GDF SECOND-LINE DRUG MARKET: PATIENT TREATMENT SUPPLY



ALIGNING RESOURCES AND BUILDING ON GAINS

COMPLEMENTARY FINANCING FROM PARTNERS

The EXPAND-TB project synergistically aligned its resources with both local and international partners beyond the project, including from The Global Fund, The World Bank, the US Government, and others. The EXPAND-TB project financed the purchase of diagnostic equipment and commodities, training of laboratory staff and technology transfer. Resources from international and local partners funded the building of laboratory infrastructure in many countries. Staff in laboratories are paid with domestic resources.

BUILDING ON GAINS

The EXPAND-TB project is a pathfinder in expanding access to diagnosis for people with MDR-TB, enabling them to get the care they need. The gains from the project need to be sustained and diagnostic capacity needs to be expanded in countries.

Sustaining interventions beyond the project require smaller investments which can be covered through domestic or other partner/donor resources. Four countries have already committed to covering the cost of commodities through other resources. Planning is underway with governments and partners in the other countries to sustain the investments required to keep the project activities going.

In Djibouti, EXPAND-TB invested almost US$ 1 million to set up laboratory infrastructure and train staff. Around US$60 000 was estimated per year in ongoing needs for laboratory commodities beyond the project. UNDP has already committed to finance this using current Global Fund resources.

Project countries are in the process of revising national TB strategic plans to incorporate new and rapid technologies and expand diagnostic capacity. EXPAND-TB consultants are assisting national TB programmes in developing laboratory components of national TB strategic plans.

This push to scale up diagnostic capacity must be matched with supplies of quality-assured drugs and scaled-up country capacity to deliver effective treatment and care. High level political commitment including bolstering of domestic contributions, and collaboration with partners and donors, are critical to end the MDR-TB crisis.

FIND/Jacques Debayle

EXPAND-TB PARTNERS

The World Health Organization (WHO) Global TB Programme guides global action for a world free of TB by advancing universal access to TB prevention, care and control; framing the response to threats through norms, standards and strategy; technically supporting Member States; monitoring the burden and response; and promoting innovation.

UNITAID is a global health initiative launched in 2006 by the Governments of Brazil, Chile, France, Norway and the United Kingdom to provide sustainable funding for the fight against HIV/AIDS, malaria and tuberculosis. About 70% of UNITAID's funds come from a small levy on airline tickets. Through implementers, UNITAID finances the purchase of quality-assured drugs and diagnostics for patients in poor countries, using its market power to expand supply, promote development of new and better products, cut delivery lead times and reduce prices.

Global Laboratory Initiative (GLI) is a global network of partners, including donors, national agencies, private foundations, scientific organizations, control programmes, and technical expert groups and committees, dedicated to TB laboratory strengthening at global, regional and country levels. The GLI secretariat is hosted by WHO.

Foundation for Innovative New Diagnostics (FIND) is an international non-profit organization that drives development and delivery of innovative diagnostic solutions for poverty-related diseases.

Stop TB Partnership's Global Drug Facility (GDF) is an initiative of the Stop TB Partnership which coordinates and manages procurement and delivery of high-quality anti-TB drugs and diagnostics and enables access to such products at the lowest possible price for countries in need.

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World Health Organization
Global TB Programme
www.who.int/tb
20, Avenue Appia
CH-1211 Geneva 27


Stop TB Partnership
GLOBAL DRUG
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foundation
for innovative new diagnostics

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