

IMPACT STORY: IMPROVING USE OF TUBERCULOSIS DIAGNOSTICS

*Fighting antimicrobial resistance
with innovation*

The problem

Multidrug-resistant tuberculosis (MDR-TB) is a major public health threat.

More than 10 million cases of tuberculosis (TB) occur each year. An estimated 600,000 of these are drug resistant tuberculosis (DR-TB), the majority of which are multidrug resistant¹ (MDR-TB). Resistance to antibiotics is a global concern. DR-TB could account for 1 in 4 deaths associated with antimicrobial resistance (AMR) by 2050, if left unaddressed².

In 2010, fewer than 10 percent of MDR-TB cases were diagnosed due to weaknesses in centralised laboratory-based facilities. Long turnaround times for test results means some people never receive their results. This makes it less likely for MDR-TB cases to be linked to appropriate treatment and increases the risk of onward transmission.

An innovative testing technology, GeneXpert, was made available and was strongly recommended by the World Health Organisation (WHO) as an initial diagnostic test for suspected MDR- and HIV-associated TB cases³. However, the cost of GeneXpert was too high for many low- and middle-income countries, resulting in low uptake.

The solution

What did Unitaid do?

In 2012, Unitaid invested US \$4.1 million to secure a 40 per cent price reduction for GeneXpert test cartridges⁴, and a further US \$25.7 million to procure 1.4 million GeneXpert cartridges for use in 21 countries. The investments enabled detection of more than 50,000 DR-TB cases. Most importantly, the investments created market conditions for broader adoption and scale up.

Where are we now?

Today, 130 countries procure over 7 million GeneXpert cartridges per year at the lower price negotiated by Unitaid and partners. Global procurement volumes are five times greater than before this price reduction was secured, and GeneXpert is now a core component of national TB programmes in many countries.

So far, there is limited evidence of the additional impact of GeneXpert: studies have shown similar cure rates compared to conventional testing⁵. This could be because health systems worldwide miss one third of estimated TB cases; thus patients never seeking care cannot benefit from faster

diagnostics. Patients that do seek care for symptoms of TB may be started on treatment without a diagnostic test result; here, the added value of GeneXpert—faster detection—is diminished.

What impact could GeneXpert have?

GeneXpert has been widely accepted because it is easier to use. Rapid detection of TB and MDR-TB could potentially offer more efficient and effective delivery of TB care. Bringing testing closer to patients could provide quicker diagnosis and treatment, improve clinical decisions due to the high accuracy of the GeneXpert test, reduce onward transmission of MDR-TB, and minimise the financial impact on individuals and families. Diagnostic testing can also reduce the misuse of antibiotics, which could mitigate some of the problems associated with antimicrobial resistance.

Looking ahead, delivering maximum impact from GeneXpert requires the reinforcement of health systems to find as many TB and DR-TB cases as possible.

¹ MDR-TB is defined as resistance to both isoniazid and rifampicin, the two most important first-line drugs.

² Tackling Drug-Resistant Infections Globally: final report and recommendations – Review on Antimicrobial Resistance.

³ Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: xpert mtb/rif system policy statement

⁴ In partnership with Bill and Melinda Gates Foundation and the United States Government including PEPFAR and USAID.

⁵ Xpert MTB/RIF versus sputum microscopy as the initial diagnostic test for tuberculosis: a cluster-randomised trial embedded in South African roll-out of Xpert MTB/RIF; Churchyard, Gavin J et al.

The main contributors to Unitaid are: France, United Kingdom, Brazil, Norway, Chile, South Korea, Mauritius, Madagascar, Spain and Bill & Melinda Gates Foundation.

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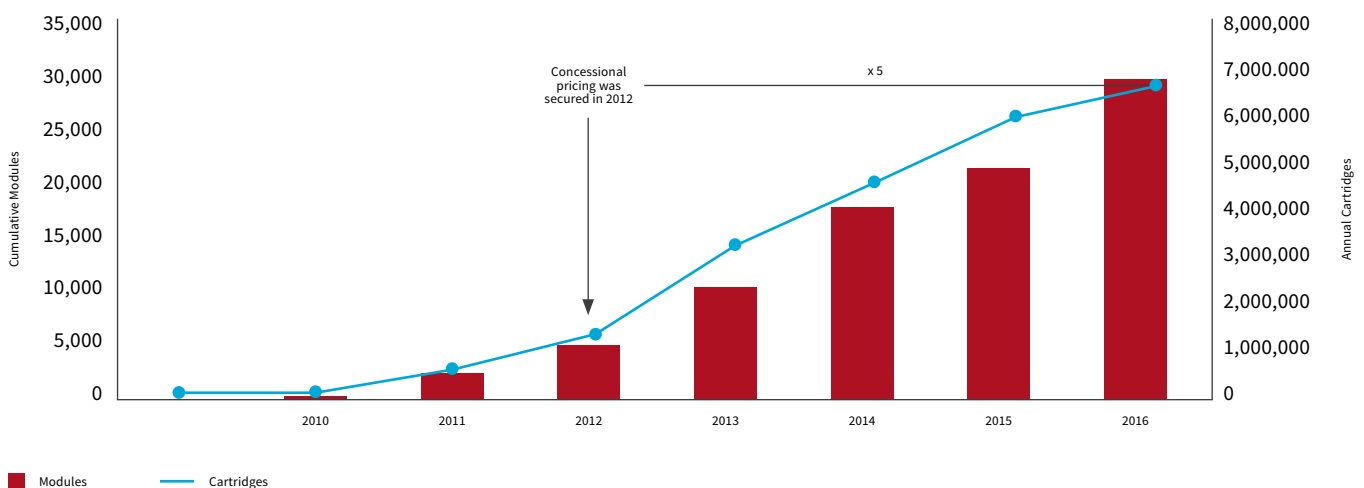
GeneXpert offers faster and more convenient TB testing.

		SMEAR MICROSCOPY	GENEXPERT
INITIAL DIAGNOSTIC TEST	Test to results	1 day	2 h
	Test performance (in adults, pulmonary TB)	Sensitivity variable Specificity >90%	Sensitivity 88%* Specificity 99%*
		CULTURE (CONVENTIONAL)	GENEXPERT
RIFAMPICIN RESISTANCE TEST	Test to results	6-8 weeks	2 h
	Test performance (in adults, pulmonary TB)	Gold standard	Sensitivity 95%* Specificity 99%*
DELIVERY MODEL		<ul style="list-style-type: none"> 1-3 patient visits RR test done centrally 	<ul style="list-style-type: none"> 1 patient visit Highly decentralised

* Policy update: Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children

By 2016, global procurement of GeneXpert cartridges increased five-fold following the price reduction facilitated by Unitaid and partners.

Number of GeneXpert instrument modules and Xpert MTB/RIF cartridges procured under concessional pricing



Source: WHO

* The GeneXpert System is available in single or multiple module configurations. They use the same cartridge technology for every test.