



**UNITAID**

**MID-TERM EVALUATION OF THE TBXPERT PROJECT**

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**FINAL REPORT**

Submitted by:

**Cambridge Economic Policy Associates Ltd**

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## ACRONYMS AND ABBREVIATIONS

Acronym	Full description
ASLM	African Society for Laboratory Medicine
BMGF	Bill and Melinda Gates Foundation
CEPA	Cambridge Economic Policy Associates
CHAI	Clinton Health Access Initiative
FIND	Foundation for Innovative New Diagnostics
GAL	Grant Agreement Letter
GDF	Global Drug Facility
GLI	Global Laboratory Initiative
icddr,b	International Centre for Diarrhoeal Disease Research, Bangladesh
IRD	Interactive Research and Development organisation
LIC	Low Income Country
LMIC	Lower Middle Income Country
LoA	Letter of Agreement
M&E	Monitoring and Evaluation
MDR-TB	Multidrug-resistant tuberculosis
MoU	Memorandum of Understanding
NTP	National Tuberculosis Programme
PEPFAR	President's Emergency Plan for AIDS Relief
POC	Point of Care
PPM	Public-private mix
PRC	UNITAID's Proposal Review Committee
STP	Stop TB Partnership
TBR	TB REACH
TOR	Terms of Reference
UMIC	Upper Middle Income Country
USAID	United States Agency for International Development
WHO	World Health Organization

## **EXECUTIVE SUMMARY**

This report presents the findings, conclusions and recommendations of Cambridge Economic Policy Associate's (CEPA's) mid-term evaluation of the TBXpert project.

Approved by UNITAID in June 2012, the TBXpert project aims to support the scale-up of rapid diagnosis of TB, HIV-associated TB and drug-resistant TB through the increased uptake of Xpert MTB/RIF. Xpert MTB/RIF is a breakthrough TB diagnostic tool, manufactured by Cepheid and recommended for use by WHO to simultaneously detect TB and rifampicin drug resistance in less than two hours. The project timeframe is 2013-15, following a buy-down arrangement negotiated by the Gates Foundation, USAID/PEPFAR and UNITAID for a price reduction of Xpert MTB/RIF cartridges from US\$16.86 to US\$9.98 in 145 high-burden and developing countries. Total UNITAID funding for the project is US\$25.9m to support the roll-out of the diagnostic tool in 21 low- and middle-income countries. The lead implementers are the WHO Global TB Programme (referred to as WHO going forward) and the Stop TB Partnership/ TB REACH initiative.<sup>1</sup>

In line with the evaluation objectives, we have structured our evaluation framework around three dimensions that aim to assess:

- the **relevance** of the project, given UNITAID's mandate as well as the current TB diagnostic landscape and country needs;
- the **efficiency** and **effectiveness** of project implementation, considering timeliness, budget management, coordination, roll-out of the Xpert tool (including through the public-private mix (PPM) models), procurement arrangements; and
- the **public health and market impact** as well as the **sustainability** of the project.

A mixed-methods approach has been employed including: document and data review; consultations with project partners and other stakeholders; and field visits to India, Indonesia and Tanzania.

Our main findings across the evaluation dimensions as well as summary conclusions and recommendations are presented below.

### **Evaluation dimension 1: Relevance**

The TBXpert project is well-aligned with UNITAID's mission and objectives. The project supports UNITAID's mandate and comparative advantage of circumventing market challenges for TB diagnostics, however the scale-up objective of the project is constrained by the limited affordability of Xpert MTB/RIF (despite the negotiation of a lower cartridge price through the buy-down arrangement). The project design works well, however a key issue is the almost

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<sup>1</sup> TB REACH also provides US\$16.7m of complementary funding for select grants.

exclusive commodity focus of the funding, with limited funding for technical assistance which is critical to support the introduction of a new technology in countries.

Xpert MTB/RIF is not becoming the new standard technology for TB diagnosis due to its relatively high cost and well-embedded nature of sputum smear microscopy in National TB Programme (NTP) policies and country health systems. Although the project has successfully rolled-out Xpert MTB/RIF at the decentralised level and has improved access for hard-to-reach and vulnerable populations, weak referral links for culture/DST and treatment and lower capacity at this level are important challenges.

## **Evaluation dimension 2: Efficiency and effectiveness**

Our review encompasses a number of aspects of the efficiency and effectiveness of project implementation and key findings are as follows:

- **Timeliness and budget management:** There has been a lengthy process to project approval (almost two years) and a number of key delays at project commencement, including manufacturing delays and a range of country-specific issues (e.g. preparation of project sites, customs clearance). These have resulted in testing starting later than planned and indicates somewhat ambitious targets in relation to the time required to “get started”. The budget is overwhelmingly focused on commodity procurement, with inadequate monies for technical assistance and supporting costs for the introduction of a new technology, which has posed a challenge for effective implementation.
- **Delivery and coordination:** Delivery by project partners has worked well, but there have been some issues with lack of experience of the TA partner African Society for Laboratory Medicine (ASLM) and some discontinuities caused by high staff turnover at UNITAID. Global-level coordination has been facilitated well under the project, although constrained by limited funding. However, the extent of country-level coordination across the NTP, NGO grantees and other donors has varied depending on the involvement of the local WHO office, provision of effective technical assistance and relationship between the NTP and project grantees.
- **Product implementation:** Evidence from consultations suggests that the principal challenge has been module failure due to dust and calibration. Cepheid introduced a number of preventative and corrective measures, which have largely been satisfactory. However, the warranty arrangements for the instruments have been a key concern, due to their high cost and inconsistent experiences across implementers in terms of the response by Cepheid and awareness of coverage details. In addition, a number of major issues have affected the implementation of the technology, including: (i) inadequate infrastructure; (ii) lack of training for correct utilisation and maintenance; (iii) restrictive diagnostic algorithms; (iv) weak linkage with referral systems; and (v) lack of real time reporting systems. The range of these issues highlight

the challenges involved in introducing and rolling out the technology, where it has been indicated that access to additional funds for technical assistance and to support implementation would be useful.

- **Functioning of PPM models supported by the project:** The three PPM projects in Dhaka, Karachi and Jakarta have been innovative in encouraging the use of Xpert MTB/RIF in the private and non-NTP sector, but have faced a number of challenges including delays in getting started, issues around ensuring adequate referrals to support the planned revenue generation, and challenges establishing effective linkages with treatment. These have affected the results achieved, which, though improving over the period examined, are short of targets.
- **Procurement arrangements:** The procurement arrangements and processes, including lead times have largely been efficient, on account of the efforts of project implementers and Cepheid. Key issues have been with regards to poor accuracy of cartridge forecasts and customs clearance in countries (resulting in delayed delivery to project sites).

### **Evaluation dimension 3: Results and sustainability**

The project M&E framework is well-designed and reporting by implementing partners has been timely and high-quality, although could be improved with project-specific information (to help better understand good and poor experiences) and more detailed narratives supporting the reporting.

Both public health and market impact have been lower than planned to date, largely due to the delays in the initiation of the project in 2013 and, to some extent, over-ambitious targets and timelines. The project has however made substantial “catch-up” progress in 2014.

- Up to mid-2014 the project has supported the detection of 32,154 cases of incident TB (23% of target), 3,554 cases of HIV-positive TB (16% of target) and 8,646 cases of MDR-TB (27% of target) in the 21 focus countries. The broader public health impact of the project in terms of linkages with treatment has had mixed experience to date, with some countries/ projects exhibiting ongoing improvements in treatment initiation and success and others with some key gaps in the diagnosis-treatment linkage.
- Cartridge procurement up to December 2014 has been 607,240 (42% of target) in the project countries. The project partners are presently discussing a “re-allocation plan” wherein cartridges will be provided to projects with higher absorption capacity. Our assessment is that this is sensible from an efficiency perspective, but detracts from the project goal/ objectives by virtue of not supporting “difficult/ challenging” projects. We understand that there is no provision within the project to provide additional support to these challenging countries.

- The global procurement of Xpert cartridges has increased substantially since the buy-down agreement and the commencement of the TBXpert project (also in terms of the number of countries procuring cartridges). However the market is heavily dominated by South Africa, with limited expansion across other countries.
- The savings achieved from the price reduction under the buy-down agreement have been significant, though we note that the potential for broader market impacts in terms of further price reductions for Xpert MTB/ RIF are limited at the current/ near term market size. However the project has the potential to contribute to encouraging the market for molecular-based diagnostic tests.

Sustainability is a critical measure of the project's success, and while WHO and TB REACH have made important efforts to support sustainability (through discussions with NTPs, Global Fund), this has not been approached systematically to date. Planned transition plans for countries have not been developed and a planned UNITAID transition tool has not been shared with the implementing partners. It is noted however that Xpert funding has been included in some country concept notes for Global Fund support.

### **Conclusions, lessons learned and recommendations**

Our overarching conclusion is that the TBXpert project is a significant intervention, given the need to enhance TB diagnosis and the “breakthrough” nature of this technology. However, with the initial delays in project commencement and the relatively limited rate of scale-up across project countries due to issues with affordability and some implementation challenges, the potential for Xpert MTB/RIF to become the standard TB diagnostic in the near future is low. That said, the project is playing an important role in encouraging countries to adopt newer, more efficient TB diagnostics that may become available in the medium term. As such, we conclude that the project provides positive value for money, however this may be at risk unless sustainability planning is more effectively and systematically carried out.

Based on our evaluation findings and conclusions, we provide some recommendations on what might be feasible to implement within the remaining timeframe of the project. Some of the recommendations also extend to UNITAID project planning and funding more generally.

**Recommendation 1:** UNITAID should discuss and agree with the implementing partners an appropriate project extension (e.g. at least for one year and at no additional cost) and related revision of targets. In the absence of an extension, project achievements may be lower than optimal, there may be a significant risk of curtailing scale-up in countries when progress is just beginning to be made as well as potentially negative “demonstration effects” to diagnostic developers/ manufacturers.

**Recommendation 2:** Sustainability planning should be expedited for all countries/ grantees through: (i) the development of the planned UNITAID transition tool; (ii) increased engagement by implementing partners with NTPs, Global Fund, other donors and (where relevant) local private sector; (iii) establishment of a comprehensive database to support

tracking of replacement funding; (iv) encouragement of grantees to develop their sustainability plans; and (v) a broad-based approach to sustainability planning in terms of funding for machines and cartridges as well as project support costs. Robust sustainability plans should be included in the design of all UNITAID-supported projects, with focused efforts at ensuring delivery against the plan from the start of the project.

**Recommendation 3:** A grantee by grantee review should be conducted to consider where lack of TA support and additional monies to support implementation are serving as key bottlenecks, and find appropriate solutions on a case-by-case basis. More generally, UNITAID should include some provision for TA and ancillary costs (alongside commodity funding) to ensure effective introduction and roll-out of a new technology.

**Recommendation 4:** A critical appraisal of the PPM models needs to be conducted and appropriate revisions to their targets considered. The projects may benefit from greater focusing of efforts, development of a detailed financial model that considers scenarios for revenues and costs, revision of current targets, and documentation of key experiences to foster learning.

**Recommendation 5:** Support should be provided for the use of remote monitoring tools, both for the present TBXpert project and other relevant commodity projects. Remote monitoring tools/ softwares, such as GXalert and RemoteXpert for the Xpert MTB/RIF tool, provide visibility on the use of GeneXpert machines and enable countries to use the machines more efficiently.



## 1. INTRODUCTION AND EVALUATION APPROACH

Cambridge Economic Policy Associates (CEPA) has been appointed by UNITAID to undertake a mid-term evaluation of “the TBxpert project”, under UNITAID’s long-term agreement on evaluations with CEPA. This report presents our evaluation findings, conclusions and recommendations.

In this introduction section, we provide a brief description of the UNITAID TBxpert project (Section 1.1), the evaluation framework and methodology (Section 1.2), and the structure of the report (Section 1.3).

### 1.1. Background to the TBxpert project

In June 2012, UNITAID approved the TBxpert project that aims to support the scale-up of rapid diagnosis of TB, HIV-associated TB and drug-resistant TB through the increased uptake of Xpert MTB/RIF. Xpert MTB/RIF is a “breakthrough” TB diagnostic tool, manufactured by Cepheid and recommended for use by the World Health Organisation (WHO), to simultaneously detect TB and rifampicin drug resistance in less than two hours.<sup>2</sup> The project goal and specific outputs are presented in Table 1.1.

*Table 1.1: Project goal and outputs*

<b>Goal</b>	Increase access to rapid diagnosis of TB, HIV-associated TB and drug-resistant TB among vulnerable populations in low- and lower middle-income countries, via increasing uptake of Xpert MTB/RIF
<b>Outputs</b>	<ol style="list-style-type: none"><li>1. Timely procurement of 223 Xpert MTB/RIF instruments in project sites in 21 low and middle-income countries, utilising 1,444,960 Xpert MTB/Tests.</li><li>2. Rapid testing for TB and drug resistance in at-risk populations available at lower health services, using effective diagnostic algorithms integrated into laboratory networks and in cooperation with partners.</li><li>3. Ensuring effective use of procured commodities.</li><li>4. Increased market penetration of Xpert MTB/RIF in the private and public non-NTP sector to accelerate uptake and increase demand from this largely un-tapped new market.</li><li>5. Ensuring country coordination with other technical agencies and donors.</li><li>6. Transitioning out to ensure continuation of use of instruments after project conclusion.</li></ol>

During the project design phase, UNITAID along with the Bill and Melinda Gates Foundation (BMGF), United States Agency for International Development (USAID) and the President’s Emergency Plan for AIDS Relief (PEPFAR) negotiated a reduction in the price of the Xpert

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<sup>2</sup> The technology is based on the GeneXpert platform and was developed as a partnership between the Foundation for Innovative New Diagnostics (FIND), Cepheid Inc. and the University of Medicine and Dentistry of New Jersey, with support from the US National Institutes of Health. FIND led negotiations in 2010 to reduce the price of the instrument by 75% for low and middle income TB endemic countries.

MTB/RIF cartridges through a buy-down arrangement with Cepheid.<sup>3</sup> This price reduction has been made available to public sector purchasers in 145 countries, including the 21 countries of focus under the TBxpert project.

The project timeframe is 2013-15, with funding of US\$25.9m from UNITAID. The lead implementers are the WHO Global TB Programme (referred to as WHO going forward) and the Stop TB Partnership (STP) along with a consortium of partners comprising the TB REACH initiative, Global Drug Facility (GDF), African Society for Laboratory Medicine (ASLM), Interactive Research and Development organisation (IRD), the Global Laboratory Initiative (GLI) and the Expand-TB project.<sup>4</sup> The project grantees implementing the Xpert testing on ground are both National TB programmes (NTPs) and non-governmental organisations.

## 1.2. Evaluation framework and methodology

As per the Terms of Reference (TOR) and discussions with the UNITAID Secretariat, the aim of the evaluation is to assess grant performance and consider project achievements and lessons learnt, to inform mid-course correction, as required.

As such, we have structured an evaluation framework with three dimensions as follows (refer Figure 1.1):

- **Relevance:** an assessment of the alignment of the project with UNITAID's mission and strategic objectives as well as the relevance of the Xpert MTB/RIF tool given the current diagnostic landscape and country needs.
- **Efficiency and effectiveness:** considering timeliness, budget management, coordination, experience with roll-out of the Xpert tool (including through the public-private mix (PPM) models) and adequacy of procurement arrangements.
- **Results and sustainability:** a review of the project M&E arrangements, whether it is on track to achieve its targets on public health and market impact, and sustainability of the project following UNITAID's funding.

Within each dimension we have structured specific evaluation questions that capture the key issues relevant for this evaluation. Our analysis across these evaluation questions forms the basis for the development of evaluation conclusions (including on the value for money (VfM) of the project), lessons learnt and recommendations.

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<sup>3</sup> The buy-down arrangement was for US\$11.1m, of which UNITAID contributed up to US\$4.1m and the Gates Foundation and US Government (USAID and PEPFAR) contributed up to US\$3.5m each. There was an additional agreement between Cepheid and UNITAID, whereby UNITAID's proportion of the buy-down would be reduced, depending on global volume thresholds in 2013 and 2014. The threshold was surpassed in August 2013, so UNITAID did not disburse its final tranche of US\$0.9m to Cepheid.

<sup>4</sup> EXPAND-TB is a UNITAID funded project that aims to accelerate access to rapid diagnostics for patients at risk of multidrug-resistant tuberculosis (MDR-TB).

Figure 1.1: Evaluation framework

Evaluation Dimensions	Evaluation questions
<b>Dimension 1: Relevance</b>	1. To what extent is the project <b>aligned</b> with UNITAID’s mission and strategic objectives? 2. How <b>relevant</b> is the project given the current TB diagnostic landscape and country needs?
<b>Dimension 2: Efficiency and effectiveness</b>	3. Has project implementation to date been <b>efficient</b> in terms of: <ol style="list-style-type: none"> <li>timeliness and budget management;</li> <li>delivery and communication between project partners - UNITAID, WHO, STP (including TBR and GDF), IRD, ASLM, GLI, Expand TB; and</li> <li>coordination with NTPs and broader in-country donors?</li> </ol> 4. Has the project been implemented <b>effectively</b> and what factors have influenced results, in terms of: <ol style="list-style-type: none"> <li>product implementation issues (including module failure, maintenance and warranty arrangements, etc), supplier responses to issues and overall customer satisfaction;</li> <li>implicit costs of accessing the diagnostic tool and test turn around times; and</li> <li>implementation of the public-private models (PPM).</li> </ol> 5. Are the <b>procurement arrangements consistent</b> with plans and have they worked well in practice?
<b>Dimension 3: Results and sustainability</b>	6. Have the project <b>M&amp;E arrangements</b> been appropriately designed and implemented in practice? 7. Is the project <b>on track to achieve its targets</b> and what have been the <b>results</b> to date, in terms of: <ol style="list-style-type: none"> <li>public health impact of improving diagnosis and treatment of TB, HIV/TB and MDR-TB; and</li> <li>market impact of scale-up of Xpert MTB/RIF.</li> </ol> 8. Are the project activities likely to be <b>sustained</b> after UNITAID funding?
<b>Evaluation conclusions (including on value for money), lessons learnt and recommendations</b>	

We have employed a mixed-methods approach for the evaluation including desk-based review of the project documents and the broader literature on the Xpert MTB/RIF diagnostic tool; consultations with project partners and select external consultees (e.g. BMGF, USAID); country field visits to India, Indonesia and Tanzania; and select quantitative analysis of the project budget and results. Key limitations of our methodology are the limited time for the country visits (due to time and budget constraints) and availability of progress data until mid-2014 only (resulting in only one data point for some indicators which are reported annually).

### 1.3. Structure of the report

The report is structured as follows:

- Sections 2-4 present our findings across the three evaluation dimensions of (i) relevance; (ii) efficiency and effectiveness; and (iii) results and sustainability; and
- Section 5 concludes and provides recommendations.

The report is supported by the following annexes (included as a separate document): Annex 1 presents the evaluation methods and limitations in detail; Annex 2 presents the bibliography; Annex 3 provides the list of consultees and the interview guide; Annex 4 presents our analysis of diagnosis costs for patients with Xpert MTB/RIF; Annexes 5-7 present the country reports for Tanzania, India and Indonesia; and Annex 8 presents an analysis of select TBXpert progress indicators.

## 2. EVALUATION DIMENSION 1: RELEVANCE

The first evaluation dimension on relevance assesses the alignment and contribution of the project to UNITAID's mission and objectives as well as in the context of the TB diagnostic landscape and country needs. Each of these aspects is considered in turn below.

### 2.1. Alignment with UNITAID mission and objectives

Our evaluation question is as follows:

**Qs 1: To what extent is the project aligned with UNITAID's mission and objectives?**

We consider the alignment of the TBxpert project with UNITAID's mission and 2013-16 Strategic Objectives, as well as in the context of its overall mandate and key project selection criteria.<sup>5</sup>

In general, given the objective of increasing uptake and scaling-up access to the latest and revolutionary TB diagnostic technology, the project is well-aligned with UNITAID's mission to *"contribute to scaling-up access to treatment for HIV/AIDS, malaria and TB for people in developing countries by leveraging price reductions of quality drugs and diagnostics, which are currently unaffordable for most developing countries and to accelerate the pace at which they are made available"*.<sup>6</sup> While Xpert MTB/RIF is not a point-of-care (POC) diagnostic tool, it can be made available at a more decentralised level than other technologies and hence the project supports UNITAID's Strategic Objective (SO) 1, which aims to *"increase access to simple, point-of-care diagnostics for HIV/AIDS, TB and malaria"*.<sup>7</sup> Our project consultations have highlighted the strong alignment of the project with UNITAID's mandate given the significance of the Xpert MTB/RIF technology and its current access challenges.

We make the following specific points on the project objectives and design in relation to UNITAID's mandate and key project selection criteria:

**In line with UNITAID's mandate and comparative advantage, the project focuses on addressing key market shortcomings for TB diagnostics, but some challenges remain.**

As per its current strategy, UNITAID's comparative advantage lies in focusing *"exclusively on addressing market shortcomings at the global level as a means to sustainably increase access to health products for people specifically in developing countries"*.<sup>8</sup> With up to 40% of people with active TB not having access to initial diagnostics, and ever fewer with access to drug-susceptibility testing (DST), the availability of the "game-changing" technology of Xpert

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<sup>5</sup> First tier criteria include public health effects, market effects, value for money and innovation, whilst second tier-criteria draw on the principles of UNITAID's Constitution, which are leverage, value add, equity and ability to transition (if applicable). Reference: UNITAID (2013) UNITAID Strategy 2013-16, p.27-28 and p.97.

<sup>6</sup> <http://www.unitaid.eu/en/who/mission-and-strategy>

<sup>7</sup> UNITAID (2013) UNITAID Strategy 2013-16, p. 15.

<sup>8</sup> UNITAID (2013) UNITAID Strategy 2013-16, p. 26.

MTB/RIF has considerable potential but requires addressing market challenges relating to availability, acceptability, affordability and efficient delivery.

The key market challenge was addressed through the UNITAID-BMGF-USAID/ PEPFAR buy-down arrangement with Cepheid that brought down the price of the Xpert MTB/RIF cartridge from US\$16.86 to US\$9.98 for 145 countries (thereby also supporting UNITAID's principle on "leverage" by increasing global access to products); and this scale-up project aims to build on this achievement to support increased uptake of the technology in countries. However there is a challenge given the current monopolistic market for the technology and the fact that the scale-up objective is still constrained due to affordability – as also discussed in the subsequent sections below.

Notwithstanding this constraint, UNITAID's value as a key partner for the buy-down agreement and an important donor for encouraging scale-up is recognised.

**The project design in terms of selection of lead implementing partners works well, however there are issues with regards to an almost exclusive commodity focus of the funding, and to some extent, country selection.**

The project design, in terms of the lead implementing partners of the WHO Global TB Department and the Stop TB Partnership/ TB REACH initiative, works well given the role of the former in coordinating and supporting TB programmes globally and the experience of the latter in supporting Xpert MTB/RIF and other innovative approaches to TB case detection.<sup>9</sup> As such, the project supports UNITAID's key principles of "complementarity" by working through strong partners with relevant experience; "leverage" by drawing in US\$16.7m of complementary funding from the TB REACH initiative for select grants; and alignment/ coordination with other partner work (e.g. one of the key factors for country selection was the country focus of the EXPAND-TB project to encourage cross-project synergies).

However, a key issue is the almost exclusive focus on commodity funding (81% of the total budget), with limited additional monies for technical assistance (TA) support, which is viewed as critical for supporting the introduction of a new technology (notwithstanding the relative simplicity of Xpert MTB/RIF). This is also discussed in more detail in Section 3.1 below.

Additionally, while we understand that country focus was subject to considerable discussion and review during the proposal development and finalisation stages, the inclusion of particularly challenging countries such as Congo (not a high-burden country (HBC) and with low country readiness for introduction both in terms of laboratory capacity and ability to treat patients detected with TB/ MDR-TB) have posed an issue in terms of encouraging/ demonstrating results/ scale-up. That said, country selection has been based on a number of relevant factors (including TB burden and capacity) and UNITAID has exhibited flexibility by

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<sup>9</sup> We discuss delivery against roles and responsibilities of all project partners in detail in Section 3.2, where we highlight some issues.

supporting countries such as India and Moldova that would encourage the scale-up objective of the project (whilst not being priority countries for UNITAID).<sup>10</sup>

**The project design also supports a number of other key UNITAID principles/ project selection criteria.**

For example:

- The project is supporting “innovation” on two levels: (i) *technological innovation*, through the introduction and roll-out of the Xpert MTB/RIF tool as the newest and most innovative technology in the TB diagnostic market; and (ii) *programmatic innovation*, through the design and implementation of new models for TB case detection, in particular PPM approaches.
- The project has a strong “equity” attribute in that: (i) it is supporting countries which have the highest burden of TB, MDR-TB and TB-HIV (81% of TBXpert project countries are either TB HBCs or MDR-TB HBCs; 62% of project countries are also categorised as high TB-HIV burden countries); and (ii) through TB REACH, the project is targeting hard-to-reach and vulnerable populations (e.g. prisoners in Tanzania; urban working poor in Bangladesh, Indonesia and Pakistan; rural populations in Ethiopia; children in Swaziland; etc).

**The TBXpert project is well-aligned with UNITAID’s mission and objectives. The project supports UNITAID’s mandate and comparative advantage of circumventing market challenges for TB diagnostics, however the scale-up objective of the project is constrained by the limited affordability of the Xpert MTB/RIF technology (despite the negotiation of a lower cartridge price through the buy-down arrangement). Further, the almost exclusive commodity focus of the funding implies limited funding for technical assistance which is required to support country introduction of a new technology.**

## **2.2. Relevance given diagnostic landscape and country needs**

Our evaluation question is as follows:

**Qs 2: How relevant is the project given the current TB diagnostic landscape and country needs?**

Although not a POC diagnostic, Xpert MTB/RIF is more sensitive compared to smear microscopy, is able to detect rifampicin resistance and HIV-associated pulmonary TB and can be placed at decentralised levels given lesser need for direct linkage with the central reference laboratories (although linkages with central laboratories are still required for confirmatory culture/ DST). In this context, we examine the following key issues:

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<sup>10</sup> UNITAID (2012) Response to UNITAID questions for clarification, p. 4.

- whether Xpert MTB/RIF is becoming the new standard test for diagnosing TB/ MDR-TB and crowding out other diagnostics (or becoming complementary to other methods of TB diagnosis); and
- the relevance of the decentralised placement of the technology in countries.

We consider each of these aspects in turn below.

### 2.2.1. Extent of standardisation of Xpert MTB/RIF

Although the introduction and roll-out of Xpert MTB/RIF is taking place across the 21 project countries (albeit at different paces), feedback from our project consultations consistently indicated that Xpert MTB/RIF is *not* becoming the new standard TB diagnostic technology. That said, consultations did indicate that Xpert MTB/RIF is indeed becoming more of a standard technology to identify MDR-TB and HIV-associated TB, as reflected in countries changing their diagnostic algorithm to use Xpert MTB/RIF rather than smear microscopy as the initial diagnostic test for TB-HIV patients and as a rapid test to identify MDR-TB patients (rather than waiting for patients to fail first-line drug therapy before being tested for MDR-TB through culture and DST).<sup>11</sup> The key challenges impeding the broader standardisation of Xpert MTB/RIF include:

- **The relatively high cost of the Xpert MTB/RIF instrument and cartridges:** Consultation feedback indicated that the cost of the instrument as well as each cartridge at approximately US\$10 limits the ability of Xpert MTB/RIF to become the standard technology for TB diagnosis. With the exception of Brazil and Russia, who currently fund their Xpert MTB/RIF testing from domestic resources, the roll-out of Xpert MTB/RIF in other countries continues to be predominantly donor funded.<sup>12</sup> Our consultations with NTPs for the project indicated unaffordability as a key issue impacting the potential for scalability.
- **The well-established nature of sputum smear microscopy and the role of other tests:** Despite its low sensitivity, smear microscopy has been the most commonly used TB diagnosis test since it was developed in 1880, and is thus deeply entrenched in countries' approach and health systems structure for TB diagnosis.<sup>13</sup> Data on laboratory diagnostic services from WHO indicates that in 2013, the 21 TBXpert project countries had 33,394 laboratories providing TB diagnostic services using smear microscopy as compared to only 417 laboratories using Xpert MTB/RIF.<sup>14</sup> Findings

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<sup>11</sup> Our assessment is based on a select number of consultations and country reviews carried out under this evaluation and should be further verified based on data. Specifically, in India and Indonesia, the algorithms have been changed to include Xpert testing of HIV patients with presumptive TB.

<sup>12</sup> Qin, Z.Z. et al. (2015).

<sup>13</sup> [http://www.finddiagnostics.org/programs/tb/tb\\_diagnostics.html](http://www.finddiagnostics.org/programs/tb/tb_diagnostics.html)

<sup>14</sup> WHO database on laboratory diagnostic services available at <http://www.who.int/tb/country/data/download/en/>

from a recent review of the implementation of Xpert MTB/RIF in 22 high TB burden countries found that “wide-scale implementation of Xpert has only occurred in South Africa, while other HBCs continue to rely heavily on smear microscopy”.<sup>15</sup> Further, feedback from country consultations has noted Xpert MTB/RIF will not become the standard technology for TB case detection due to its inability to detect other forms of TB drug resistance (e.g. isoniazid resistance), for which validation by culture/ DST is still required.

Some relevant findings from our three country visits are reflected in Table 2.1.

Table 2.1: Changing approach to Xpert MTB/ RIF in select countries

Country	Details
India	The NTP has revised its clinical algorithm in 2013 to focus Xpert MTB/RIF use to identify MDR-TB patients. While the NTP plans to roll out 950 sites with Government of India and Global Fund support by 2017, Xpert MTB/RIF is considered expensive and viewed as an “add-on test” that will not replace smear microscopy in the near future.
Indonesia	The NTP has revised its policy and algorithm to allow TB and DR-TB symptomatic patients with a negative sputum smear test to have an Xpert MTB/RIF test (instead of waiting for the result of two weeks treatment with a non-specific broad-spectrum antibiotic followed by a repeat sputum smear test). Indonesia plans to roll out Xpert technology to about 500 districts by 2019. However, Xpert is not expected to replace sputum smear microscopy any time soon due to its high cost. Instead, it is seen as an additional diagnostic test, in cases where clinical suspicion for TB is high and sputum smear microscopy is not conclusive.
Tanzania	Tanzania recently adapted the national algorithm for TB diagnosis, in line with the WHO recommendation, for Xpert MTB/RIF to be used to test all TB suspects (including people living with HIV and paediatric TB suspects), where resources and Xpert capability is available. In support of this objective, the expansion of GeneXpert machines to the majority of Tanzania’s 169 districts is due to be included in the NTP Strategic Plan for the period 2015-20 which will be launched later this year. However funding and capacity constraints may serve as a key impediment.

### 2.2.2. Decentralised placement of the diagnostic

WHO guidelines recommend the placement of Xpert MTB/RIF outside central reference laboratories and at locations which are closest to patients. In line with this guidance, the TBXpert project supports the decentralised placement of Xpert MTB/RIF testing to “reduce diagnostic delays, improve time-to-appropriate-treatment for patients, and reduce the period of patient infectiousness, resulting in reduced transmission”.<sup>16</sup> Our review of the actual extent

<sup>15</sup> The authors calculated the ratio of smear volumes to the number of Xpert cartridges procured during a roughly similar period of time: the ratio of smears performed for each Xpert test was significantly lower in South Africa (1.6) compared to all other HBCs (wherein it ranged between 40-70). Ref: Qin, Z.Z., Pai, M., van Gemert, W., Sahu, S., Ghiasi, M., and Creswell, J. (2015) How is Xpert MTB/RIF being implemented in 22 high tuberculosis burden countries? In European Respiratory Journal, 45:549-554.

<sup>16</sup> Project Plan, p.8



of decentralised placement of Xpert MTB/RIF testing indicates that, by the end of 2013, 98% (217 out of 222) of GeneXpert machines procured have indeed been placed at sites outside of central-level TB reference laboratories.<sup>17</sup>

Evidence from project document review and the evaluation field visits suggests that the decentralised placement of the Xpert MTB/RIF test has:

- facilitated access for populations that would previously not have had access to TB diagnosis, for example mining and pastoral communities in Tanzania and migrant populations from neighbouring countries in Uganda; and
- increased access to TB testing for populations which would have previously had more limited access, such as children and working urban poor (the latter through the PPM models in Bangladesh, Indonesia and Pakistan).

Notwithstanding these positives in terms of access, we note the following challenges with decentralised placement of the test:

- **Weak referral links for culture/DST and treatment:** Ensuring that patients diagnosed with TB are referred to culture/ DST and then linked to treatment is an issue that has been noted with the decentralised implementation of Xpert MTB/RIF. Our project consultations (particularly during field visits) noted that in decentralised settings, lack of awareness and training of clinicians on need/ approach to referrals has been low.
- **Weak capacity at decentralised settings:** Despite being an “easy-to-use” technology, Xpert MTB/RIF requires some degree of technological know-how and computer literacy. Feedback from consultations highlighted that in some decentralised settings this can be a challenge – e.g. consultees noted that in some sites there is limited capacity to undertake maintenance/ calibration or knowledge of how to respond to module failure, resulting in machines being “out-of-use” for periods of time.
- **Limited monitoring due to remoteness of Xpert MTB/RIF decentralised sites:** Due to the remoteness of some project sites, there is limited monitoring of the use of Xpert MTB/RIF (and thus limited information in terms of numbers of tests undertaken, module failures, etc. which would support forecasting and troubleshooting).<sup>18</sup>

**Xpert MTB/RIF is not becoming the new standard technology for TB diagnosis due to its relatively high cost and well-embedded nature of sputum smear microscopy in NTP policies and country health systems. Although the project has successfully rolled-out Xpert MTB/RIF at the decentralised level and has improved access for hard-to-reach and vulnerable populations, weak referral links for culture/DST and treatment and lower capacity at this level are important challenges.**

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<sup>17</sup> Source: 2013 Annual Programmatic Report, Annex 1, “number and percentage of instruments procured for use at sites outside of central-level TB reference laboratories within framework of TBxpert Project”.

<sup>18</sup> In a number of TB REACH supported projects (e.g. in Mozambique, Malawi and Pakistan), there is real-time remote monitoring of tests with daily data available on machine performance and test results.

### 3. EVALUATION DIMENSION 2: EFFICIENCY AND EFFECTIVENESS

The second evaluation dimension examines whether project implementation has been efficient and effective, through the following key questions:

**Qs 3: Has project implementation to date been efficient in terms of:**

- a. timeliness and budget management;
- b. delivery and communication between project partners - UNITAID, WHO, STP (including TBR and GDF), IRD, ASLM, GLI, Expand TB; and
- c. coordination with NTPs and broader in-country donors?

Following the OECD DAC definition of the evaluation criteria of “efficiency” we review whether the resources have been used productively to achieve the desired results. Our review encompasses project timelines and expenditures, delivery and communication between project partners, and coordination with NTPs and broader in-country donors.

**Qs 4: Has the project been implemented effectively and what factors have influenced results, in terms of:**

- a. product implementation issues (including module failure, maintenance and warranty arrangements, etc.), supplier responses to issues and overall customer satisfaction;
- b. implicit costs of accessing the diagnostic tool and test turn around times; and,
- c. implementation of the public-private models (PPM).

We examine the experience with product introduction and roll-out in countries including any issues faced with the implementation and use of the technology as well as the impact on patient costs and test turnaround times. We also review the implementation of the PPM models.

**Qs 5: Are the procurement arrangements consistent with plans and have they worked well in practice?**

We consider the suitability of the procurement arrangements of the project, including planning and forecasting, the implementation efficiency of the procurement process and country-level procurement issues.

Each of these aspects in the above-noted evaluation questions are discussed in turn below.

#### 3.1. Timeliness and budget management

##### Timeliness

The TBXpert project has a three year timeframe from January 2013 to December 2015, with annual review of procurement plans and ongoing procurement, testing and monitoring of Xpert MTB/RIF.

Our review suggests a relatively lengthy process to project approval. Further, there have been several delays in the initial few months of the project resulting in testing being initiated at only one site by June 2013.<sup>19</sup> Specifically:

- **Lengthy process to project approval:** We understand that while the Xpert MTB/RIF test was approved by WHO in 2010, the project development and negotiation process took almost two years. Discussions with the UNITAID Secretariat suggest that this is in line with the average time taken for project approvals at UNITAID, however other stakeholders have commented on this being a relatively lengthy process for funding approval.
- **Manufacturing delays:** At the end of 2012, Cepheid experienced manufacturing capacity issues as it was investing in developing its production line to meet increasing demand. This resulted in a global shortage of cartridges at the start of the project with 15 out of the 21 countries reporting this as a key challenge to project commencement in the 2013 Annual Progress Report. Better alignment of the project timelines with manufacturing capacity may have prevented the need for the project to “catch up” and extension of overall timelines as discussed below.
- **A range of country-specific issues:** The Progress Reports and our consultations/ country visits highlight the following country-specific challenges:
  - *Delays in signing grantee contractual documents:* As per the original Project Plan, the Letters of Agreement (LOAs) and the Grant Agreement Letters (GALs) were planned to be signed by the end of February 2013. However, in 2013, only four out of 20 GALs and five out of 21 annual LOAs were signed on time.<sup>20</sup> This improved in 2014, with 14 out of 21 LOAs signed within the planned timeframe.<sup>21</sup> Reasons for the delays vary. Consultees from Kenya and Tanzania attributed these delays to extended negotiations between the NTPs and other grantees on the scope of the project and placement of the machines. Other issues included the finalisation of site locations for GeneXpert instruments (e.g. in Pakistan) and the change in the recipient who would be importing Xpert MTB/RIF (e.g. in Uzbekistan).<sup>22</sup>

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<sup>19</sup> Only the International Organisation for Migration in Nepal reported that testing had started in the 2013 Semi-Annual Report.

<sup>20</sup> GALs are one-off agreements between TB REACH and grantees to provide financial support for the project. LOAs on the other hand are an agreement between the NTP and the TBXpert project, often in conjunction with implementing partners, to declare the types and amounts of commodities requested for the coming year. Each project country develops and signs an LOA at the beginning of each calendar year.

<sup>21</sup> By June 2014 two LOAs had still not been signed (Mozambique and Tanzania).

<sup>22</sup> The project MoU recognises the risk of timely signing of agreements, with the approach to risk mitigation being to rely on the experience of the WHO and TB TREACH offices in facilitating such agreements.

- *Delays in the delivery of the instruments to the project sites due to issues with clearing customs – e.g. in Tanzania, Mozambique, Indonesia, Ethiopia, amongst other countries.*
- *Preparation of sites, in terms of physical infrastructure and ensuring staff had the capacity to run the instruments and the centres. This was especially problematic for the NTP sites, which were initiating the project without prior experience of using Xpert MTB/RIF, while some TB REACH grantees were continuing and scaling up previous Xpert projects.*

These issues point towards a number of challenges in “getting started” for the introduction and roll-out of a new technology, despite the relative simplicity of the Xpert MTB/RIF tool. As such, our assessment is that the overall project timeframe is optimistic (as was also communicated to us by TB REACH based on their prior experience with supporting the introduction of TBXpert in countries).

### Budget management

The TBXpert project has a total budget of US\$25.9m (Table 3.1).

Table 3.1: TBXpert project budget

Budget Line	US\$	% of total budget
<b>WHO/ TB REACH</b>	<b>24,892,970</b>	<b>96%</b>
Commodities	21,059,631	81%
Direct Project Costs	2,833,230	11%
<i>WHO</i>	<i>1,763,800</i>	-
<i>STOP TB Partnership</i>	<i>1,069,430</i>	-
WHO/Programme Support Costs	1,000,109	4%
<b>Technical Assistance</b>	<b>1,007,000</b>	<b>4%</b>
<i>IRD</i>	<i>782,000</i>	-
<i>ASLM</i>	<i>225,000</i>	-
<b>Total</b>	<b>25,899,970</b>	<b>100%</b>

Sources: UNITAID (2013) MoU and Annexes, UNITAID (2013) IRD LOA, UNITAID (2013) ASLM LOA

Our review of the overall budget and expenditure to date is as follows:

- **Appropriateness of budget allocation:** As shown in Table 3.1, 81% of the budget is for the procurement of commodities. We understand that this was a requirement by UNITAID, however consultations with stakeholders have suggested that the limited funding for technical assistance and supporting costs to facilitate introduction of the new technology have posed a challenge for efficient implementation. In particular:
  - *The NTP projects sites do not receive any funding for supporting costs including site management, training, etc.* On the other hand, the TB REACH project

grantees are supported by additional TB REACH funds to support the introduction and scale-up of Xpert MTB/RIF. Feedback from consultations suggests that this has resulted in TB REACH supported projects establishing sites quicker and continuously running the machines and tests. For example, in Tanzania the lack of budget to the NTP to support active case finding approaches has limited the number of tests conducted, as compared to the two TB REACH grantees.

- *The allocation of funds for technical assistance is limited.* Under the project, the only funding for technical assistance is for ASLM support to five of the eight African countries over three years on a budget of \$75,000 p.a. (Congo, Ethiopia, Kenya, Mozambique, Tanzania). However, it was repeatedly suggested during our consultations that additional funding for TA (and through the most appropriate modality) is critical to ensure effective introduction and use of the new technology.
- **Spending against planned budget in 2013:** There were some areas of over- and under-spend reported in the 2013 Progress Report. As per Table 3.2, there was a significant underspend on Outputs 2-4 that can be attributed to the delayed start of the project. Further, some efficiencies have been secured for shipping and transport costs with a total under-spend of 58%, or \$413,503, against the budget in 2013.

Table 3.2: Planned vs. actual expenditure by output in 2013

Output	Total Budget 2013 (US\$)	Actual Expend. 2013 (US\$)	% Spend
1: Timely procurement of commodities	8,710,717	8,286,620	95%
2: Rapid testing for TB and drug resistance	60,000	33,013	55%
3: Effective use of commodities	26,000	15,838	61%
4: Increased market penetration of Xpert	8,000	3,496	44%
<b>Total</b>	<b>8,804,717</b>	<b>8,338,967</b>	<b>95%</b>

Source: TBXpert 2013 Annual Programmatic and Financial Report, Annex 2

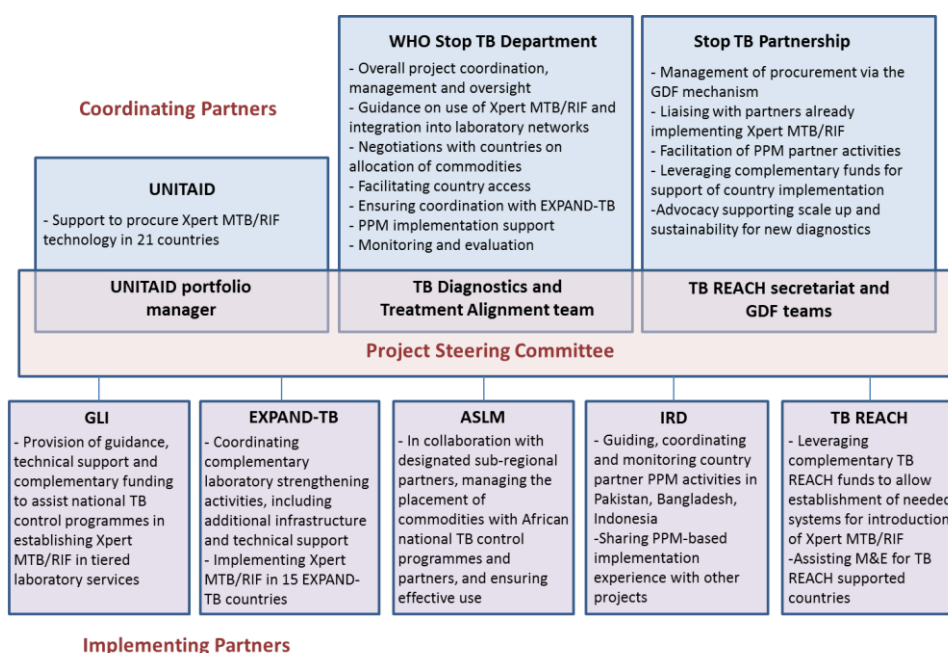
**There has been a relatively lengthy timeframe to project approval. There have also been a number of key delays at project commencement which have resulted in countries/ grantees initiating testing many months later than planned. This indicates over-ambitious targets with regards to the time taken to get started when introducing a new technology.**

**The budget is overwhelmingly focused on commodity procurement with inadequate monies for technical assistance and supporting costs for the introduction of a new technology.**

### 3.2. Delivery and communication between project partners

Figure 3.1 sets out the main project partners and their key roles and responsibilities.

Figure 3.1: Summary roles and responsibilities of TBXpert project partners



Source: UNITAID (2013) MOU, Annex 1 TBXpert Project Plan

There was unanimous positive feedback from consultees (UNITAID Secretariat, country grantees and external stakeholders of the project) on the responsiveness and proactive delivery of the project by WHO and TB REACH. Overall project coordination also appears to be working well with an increasing frequency of meetings of the Project Steering Committee, periodic calls between WHO and ASLM and bi-annual meetings between UNITAID, TB REACH, IRD and the three countries implementing the PPM approaches.<sup>23</sup>

However, some issues noted with regards to partner roles and delivery are as follows:

- **UNITAID:** Project implementing partners have noted that high staff-turnover and complex internal processes at UNITAID have resulted in long timelines for feedback/ approval of requests/ issues during the project. There have been some delays in disbursement of funds from UNITAID to the implementing partners: the progress reports reveal that disbursement of funds in the first year of the project was delivered to plan, but that in 2014 the first tranche of disbursements was four months late.
- **GDF** was part of the original Project Plan, with the responsibility of: (i) developing procurement plans in cooperation with NTPs and partners; and (ii) managing the procurement process. However, these functions are delivered by TB REACH and WHO, with no engagement of GDF staff in the project (discussed further in Section 3.7 below).

<sup>23</sup> Though only three quarterly Project Steering Committee meetings were held in 2013, two were reported in the first half 2014. Reference: UNITAID (2013) Annual Report, UNITAID (2014) Semi-Annual Report

- **ASLM:** The role of ASLM is to coordinate technical assistance to NTP projects in five countries, including negotiating placement of commodities, supporting laboratory capacity building and training.<sup>24</sup> However, with ASLM being a relatively nascent organisation, feedback from consultations indicate it has not had the capacity to fully deliver on this role, having sub-contracted consultants in most of the five project countries (e.g. FIND in Tanzania, Management Sciences for Health in Kenya and Congo). Further, ASLM consultant support has been weak in some countries – e.g. in Mozambique where the consultant was in place for a few months only. More generally, there is a question as to how best TA support for the project may be designed – with an argument presented for more systematic and longer term TA than that envisaged to be delivered by ASLM.

**Delivery and communication between project partners is generally working very well. Only issues have been with regards to lack of experience of ASLM and some discontinuities caused by high staff turnover at UNITAID.**

### 3.3. Coordination with NTPs and donors

Given the ongoing global roll-out of Xpert MTB/RIF by a range of partners, coordination at both the country and global level is critical to minimise duplication of efforts and ensure a harmonised approach with country implementers.<sup>25</sup> This is well recognised in the project design and is one of the six key outputs of the project (Output 5 is “*strengthened country coordination with other technical agencies and donors*”).<sup>26</sup>

Our review of the extent of global and country-level coordination facilitated under the project is as follows:

#### Global-level coordination

As per the Project Plan, WHO was tasked with the role of ensuring global-level coordination through annual meetings, quarterly teleconferences and regular information dissemination (measured in the programmatic reporting through indicators O5.1-5.3). We note a number of positive achievements to date in terms of global coordination:

- *Annual meeting of Xpert MTB/RIF partners:* Within the framework of the project, two global meetings in 2013 and two in the first half of 2014 have been held. These include two annual “Global Forums of Xpert MTB/RIF Implementers” organised by WHO/GLI and two focused meetings organised by GDF on warranties and the supply chain. These meetings have involved key stakeholders, including major procurers, donors, civil society and Cepheid.<sup>27</sup> However, we note that the project budget does not

<sup>24</sup> Congo, Ethiopia, Kenya, Mozambique, Tanzania.

<sup>25</sup> PEPFAR, USAID/TB CARE, MSF and the World Bank are also supporting the roll-out of Xpert (machines and/or cartridges) in a number of countries, some of which overlap with the TBXpert project.

<sup>26</sup> UNITAID (2013) MOU, Annex 1 TBXpert Project Plan, p.48

<sup>27</sup> *ibid*

allocate any funding to support meetings and workshops (and in fact, the Global Forums have been funded through a USAID grant to WHO). This has inevitably limited the number of and reach of meetings/ workshops that can be undertaken, especially in terms of sharing experiences and lessons learnt across the 21 project countries.

- *Unified forecasting initiative*: In response to the global shortage of cartridges at the start of the project, in April 2013, WHO launched the *unified Xpert MTB/RIF forecasting initiative* which aims to collate data on country level forecasts from major public procurers.<sup>28</sup> Quarterly calls are organised by WHO with stakeholders to aide Cepheid in planning production to meet future demand. Despite its limitations (e.g. the voluntary nature of the initiative means that not all procurers regularly provide forecasts), the initiative has been regarded as a useful supporting tool by the manufacturer.

As such therefore, global-level coordination has been facilitated well under the project (and our consultations with select donors noted that WHO has played an important coordinating role). However, limited funding for these activities within the project has implied limited reach of certain initiatives.

### Country-level coordination

Although the responsibility for country level coordination lies with the NTP, the Project Plan notes that *“to facilitate coordination at country level, WHO will coordinate with major partners, technical agencies, and donors to ensure country-level needs are met for implementation”*.<sup>29</sup> We understand that WHO Geneva and TB REACH have been supporting country-level coordination with other partners (e.g. through country missions, liaising with WHO local offices and other partners by telephone, etc.), with a number of these coordination activities being supported by their own budgets outside of the TBXpert project.

Feedback from consultations suggests varying experience with regards to in-country coordination due to: the varying role and leadership of local WHO offices; the availability of TA money to provide NTP support; and the relationship between grantee and NTP. In particular:

- **Coordination through the WHO country office varies substantially across countries.** For example, in Nepal, the leadership of the WHO country office was instrumental in establishing regular meetings with the NTPs and other partners running Xpert MTB/RIF (during which they discuss challenges and share lessons learned).<sup>30</sup> In India, coordination between the project and the NTP is also viewed as very positive, given the involvement and support provided by the local WHO office, as well as oversight

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<sup>28</sup> The initiative brings together both donors supporting Xpert MTB/RIF roll-out (e.g. USAID, PEPFAR, Global Fund etc.) and countries procuring Xpert MTB/RIF directly (e.g. South Africa, Brazil etc.)

<sup>29</sup> UNITAID (2013) Project Plan, p.40

<sup>30</sup> The active involvement and good performance of the TB REACH grantees in Nepal has also contributed to this.



from a TBXpert focal person appointed at the Central TB Division on the request of WHO. However in Indonesia the WHO office has not been actively involved due to lack of clear directive on their role from headquarters.

- **Coordination has been supported through ASLM TA monies in select countries.** In Tanzania, FIND's involvement in the TBXpert project (as the subcontractor to ASLM) supported the establishment of the country's GeneXpert Focal Team as well as a range of ongoing activities, including a mapping of all GeneXpert machines in the country and their respective funders; ongoing data collection/ analysis of project sites; and support for a partner's meeting for all agencies implementing Xpert MTB/RIF in an attempt to improve coordination with the NTP.
- **Poor coordination due to the weak relationship between the NTP and the grantee has been reported in some countries.** For example, in Indonesia, given PT ISI's first time experience of working with the government, coordination has been weak and has resulted in the limited sharing of key information on the design and purpose of the project, the placement of machines and the approach to screening of presumptive TB patients. In particular, the lack of coordination has resulted weak linkages with the routine TB programme, leading to delays in the initiation of treatment and likely losses along the referral process (see Annex 7 for further details).

**Global-level coordination has been facilitated well under the project, although is constrained by limited funding. The extent of country-level coordination across the NTP, NGO grantees and other donors has varied depending on the involvement of the local WHO office, provision of effective TA by ASLM and relationship between the NTP and project grantees.**

### 3.4. Product implementation issues

In this section, we examine the experience with product introduction and roll-out in countries including issues faced with: (i) module failure; (ii) warranties; and (iii) other implementation issues.

#### Module failure

Module failure occurs when there is a high error rate; Cepheid recommends that intervention is required when the module produces more than 5% of errors. We consider the reasons for module failure, select country experience to date and Cepheid responsiveness to dealing with the failures.

The two main reasons for module failure to date have been interference of dust and failure at calibration.<sup>31</sup> Specifically:

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<sup>31</sup> The issue of high rates of module failure was first identified after pilot sites for Remote Xpert in India and South Africa generated performance data which detected error patterns, including some modules progressively exhibiting higher error rates over time. Cepheid (2014), Module Issue Investigation, presented by Martin Colla at the Xpert MTB/RIF Implementers Global Forum, May 2014

- **Dust:** When machines are placed in dusty environments, the fans designed to cool the system draw dust into the module coating the windows of the emitter and blocking the detector which causes loss of sensitivity and results in errors.
- **Calibration:** If calibration is not undertaken properly and on time, then cartridges can become jammed and more errors are produced.

Given the lack of a centralised system to monitor the performance of GeneXpert machines in countries (an issue that is discussed further below), there is no comprehensive data on the number of module failures.<sup>32</sup> As such, our evidence base relies on anecdotal information from our consultations and country visits, which suggest that module failure is *the* most common challenge faced in the use of the technology. Information from our interviews is as follows:

- **Bangladesh, iccdr,b:** To date, 23 out of the total 96 modules have failed during use (i.e. 24%) and a further 11 modules out of the 54 which have been calibrated have also failed (i.e. 20%).<sup>33</sup>
- **India, NTP:** 11 of the 164 modules or 8% failed in 2014, and another 9-10 module failures have been reported in 2015 already, following online calibrations. See Box 3.1 for more information.
- **Indonesia, REMDEC/ PT ISI:** In the last six months of 2014, nine out of 32 modules in 8 GeneXpert machines (or 28%) have failed.
- **Nepal, IOM:** During calibration in the 1<sup>st</sup> year, almost 50% of the modules failed.
- **Tanzania:** While we do not have information on the number of module failures, stakeholders noted that this has been a common issue, particularly at more rural sites. Further, while many sites have been able to keep operating when a single module has failed, in two cases during the TBXpert project at different sites, four modules on the same machine have failed at once

Further a TB REACH study across project sites in mid-2014 showed that, out of 117 machines surveyed, two machines failed, and 25% of the machines that had been calibrated reported module failure.<sup>34</sup> Our data is also broadly aligned with this figure of one-quarter of modules having failed (although there is considerable variation by country). However discussions with Cepheid also note that some of the modules they have replaced have not actually failed – so the actual failure rate would be lower (although we do not have any statistics to quote on this).

In response to the rates of module failure across countries, Cepheid launched an investigation into the issue as well as providing technical assistance where necessary (both remotely and through local service providers) and replacing failed modules. The investigation lasted around

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<sup>32</sup> We asked Cepheid for this information, however they have not provided this data.

<sup>33</sup> iccdr,b (2015) Experiences with GeneXpert System, Bangladesh update January 2015

<sup>34</sup> Only 53 machines had been calibrated, of which 13 reported module failure. This data was shared by TB REACH.

a year and in response Cepheid has adopted both corrective and preventative measures to reduce the error rate: *preventative measures* included the development of cleaning tools and accompanying training guidelines; and *corrective actions* consist of upgrading the filters on the fans; providing spare filters for periodic replacement; and supplying dust covers for the instruments. Cepheid has also been working on improving calibration kits that have a lower rate of blockage. The adoption of remote monitoring systems on GeneXpert machines (despite limited adoption to date) also allows for closer monitoring of error rates, module failure and machines performance.

#### **Box 3.1: Module failure caused by dust in India**

Although data on the country-wide number of dust-related failures is not available, we understand that module failure experienced in India was predominantly on account of dust interference and was identified at the beginning of 2013.

As a result, the GeneXpert locations were improved to avoid dust coming into the labs and Cepheid made a number of modifications to the platform design to reduce the extent of module failure. In particular, Cepheid has introduced a filter that can deal with fine dust and a brush for cleaning the machine. There is currently a pilot of this upgraded system taking place in 10-12 sites, from which the feedback has been positive with a reduced number of incidents. This pilot was introduced in mid-2014, indicating that Cepheid took about 12 months to resolve the issue. Feedback from stakeholders in India on Cepheid's response to the issue has been positive, and the Cepheid local service provider in India reported that all GeneXpert systems were functional in India as of March 2015, which demonstrates the effectiveness of the corrective and preventative actions taken.

## **Warranties**

Under the project, each instrument procured has an initial two year warranty.<sup>35</sup> The warranty covers repairs to the instrument, replacement of parts, and is provided free of charge except for calibration costs (which must be carried out annually in order for the warranty to remain valid). Following the standard two-year warranty, countries need to purchase an extended warranty coverage. As of 2014, an extended warranty, which includes calibration costs, may be purchased for US\$2,900 p/a, or for a discounted price (US\$7,900 instead of US\$8,700) if purchasing a 3-year package.<sup>36</sup> Discussions with the Implementing Partners suggest that savings under the project are being proposed to purchase an additional year of warranty cover for all machines procured under the project.

Reports of Cepheid honouring the warranty agreement have been positive. However, there are concerns over the affordability of the warranty, the timeframe for response, and the awareness of coverage details amongst key stakeholders:

- **Affordability of warranties:** The cost of the warranty extension is considered to be too high for project implementers. Further, the warranty does not cover the travel expenses of the local service provider or Cepheid staff member if the instrument

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<sup>35</sup> Subject to the following conditions: the warranty starts on the date of the initial installation of the instrument, and if the machines is not calibrated after one year, the second year of cover is not valid.

<sup>36</sup> GLI (2014) Maintenance presentation, Xpert MTB/RIF Training Package.

cannot be fixed through remote assistance. Considering the decentralised and remote locations of sites, this expense can be considerable. A paper published by GDF examining financing schemes for GeneXpert found that Cepheid's warranty package was more expensive in comparison to a diagnostic with a similar level of service and maintenance coverage, and recommends Cepheid to review either the price or the content of the warranty.<sup>37</sup> The affordability of the warranties is also a key issue for the sustainability of Xpert MTB/RIF, as discussed in Section 4.3. However during our discussions with Cepheid, they maintain that the warranty price is a fair price, which is usually around 10-15% of the instrument price.

- **Timeframe for response:** The warranty does not include any agreement on timelines for replacement of parts; although Cepheid has generally been responsive (albeit with variations across countries – e.g. very responsive in India but not in Indonesia), the timelines for replacing modules have been reported as lengthy, given that countries are not able to keep a stock of modules in-country and replacement modules must be imported from France. Feedback from project grantees indicates that this can take 1-3 months. This is particularly problematic when multiple modules in a machine fail simultaneously, essentially rendering the machine “out-of-order”.
- **Awareness of coverage details:** Feedback from country visits and consultations suggest that there is often a lack of awareness about the terms of the warranty. For example, consultees in Tanzania reported that they had not initially understood the annual calibration requirement, and as a result had not calibrated their machines in time, which had invalidated their warranty. Further, project grantees voiced concerns about the level of knowledge of the warranties by Cepheid's local service providers, which has resulted in longer response times.

### Other implementation issues

Other major issues that have affected implementation of the project have included the following:

- **Inadequate infrastructure affects the utilisation of GeneXpert instruments:** Unreliable electricity supply, both in terms of outages and fluctuations in power, especially in remote areas, affects the utilisation of the instruments (e.g. the test becomes invalid). Some projects have supplemented their facilities with uninterruptable power supplies (UPS), but these rely on regular charging and maintenance. In addition, many of the project sites have required construction or refurbishment of screening centres and other fundamental infrastructure requirements (not funded by UNITAID), which has delayed testing initiation.

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<sup>37</sup> GDF (2014) Diagnostic equipment's' financing and warranty/ after-sales schemes.

- Lack of training limits the correct utilisation and maintenance of the machines:** Although considered an “easy-to-use” technology, staff training on Xpert MTB/RIF functioning and maintenance is key to ensure the correct utilisation and reduce the occurrence of failures. Although, project consultees have noted that staff training on Xpert MTB/RIF has been generally provided at the beginning of the project (led either by the local service providers like in India and Kenya, or with support from ASLM sub-contractors such as in Tanzania), there are concerns that this is not a sustainable model: a high turnover of staff, especially within NTPs and reference laboratories, means that new staff do not receive training. Feedback from consultations suggests the need to empower country ministries to provide regular training, both to new staff as well as refresher training, especially on good maintenance practices.
- Restrictive country diagnostic algorithm limits the utilisation of Xpert MTB/RIF as well as case finding:** The introduction of Xpert MTB/RIF requires the revision of a country’s national diagnostic algorithm to support case finding through the use of Xpert MTB/RIF. However, the revision of a country’s algorithm has been noted as a key issue for countries given capacity constraints and countries’ “conservatism” associated with changing diagnostic algorithms in line with WHO recommendations.<sup>38</sup> There has been varying experience across countries – e.g. some country algorithms have been against WHO guidelines (e.g. in Malawi, Uganda); in Tanzania, the NTP has recently revised the algorithm for Xpert testing to test all TB suspects, and in Indonesia the algorithm initially focused on testing smear-positive failure and re-treatment cases but has recently been expanded to include smear negative patients. In addition, these also need to be incorporated in the broader NTP framework and PMDT, which has been a slow process. An important contribution of the project is that given the pilot nature of TB REACH projects, TB REACH grantees have been able to propose and adopt more innovative algorithms, which are useful “pilots” for the NTPs. For example, in Uganda TB REACH grants under the TBXpert projects have provided evidence on the use of revised algorithm, which has led to the revision of the national algorithm.
- Weak knowledge/ awareness of referrals systems limits testing and the utilisation of Xpert MTB/RIF:** While the diagnostic algorithm revisions are being made, their implementation in practice is constrained by resource availability and also requires a change in current health system practices. Evidence from the project’s progress reports indicates that underutilisation of Xpert MTB/RIF is related to low levels of referrals for Xpert testing – in 2014, 10 countries reported underutilisation of GeneXpert machines, five of which attributed this to low referrals and a restrictive algorithm. In fact, feedback from consultation highlights that in addition to training

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<sup>38</sup> The Project Plan had also identified “*slow revision of diagnostic algorithms, notifications systems, forms and registers to include Xpert MTB/RIF*” as a key programmatic bottleneck. The risk mitigation strategy proposed was to ensure WHO and TB REACH collaboration with NTPs and country implementing partners. Ref: Project Plan, p. 28.

technicians on the technical use of Xpert MTB/RIF, there is a need to engage with physicians and health workers to raise their awareness for when cases should be referred to Xpert testing in line with the country's diagnostic algorithm.

- **Lack of real time reporting systems for UNITAID funded Xpert machines limits their effectiveness:** Although the UNITAID TBXpert project envisaged the set-up of the Cepheid RemoteXpert tool on the project funded machines, this has not happened due to delays in the launch of the software. Remote monitoring tools such as GXalert and RemoteXpert provide greater visibility of the use of GeneXpert machines and support countries with: (i) improving the efficiency of collecting M&E data on number of people tested; (ii) communicating results to patients – for example, under TB REACH Wave 2, IRD institutionalised a system of automated reporting from Xpert machines to patients via the XpertSMS software, which is currently being used in the TBXpert PPM projects in Pakistan and Bangladesh and has proved to be very successful in communicating Xpert test results to patients, physicians and to the NTP; and (iii) providing data on machine throughput and actual utilisation rates, which is helpful to support forecasting/ procurement planning as well as oversight of error rates and module failures. Some countries/ projects have incorporated real-time monitoring systems although not across all project countries/ grantees supported by the TBXpert project.

The range of these issues indicates the challenges involved in introducing and rolling out the technology, where it has been indicated that access to additional funds for technical assistance and to support implementation would be useful (as has been the case for the TB REACH grantees).

**The key challenge with the use of the Xpert MTB/RIF technology has been module failure due to dust and calibration. Cepheid has satisfactorily introduced a number of preventive and corrective measures to deal with these issues. The warranty arrangements for Xpert MTB/RIF pose a severe challenge due to unaffordability amongst project implementers and variable experience in terms of timeliness of Cepheid's response. There are a number of country-level challenges that have impacted effective use of the technology including inadequate infrastructure, lack of training amongst both doctors and technicians, restrictive/ slow change of diagnostic algorithms and related policies, weak knowledge/ awareness of referrals systems and lack of real time reporting on module performance. The range of these issues highlight the challenges involved in introducing and rolling out the technology, where it has been indicated that access to additional funds for technical assistance and to support implementation would be useful.**

### **3.5. Diagnosis costs and turnaround times**

The performance and value of Xpert MTB/RIF for patients is analysed by examining the costs associated with accessing the diagnostic test and the turnaround time between testing and availability of results. These are considered in turn below.

## Diagnosis costs

Although under the TBxpert project, the Xpert MTB/RIF test is offered free of cost, patients may incur other costs, such as for related tests, transport, food as well as the opportunity costs of their time (see Annex 4 for a more detailed discussion of costs). While there are a large number of studies estimating the economic burden of TB to patients, relatively few studies focus on the diagnosis stage, and even fewer examine the cost of Xpert MTB/RIF relative to other TB diagnostics. A recent study in Brazil assessed patients' cost of diagnosis using Xpert MTB/RIF against smear microscopy and found that median total patient costs were 54% higher with smear microscopy compared to the use of Xpert MTB/RIF for TB diagnosis.<sup>39</sup>

During the evaluation field visits, ten patient surveys were carried out to assess the costs associated with accessing TB diagnostic tests (see Annex 4 for the patient survey template and summary results). The information collected from these surveys needs to be considered as anecdotal only, as these were based on "on-the-spot" interviews in health facilities visited, without a defined sampling strategy given the limited time and budget for the country visits:

- On average across the 10 patients, the medical costs were US\$6 (primarily for X-rays, blood tests and at times, hospital registration fees), non-medical costs were US\$2 (primarily relating to travel<sup>40</sup>, but no additional costs such as on food or accommodation given the relatively faster test turnaround times), and indirect costs were US\$6 (although there was a substantial range in the responses based on the background of the person interviewed).
- The other costs associated with previous trips to health centres for diagnosis were the most significant, averaging at US\$28 but ranging from US\$0-157, and this was heavily dependent on the country's diagnostic algorithm/ experience of specific patients (as for example, patients interviewed in India reported treatment related costs as they had had the Xpert test after commencement of treatment).

In summary, the feedback from patients illustrates that though the Xpert MTB/RIF test is administered for free, the costs associated with TB diagnosis under Xpert can vary substantially across patients and locations.

## Turnaround times

Xpert MTB/RIF allows for the rapid diagnosis of TB (including HIV-associated TB and rifampicin resistance TB) within two hours, dramatically reducing the time between specimen collection

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<sup>39</sup> R. da Silva Antunes, M. Pinto, A. Trajman (2014): "Patient costs for the diagnosis of tuberculosis in Brazil: comparison of XpertW MTB/RIF and smear microscopy" in *International Journal of Tuberculosis and Lung Disease*, 18:5, pp.547-551.

<sup>40</sup> Given that the country visits focused largely on the capital cities, most patients interviewed did not have to travel far and this is likely to be different at more remote sites.

and availability of results for patients. Evidence from the literature on turnaround time is limited; however, a study of nine TB REACH projects found that turnaround times ranges from one day to over a week (when referral systems were in place and/or sample had to be transported from a remote facility).<sup>41</sup> Further, a study comparing Xpert testing to smear microscopy found that more patients diagnosed with Xpert MTB/RIF received same-day diagnosis (24% vs. 13%).<sup>42</sup>

The TBXpert project aims to ensure that turnaround time are reduced by tracking the “*median number of days between date of specimen collection and availability of TB testing results for patient, by TBXpert Project country (aggregated sites)*” (indicator O2.4), with a target of two days during the first year of the project, to be reduced to one day by the second year. To date, results on this indicator have been positive, with all countries with available data reporting a turnaround time of two days or less in 2013.<sup>43</sup> Further, evidence from the country visits indicates that there has been a considerable improvement in turnaround time in comparison to smear microscopy and culture diagnostic tests. Feedback from both Tanzania and India indicates that patients regularly receive their results within a day of testing. Additionally, some grantees (such as Pakistan and Bangladesh) have also adopted the XpertSMS tool to send patients their Xpert MTB/RIF test results; this means that patients do not need to return to the site of testing to collect the result, but rather receive the results as soon as they become available.

**The experience with reduced diagnosis costs for patients as well as test turnaround times has been positive (although this has not been systematically or comprehensively assessed under this evaluation and merits further study).**

### 3.6. Functioning of the public-private/ social business models

The TBXpert project provides support for some public-private mix (PPM) and social business models (SBM) to ‘*increase market penetration of Xpert MTB/RIF in the private and public non-NTP sector*’ (Output 4 of the logframe). These projects are managed by TB REACH grantees in Dhaka, Karachi and Jakarta under a Wave 3 grant of US\$1 million per country over a two year period, and are overseen/supported by IRD.<sup>44</sup> The structure of the projects varies by country, however the basic model comprises placing of GeneXpert machines in a mix of private and public hospitals along with screening of patients in diagnostic centres established under the project, where they would access the Xpert test for free but pay for adjunct tests (such as

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<sup>41</sup> Note: TB REACH project from 2011 to 2013 and not those under the TBXpert grant. Ref: Creswell, J. et al. (2014) Results from early programmatic implementation of Xpert MTB/RIF testing in nine countries in *BCM Infectious Diseases*, 2014, 14:2.

<sup>42</sup> Theron et al. (2013) Feasibility, accuracy, and clinical effect of point-of-care Xpert MTB/RIF testing for tuberculosis in primary-care settings in Africa: a multicentre, randomised, controlled trial; *Lancet*. 2014 Feb 1;383 (9915):424-35; Epub 2013 Oct 28.

<sup>43</sup> UNITAID 2013 TBXpert Annual Report 2013; results labelled ‘not applicable’ or ‘not available’ for Indonesia, Kenya, Moldova, Swaziland and Uzbekistan.

<sup>44</sup> The projects in Pakistan and Bangladesh are continuations of previous projects funded under TB REACH Wave 2, whilst the Indonesia project is a newly initiated venture.



digital X-rays, diabetes screening). The expectation is that revenue generated from the package of fee-based screening tests, would be re-invested and used to sustain the utilisation of Xpert MTB/RIF after the completion of UNITAID funding.

Consultations with the project grantees in Bangladesh, Indonesia and Pakistan have highlighted a number of challenges in establishing and operating these projects. In particular:

- **Delays in establishment of fully-equipped screening centres:** All three projects experienced severe delays in the establishment of screening centres due to lengthy negotiations around site selection, construction issues and difficulties in importing equipment. In particular, Indonesia has been unable to import the planned X-ray machines due to the current regulatory environment. This has resulted in the delayed start of testing, with the earliest testing occurring in Karachi in November 2013.
- **Weak referral systems:** Establishment of a systematic referral system from private practitioners has been an issue due to lack of awareness and a degree of private sector physicians' reluctance to make referrals (also because they have their own X-ray machines in their hospitals). In Indonesia, the knowledge of clinicians on candidate patients for Xpert MTB/RIF testing was noted as a challenge, and even after training, doctors have been reluctant to change previous practices.
- **Weak outreach campaigns and issues with screener retention:** Difficulties with outreach and communication campaigns have meant that awareness, buy-in and therefore referrals have been below targets.<sup>45</sup> Bangladesh has also faced some challenges with screener retention, which has impacted referrals from DOTS facilities.<sup>46</sup> In Indonesia, the project has found it difficult to hire adequate number of screeners within the available project budget.
- **Issues with patients' willingness to pay and access to the screening centres:** We understand that across the three cities, the dominant channel for testing has been through the public hospitals.<sup>47</sup> This is due to patients' limited willingness to pay for the fee-based tests as well as for out of pocket expenses in travelling to the diagnostic centres.

Thus the key challenges have been around the project's ability to ensure adequate patient referral numbers to the project screening centres. This is key to the sustainability of the projects as it drives the ability to generate sufficient revenues to cover costs.

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<sup>45</sup> In response, Pakistan and Bangladesh have both established marketing strategies, including increased engagement with practitioners and screeners, development of promotional materials and incentive structures in an effort to increase referrals to all centres. Ref: UNITAID (2014) Semi-Annual Report 2014

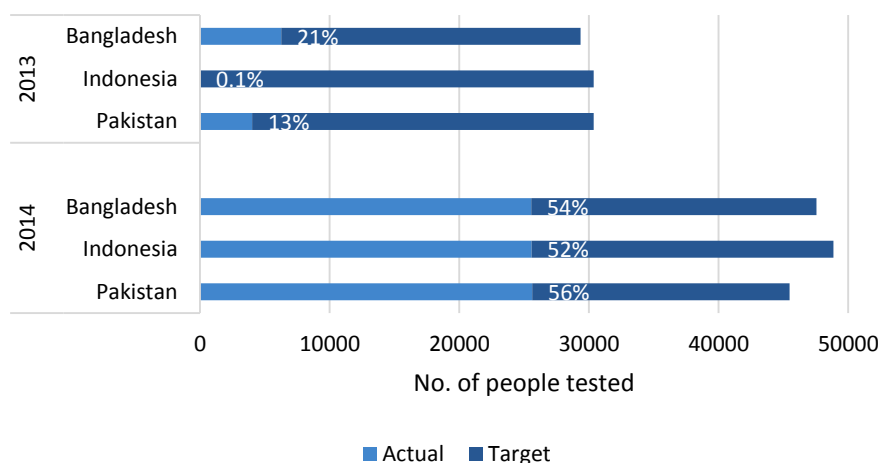
<sup>46</sup> iccdr,b (2015) Bangladesh Update, UNITAID TBXpert project, PPT Presentation, January 2015.

<sup>47</sup> The placement of some machines in the public sector has also ensured some degree of buy-in from the NTP: for example, in Bangladesh iccdr,b worked closely with the NTP (even establishing an MoU with them), which has resulted in an important collaboration and in the NTP endorsing the algorithm used under the PPM project.

## Results to date

Performance against targets has been weak across all three PPM sites, particularly in 2013 due to the above-noted delays in the start of the project and ongoing challenges in maintaining planned referral numbers.<sup>48</sup> In 2014 performance significantly improved, although results are only just above half of the 2014 targets (see Figure 3.2).

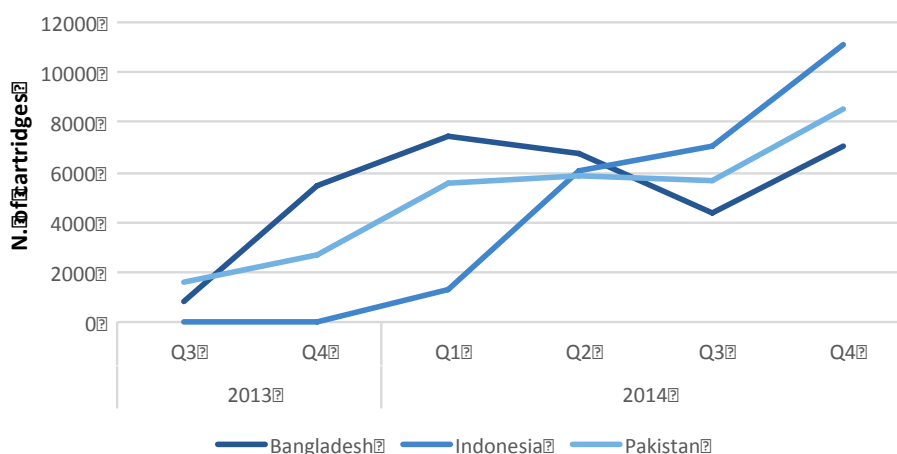
Figure 3.2: No. of people tested for TB via TBXpert PPM models, target vs. actuals 2013 and 2014<sup>49</sup>



Source: Targets and 2013 actuals from UNITAID (2013) MOU, Annex 9A TBXpert Project Programmatic Reporting and 2014 actuals from IRD (2015) Country Progress Review presentation January 31<sup>st</sup> 2015

With a slow start in 2013, the rate of cartridge consumption has been accelerating across all PPM sites in 2014 (see Figure 3.3).<sup>50</sup>

Figure 3.3: No of cartridges consumed by PPM sites Q3 2013 – Q4 2014



Source: IRD (2015) Country Progress Review presentation January 31<sup>st</sup> 2015

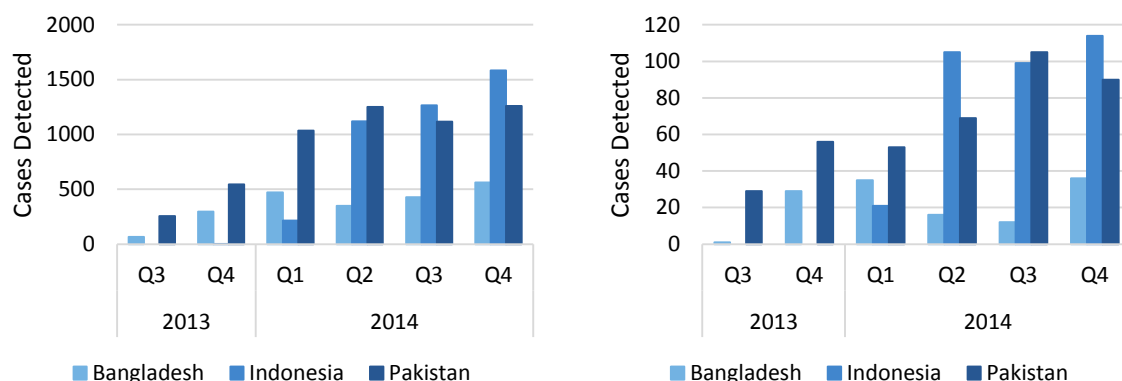
<sup>48</sup> UNITAID (2013) Annual Report 2013

<sup>49</sup> A discrepancy in the data is noted here. Bangladesh reported number of tests performed rather than number of individuals tested in Annex 9 of the 2013 Annual Report. For consistency we have maintained what is reported in the Annex across countries.

<sup>50</sup> In Indonesia, the largest share of cartridges was used for sputum smear negative symptomatic patients that were identified in out-patient departments of larger public and private hospitals.

Despite low performance on the number of people tested, all projects have identified substantial numbers of TB cases and rifampicin resistant TB, as shown in Figure 3.4. However there are critical issues with regards to linkages with treatment (e.g. in Indonesia, 50% of MDR-TB patients detected did not start treatment within three months) due to poor coordination with the NTP system.

Figure 3.4: Case detection of PPM projects from Q3 2013 to Q4 2014 for: (a) MTB; and (b) rifampicin resistant TB



Source: IRD (2015) Country Progress Review presentation January 31st 2015

### Sustainability

Table 3.3 presents the limited revenues generated by each project due to the range of challenges outlined above. As such therefore, sustainability of these projects following UNITAID/ TB REACH funding is at risk.

Table 3.3: Revenue generation across three PPM sites (in USD)

Country	2013				2014			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Bangladesh</b>	0	0	0	0	0	205	3,894	7,495
<b>Indonesia</b>	-	-	0	0	20,046	8,333	1,054	0
<b>Pakistan</b>	n/a	n/a	n/a	n/a	3,045	4,046	3,354	6,148

Source: IRD (2015) "Three country Progress Review: Bangladesh, Indonesia and Pakistan". Note: revenues not fully comparable as are Net for Bangladesh and Gross for Pakistan.

**The PPM/SBM models are innovative models to encourage the use of Xpert MTB/RIF in the private and non-NTP sector, however the three projects have faced a number of challenges to date in terms of getting started and ensuring adequate referrals to support the planned revenue generation. Despite a slow start in 2013, the number of cartridges used, patients tested and cases detected have been improving in 2014, however are way short of the targets. There have also been some challenges with ensuring effective linkages with treatment (especially in Indonesia).**

### 3.7. Suitability and efficiency of procurement arrangements

We review the efficacy of the forecasts under the project and the functioning of the procurement process as a whole.

#### 3.7.1. Planning and forecasting

The MoU sets out the number of cartridges to be procured by country and by year, however the Project Plan recognises the need to review these based on actual performance of NTPs/ TB REACH grantees. As such, the annual LoAs contain the updated number of cartridges requested by NTPs/ TB REACH grantees. However, despite the initial rigorous forecasting for the MoU and annual updates in the LoAs, there has been a substantial discrepancy between forecasts and actual procurement of cartridges (as presented in Table 3.4 for select countries), pointing towards the difficulty in developing accurate forecasts.

Table 3.4: Procurement of cartridges: forecasts vs. actual

Country	2013 LoA	2013 actual procured	% of LoA procured	2014 LoA	2014 actual procured	% of 2014 procured
India	112,334	40,000	36%	40,000	80,000	200%
Indonesia	45,000	10,000	22%	45,000	17,500	39%
Tanzania	19,407	13,500	70%	20,560	14,410	70%

Source: CEPA analysis based on country LoAs; 2013 and 2014 Annual Programmatic Reports, Annex 1.

Further, while there has been some gradual increase in forecasting accuracy (e.g. the logframe indicator O1.5 on the percentage difference between forecasts and actual procurement of cartridges reduced from 44% in 2013 to 24% in 2014), the aggregate percentage masks wide variations across countries.<sup>51</sup>

The implication of the poor forecasts is that as the project reaches its final stages, there is a substantial discrepancy between the budgeted cartridges allocation by country and its absorption capacity. As such, we understand that project partners are presently discussing a “re-allocation plan” (which is allowed for in the Project Plan), wherein cartridges will be provided to countries and projects with higher absorption capacity. Our assessment is that while re-allocation is a sensible approach from an efficiency perspective and will support the intended market impact of the project in terms of consumption of the planned number of cartridges, it detracts from the project goal/ objectives by virtue of not supporting/ encouraging “difficult/ challenging” countries or projects to scale-up. As such we understand that there is no provision within the aegis of the project to provide additional support to these challenging countries.

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<sup>51</sup> This number needs to be interpreted with caution as the denominator is not updated to reflect the revised number of cartridges as per the annual LoAs, but uses the original number of cartridges as per the Project Plan.

### 3.7.2. Procurement arrangements and processes

We consider a number of issues including the overall procurement arrangements (including roles and responsibilities), lead times, stock management and monitoring.

#### Procurement arrangements

The project procurement arrangements build on those developed by GDF since July 2011 for the procurement of the GeneXpert machine and cartridges for the TB REACH and Expand-TB projects, based on “*an innovative business model and supported by a tailored electronic Order Management System (OMS)*”<sup>52</sup>. Figure 3.5 presents the key steps involved in the procurement process and the roles of TB REACH, country-level grantees and Cepheid. We note the following:

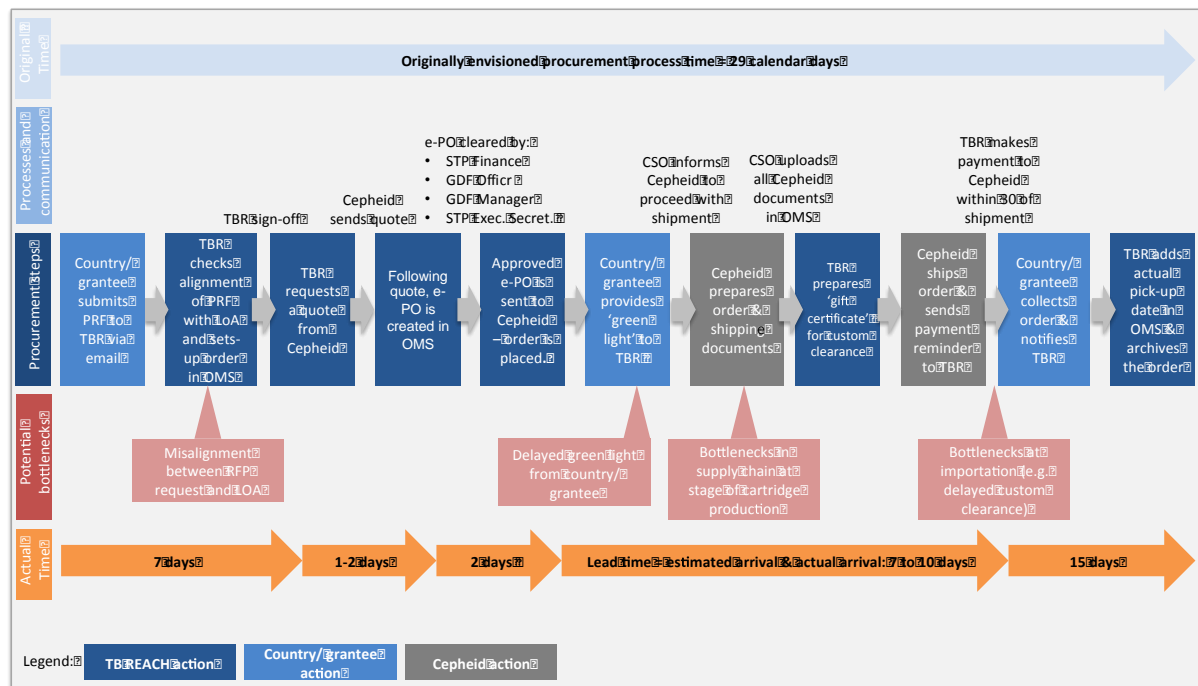
- This is broadly in line with that proposed in the Project Plan, except that procurement is handled by TB REACH staff rather than GDF (which we understand is due to the project providing funding for TB REACH management costs only). This has worked well in general, given TB REACH’s experience in leading the procurement of Xpert MTB/RIF for TB REACH Wave 2 grantees.<sup>53</sup>
- There is a Long-Term Agreement (LTA) between WHO/GDF and Cepheid which helps ensure that the project’s procurement requirements are streamlined. The LTA is based on the price negotiated in the buy-down agreement and also outlines the prices for other Xpert components (e.g. GeneXpert systems, calibration kits, module swaps and warranties costs). The LTA clearly states the pricing arrangements and does not allow for any subsequent price negotiations. As such, also given that Cepheid is the sole supplier of all Xpert products, the procurement management process is more procedural rather than requiring proactive supplier negotiations at each stage.
- The terms of the LTA ensure transparency and product quality assurance (given that a standard WHO-approved product is supplied by Cepheid).

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<sup>52</sup> UNITAID (2013) Annex 1, TBXpert Project Plan, Final Accepted, p.31

<sup>53</sup> In fact, during the project negotiations it was noted that “*aside from South Africa, the TB REACH-GDF procurement mechanism is currently the largest pooled procurement mechanism for Xpert MTB/RIF*”. Source: UNITAID (2012) PRC clarification document

Figure 3.5: TBXpert project procurement process



Source: CEPA analysis of TBXpert procurement process

## Lead times

Although the Project Plan envisaged that the procurement process from placement of order to arrival of goods in countries would take 29 days, this has varied substantially due to NTP/TB REACH grantees changing their preferred delivery date based on needs.<sup>54,55</sup> As such, our analysis of the OMS data for orders placed in 2013 and 2014 suggests that the median procurement lead time was 124 days (ranging between 19 and 560 days). This is however not an accurate measure of procurement efficiency, due to the reason outlined previously; rather, consultation feedback and our review of component lead times within the overall procurement process indicates that procurement management has worked very well, it has short lead times and is well-coordinated. In particular:

- *Placing of orders using the OMS is efficient:* As per our analysis of OMS data, the median time for order placement, which is from the moment the grantee submits a Product Request Form (PRF) to an internal order being created by TB REACH in the OMS, is seven calendar days.
- *Cepheid is very responsive in providing quotes for each order,* with an average response of 24-48 hours.

<sup>54</sup> Annex 6: Procurement and Supply Chain Management of the Project Plan.

<sup>55</sup> For example, although the NTP/ country grantee might submit an initial order to cover their annual cartridges needs, they might request the order to be shipped in separate instalments, which inevitably prolongs the total procurement lead time.

- *The internal clearing processes at the Stop TB Partnership are very quick, with a median of two days for an order to receive internal clearance, as per our analysis of OMS data.*
- *Shipping and delivery by Cepheid have been timely, with Cepheid having agreed to a standard lead time of 14 days for all Xpert products purchased under the project. Our analysis based on OMS data for 2013 and 2014 orders indicates that the median number of days has been 4 calendar days.*
- *The lead time between date of planned delivery and date of actual delivery of GeneXpert instruments and cartridges is close to the target (for 2013), although it ranges substantially across countries.<sup>56</sup> For GeneXpert machines in 2013, the median number of days between date of planned delivery and date of actual delivery was 17 days, close to the median target of 15 days. However, the lead time for the procurement of cartridges was almost double the target number of days (27 instead of 15).<sup>57</sup> This discrepancy is partly due to the initial shortage of cartridges by the manufacturer in 2013, but also due to the initial country capacity in planning for the delivery of cartridges. Our analysis of the OMS data suggest that for orders placed over 2013 and 2014, the lead time between date of planned delivery and date of actual delivery was 10 days for GeneXpert machines and 7 days for cartridges (suggesting improvements in 2014).*
- *The time to clear customs has been slightly longer than planned, but varies across countries: As per the annual 2013 report, the median number of days between arrival at port of entry and delivery to project site was 21 days for GeneXpert machines and 19 days for cartridges (as against a target of 18 days for both indicators). Our analysis from the OMS database suggest that during the first two years of the project, the median time to clear customs was 21 days for machines and 14.5 days for cartridges, indicating some delays in GeneXpert machines clearing customs.*

Overall, given TB REACH’s expertise, GDF’s efficient OMS procurement platform, and the LTA with Cepheid, the management and delivery of orders has been efficient – despite the total procurement process being around 35-37 days, which is slightly longer than the originally envisioned 29 days.

### **Stock management**

Although the project did not report any stock-outs, nor the expiration of cartridges during the first year of implementation, this should be interpreted with caution, as the majority of countries did not receive cartridge shipments until Q3 or Q4 of 2013. In general, evidence

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<sup>56</sup> The project logframe defines lead time as “Median number of days between date of planned delivery of GeneXpert instrument/ cartridges order at port of entry and date of actual delivery at port of entry, by TBXpert Project” (Indicators O1.3 and O1.4).

<sup>57</sup> Project Annual Programmatic Report (2013), Annex 1.

from field visits and select telephone consultations with grantees suggest the need for substantial capacity for stock management, not only due to the issue of poor forecasting but also because of multiple donors providing cartridge support to countries. For example, evidence from India suggests that to date stock-outs have been avoided by expediting the next supply of Xpert MTB/RIF cartridges by Cepheid and by re-allocating existing stocks from low-demand sites, requiring relevant capacity for effective management.

While data for 2014 is not available, feedback from some consultations suggested that there have been instances of cartridge expiration. For example in Nepal, 500 cartridges expired in first year of testing as a result of both the short shelf-life of the cartridges and issues with the delayed repair of broken machines, which meant the cartridges could not be used for testing. Additionally, in Kenya and Tanzania to avoid expiration, cartridges from low-demand sites have been pooled and redistributed to high-demand sites, although this may results in non-UNITAID sites using UNITAID-funded cartridges. Further, there were some comments from consultees that calibration cartridges (which have a shelf-life of 6-12 months) were sent to countries together with other shipments and expired before the annual calibration was due.

### **Procurement monitoring**

Procurement monitoring is the responsibility of TB REACH, who manages the project's procurement and actively monitors the order progress, including all communication with the country grantees and Cepheid. The information collected by TB REACH through the OMS is comprehensive and allows for adequate monitoring and tracking of the procurement process: information is collected on a number of key aspects tracked such as lead times, quantities of products, and prices of products. However, we note that despite its availability, this information is not used effectively for project management in that: (i) procurement narratives are not provided in the M&E reports (discussed further in Section 4.1); and (ii) information following arrival of goods in countries is not shared with Cepheid, although it would be helpful for them to know where the GeneXpert machines and cartridges are placed within a country (rather than just the high-level country data), so as to enable them to track the evolution of the Xpert MTB/RIF across countries.

**Cartridge forecast accuracy under the project has been poor. The planned “re-allocation plan” approach, given discrepancies between forecasts and project absorption, works well from an efficiency perspective, and will support the intended market impact of the project in terms of consumption of the planned number of cartridges. However, it detracts from the project goal/objectives by virtue of not supporting/ encouraging “difficult/ challenging” countries or projects to scale-up.**

**The procurement arrangements for the project work well and the various steps from order placement to delivery in countries are efficient, on account of the efforts and responsiveness of project implementers and Cepheid. A key bottleneck however is customs clearance resulting in delayed delivery to project sites.**



## 4. EVALUATION DIMENSION 3: RESULTS AND SUSTAINABILITY

The third evaluation dimension focuses on the results of the TBXpert project. We start with a review of the project's M&E arrangements (Section 4.1), followed by the public health and market impact to date (Section 4.2) and project sustainability (Section 4.3).

### 4.1. Efficacy of M&E arrangements

Our evaluation question is as follows:

**Qs 6: Have the project M&E arrangements been appropriately designed and implemented in practice?**

We consider the project M&E arrangements in terms of the suitability of the planned design as well as the efficacy of reporting in practice.

#### 4.1.1. Suitability of project M&E design

In general, the project M&E is well-designed. In particular the project is supported by a comprehensive logframe, which outlines a clear linkage between the project outputs and the overall goal. The logframe is further complemented by an "Indicator Template", which details all indicators that will be measured with baselines, targets, milestones and measurement frequency. Also, the logframe is linked with UNITAID's Key Performance Indicators, which are used by UNITAID to report to its Board.

A key issue with the project M&E however, in our assessment, is that it focuses on aggregate country-level data rather than project/ site level data, which provides incomplete information on progress and masks variations across project sites. Disaggregated data is also particularly important for understanding good and poor practices in the introduction and implementation of this new technology.

#### 4.1.2. Reporting by the implementing partners

WHO and TB REACH have provided timely reports to UNITAID to date, which have been considered by UNITAID to be of high-quality, especially in comparison with other projects. However, as noted in Section 3.2, implementing partners have indicated that UNITAID feedback on their progress reports, whilst detailed, has often been delayed.

Key issues with regards to reporting are as follows:

#### **The completeness of the progress reports has been raised as an issue by UNITAID**

Although the progress reports provide a good overall assessment of the project within the reporting period, consultations with the UNITAID Secretariat suggest that the reports are too data-driven and lack overarching narratives which explain what progress has been made, why selected targets are not being met, and what is being done by the implementing partners to

rectify this. Further, the procurement section of progress reports lacks information on how procurement is being undertaken, what are the key issues/ challenges faced etc. This issue has been noted in each of the three UNITAID feedback reports to date, but does not seem to have been addressed by the implementing partners in subsequent reports.

### **The process of gathering M&E information from the NTP grantees for consolidation by WHO has been challenging**

Under the project, NTP grantees do not receive any funding to carry-out M&E functions; thus consultation feedback indicates that reporting has been weak/ poor for many NTPs and that it is difficult to guarantee the quality of information gathered. For example, we understand that in Nepal, IOM (the TB REACH NGO grantee) supports the NTP in their reporting to WHO given limited capacity/ quality control.<sup>58</sup> Further, the M&E data being reported might not solely be attributable to the TBxpert project, due to the need to manage cartridge availability across sites (both UNITAID and non-UNITAID funded).

### **There have been some revisions to project targets although these do not seem to be effectively incorporated**

We note that there have been some minor revisions to project targets, but these have not been properly recorded in the M&E progress templates. For example, as part of the annual forecasting exercise, countries update the number of cartridges they plan to order, based on actual consumption of the previous six-months and projected needs. Although the updated forecasts are recorded in the annual LoA, the programmatic progress reports report against the original targets as per the Project Plan.

Further, project progress to date suggests the need to revise certain targets downwards, as they are currently over-ambitious due to the initial delays in the start of the project. However, neither the logframe nor the progress reports account for this/ detail the approach for formally documenting changes.

**The project M&E framework is well-designed and reporting by implementing partners to date has been timely and high-quality, albeit with some areas of improvement going forward.**

## **4.2. Public health and market impact**

Our evaluation question is as follows:

**Qs 7: Is the project on track to achieve its targets and what have been the results to date, in terms of:**

- a) public health impact of improving diagnosis and treatment of TB, HIV/TB and MDR-TB; and**
- b) market impact of scale-up of Xpert MTB/RIF?**

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<sup>58</sup> Based on discussions with IOM.

### 4.2.1. Public health impact

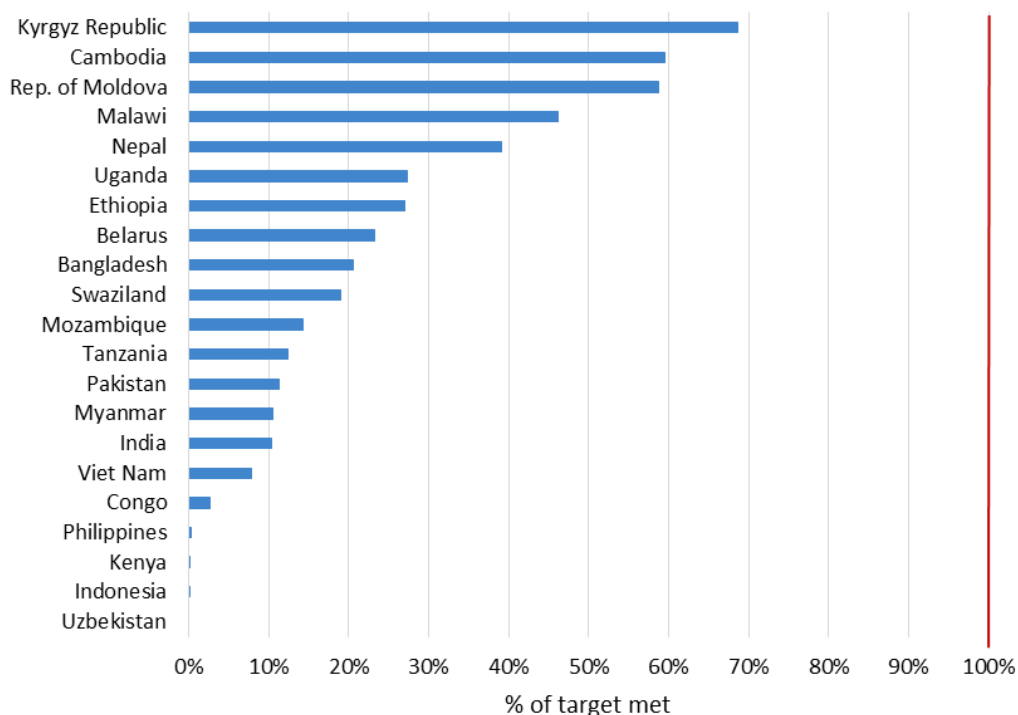
We consider the planned versus actual public health impact to date as well as the wider public health benefits in terms of the diagnostic-treatment nexus, which is closely linked to the extent to which the Xpert MTB/RIF has been embedded into the NTP framework.

#### Planned versus actual results

As per the MoU, the project’s public health impact is estimated by measuring the case detection of incident TB, HIV-positive TB, and rifampicin-resistant TB patients. We review the progress made in terms of actual number of individuals tested and case detection against the targets presented in the Project Plan.

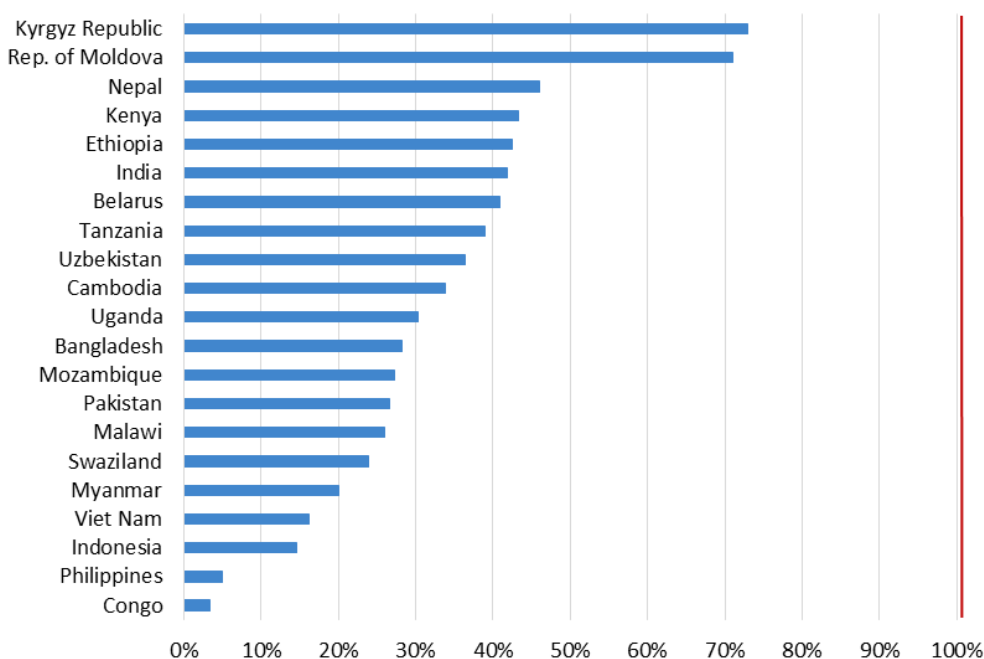
- **Number of individuals tested:** Figure 4.1 presents the percentage of the project target achieved by each of the project countries in 2013. As shown, none of the project countries achieved even 70% of their testing target, with only three countries achieving 50% of their target. This low level of testing of individuals can, in part, be explained by the delays in the procurement of cartridges due to manufacturing issues at Cepheid and other issues discussed in Section 3. However, the number of people tested has been improving in 2014, as illustrated in Figure 4.2. Actual results from the first half of 2014 illustrate that significant progress is being made across the 21 countries: whilst in 2013, 18% of the target number of individuals tested was achieved, 32% of the annual 2014 target had been achieved in the first half of 2014 alone.

Figure 4.1: Percentage of individuals tested against targets in 2013



Source: 2014 Semi-Annual Report

Figure 4.2: Percentage of individuals tested in the first half of 2014 against targets in 2014



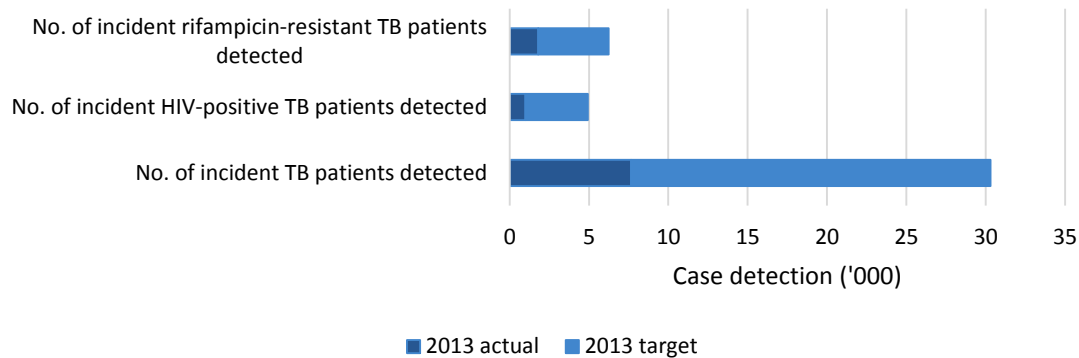
Source: 2014 Semi-Annual Report

- **Case detection:** The low level of individuals tested has translated into all three case detection indicators being significantly under-target in 2013, as illustrated in Figure 4.3 (see Annex 8 for further analysis of performance by country).
  - **Incident TB:** The only country to achieve its target for incident TB case detection in 2013 was Kyrgyzstan, which achieved 305% of its target.<sup>59</sup> Overall, across project countries, only 25% of the project target was achieved in 2013. However, progress in detecting incident TB substantially accelerated in the first half of 2014, with 53% of the annual 2014 target across all countries being reached.
  - **HIV-positive TB:** The level of case detection among HIV-positive patients has been particularly poor, with only 20% of the project target achieved in 2013; the only countries to achieve their targets were Moldova, India and Nepal. Case detection of HIV-positive TB patients was reported as one of the most common challenge in the 2014 Semi-Annual report, with 13 of the 21 countries stating that the HIV status of patients was not known or being routinely screened at project sites. In fact, by mid-2014 only 35% of the 2014 target for the detection of HIV-positive TB patients had been reached.
  - **MDR-TB:** Case detection of rifampicin-resistant TB patients has shown the most progress, achieving 29% of the project target in 2013 and 64% of the 2014

<sup>59</sup> This is largely because tests were being used in existing machines in the country and for MDR suspects only.

annual target by mid-2014. The higher level of rifampicin-resistant TB cases being identified is closely linked to the issue of countries using Xpert MTB/RIF only for detecting MDR-TB patients as a result of “restrictive” diagnostic algorithm (as discussed in Section 3.4).

Figure 4.3: 2013 achievement against targets for case detection of incident TB, HIV positive TB, and rifampicin-resistant TB patients



Source: 2013 Annual Report

### Linkages with treatment

A key issue for diagnostic tools and their public health impact is the extent to which higher case detection is followed by increased treatment of patients and consequent reductions in morbidity and mortality. As such, the link to treatment is a crucial element of establishing public health impact.

The TBXpert project does not track treatment initiation for TB cases diagnosed. However, anecdotal evidence collected from the three country visits, illustrates mixed experience in terms of linkages between patients diagnosed and treatment initiation. For example, stakeholders in India reported that there have been improvements in terms of treatment access; in particular there was mention of a period of five to ten days before patients start their MDR-TB treatment in the public sector, as a result of rigorous clinical and laboratory examinations according to protocol. In Tanzania as well, no major issues were reported with regards to treatment referrals; it was estimated that if the case detection targets are achieved, the TBXpert project will result in 3,278 TB patients, and 1,077 incident HIV-positive TB patients successfully treated. However feedback in Indonesia suggests inadequate attention being paid to the linkages with treatment due to poor coordination with the NTP, especially given that the project is not following the NTP recording and reporting system for referrals to treatment. There are also issues with the project’s approach to reporting test results to health facilities. As such, around half of the new TB patients and the majority of the

MDR-TB patients have not been able to start treatment soon after detection, with many even “getting lost” in the referral process.<sup>60</sup>

#### **4.2.2. Market impact**

The planned or intended market impact of the TBXpert project is increased procurement of cartridges, signifying market expansion and improved access to TB diagnosis. This is planned for the 21 TBXpert countries as well as the 124 other countries that are eligible for the concessional pricing of cartridges from Cepheid.

We review the experience to date on the planned versus actual market impacts, first looking at the procurement rate under the UNITAID TBXpert project, before reviewing the wider trends in global procurement of Xpert commodities. We then also consider the potential for broader market impact in terms of encouraging competition and further price reductions.

#### **Planned versus actual results**

While all project countries achieved their 2013-14 cumulative GeneXpert instrument procurement targets, procurement of cartridges has been much lower than planned at 67% of the cumulative 2013-14 target up to the end of December 2014 (Figure 4.4).<sup>61,62</sup> This was in a large part due to the slow start of projects and the manufacturing delays in 2013, when only 56% of targets were achieved. In addition, the issues discussed in Section 3 such as restrictive diagnostic algorithms and weak referral systems have also resulted in underutilisation of machines and thus impacted the rate of procurement. This improved to 76% against targets in 2014, representing a significant increase in procurement rate, though still below planned target.

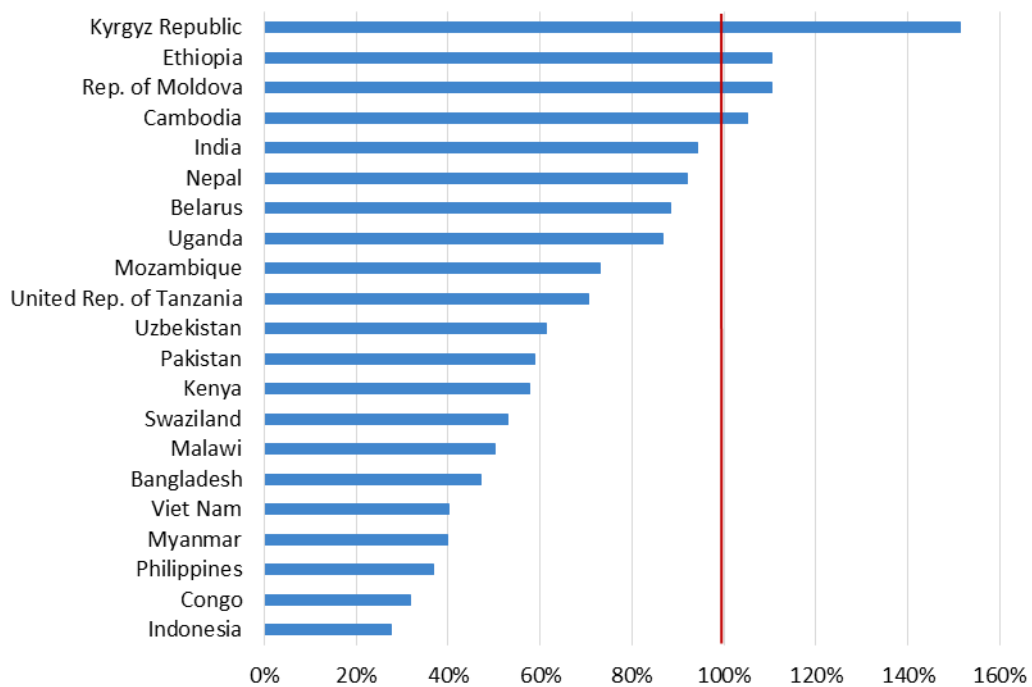
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<sup>60</sup> For Q2 and Q3 of 2014, 52% of the TB patients detected were put on treatment and only 16% of the MDR-TB patients were put on treatment. Ref: Indonesia Country Report for further details.

<sup>61</sup> As noted in the India Country Report, India actually acquired an additional three machines from UNITAID. This is due to a request from the NTP to place and these additional 2-module GeneXpert machines in the Andaman and Nicobar Islands to facilitate access to TB testing.

<sup>62</sup> Procurement data has been provided to us by WHO up to end 2014; however public health impact data is available only until mid-2014 (data until end 2014 is currently being analysed).

Figure 4.4: Percentage of cartridges procured against targets in 2013-14

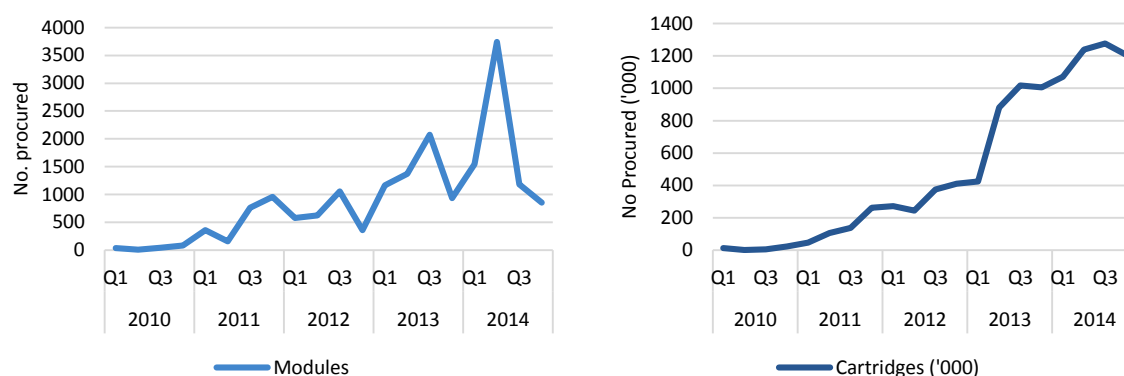


Source: Data provided by WHO – numbers submitted for the 2014 TBXpert Annual Progress Report

Figure 4.5 illustrates the level of Xpert MTB/RIF roll-out at the global level (i.e. beyond the TBXpert project), presenting data on the procurement of Xpert MTB/RIF modules and cartridges across all eligible countries from 2010. We make the following observations:

- The number of modules and cartridges has been increasing since 2010, with the rate of procurement of cartridges increasing sharply at the beginning of 2013 (in line with buy-down arrangement and the beginning of the TBXpert project). Cartridge procurement rose from around 400,000 in Q1 to 1 million in Q4 of 2013. Furthermore, the level of procurement has been sustained into 2014, rising steadily. The 2014 semi-annual progress report indicates that among the 124 non TBXpert project countries, the number of cartridges procured in Q1-Q2 2014 was almost double the number procured in Q1-Q2 2013 (ratio: 1.9).
- The global procurement data provided by WHO shows that the number of countries procuring Xpert commodities has risen from 18 in 2010 to 124 countries in 2013 (including the 21 TBXpert project countries, though we do note that some of these countries have procured commodities for training, study or trial purposes).

Figure 4.5: Global Xpert MTB/RIF procurement 2010-2014: (a) modules; and (b) cartridges



Source: Data provided by WHO

Notwithstanding these achievements, we note that the distribution of commodities procured across eligible countries is uneven. In particular, the top four consumers of cartridges, modules and machines are South Africa, India, China and Brazil, which cumulatively procured 74% of cartridges between 2010 and 2014. Of these, South Africa is by a substantial amount the largest user of GeneXpert, having procured 62% of cartridges, and 31% of modules between 2010 and 2014; in 2014 alone South Africa purchased 51% of global cartridges procured at the concessional price.<sup>63</sup> As such therefore, while there has been a rapid uptake and scale up of Xpert MTB/RIF globally since the TBXpert project in 2013, the vast majority of this comprises purchases from South Africa.

The savings achieved from the price reduction under the buy-down agreement is one of the most significant market impacts from the TBXpert project. By reducing the price from US\$16.86 to US\$9.98, the global savings on cartridge procurement have been significant, amounting to almost US\$56m in 2013 and 2014 (see Table 4.1).

Table 4.1: Savings made 2013-2014 as a result of the 2012 buy-down agreement with Cepheid

Year	Total spend at pre-buy-down price of \$16.86	Total spend at post-buy-down price of \$9.98	Savings
2013	\$56.1 m	\$33.2 m	\$22.9 m
2014	\$80.8 m	\$47.8 m	\$33.0
<b>Total</b>	<b>\$136.9 m</b>	<b>\$81.0</b>	<b>\$55.9 m</b>

Source: Procurement based on data provided by WHO

### Potential for broader market impact

More generally, while not the target or direct result of the project itself, it is expected that the project would contribute to broader market impacts in the long run by generating evidence on a solid business case for new entrants to the diagnostics market, and thereby,

<sup>63</sup> Based on data provided by WHO



greater competition and exploitation of economies of scale which would allow for reduced prices (and consequently cost per test).

It is too early to comment on the contribution of the project to these longer term market impacts, however we note the following from our project review and consultations (which focus on *potential* of the project realising the above-noted long term results at some point):

- Further price reductions in the instrument and cartridge price for Xpert MTB/RIF are warranted to encourage scale-up, on account of the lack of affordability at the current price. However, our consultations with Cepheid as well as other stakeholders that have been liaising with Cepheid over the years suggest that there is no scope for Cepheid to reduce prices at the current/ near term market size.
- That said, Cepheid has been investing in developing a more sensitive Xpert MTB/RIF cartridge – *Xpert MTB/RIF Ultra* – which we understand will be offered at the same concessional pricing as the current Xpert test.<sup>64</sup> There is a mixed view on the “benchmark” of US\$9.98 that has been created for the cartridge as a result of the buy-down arrangement – some view this positively as it is a reduced/ concessional price, while others view it negatively as they think that it represents a “lower limit” price which Cepheid and other manufacturers will use as a base for their future pricing strategies.
- Cepheid have communicated to us that the UNITAID funding of the TBXpert project has encouraged them to make more investments in the Xpert MTB/RIF test in particular, and molecular diagnostics more generally. They do not necessarily attribute this to the TBXpert project alone, but also to the efforts made by UNITAID in the TB diagnostics market more generally (e.g. in terms of developing diagnostics landscapes, etc.), amongst other non-UNITAID related factors.
- The TBXpert project has the potential to have an important “demonstration effect” for the development of other molecular based diagnostic tests. In fact, the UNITAID 2014 TB Diagnostic Landscape notes that “*the ongoing rollout of Xpert MTB/RIF has had a positive influence on the TB diagnostics landscape, and has attracted new investments, product developers and a robust pipeline of promising technologies*”.<sup>65</sup> Although no further diagnostic technologies have yet received endorsement from WHO, R&D in this field is ongoing and the pipeline of promising technologies is continuously being strengthened.

**The public health and market impact of the project has been lower than planned to date, given the delays in “getting started”, and to some extent, over ambitious targets and timelines. The project has however made substantial “catch-up” progress in 2014.**

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<sup>64</sup> <http://ir.cepheid.com/releasedetail.cfm?releaseid=878540>

<sup>65</sup> UNITAID (2014) Tuberculosis: Diagnostic Technology and Market Landscape, 3<sup>rd</sup> edition. p.78.

- Up to mid-2014 the project has supported the detection of 32,154 cases of incident TB (23% of target), 3,554 cases of HIV-positive TB (16% of target) and 8,646 cases of MDR-TB (27% of target) across the 21 focus countries.

- Cartridge procurement up to December 2014 has been 607,240 (42% of target).

The global procurement of Xpert cartridges has increased substantially since the buy-down agreement and the commencement of the TBXpert project (also in terms of the number of countries procuring cartridges). However the market is heavily dominated by South Africa, with limited expansion across other countries.

The broader public health impact of the project in terms of linkages with treatment has had mixed experience to date, with some countries/ projects exhibiting ongoing improvements in treatment initiation and success and others with some key gaps in the diagnosis-treatment linkage.

The potential for broader market impacts in terms of further price reductions for Xpert MTB/ RIF are limited at the current/ near term market size. However the project has the potential to contribute to encouraging the market for molecular-based diagnostic tests.

### 4.3. Sustainability

Our evaluation question is as follows:

#### Qs 8: Are the project activities likely to be sustained after UNITAID funding?

Given the objective of the TBXpert project is to introduce a new technology and encourage future scale-up, sustainability after the end of UNITAID funding is a critical measure of the success of the project. The importance of ensuring sustainability has been well recognised from the outset of the project, with Output 6 of the logframe being “*transitioning out to ensure continuation of use of instruments after project conclusion*”. Discussions with UNITAID senior management also indicate that UNITAID aims to plan for sustainability of its funding from project commencement.

In general, WHO and TB REACH have been making efforts to support sustainability through:

- their ongoing discussions with country NTPs and donors, predominantly the Global Fund; and
- creating greater awareness of the Xpert tool through publishing of papers, participation in global meetings, etc.<sup>66</sup>

However, our assessment is that this has not been done systematically under the project to date. In particular the Project Plan proposes the development of “transition plans” which would identify alternative sources of funding either through donor partners or domestic resources, although there has been no clear agreement between UNITAID and the Implementing Partners on the structure/ approach to these plans. The Project Plan also notes that “*country-specific negotiations will start in the middle of the second year of the project with NTPs and partners*”, however we understand that systematic planning for sustainability has not yet commenced. Further, sustainability planning was to be based on a standardised

<sup>66</sup> Sustainability is also emphasised in all TB REACH applications (Section 5d of the application form asks grantees to describe their proposal to sustain/ scale-up activities beyond the TB REACH grant).

UNITAID transition tool, however this has not been finalised by UNITAID as of now. A key issue impacting sustainability planning under the project however has been the lack of certainty on future funding of TB REACH.

The potential for future sustainability varies across countries: for LMICs, sustainability will depend on the degree to which they prioritise this intervention in their national TB plans, whilst for LICs the sustainability of Xpert MTB/RIF is likely to depend on donor support (particularly the Global Fund). The Global Fund has been providing support to countries on Xpert MTB/RIF:

- in 2013 it provided support for 801 machines and 760,698 cartridges in 23 countries and in 2014 for 937 machines and 1,102,759 cartridges in 18 countries.
- of the 42 supported by the Global Fund over the past two years, 10 are also TBXpert project countries.

However, future Global Fund support for Xpert MTB/RIF depends on the approval of concept notes under the New Funding Model (NFM), which is still being finalised. For countries unable to access Global Fund support, the GeneXpert machines represent “tangible products”, which are attractive to other donors and can help to secure additional funding going forward.

Experiences from the field visits and consultations suggest that countries/ projects are at different stages in their sustainability planning (see Box 4.1).

**Box 4.1: Varying experiences with sustainability – evidence from field visits and consultations**

**India** has already started thinking about the sustainability of its UNITAID-supported GeneXpert machines and the NTP is planning to adopt a mix of domestic and donor resources: it has requested support for 300 machines to be funded through its Global Fund grant over 2014-16, whilst a further 100 in 2014-15 and 200 in 2015-16 will be funded by the national government. Further, the NTP has developed a plan for the state governments to “take over” funding of the warranties for the machines, although a clear budget allocation for this has not yet been made.

Consultations in **Indonesia** indicated that discussions between the NTP, the Provincial Health Office and the project implementer regarding a transition plan for Xpert had taken place, but that no clear conclusions had been reached. The NTP has also explored the option of including funding for the maintenance of GeneXpert machines under the national health insurance programme, especially since TB drugs and smear microscopy are included. However, this process will likely require time following official government procedures, and will require the involvement of the Ministry of Finance to create an additional budget for the machines and their running costs. Further, the private hospitals and clinics that have received Xpert MTB/RIF through UNITAID will need to budget for maintenance, including calibration and warranty from the end of 2015, but planning for this has not yet started. As such therefore, without focused sustainability planning and efforts to make these materialise, the sustainability of the UNITAID-supported GeneXpert machines is at risk.

There is considerable uncertainty as to whether the NTP in **Tanzania** will be in a position to fund the operating costs following the project period. In the short-term, the NTP is confident that it can support the machines’ operating costs using its own resources and that received from other donors. However, in the medium- and long-term, the country is expected to require support from external donors, such as the Global Fund. The two TB REACH grantees are also planning to “hand over” their GeneXpert machines to NTP at the end of their TB REACH grant and the NTP is currently trying to

establish whether they need to order cartridges in advance of the completion of the TB REACH projects to ensure a smooth transition.

As discussed in Section 3.6, the sustainability of the **PPM/SBM projects** has been a key challenge and self-sufficiency will not be achieved within the lifetime of the project; however, based on lessons learned, there is the possibility to revise these business models to ensure greater revenue generation potential going forward.

Our consultations have emphasised that the lack of sustainability planning has led to situations where donor funded machines are lying unused and thus sustainability planning through engagement with the NTP and other donors is critical to ensure the ongoing utilisation of the GeneXpert machines both in the near future and in the long-term.

**Sustainability planning has not been approached systematically to date, posing a critical risk for the future sustainability of a number of projects.**

## 5. CONCLUSIONS, LESSONS LEARNT AND RECOMMENDATIONS

This final section provides our mid-term evaluation conclusions and lessons learnt on the TBXpert project (including with regards to value for money (VfM)) as well as key recommendations to guide effective performance going forward.

### 5.1. Summary findings

The TBXpert project, with its aim to encourage scale-up of Xpert MTB/RIF, is a significant intervention, given the need to enhance TB diagnosis and the “breakthrough” nature of this technology. However, with the initial delays in project commencement and the relatively limited rate of scale-up across project countries (and the other 124 eligible countries except South Africa), due to issues with affordability and some implementation challenges, the potential for Xpert MTB/RIF to become the standard TB diagnostic in the near future is low. That said, the project is playing an important role in encouraging countries to adopt newer, more efficient TB diagnostics that may become available in the medium term, also on account of the potential demonstration effect of the project on the diagnostics market.

Our summary conclusions on the key evaluation criteria used for assessing the TBXpert project are as follows:

#### Relevance

The TBXpert project is well-aligned with UNITAID’s mandate and comparative advantage of addressing key market shortcomings preventing access to effective TB diagnosis. However, challenges related to affordability remain due to the monopoly market structure, which are preventing the standardised use of the diagnostic. As such therefore, while diagnostic algorithms are being revised to incorporate Xpert, these have been slow to change, with Xpert MTB/ RIF viewed as an “add-on test” that will not replace smear microscopy in the near future. Decentralised placement of the test has facilitated access for populations, however there are also issues in terms of weak capacity and referral linkages for culture/DST and treatment at this level.

#### Implementation efficiency and effectiveness

A number of aspects of project implementation have worked well including effective delivery by the lead implementing partners, good efforts at global coordination of Xpert as well as efficient procurement arrangements and processes. There have also been a number of good experiences with country-level grantees in terms of effective management of the Xpert technology introduction and roll-out (for example, the NTP in India and the TB REACH grantee IOM in Nepal). However, there have also been a number of key issues that have impeded efficient and effective implementation including:

- *The almost exclusive commodity focus of funding, which has created challenges in terms of limited funding for technical assistance and supporting costs for NTP grantees*

(e.g. for site selection and management, training, etc.); this is available to the TB REACH grantees through TB REACH funding. TA and supporting funding has been viewed by many stakeholders as critical to support the introduction and roll-out of a new technology in countries (despite its relative simplicity).

- *Several delays in project commencement*, due to initial issues with Cepheid manufacturing capacity but also on account of longer than planned time taken for grantees to get started (due to discussions with the NTP, preparation of project sites, issues with customs clearance for importation of machines, etc.).
- *Challenges with product use and roll-out*, in terms of (i) module failures – which have been effectively resolved by Cepheid, although the response times have been lengthy at times; (ii) restrictive and slow revision of diagnostic algorithms and related policies; and (iii) programmatic bottlenecks, such as low levels of training, monitoring and weak referral systems. These issues highlight the challenges involved in introducing and rolling out a new technology with limited technical assistance and support funding. While Cepheid has been very responsive, the variable support provided in some countries as well as the issue of low affordability of warranties going forward suggests the need for an agreement at the outset with a manufacturer that sets out levels of service (e.g. response times) and complementary costs.
- *Varied experiences in terms of country-level coordination with NTPs and other donors*, based on the extent of involvement of local WHO offices (strong in India but weaker in Indonesia), support from ASLM (key to progress in Tanzania but weaker in other countries) and the relationship between the NTP and grantee.
- *Poor accuracy of cartridge forecasts for the project*, implying the need for effective management by the implementing partners as well as a planned re-allocation across countries to ensure project budget use. Our assessment is that the re-allocation is an efficient approach, but also somewhat detracts from the project goal by virtue of not supporting “difficult/ challenging” countries or projects to scale-up.
- *A number of challenges with the PPM/SBM models*, in terms of getting started and ensuring adequate referrals to support the planned revenue generation. Despite a slow start in 2013, both the number of cartridges used, patients tested and cases detected have been improving in 2014, however fall way short of the targets. There have also been some challenges with ensuring effective linkages with treatment (especially in Indonesia).

## Results

The project M&E framework is well-designed, although there have been some challenges with reporting in terms of absence of a detailed narrative from implementing partners and constraints with gathering information from NTP grantees. The initial delays coupled with the

implementation-related challenges on the ground, have impacted the degree to which project targets are being achieved. Specifically:

- In terms of *public health impact*, case detection of TB, HIV-TB and MDR-TB has fallen short of the targets in 2013, with some acceleration of progress in the first half of 2014. More broadly, effective linkage with treatment has varied by country/ project – e.g. being more effective in India than under the PPM model in Indonesia.
- On *market impact*, progress has been in line with the targets for procurement of GeneXpert machines (with all countries achieving their 2013 targets), but lower than planned (however still an achievement given the initial manufacturing delays in particular) for the procurement of Xpert MTB/RIF cartridges (only 42% of overall cartridge procurement has been achieved by end 2014). There has been an increase in the number of countries procuring Xpert MTB/RIF as well as in the global levels of cartridges procured, although this is dominated by South Africa’s purchases. More generally, the project appears to have no potential to impact further price reductions for Xpert MTB/RIF (also given the monopolistic nature of the market), however may contribute to encouraging greater investments and competition for new and efficient TB diagnostics.

## Sustainability

Although project partners have been engaging NTPs and donors such as the Global Fund, sustainability planning has not been approached systematically to date, with no TBXpert project grantee having developed a clear transitioning-out plans with identified sources of funding. There has been varying experiences across project countries, with some planning to sustain the TBXpert project investments through government and Global Fund resources (e.g. India), but others with greater uncertainty (e.g. Tanzania). An issue impacting sustainability planning has been the lack of certainty around continued funding for the TB REACH initiative.

### 5.2. Value for money

In simple terms, the concept of VfM relates to the value or benefits of a project in relation to its costs.<sup>67</sup> Our evaluation findings have informed our assessment of the VfM of the TBXpert project, which is as follows:

- The TBXpert project is highly relevant given its role in supporting the introduction and roll-out of a novel TB diagnostic technology across a wide-range of HBCs.
- Whilst not the first donor to support Xpert MTB/RIF (as both TB REACH and USAID have been providing support to countries since 2011), UNITAID’s investment in the

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<sup>67</sup> VfM is one of UNITAID’s “guiding principles” as well as a project selection criteria. We understand that UNITAID is currently developing a framework for measuring the VfM of its projects, considering key principles such as equity, efficiency and effectiveness (which have also been key areas for assessment in our evaluation framework). Ref: UNITAID (2013) UNITAID Strategy 2013-16, p. 18.

TBXpert project is of important value given its consolidated support for encouraging introduction and scale-up across a range of countries.

- Through the buy-down agreement, undertaken within the framework of the TBXpert project, the project has achieved a significant lowering of the price of Xpert MTB/RIF cartridges (notwithstanding the fact that affordability constraints remain), which has been made available to public sector purchasers in 145 high TB burden and low-income developing countries. Savings from the global sales of Xpert MTB/RIF cartridges have amounted to almost US\$56m over 2013-14, substantially greater than the buy-down agreement monies of US\$11.1m.
- The project has potential for broader market impact, through a “demonstration effect” to encourage investments for the development of other new and efficient molecular based TB diagnostic tests (although this remains to be seen).
- While lower than planned, the project has had an important public health impact by increasing the numbers of TB, TB-HIV and MDR-TB patients detected, some of whom may not have had access to effective diagnosis which has been facilitated through the decentralised placement of the technology.
- Finally, while the project will not ensure the standardised use of Xpert MTB/RIF across the project countries, it is playing an important role in encouraging countries to adopt newer, more efficient TB diagnostics that may become available in the medium term.

As such therefore, our assessment is that the project provides positive VfM. In the absence of an agreed or baseline “benchmark” or “rate of return” to assess the project’s performance, we are unable to carry out a full VfM assessment (a comparison across UNITAID investments is outside of our scope), however we note that the value highlighted above would be worthwhile in relation to the investments that have been made should sustainability planning be effectively and systematically carried out.

### **5.3. Recommendations**

Based on our evaluation findings and conclusions, we make a number of key recommendations to improve the efficiency and effectiveness of the TBXpert project going forward. Our recommendations are cognizant of what might be feasible to implement within the remaining timeframe of the project. Some of the recommendations also extend to UNITAID project planning and funding more generally.

We describe the main thrust of our recommendation, although do not provide details in terms of “how” UNITAID might implement any of the proposed suggestions.



### **Recommendation 1: Discuss and agree an appropriate project extension with project partners and revise targets as needed**

Given initial delays in cartridge procurement and commencement of testing, the project is unlikely to achieve its public health and market impact targets by the planned end date of December 2015.<sup>68</sup> However, both our data analysis and feedback from consultations indicate that the project is showing clear improvements in procuring cartridges and testing individuals. In light of this, we recommend that at a minimum, a no-cost extension of a year be granted to allow project grantees to work towards reaching the originally envisioned targets. In the absence of an extension, project achievements may be lower than optimal, there may be a significant risk of curtailing scale-up in countries when progress is just beginning to be made as well as potentially negative “demonstration effects” to diagnostic developers/manufacturers. Should it be required, UNITAID and project partners should also discuss where there are any key expenses that need to be funded in the extension period to ensure effective delivery.

Related to this, there is a need to critically review planned project targets (in total and by country/ grantee) and consider selected appropriate revisions.

- Market impact targets should be revised by country/ grantee in line with the planned reallocation approach to ensure overall project targets are met. That said, specific targets for poorly performing countries/ grantees should also be considered, in keeping with the overall objective of the project of encouraging scale-up of Xpert MTB/ RIF across a range of countries.
- Related public health impact targets should also be reviewed closely to assess the need for target revision (both upwards and downwards). Given that for the three case detection indicators a target range (low and high targets) has been included in the original project logframe, these should be used as a benchmark for project performance and indicator revision.

### **Recommendation 2: Expedite sustainability planning for all countries/ grantees**

Given the lack of systematic planning for sustainability, we recommend that:

- *UNITAID expedite the development of its planned transition tool for projects.* If it is not possible to finalise the UNITAID tool very soon, the project partners (UNITAID and the implementing partners) should design and agree a focused tool to support planning for near and long-term sustainability of the TBXpert project.
- *Project implementing partners should enhance their engagement with NTPs, Global Fund and other donors* to identify relevant opportunities for take-over financing. In

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<sup>68</sup> Discussions with the project implementers suggest that if the project were to end in December 2015, there would be approximately 280,000 cartridges not procured, which is almost 20% of the projects total cartridges.

addition, local private sector financing options should be explored (especially in countries such as India with a dynamic private sector).

- *Project implementing partners should develop a database to support the tracking of sustainability plans and potential for sustainability for each project country.* The database should detail key partners engaged in sustainability discussions, amount of secured funding, potential funding, etc. The database should be accompanied by a progress rating system updated on a regular basis to indicate the country's progress towards sustainability.
- *Grantees should be encouraged to develop sustainability plans and report on progress to the implementing partners.* As the ultimate responsibility for sustainability lies with the country project grantees, they should be encouraged to actively seek out financing options. These may be included as requirements in future LoAs or as part of the disbursements to ensure proactive efforts. More generally for non-NTP grantees, in order to encourage sustainability, they should work in close coordination with the NTP.
- *Broad-based approach to sustainability planning.* Project sustainability needs to be thought about in terms of funding for machines and cartridges, as well as supporting costs (such as for training, maintenance, warranties and cost of annual calibrations).

*More generally, the sustainability plan for UNITAID projects needs to be included in the project design, with focused efforts at ensuring delivery against the plan from the start of the project. An approach employed by some other funding organisations to encourage sustainability is to require grantees to “explicitly” co-fund the project (i.e. require a clear contribution to the cost of commodities). Especially in the case of government grantees, this allows for the creation of a budget line and hence greater potential for take-over after the completion of donor funding. Different levels of co-funding based on the grantee characteristics and type of support can be devised.*

### **Recommendation 3: Review provisions for TA and supporting costs**

One of the key issues that has constrained effective implementation of the project has been the limited funding availability for TA and supporting costs for NTP grantees. In addition, while the project has made a provision for TA support from ASLM for five African countries, ASLM has been capacity constrained and its support has been variable across countries.

Whilst we recognise that extensive re-programming for TA and supporting costs is not feasible at this stage of the project (and may also go against the principle of ensuring sustainability), we make the following recommendations:

- Conduct a grantee by grantee review to consider where lack of TA support and additional monies to support implementation are serving as key bottlenecks, and find appropriate solutions on a case-by-case basis – e.g. where ASLM can deliver effective

support this should be continued else other partners (such as FIND) should be brought on board, cost savings under certain budget lines (e.g. on shipping costs) may be re-allocated for TA and support costs for select grantees, etc.

- Make efforts to support the documentation and sharing of lessons learnt/ best practices – whether through in-person meetings or virtual forums so that country grantees can learn from each other’s experiences.

*More generally, our recommendation would be for UNITAID projects to include some provisions for TA and ancillary costs (alongside commodity funding) to ensure effective introduction and roll-out of a new technology.*

#### **Recommendation 4: Critically appraise the PPM/SBM models and consider appropriate revisions to their targets**

The performance of the three PPM/SBM models to date, while improving, has been lower than planned. The expectation that these projects would meet their targets (not only for public health and market impact but also revenue generation and self-sufficiency) are unlikely. As such therefore, we recommend:

- The projects in the three countries are closely reviewed and select strategies/ approaches are focused upon rather than conducting multiple activities. For example, our high-level assessment is that there is scope to focus on a few active case finding strategies rather than “spreading the project too thin”. While we would encourage more focusing of these projects rather than expansion, alternative “add-on strategies” to include further adjunct diagnostic services (beyond TB) may also be considered to foster revenue generation. For example, new business-lines can be added to the original chest X-ray driven model and/ or the screening centres could become multi-purpose diagnostic platforms for the screening of both TB and HIV (more relevant for Pakistan than Indonesia given HIV status).
- A detailed financial model is developed for the agreed strategies, with actual and forecasted revenues and costs, and related public health and market impact. Alternative scenarios and ranges should be included in this model to support planning and course-correction as required.
- The public health and market impact targets are revised suitably to reflect potential results that are achievable within the project timeframe.
- Documentation of lessons learnt and experiences is encouraged, given the innovative nature of these projects and the need to foster learning.
- Clear plans are made to ensure take-over and maintenance of the assets purchased through UNITAID/ TB REACH support.

## Recommendation 5: Provide support for/ encourage the use of remote monitoring tools

Remote monitoring tools/ softwares, such as GXalert and RemoteXpert for the Xpert MTB/RIF tool, provide visibility on the use of GeneXpert machines and support countries to: (i) develop more accurate forecasts based on the actual machine throughput; (ii) monitor failure rates and support troubleshooting of technical issues; and (iii) improve data collection and data quality for rigorous assessment of public health and market impact. Despite being envisioned in the Project Plan (although with no specific funding allocation), these monitoring tools have not been adopted across the project.

While we have not reviewed the different monitoring tools and their functionality, we recommend that an appropriate monitoring tool be adopted for the TBXpert project countries as soon as feasible. Our high-level view is that given that RemoteXpert is expected to be free of charge (as communicated to us by Cepheid), this would not require any budget re-allocations<sup>69</sup>; however it would be important that TBXpert countries have the capacity, both technical and operational, to use it effectively.

*More generally, we recommend that the introduction/ scale-up of a new technology by UNITAID is supported with active monitoring systems that provide greater visibility on the use and effectiveness of the technology. We recommend that in future projects, UNITAID allocate an adequate budget to ensure the purchase and running of such systems.*

## Other recommendations

We make the following additional recommendations for UNITAID:

- Given that the TBXpert project took almost two years for approval, UNITAID should work towards instituting processes to encourage faster (yet robust) project proposal reviews to minimise transaction costs for all parties involved.
- Given the high turnover of UNITAID staff responsible for the TBXpert project, UNITAID should ensure that project requirements are well documented and hand-overs are efficiently carried out.

In addition to the standard requirements for an end-of-project evaluation in terms of assessment of achievements against targets, we recommend that the planned evaluation for this project also focus on: (i) reviewing performance at the grantee level (i.e. beyond the country-level that is tracked under the project M&E), to draw lessons on what works and challenges faced across project sites; (ii) conduct country visits in a mix of good and poor performing countries so as to understand both success factors and challenges for scale-up; and (iii) conduct a more detailed assessment of VfM, drawing on UNITAID's VfM framework that is currently under development.

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<sup>69</sup> Current High Burden Developing Country customers can receive RemoteXpert connectivity free of charge if they have a service agreement. <http://ir.cephid.com/releasedetail.cfm?releaseid=903011>



**UNITAID**

**MID-TERM EVALUATION OF THE TBXPERT PROJECT**

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**12 MAY 2015**

**FINAL REPORT – ANNEXES**

Submitted by:

**Cambridge Economic Policy Associates Ltd**

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## ANNEX 1 EVALUATION METHODS AND LIMITATIONS

This annex presents our evaluation methods in detail. It also presents key methodological limitations.

### Evaluation methods

The evaluation has been conducted using a mixed-methods approach including the following core techniques:

- **Desk-based document review** including project documents (e.g. the Memorandum of Understanding (MoU) and annexes, annual and semi-annual progress reports, grantee proposals and progress reports for TBR projects, project documentation on the PPM models), key UNITAID Board papers and resolutions, Proposal Review Committee (PRC) documentation on the project, reports from Xpert global coordination meetings as well as a broader literature review on the Xpert tool. Annex 2 provides a bibliography.
- **Structured telephone interviews** were conducted with select members from the UNITAID Secretariat, project implementers (including WHO, TB REACH, GDF, IRD, ASLM), Cepheid as the Xpert MTB/RIF manufacturer, partners of the buy-down agreement (USAID and BMGF) and other TB/ diagnostics focused organisations (including the Global Fund, FIND, TBCTA and CHAI). We also consulted with three project grantees to add to the findings from country visits (see next point). These included the iccrd,b in Bangladesh, International Organisation for Migration in Nepal, and the NTP in Kenya (selected randomly on the basis of a mix of geographies, grantee types and progress to date). Annex 3 provides a list of consultations and presents the interview guides used.
- **Country visits** – Field visits were conducted to India, Indonesia and Tanzania by one CEPA team member for a period of three days each. The primary objective of the country visits was to conduct face-to-face interviews with the grantees implementing the TBXpert project (both NTPs and TB REACH grantees), to understand what is working well and what have been the challenges/ key issues to date. Additional objectives of the country visits were to: (i) conduct interviews with other in-country stakeholders to understand the relevance, experience and results from the projects (e.g. the NTP (where not a project grantee), the central TB reference laboratory, in-country TB-focused donors and civil society); and (ii) collect data (quantitative and qualitative) on costs incurred in relation to the Xpert MTB/RIF test, through short and focused patient surveys at project sites.
- **Quantitative analysis** – We undertook the following data analysis: (i) project budget and expenditure; (ii) key metrics on efficiency and efficacy of project implementation, including lead times for procurement; (iii) patient costs (included in Annex 4); (iv) test

turn-around times; (v) results achieved under the project to date (included in Annex 8).<sup>1</sup>

### Limitations of the evaluation

The limitations of our evaluation methods are noted below.

- **Duration/depth of country visits:** A key objective the TBXpert project is to ensure equitable access to the diagnostic tool through the decentralised placement of the instruments. However, because of time and budget limitations and accessibility, the country visits were limited to three days and did not include visits to sites that were located outside of the capital cities – except in India where we conducted a site visit to Rohtak, a neighbouring district near Delhi. To minimise this impact, phone calls and, where possible meetings in the capital, with implementers of remote sites were arranged, though these were limited. In general, the short duration of the country visits limited in-depth review of the projects.
- **Stakeholder bias:** Given that stakeholder consultations have been a key evidence source for this evaluation, there is scope for bias and subjectivity in feedback. We have attempted to minimise the impact of this by triangulating views across stakeholders and other sources of evidence, to the extent possible.
- **Availability of progress data until mid-2014 only:** TBXpert project M&E data is reported on a semi-annual basis, and at the time of this evaluation, information is only available for the 2013 annual and semi-annual reports and the 2014 semi-annual report. Some indicators are only reported on an annual basis, and hence we have had only one data point for analysis.
- **Limited review of country projects:** We have reviewed select projects only through our field visits and telephone consultations and as such the evaluation does not capture the full experiences of the project given substantial variations across countries.

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<sup>1</sup> Most of the quantitative analysis was based on the data and information included in the project progress reports submitted to UNITAID, as well as additional information supplied by the WHO and the data gathered during the country visits.



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## ANNEX 3 GLOBAL CONSULTATION LIST AND INTERVIEW GUIDE

This annex presents the list of global stakeholders consulted in the Inception and Core Phases as well as the main interview guide.

### Consultation List

Table A3.1: Consultation list

Stakeholder category	Organisation	Name	Position
UNITAID Secretariat	UNITAID	Taufiqur Rahman	Operations coordinator
		Kate Strong	M&E Officer
		Daniela Vasile	TB Portfolio Manager (PM)
		Yamuna Mundade	TB Portfolio Officer
		Robert Matiru	HIV PM (former TB PM)
		Lorenzo Llewellyn Witherspoon	Procurement Officer
		Brian Kaiser	Market dynamics
Project Implementers	WHO	Wayne Van Gemert	Technical Officer
	WHO	Faud Mirzayev	Medical Officer
	TB REACH	Jacob Creswell	TB REACH Team Leader
	TB REACH	Christina Mergenthaler	Country Support Officer
	GDF	Thomas Verges	GDF Procurement Officer
	IRD	Amir Khan Saira Khowaja Imran Zafar	IRD Executive Director Director, Program Development
	ASLM	Dr Aytenew Ashenafi Rediet Argaw / Mesfin Tibebu	Project Officer Finance and Operation Managers
Project Buy-Down Partners	USAID/PEPFAR	Amy Piatek	USAID TB Technical Officer
	Bill and Melinda Gates Foundation	Dr Peter Small	TB Deputy Director
Manufacturer	Cepheid	Philippe Jacon	Executive Vice President of Emerging Markets
		Martin Colla	Project Director Asia
	Cepheid Local Service Provider Kenya	Peter Muchira	CEO Caroga Diagnostics

Stakeholder category	Organisation	Name	Position
Select Project Grantees	Bangladesh - iccdr,b	Dr Toufiqur Rahman Dr Sayera Banu	Associate Scientist Senior Scientist
	Nepal - IOM	Bishwa Rai	Project Coordinator
	Kenya - NTP	Jeremiah Ogoro Joel Kangangi	NTP Xpert focal point WHO Kenya Office
TB Diagnostics Organisations	FIND	Daniel Orozco Jeff Lemaire	Expand TB Project Manager Access Project Manager
	The Global Fund	Mohammed Yassin	Senior TB Advisory
	TBCTA PMU	TBCARE 1 Program Director Indonesia TBCTA Lead Consultant	Maarten van Cleeff Sanne van Kampen
	CHAI	Paolo Maggiore Damien Fuller	Senior Manager Country Associate

### Interview guide

Consultations were based around the following high level questions, though questions were tailored appropriately for each consultee. For example, IRD consultation was more focused on the PPM model and the discussion with Cepheid was focused on the detailed aspects relating to the Xpert technology.

1. What is the relevance/ value-add of the project given the current role/ position of Xpert in diagnostic TB landscape as well as country needs for TB diagnosis? Specific areas for discussion include:
  - a. whether Xpert is becoming the new standard diagnostic technology and replacing standard microscopy (or being used in parallel/ as an “add on”); and
  - b. the impact of decentralised placement of the machines.
2. What is your assessment of the market impact achieved through the UNITAID Xpert scale-up project? Together with the buy-down agreement is the key market challenge being addressed or what more is required?
3. To what extent has the project been supporting global/ country-level coordination and proactively engaging with key stakeholders (especially country NTPs and donors) in the roll-out of Xpert?
4. What has worked well and not so well in the implementation of the UNITAID-funded Xpert scale-up project? Areas for discussion may include any information you may have on country and project site selection, product introduction and use in countries, coordination

and support from Cepheid, coordination with NTPs and other in-country donors, WHO's unified Xpert MTB/RIF forecasting initiative, performance of the PPM models, potential for sustainability, amongst others.

5. What is your view on the sustainability of the UNITAID funding for Xpert machines and cartridges? What should UNITAID and project partners do to ensure longer term sustainability?

## ANNEX 4 PATIENT COSTS FOR THE DIAGNOSIS OF TUBERCULOSIS

This annex presents a brief literature review on the cost to patients in accessing TB diagnosis, the questionnaire used to collect cost information from patients during country visits, and a summary of the results of the survey.

### Literature Review

This section summarises the academic literature on the costs faced by patients trying to access TB diagnosis. Although diagnosis services are often offered free at the point of use, patients incur other direct costs on items such as transport, food and informal drugs as well as the opportunity costs of their time.

#### *How does the literature attempt to calculate patient costs?*

The approach that is used most frequently follows guidelines set out in “The Tool to Estimate Patients’ Costs” which was developed in 2008 with funding from USAID.<sup>2</sup> The Tool defines three main types of costs:

- Direct medical (charges for health services)
- Direct non-medical (transport, accommodation and subsistence)
- Indirect (lost income, productivity and time)

In addition to this framework, two studies in Malawi and Bolivia have defined delays as a further cost-type for the diagnosis stage<sup>3</sup> to reflect the treatment benefits of fast diagnosis.

Indirect costs are perhaps the most difficult of these to measure. When patients go to testing facilities they incur an opportunity cost of forgoing whatever they would otherwise be doing in that time. A popular approach for evaluating this opportunity cost is to multiply the time spent either at or travelling to a service-provider by the patient’s wage rate. However, some patients do not earn any income but still face the cost of forgoing leisure, housework, or other unpaid activities. There is no single correct way of dealing with this problem, but one paper uses the national minimum wage to estimate the indirect costs of non-working patients.<sup>4</sup>

#### *What are patients’ costs of TB diagnosis?*

Although there are a large number of studies estimating the economic burdens of TB to patients, comparatively few focus on the diagnosis stage. Tanimura et al. (2014)<sup>5</sup>

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<sup>2</sup> TBCTA – Tuberculosis Coalition for Technical Assistance (2008): “The Tool to Estimate Patients’ Costs”

<sup>3</sup> Kemp et al (2007): “Can Malawi’s poor afford free tuberculosis services? Patient and household costs associated with a tuberculosis diagnosis in Lilongwe”, *Bulletin of the WHO* 85, 580-585; and Lambert et al. (2005): “Delays to treatment and out-of-pocket medical expenditure for tuberculosis patients, in an urban area of South America”, *Ann Trop Med Parasitol*.99(8), 781-7

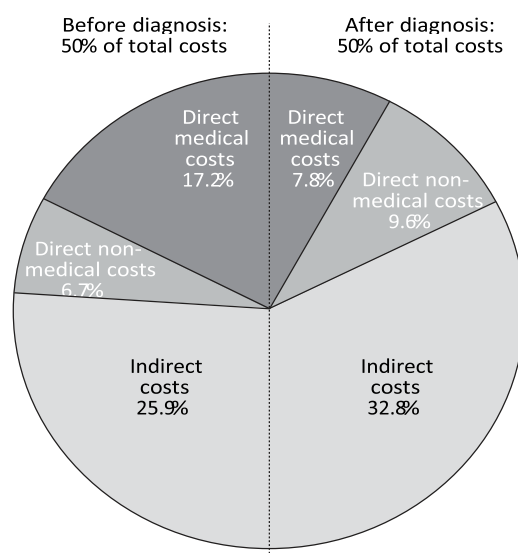
<sup>4</sup> R. da Silva Antunes, M. Pinto, A. Trajman (2014): “Patient costs for the diagnosis of tuberculosis in Brazil: comparison of XpertW MTB/RIF and smear microscopy”

<sup>5</sup> T. Tanimura, E. Jaramillo, D. Weil, M. Raviglione and K. Lo’nnroth (2014): “Financial burden for tuberculosis patients in low- and middle-income countries: a systematic review”



systematically review 49 studies of the financial burdens faced by TB patients, but only 8 of these broke down costs before and after treatment. Figure A4.1 shows the results of this review:

Figure A4.1: Breakdown of direct and indirect costs before and during treatment (eight studies). Percentages are proportion of respective sub-component cost out of the total cost. Amounts were not reported



A recent study based in Brazil specifically assessed patients' cost of diagnosis using TB Xpert against smear microscopy.<sup>6</sup> The study interviewed 218 patients diagnosed with TB during the previous 4 months by Xpert or smear microscopy. Information was gathered on non-medical direct costs for transportation and food, indirect costs for time spent during diagnostic visits, and socio-demographic data. The study found that Median total costs incurred by patients were 54% higher with the smear process than with Xpert (US\$25.24 vs. US\$16.44, P, 0.000) due to higher indirect and direct costs. The median difference between the costs of both tests for patients represented 4% of their median income and 5% of the minimum wage. The difference was mostly due to the smear method requiring a median of three visits rather than two. The study concluded that, compared to standard care, Xpert reduced the financial burden for patients. Table A4.1 gives the study's summary statistics.

Table A4.1: Non-medical direct and indirect costs of 218 pulmonary tuberculosis patients by diagnostic process, Manaus and Rio de Janeiro, 2012–2013<sup>7</sup>

Costs	Xpert (n=120) median (range)	Smear microscopy (n=98) median (range)	Difference of medians	P value
Non-medical direct costs, US\$*				
Transport	5.56 (1.34–243.90)	8.63 (4.88–97.56)	3.07	0.002

<sup>6</sup> R. da Silva Antunes, M. Pinto, A. Trajman (2014): "Patient costs for the diagnosis of tuberculosis in Brazil: comparison of XpertW MTB/RIF and smear microscopy"

<sup>7</sup> Ibid.

Costs	Xpert (n=120) median (range)	Smear microscopy (n=98) median (range)	Difference of medians	P value
Food	4.88 (1.95–31.22)	7.32 (1.95–30.73)	2.44	0.218
Direct costs (total)	9.27 (1.34–256.10)	13.02 (1.95– 107.32)	3.75	0.003
Indirect costs				
Number of visits	2 (1–15)	3 (1–10)	1	<0.000
Hours lost per visit	1.7 (0.02–13.4)	2.3 (0.7–24.9)	0.6	<0.000
Total hours lost	3.0 (0.3–31.7)	6.7 (1.3–49.8)	3.7	<0.000
Indirect cost per visit	3.00 (0.25–146.34)	3.92 (1.29–244.39)	0.92	<0.000
Indirect cost (total)	6.51 (1.00–365.85)	12.40 (2.00– 353.17)	5.89	<0.000
Total non-medical costs				
Total costs (direct + indirect)	16.44 (1.50– 621.95)	25.24 (2.00– 757.32)	8.8	<0.000

*\*Those without transport and/or food costs excluded (US\$1 = R\$2.05)*

### Questionnaire on cost to patients for TB diagnosis

This annex presents the questionnaire that was used to collect data on costs to patients in accessing TB diagnosis, during the country visits. The questionnaire is focussed on specific questions/ information requirements for the evaluation and the time available in country.

Following the guidelines provided in the 'Tool to Estimate Patients' Costs' we aimed to: (i) provide an introduction and explain the context for our questionnaire; (ii) communicate that this is a voluntary survey, anonymous and all responses will be kept confidential; (iii) assure the respondent participation (or not) in this survey will not impact care and treatment received/ entitlement at the clinic; and (iv) assure that if the respondent chooses to participate in the study they may withdraw at any stage without the need to provide any explanation for the withdrawal.

Date of interview (dd/mm/yy)	Country	Name of facility	
...	...	...	
<b>Patient information</b>			
1. Gender	<input type="checkbox"/> Male	<input type="checkbox"/> Female	
2. Age	...		
3. How have you been diagnosed for TB?	<input type="checkbox"/> Xpert MTB/RIF test	<input type="checkbox"/> Sputum microscopy	<input type="checkbox"/> Other (please specify) ...
<b>Costs incurred</b>			
<b>4. What type of costs have you incurred to be diagnosed <u>during this visit (or during the visit when you were diagnosed)</u>?</b>			
<b>4a. Medical costs</b>			
<i>TB diagnosis test costs</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	How much? ...
<i>Additional tests costs (e.g. X-rays)</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	How much? ...
<i>Admin costs (e.g. registration)</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	How much? ...
<b>4b. Non-medical costs</b>			
<i>Travel costs</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	How much? ...
<i>Food costs</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	How much? ...
<i>Accommodation costs</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	How much? ...
<b>4c. Indirect costs</b>			
<i>Total visit time</i>	...		
<i>Total travel time</i>	...		
4d. Did you spend any other money on getting diagnosed <u>during this visit (or during the visit when you were diagnosed)</u> ?	<input type="checkbox"/> Yes If yes, how much did you spend and on what?	<input type="checkbox"/> No	
5. Did someone accompany you <u>during this visit (or during the visit when you were diagnosed)</u> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
5a. If yes, did you incur any costs for them to accompany you?	<input type="checkbox"/> Yes If yes, what types of costs and how much? ....	<input type="checkbox"/> No	

6. Did you incur other costs <u>during any previous visits to be diagnosed?</u>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
6a. If yes, what type of costs and how much?	<input type="checkbox"/> Medical How much? ....	<input type="checkbox"/> Non-medical How much? ....	<input type="checkbox"/> Income/ time loss How much? ....
<b>Time from testing to diagnosis</b>			
7. How long after testing did you have to wait before getting your results?	<input type="checkbox"/> Same day results	<input type="checkbox"/> 1-3 days	<input type="checkbox"/> More than 3 days
8. How did you receive your test results?	<input type="checkbox"/> Verbal at clinic	<input type="checkbox"/> SMS	<input type="checkbox"/> Other (please specify) ....

## Summary of questionnaire results

Table A4.2: Diagnosis costs reported in patient interviews (all prices in US\$)

Description	India	Indonesia	Tanzania
<b>Context of patient interviews</b>	2 patients were interviewed at the R. B. Institute of Pulmonary Medicine in Delhi and 3 at the District TB Centre in Rohtak. All patients had previously undergone sputum diagnosis and 4 had undergone Xpert MTB/RIF (2 were awaiting results at the time of interview).	Due to limited opportunities for patient interviews, only 1 patient was interviewed at Saint Carolus Hospital in Jakarta.	2 patients were interviewed at each of Amana and Temeke Hospitals in Dar es Salaam. The GeneXpert machines located in both are non-UNITAID supported, but the Temeke site receives UNITAID-supported cartridges through the NTP.
<b>Medical costs</b>	No medical costs were incurred, though a nominal registration fee of US\$0.10 was reported.	Costs for additional tests and an administration fee for a total of US\$16 were reported.	Costs were incurred for additional X-ray and blood count tests, ranging from US\$0-15.
<b>Non-medical costs</b>	Travel costs to the central hospital ranged from US\$1-3. Travel to the district centre was lower with only one patient reporting travel costs of US\$1.	Travel costs of US\$2.	Travel costs varied by patient depending on distance. Costs averaged US\$3 and ranged from US\$0-6. However, it is noted that this may not be indicative of costs across the country because sites are located in Dar where many patients live within 30 minutes of the health centre. Costs are likely to be higher in rural settings.
<b>Indirect costs</b>	Only one patient reported that they had foregone income (US\$5) because of the visit.	No indirect costs were reported.	Ranged from US\$3-33 largely based on the occupation of the patient: one patient was unemployed and another was a business woman.
<b>Other</b>	The algorithm in India requires patients to undergo sputum microscopy first before being referred for Xpert MTB/RIF, resulting in costs associated with returning for various stages of diagnosis and treatment. Those interviewed were at different stages. One patient reported other costs as high as US\$157 due to previous treatment, travel and diagnosis costs and indirect costs incurred by a companion.	Additional costs for previous trips to the hospital of around US\$0.5. The NTP arranges courier services for sputum collection, limiting the need for patients to travel.	Additional costs reported included those related to malaria and urine tests as it was not immediately clear that TB was the likely cause of their symptoms.

## ANNEX 5 TANZANIA COUNTRY REPORT

### 1. Introduction

This annex presents the country visit report from Tanzania, which was carried out by one CEPA team member between 25-27 February 2015.

The report is structured as follows: Section 2 presents some background information on the state of TB and the TBXpert project in Tanzania; Section 3 presents key findings from the field visits for each of the three evaluation dimensions (relevance, efficiency and effectiveness, and results and sustainability); and Section 4 provides a conclusion and some recommendation from the country experiences with Xpert. A list of country stakeholders consulted is included at the end of the report.

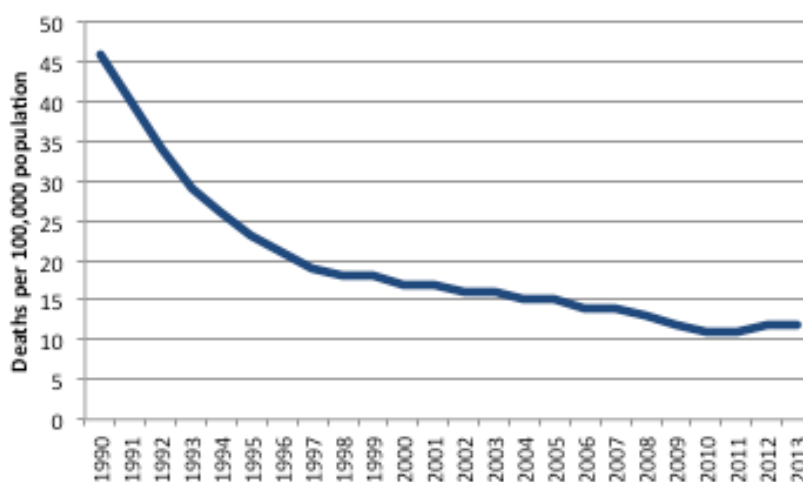
### 2. Background

This section provides a brief background on the status of TB and a summary of the TBXpert project sites and progress with the rollout of GeneXpert in Tanzania.

#### Status of TB in Tanzania

Tanzania is a high TB, HIV, and MDR-TB burden country in East Africa with a population of 49m (2013).<sup>8</sup> TB is one of the three largest causes of mortality and morbidity in the country, along with HIV/AIDS and malaria. The mortality rate for TB has however decreased from 46 per 100,000 population in 1990 to 12 in 2013 (see Figure 2.1).

Figure A5.1: Deaths due to TB among HIV-negative people (per 100,000 population)



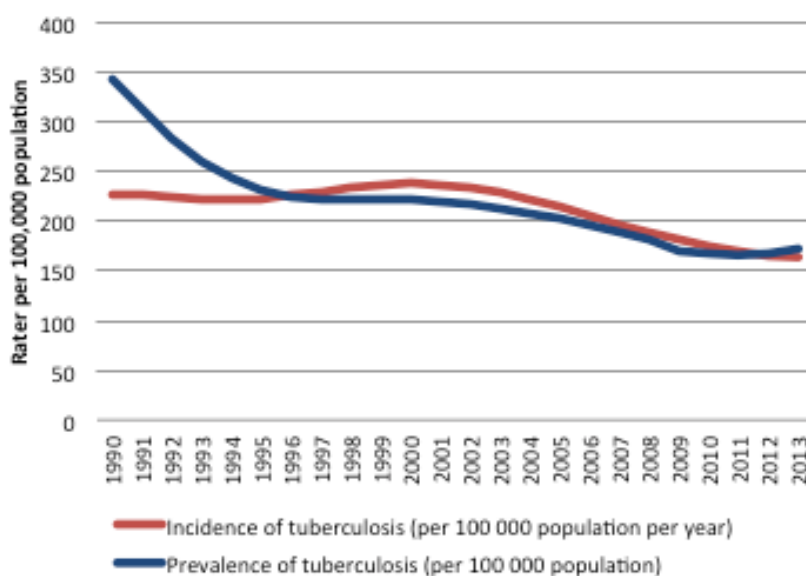
Source: WHOSIS

The TB prevalence and incidence rates (both including HIV+TB) have also shown steady declines over the period – see Figure A5.2.<sup>9</sup>

<sup>8</sup> World Health Organisation (2014): Global Tuberculosis Report 2014. The document can be accessed here: [http://apps.who.int/iris/bitstream/10665/137094/1/9789241564809\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/137094/1/9789241564809_eng.pdf)

<sup>9</sup> World Health Organisation (2014): Global Tuberculosis Report 2014.

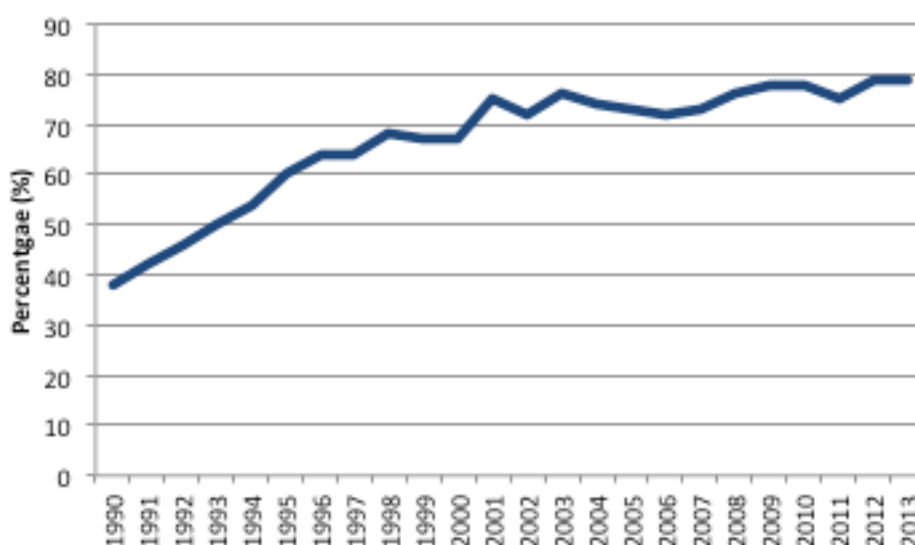
Figure A5.2: Incidence and prevalence of TB (per 100,000 population)



Source: WHOSIS

The total number of TB cases notified in 2013 was 65,732 (including previously treated (1,679) and relapse cases (1,101)), while the case detection rate for all forms of TB increased from 38% in 1990 to 79% in 2013 (see Figure A5.3).<sup>10</sup>

Figure A5.3: Case detection rate for all forms of TBs (%)

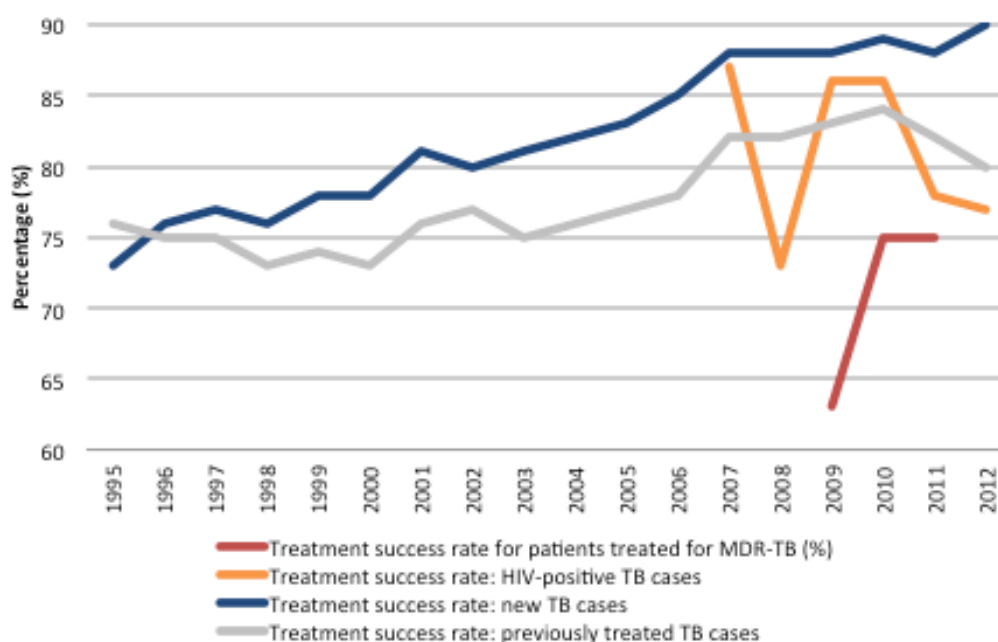


Source: WHOSIS

As shown in Figure A5.4, treatment success rates for new TB cases have increased from 73% in 1995 to 90% in 2012, although treatment success rates for previously treated TB cases has increased more slowly, from 76% in 1995 to 80% in 2012. There is little data on treatment success rates for patients treated for MDR-TB, and HIV-positive TB cases.

<sup>10</sup> World Health Organisation (2014): Global Tuberculosis Report 2014.

Figure A5.4: National treatment success rates



Source: WHOSIS

Funding for TB control is far below the country’s required US\$61m to implement the national strategic plan for TB control. In 2014, the proportion funded domestically was 13%, while international funding accounted for 17%, leaving 69% unfunded.

The major donors for TB control are the United States (US\$12.5m between 2009 and 2013), Global Fund (US\$9m between 2009 and 2013), IDA (US\$4.5m between 2009 and 2013) and Norway (US\$1.5m between 2009 and 2013).<sup>11</sup>

### TBXpert support in Tanzania

Under the TBXpert project, UNITAID offered through its invitation letter to Tanzania, 10 4-module GeneXpert machines between 2013 to 2015, along with 62,000 cartridges.

In line with the Letter of Agreement between the interested stakeholders, signed on 4 November 2013 and renewed on 5 August 2014, the TBXpert project in Tanzania has been implemented by three separate parties, as outlined under the headings below.

#### *The National Tuberculosis and Leprosy Programme (NTLP)*

UNITAID provided four GeneXpert machines to the NTLP, which were placed at four regional hospitals (Dodoma, Ligula, Sokoine and Shinyanga). UNITAID also provided 5,000 cartridges

<sup>11</sup> OECD Creditor Reporting System, as at 1 March. Figures show Official Development Assistance (ODA) gross disbursements in constant 2012 US dollars.



to the NTL, which were distributed between these four sites and six others that had existing GeneXpert machines.<sup>12</sup>

To assist with the implementation of the TBXpert project, FIND were contracted by ASLM to provide training, on-site mentoring and technical assistance to staff at the four sites where UNITAID-funded GeneXpert machines were installed.

#### *National Institute for Medical Research (NIMR)*

This is a TB REACH project where NIMR, Mbeya Medical Research Centre (MMRC), Medical Mission of Germany and Stichting PharmAccess International implement the project activities, with the University of Munich acting as the grant holder. The project is focused on using GeneXpert as a routine screening tool for the populations of five central prisons.

Under the TBXpert project, two 4-module GeneXpert machines were provided, one at Butimba Prison in Mwanza and one at Segerea Prison in Dar es Salaam. UNITAID also provided 7,140 cartridges, which were distributed between these two sites and three others that had existing GeneXpert machines.<sup>13</sup>

The total budget for the project is US\$500,418, comprised of US\$246,401 for the GeneXpert equipment and US\$245,018 in other costs, including human resources, travel, operational research and M&E.

#### *The University of Maryland, Baltimore (UMB)*

This is a TB REACH project where UMB are the primary grant holders, implementing the project alongside partners Catholic University of Health and Allied Services and Interactive Research and Development (IRD). This project, known as the TUNAWWEZA ('we can') project, is focused on increasing: community level awareness on TB and the TB suspects referral system; active TB case finding among high risk populations (e.g. mining and pastoral communities, People Living with HIV (PLHIV) and children under 15); TB diagnostic capacity, including through the use of GeneXpert; and the collection, reporting and use of TB data.

Under the TBXpert project, four 4-module GeneXpert machines were provided, one at Bombo Regional Referral Hospital in Tanga Region, Geita District Hospital, Babati (Mrara) Hospital in Manyara Region, Orkesumet Urban Government Hospital in Simanjiro District in Manyara Region. UNITAID also provided 8,210 cartridges, which were distributed between these sites, and one other site where UMB had procured a GeneXpert machine through a previous wave of TB REACH funding.

The total budget for the project is US\$850,175, comprised of US\$263,756 for the Xpert equipment and US\$586,419 in other costs, including human resources, operational research and M&E.

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<sup>12</sup> These are the Central TB Reference Laboratory in Dar es Salaam, Keyela District Laboratory, Mbeya Referral TB Laboratory, Mbeya Regional TB Laboratory, Mwananyamala Regional Laboratory in Dar es Salaam, and Temeke Regional Laboratory in Dar es Salaam.

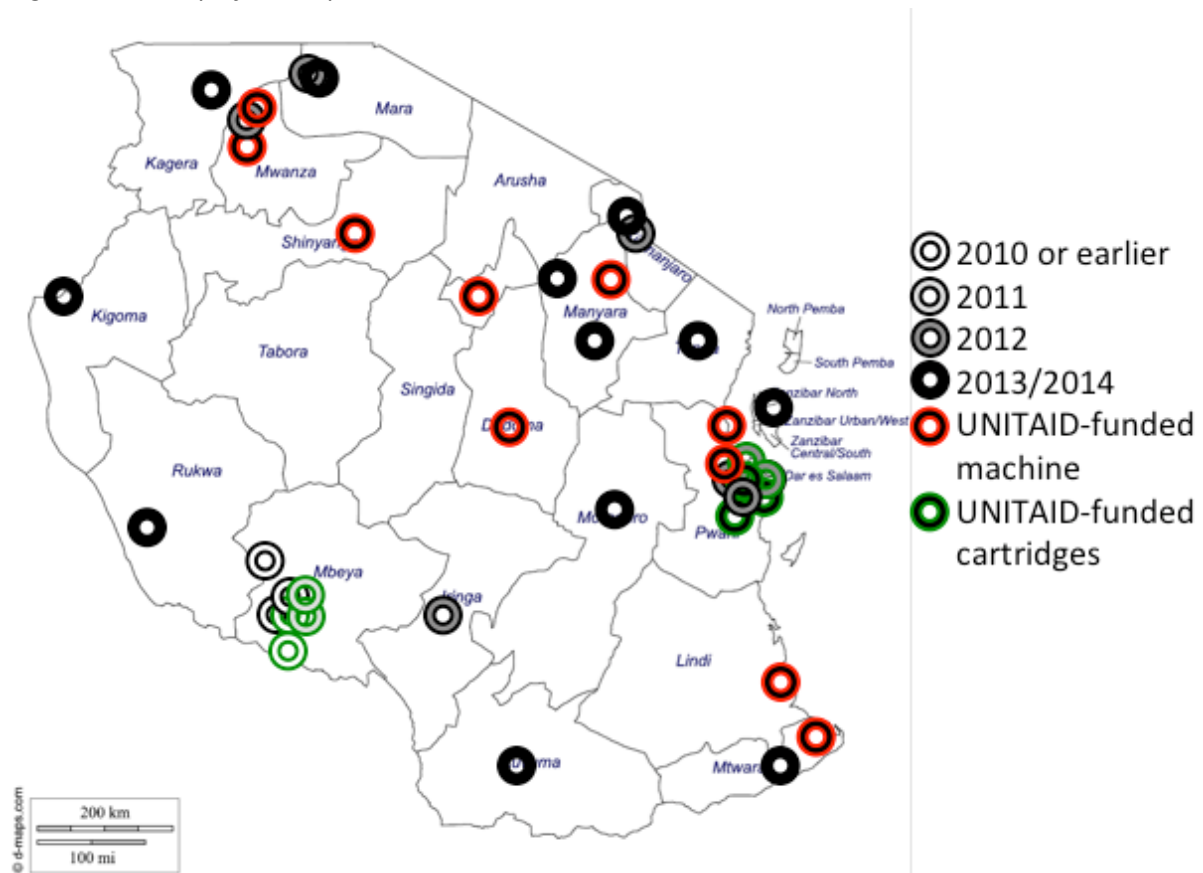
<sup>13</sup> These are Ruanda Prison in Mbeya, and Keko Prison and Ukonga Prison in Dar es Salaam.

### Summary of UNITAID-supported GeneXpert sites

There were 17 GeneXpert machines in Tanzania before 2013, when the TBXpert project started. These were supported by a number of external partners, were used for both regular TB diagnostic testing and for research purposes. The number of machines has since increased to 42, including the 10 UNITAID-supported machines, with a further 14 expected to be installed by the end of March 2015.

The ten 4-module GeneXpert instruments supported by UNITAID were procured in 2013. All of these machines have been placed around the most of the country's northern regions, outside of central level TB reference laboratories (see Figure A5.5 below). The TBXpert project has also supported a number of other sites through the provision of cartridges. As also shown in Figure A5.5, these sites have clustered in Mbeya region and Dar es Salaam, including for the Central TB Reference Laboratory.

Figure A5.5: Map of GeneXpert machines in Tanzania as at December 2014



### 3. Evaluation findings

This section presents our findings from the country visit on the three evaluation dimensions of: (i) relevance; (ii) efficiency and effectiveness; and (iii) results and sustainability.

## Relevance

There is broad consensus among stakeholders that the use of GeneXpert, and more specifically the TBXpert project, is highly relevant in Tanzania. This is based on the:

- country's needs for improved rapid diagnostic testing for TB, particularly in rural areas (project site selection is explored in more details below);
- complementary way that GeneXpert can be used with existing TB diagnostic tests, including sputum microscopy which is used to follow up with patients two months after they have been diagnosed with TB and started treatment; and
- potential to use GeneXpert for HIV diagnosis in the future, when this capability is rolled out by Cepheid.

The TBXpert project activities in Tanzania are also aligned with UNITAID's objective to improve access to vulnerable populations, with many project sites being selected to target prison, mining and pastoral communities, as well as PLHIV and TB suspects under 15.

GeneXpert is becoming recognised as the standard test for TB diagnosis in the country, and is highly embedded in the NTLP's processes and strategic planning. For example, Tanzania recently adapted the national algorithm for TB diagnosis, in line with the WHO recommendation, to reflect that GeneXpert should be used to test all TB suspects (including people living with HIV and paediatric TB suspects) in the country, where resources and GeneXpert capability is available. In support of this objective, the expansion of GeneXpert machines to the majority of Tanzania's 169 districts is due to be included in the NTLP Strategic Plan for the period 2015-2020 which will be launched later this year.

There is some anecdotal evidence to suggest that UNITAID's timely funding of Xpert MTB/RIF in 2013, in particular through the TB REACH Initiative, has helped to build support for the increased use of Xpert MTB/RIF in Tanzania by demonstrating the significant benefits of the technology that are achievable in a relatively short timeframe. However, stakeholders were largely not aware that UNITAID was responsible for the provision of GeneXpert machines. As such, rather than the TBXpert project being seen as a unified push to scale up the number of GeneXpert machines in the country, the support appears to be fragmented, coming from both TB REACH and WHO through a variety of different implementing partners. It is also noted that considerable uncertainty associated with the sustainability of projects supporting the implementation of GeneXpert machines with a short term duration, such as the TBXpert programme, has led to the NTLP decreasing the number of machines it plans to introduce in the country, from one per district (169 in total) to 100 in total for the country, to ensure that the country can afford to sustain them on an ongoing basis (see below).

## Efficiency and effectiveness

### *Timeliness*

All three projects within the TBXpert project have suffered significant delays before starting implementation. This was initially due to extended negotiations between the NTLP and TB REACH grantees to reduce the scope and size of their proposed interventions in line with the overall resource envelope available under the TBXpert project for Tanzania – these negotiations lasted from January 2013 until April 2013. For UMB, this involved reducing the number of GeneXpert machines from ten to four, and reducing the budget from around US\$10m to under US\$1m. For NIMR, this involved reducing the number of GeneXpert machines from 16 to two, and reducing the budget from around US\$1m to US\$0.5m.

Additional delays to the start of each project resulted from:

- **NIMR:** The arrival of Xpert MTB/RIF commodities at project sites was delayed until 10 July 2013 due to issues importing the commodities into the country.
- **NTLP:** The Xpert MTB/RIF commodities were also subject to significant additional importation delays, although this was exacerbated by the NTLP's lack of awareness that the commodities had arrived in the country. This led to the NTLP not collecting the commodities from customs and delivering them to the designated sites until 29 December 2013.
- **UMB:** The UMB project was further delayed by internal contractual processes, and in obtaining the required signatures amongst project partners. While the Xpert commodities were also delayed until 13 August 2013, this did not affect the inception of the project activities.

Once the implementation of activities had started, there appear to have been limited delays to the delivery of the projects – this is with the exception of delays caused by product implementation issues that are dealt with below.

### *Budget*

The budgetary negotiations noted above were not expected by NIMR and UMB and led to some confusion on how the TB REACH/ TBXpert competitive process works in terms of allocating resources.

The significant reduction in budgets led to NIMR and UMB drastically altering the scope of their projects, and it was reported that this led to management, travel and administration costs being higher as a proportion of the overall budget than initially envisaged.

Despite the reduced scope of their projects, the revised budgets for NIMR and UMB were still found to be inadequate, with both grantees reporting that the TBXpert project activities had to be substantially subsidised by their other donor supported activities. This was partly due to being over optimistic on what was achievable (which was influenced by TB REACH's policy that the cost per case detected should be within a set level), and a range of unforeseen costs

associated with the Xpert technology (e.g. second year calibration kits, shipping costs for replacement parts, uninterruptible power supply (UPS) kits).

The lack of funding provided to the NTLP to support the implementation of the Xpert commodities was not noted as a particular issue in Tanzania, although stakeholders commented that this was largely due to FIND's valuable support in providing training, on-site mentoring and technical assistance on a relatively modest budget. However, it was noted that the lack of budget to support active case finding approaches had limited the number of tests conducted, as compared to the TB REACH grantees.

#### *Support provided*

Project stakeholders noted that the level of support provided by WHO/ TB REACH at the central level has been appropriate and provided in a timely manner. However, WHO at the country level appears to have been relatively disengaged from the TBXpert project activities, and has not supported the implementation of activities to any great extent.

#### *Country management and coordination*

At the outset of the TBXpert project, communication and coordination between partners, in-country donors and the NTLP was very limited. For example, the NTLP did not know how many GeneXpert machines were being used in the country, where they were located, and who was supporting them.

Communication and coordination has however improved over time with the initiation of the GeneXpert Focal Team. The Focal Team is comprised of the Head of the Central Reference Laboratory, the GeneXpert Focal Person on behalf of the NTLP, an alternate GeneXpert Focal Person, and a consultant from FIND. The Team is in regular contact with regards to implementation issues encountered and suitable remedial actions, coordination of stakeholders, placement of GeneXpert machines, procurement of cartridges, arrangement for warranties, collecting and analysing Xpert reporting information, arranging for training of staff, etc. FIND have further supported the coordination functions of the Focal Team by conducting a range of activities, including an assessment of where the GeneXpert machines are in the country and who is funding them, ongoing data collection/ analysis of project sites, and support for a partner's meeting for all agencies implementing GeneXpert in an attempt to improve coordination with the NTLP.

#### *Product implementation issues*

Machine and module failure has been a common issue among the TBXpert project stakeholders, particularly at more rural sites. There have been a number of reasons for such failure:

- **Lack of maintenance:** Module failures have occurred where staff have not adequately maintained the machines – this is particularly the case in dusty environments where some simple procedures can alleviate the problem. The lack of such maintenance is reportedly due to a lack of training, rather than neglect, and is an area that Caroga

(who work with Cepheid to support the roll out of Xpert), is aiming to address through training, and Cepheid through the provision of brushes, fan filters and dust covers.

- **Stable power supply:** Where the power supply cuts out during testing, the test must be started again and the cartridge is wasted. This has happened frequently in many sites, particularly those in more rural areas. Frequent fluctuations in the power levels also damage the GeneXpert battery components, which in turn damages the GeneXpert machine as a whole in the longer term.
- **Temperature:** High temperatures have at times caused the machines to shut down during testing, thereby invalidating the test and wasting the cartridges. This is not thought to have had any lasting damage and has been mitigated by ensuring the air conditioning units are working properly in the rooms where the machines are operating.
- **Computer viruses:** Use of the GeneXpert computers for other purposes (e.g. accessing the internet and playing music) has led to some computers getting viruses which has affected the functioning of the machines and required replacements.
- **Antivirus software:** The firewall created by antivirus software has caused some communications issues between the GeneXpert machine and computer. This issue was faced when software was installed on a machine to implement a remote SMS monitoring tool, causing the computer to crash and requiring a replacement.

The impact of the delays caused by machine/ module failures has varied. While many sites have been able to keep operating when a single module has failed, in two cases during the TBXpert project at different sites, four modules on the same machine have failed at once. This has led to the site not being able to run any tests until the replacement modules were received – a period of around three months in each case. Some of these issues have also incurred significant additional costs for the TBXpert stakeholders. For example, NIMR, who initially purchased the Cepheid UPS kit for around US\$1,000, had to purchase a more powerful UPS kit for an additional US\$2,000 to ensure the GeneXpert machines could run for the full duration of the test should the power fail early on during testing. This issue has been widespread among the users of Xpert in the country, and is not just confined to the TBXpert stakeholders.

Where issues with module failure have been encountered and machines are under warranty, Cepheid has been quick to replace parts. However, the reason for the observed lead times of around one to three months for replacement parts has been caused by delays importing the parts into the country. Despite these issues, Cepheid has been unwilling to provide spare Xpert commodities (e.g. modules) to the project stakeholders. Cepheid's reluctance to provide spare commodities is unclear, although it was felt by stakeholders that this would have expedited the process of repairing broken machines.

There have also been issues with the warranty offered by Cepheid. As noted above, UMB's failure to calibrate the machines within Cepheid's timeframe is thought to have invalidated the warranty for each of UMB's four machines, a condition that was not fully understood when the machines were initially received. NIMR also reported that they did not fully understand the terms and conditions of the Xpert warranty, and initially paid Cepheid for calibration kits and module replacements, before being reimbursed when the error was realised – Cepheid did not alert NIMR to this issue.

Despite these issues, the NTLP has expressed its keenness to purchase additional warranties for the GeneXpert machines once the current warranties expire. While these are felt to be expensive, they are also felt to represent reasonably good value for money, given the high costs of replacing the machine components and modules.

#### *Other implementation related issues*

##### **Project site selection**

As noted above, the communication and coordination between stakeholders was very limited at the outset of the TBXpert project, and in part led to the selection of project sites being considered as a political exercise to spread the machines across a range of regions, rather than a strategic exercise to maximise public health impact.

There is some discrepancy among stakeholders as to whether the type of project sites selected has been optimal. More specifically, some stakeholders suggested that the machines had been placed in relatively well-resourced health facilities that were able to perform sputum microscopy – the implication being that asking staff who are able to perform sputum microscopy to perform Xpert tests is a waste of skilled human resources. This view was not widely shared however, with other stakeholders advocating that GeneXpert machines should be restricted to such well resourced health facilities, where the conditions for operating the machines are appropriate (i.e. dust free with good power supply) and where staff are well trained and able to properly interpret the results and detect problems with the machines as they occur.

##### **Training of staff**

Another aspect of FIND's support has been to train staff at each of the sites where there is a GeneXpert machine. This has been a successful strategy to improve local capacity, and has resulted in a network of 'super users' in each region who are regularly called upon to troubleshoot issues at nearby sites.

However, a number of the sites with UNITAID-supported machines have not received such training, which is thought to have negatively affected the implementation of their activities. For example, at the outset of the TBXpert project, UMB staff at the central and health facility level were not trained in the use of the GeneXpert machines. This is thought to have contributed to UMB not understanding that the machines require calibrating annually, or how

to do this. As a result, the machines have not been calibrated since they were installed in August 2013, with a number of implications:

- The failure to calibrate the machines within Cepheid's timeframe is thought to have invalidated the warranty for each of UMB's four machines.
- Increased error rates.
- Inability to tell if increased error rates are due to broken modules.
- Reduced reliability of results.

### **Procurement planning**

The forecasted number of cartridges required for Tanzania was initially based on discussions between WHO/ Stop TB Partnership and the NTLP. The forecasted number of cartridges required for each project site was then based on discussions between the NTLP and the project grantees. However, this forecasting has not been sufficiently accurate, as some sites have performed more tests than others. It has also required a significant effort from FIND, in support for the GeneXpert Focal Team, to redistribute the cartridges to other sites before their expiry dates. This has been a successful reactive strategy, although would not have been required with proper planning.

### **Monitoring and evaluation**

The M&E reporting requirements have required some time and training for the grantees to adhere to, and are viewed as more rigorous than that for other donors. However, they are viewed positively, with the richness of information on results making the reporting worthwhile.

The results are also valued by the NTLP who have adjusted their reporting timeframe for all health facilities by around a month to ensure that the TB REACH project results can be incorporated into national statistics in a timely manner – it is understood that this change took place during the TB REACH Wave 2 projects.

An issue was however identified with the format of the NTLP's reporting mechanism, which does not accurately report Xpert results. In particular, where Xpert has returned a microbiologically positive result, but sputum microscopy has returned a smear negative result, these are thought to have been recorded by the NTLP as smear negative cases only as the reporting format does not allow for additional information to be entered. It is unclear whether and how this has affected the reported results (see section below on results).

#### *Cost of accessing diagnostic test and test turn-around times*

To assess the costs associated with accessing diagnostic tests for TB, four patients were interviewed at Amana Hospital and Temeke Hospital – both of these hospitals are based in Dar es Salaam and have GeneXpert machines. Neither of these sites received UNITAID-supported GeneXpert machines, although the Temeke site receives UNITAID-supported



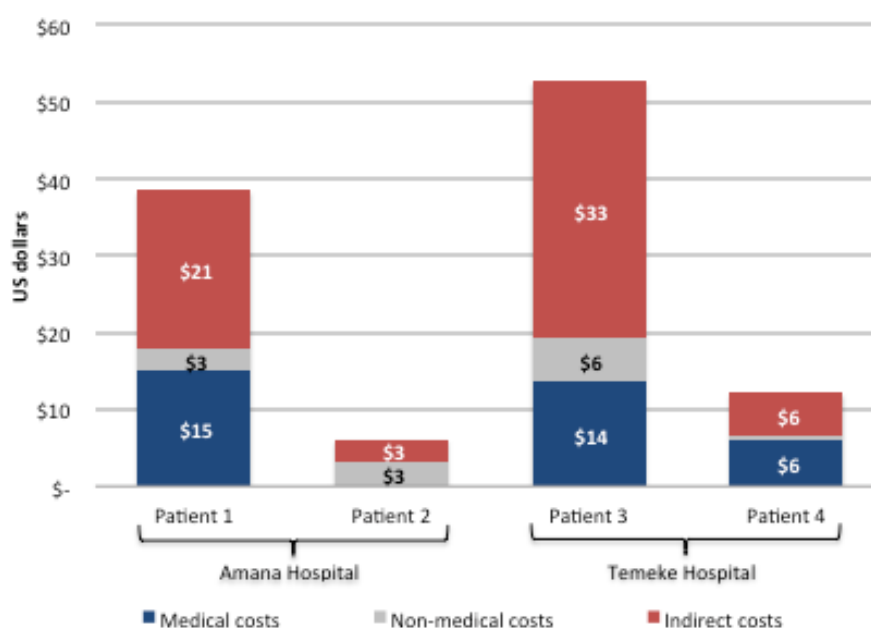
cartridges through the NTLP. These patients reported that a range of costs were incurred, which can be categorised as follows and shown in Figure A5.6:

- **Medical costs (including testing and related administration costs):**<sup>14</sup> While the cost of the actual Xpert MTB/RIF test was free for all patients, costs were incurred for additional X-ray and full blood count tests, as well as administration costs. These costs ranged between US\$6 (where only an X-ray was charged for) to US\$15 (where an X-ray and full blood count test was charged for).
- **Non-medical costs (i.e. travel, food and accommodation costs):** These costs also varied by patient, with one patient who lived nearby to the health facility not incurring any non-medical costs, while another incurred costs of US\$6 in travel and food costs. None of the patients interviewed incurred any accommodation costs.
- **Indirect costs (i.e. income foregone, costs for other diagnostic tests, and companions attending the diagnosis):** These costs varied significantly from US\$3 to US\$33 largely due to the estimated income foregone for TB diagnosis, with one patient being unemployed while another was a business woman. Other points to note are as follows:
  - The average visit time for diagnosis was 53 minutes, although this was only reported to be 15 minutes for two of the patients.
  - The average travel time for diagnosis was 43 minutes.
  - One patient reported that they had incurred costs related to malaria and urine tests as it was not immediately clear that TB was the likely cause of their symptoms.
  - All the patients reported that the test results were received verbally at the test centre, at an average of one day after the test was conducted.

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<sup>14</sup> One patient was not aware of the costs incurred, as these were paid by a family member.

Figure A5.6: Patient costs of accessing diagnostic tests



Source: CEPA analysis

There are however a number of reasons as to why these costs may not be indicative for TB patients across the country. Primarily, the sites visited were both in Dar es Salaam, where the patients were found to live within a 30 minute journey to the health centre. In rural areas, patients are much more likely to live further away from the health facility, which has implications for the cost of accessing services, including:<sup>15</sup>

- Transport costs are likely to be higher for those living further away, although it is noted that the cost of transport per kilometre may be cheaper in rural areas.
- There is an inverse relationship between the length of an individual's journey to access a TB diagnostic test, and their ability to return to work on the same day. As such, people living in rural areas are likely to have a greater opportunity cost of income foregone associated with accessing TB diagnostic services.

The use of Xpert MTB/RIF to diagnose TB is widely acknowledged to have led to a dramatic reduction in test turnaround times, from 2-3 days with sputum microscopy (including multiple visits to the health centre to deliver sputum samples), to approximately 1 day (where only 1 visit to the health centre is required). However, we were not able to assess this quantitatively as all patients interviewed during the country visit had been tested using both GeneXpert and sputum microscopy. The simultaneous use of both diagnostic tests is reported to be widespread across the country due to two main reasons:

- a lack of guidance from the NTLF on the application of the GeneXpert machine, such as in the form of a national algorithm and implementation guidelines clarifying how

<sup>15</sup> It should also be remembered that people accessing TB diagnostic tests are often accompanied, particularly where they are not feeling well. As such, these costs are often amplified.

and when to use which diagnostic tests – it is understood that the revised national algorithm, training and guidelines are now being rolled out in the country to address this issue; and

- research projects being conducted on alternative methods for diagnosing TB, where the methods being evaluated are being compared to the results from sputum microscopy (as such, Xpert being used as an additional and supplementary diagnostic test).<sup>16</sup>

### Results and sustainability<sup>17</sup>

As shown in Table A3.1, Tanzania has procured 17,910 GeneXpert cartridges through the TBXpert project up to December 2014, from an initial estimate of 61,116. To put this in context, the country as a whole procured 103,400 cartridges over the period June 2013 to December 2014. As such, the TBXpert project accounted for around 17% of the country's total demand for cartridges between June 2013 and December 2014, but would have accounted for 42% if the country's total demand for cartridges had matched initial expectations.

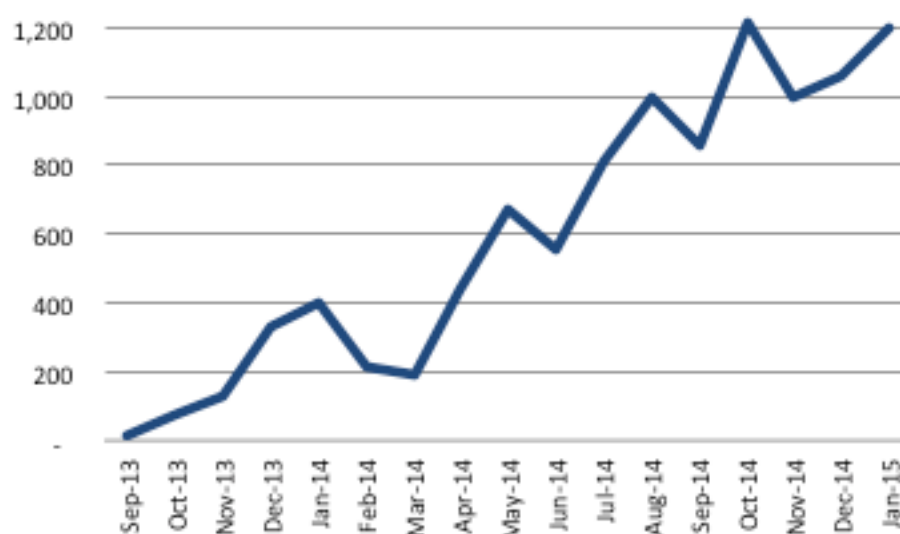
The project sites where UNITAID-supported GeneXpert machines were placed have performed 8,968 tests to December 2014. These tests have detected 1,090 incident TB patients, 6 incident HIV-positive TB patients, and 56 incident rifampicin-resistant TB patients. With the exception of the number of incident rifampicin-resistant TB patients detected, these results are significantly lower than the proposed targets. This is partly due to the projects not having completed their activities – this is especially true of the NTLP project that has been particularly delayed. As the project activities increase to maximum capacity, these results are expected to increase at a higher rate than has been previously observed – Figure A5.7 shows the total number of Xpert MTB/RIF tests conducted by month. It should also be noted that the results presented in Table A5.1 only include the sites where UNITAID-supported GeneXpert machines have been placed, not the additional nine facilities where UNITAID-supported cartridges have also been placed.

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<sup>16</sup> The specific research project involved at the two project sites visited is the Apopo Hear Rat project (<https://www.facebook.com/heroRAT?fref=photo>). This explanation was given as the reason for both sputum microscopy and GeneXpert being used simultaneously at the two health facilities visited (Temeke and Amena), and is thought to be contained to health facilities in and around Dar es Salaam.

<sup>17</sup> The results information presented in this section covers the period from the inception of each of the projects until June 2014. This is a period of approximately six months for the NTLP project, and one year for the TB REACH projects. Information is extracted from the TBXpert Project 2014 Semi-annual Programmatic and Financial Report (January to June 2014). Unfortunately, it was not possible to obtain more up to date results data in country.

Figure A5.7: Number of tests conducted by UNITAID-supported GeneXpert machines per month



Source: NTLP data

Despite the acknowledgment from the TBxpert stakeholders that the targets are not realistic and are unlikely to be achieved, it is strongly felt that the TBxpert project activities are positively influencing TB case detection in challenging settings, and are extremely valuable and worthwhile.

Table A5.1: Results of the TBxpert project in Tanzania, as at January 2015

Indicators	Total proposed	Total achieved
Number of Xpert cartridges procured	61,116	27,910
Number of Xpert tests performed	61,116	8,968
Number of individuals tested with Xpert	57,738	8,085
Number of incident TB patients detected using TBxpert project commodities	3,642	1,090
Number of incident HIV-positive TB patients detected using TBxpert project commodities	1,398	6 <sup>18</sup>
Number of incident rifampicin-resistant TB patients detected using TBxpert project commodities	40	55

As shown in Table A5.1 below, the UNITAID-supported GeneXpert machines have not performed as many tests as expected. Assuming that each machine is able to perform 100 tests per week, the NTLP estimates that only 31% of the capacity of these machines has been utilised to date. While this is in line with the average utilisation for all GeneXpert machines in the country, it nevertheless indicates that the machines have not been implemented efficiently to date. There is acknowledgement from the NTLP and UMB stakeholders that this is partly due to not sufficiently pursuing active case finding approaches to increase demand for testing. This is particularly true for the machines provided directly to the NTLP, where there was no budget provision under the TBxpert project to pursue such activities. While this

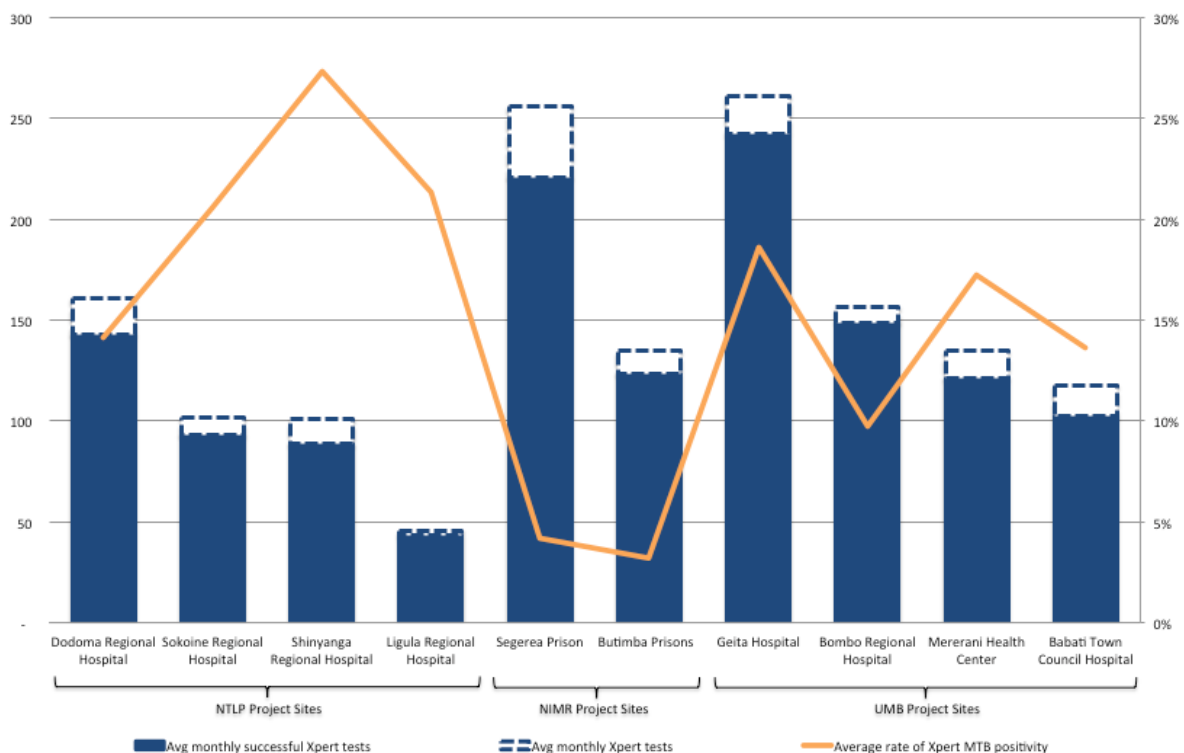
<sup>18</sup> Data only available to June 2014.

was not an issue for NIMR, there were difficulties associated with motivating prison staff to perform routine testing on prisoners, which goes some way to explaining the low level of utilisation for these sites.

Further, results have varied significantly between project sites, with two project sites performing a total of over 1,500 tests in the project period, while another project site has performed less than 300. This is however influenced by the length of time that each site has been operational. To counter this influence, Figure A5.8 shows the average number of Xpert MTB/RIF tests performed by month at each project site, along with the average rate of Xpert MTB positivity.

Further, Figure A5.8 shows there is still a significant divergence in the average number of Xpert MTB/RIF tests being conducted by project site, with Ligula Hospital performing less than 50 tests per month, while Geita Hospital and Segerema Prison are conducting more than 250. On average, the NTLP sites are performing fewer tests the NIMR and UMB project sites, although as these sites have been set up more recently, they may not yet be operating at full capacity. There is also a considerable divergence in the average rate of MTB positivity, with the Shinyanga Regional Hospital reporting a 27% average rate of MTB positivity, while both NIMR prison sites report an average rate of MTB positivity of less than 5%.

Figure A5.8: Average number of Xpert MTB/RIF tests performed per month by project site



Source: CEPA analysis

Stakeholders did not report any issues with the subsequent treatment of patients diagnosed with TB using UNITAID-supported GeneXpert machines, although it was not possible to collect data on this. However, as noted above, stakeholders did note an issue with the NTLP's

reporting of Xpert results, although it is unclear how this has affected the project results reported above.

Using the latest data on treatment success rates, it is estimated that the patients diagnosed with TB with commodities provided through the TBXpert project will result in 981 TB patients successfully treated, 5 incident HIV-positive TB patients successfully treated, and 41 incident rifampicin-resistant TB patients successfully treated. If the case detection targets are achieved, it is estimated that the TBXpert project will result in 3,278 TB patients, and 1,077 incident HIV-positive TB patients successfully treated.

### *Sustainability of project*

Sustainability is noted as a key issue for the NTLP and other stakeholders in Tanzania, and there is a fear that the overall three year timeframe of the TBXpert project (two years for TB REACH grantees) will not be sufficient to make all stakeholders aware of the full benefits of the GeneXpert machines.

The first issue relates to the forward planning of the GeneXpert machines procured through the TB REACH grantees. The current understanding of UMB and NIMR is that when their respective projects finish this year, the NTLP will assume the operating costs of the GeneXpert machines. Working on this basis, UMB and NIMR are in the process of only ordering sufficient quantities of cartridges for the remainder of their project periods. Having only recently become aware of this, the NTLP is currently trying to establish whether they need to order cartridges in advance of the completion of the TB REACH projects to ensure a smooth transition to the NTLP where the GeneXpert machines can continue to be utilised. Some of this uncertainty is due to a lack of clarity within the NTLP on whether UNITAID will continue to support the implementation of the existing GeneXpert machines through the provision of cartridges, and/ or intends to further support the scale up the number of GeneXpert machines in the country.

The second issue relates to the provision of funding to support the ongoing operating costs of the GeneXpert machines – this includes the cost of cartridges, warranty extensions, calibration, maintenance and other items. In particular, stakeholders have questioned the rationale for only providing support over a two-year period, given that there is considerable uncertainty as to whether the NTLP will be in a position to fund the operating costs following the project period. In the short-term, the NTLP are confident that they can support the machine operating costs using their own resources and those received from other donors.<sup>19</sup> However, in the medium- and long-term the country is expected to require support from external donors, such as the Global Fund. However, such arrangements are uncertain, and in the case of the Global Fund, any funds would not be received for at least another two years.

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<sup>19</sup> This may include arrangements similar to how the TBXpert project has funded other GeneXpert machines in the country, or arrangements similar to how the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) has assumed the operating costs of a machine in a health facility where it is also implementing an HIV programme. There have also been some early discussions on options for the private sector to become involved in the diagnosis of TB using Xpert MTB/RIF, although how this would work in practice is yet to be determined.

As such, there is a possibility that the NTLP will not be able to support the operating costs for the machines in the longer term, although this is yet to be determined. As noted above, the uncertainty surrounding this issue has led to the NTLP decreasing the number of machines it plans to introduce in the country, from one per district (169 in total) to 100, to ensure that the country can afford to sustain them on an ongoing basis.

#### **4. Conclusion and recommendations**

This section provides some conclusions and recommendations from the country visit, based on CEPA's analysis of the suggestions made by the country stakeholders during the consultations.

The conclusions and recommendations are made in the following areas:

##### **Further scale up of Xpert MTB/RIF**

Xpert MTB/RIF is highly embedded within the NTLP's planning for the diagnosis of TB going forward, as reflected in the latest national algorithm and strategic plan. UNITAID and the TB REACH Initiative are indirectly credited for creating the supporting environment that led to these actions, by demonstrating the significant benefits of the technology at a time when the technology had not long been on the market. There may also be a role for UNITAID in supporting the further scale up of GeneXpert machines being used in the country, in line with the national strategic plan.

##### **Coordination**

While coordination of GeneXpert activities has improved dramatically over the last year, this is credited largely with FIND's involvement in supporting the GeneXpert Focal Team. As such, there is a real case for continuing FIND's existing contract to further support the GeneXpert Focal Team's functions.

##### **Implementation**

Issues with the implementation of the GeneXpert machines (i.e. machine and module failure) have been common throughout the TBXpert project, which has delayed implementation and incurred unforeseen costs on project stakeholders. These issues have been more pronounced in rural settings, where power supply has been irregular and the environment is often dusty. Our recommendation in this regard is for UNITAID to make provision for greater awareness building, training and support at the country level. More specifically, UNITAID/ WHO should provide more active guidance to countries to ensure that:

- Machines are placed in suitable facilities, both to ensure that public health impact is maximised, and the environment is appropriate for the operation of the machine. It is understood that FIND have been conducting site assessments, although it is not clear if they will continue to do this after the TBXpert project has concluded.
- Grantees are fully aware of the required maintenance for the GeneXpert machines and the type of UPS that is able to run the machine for a full testing cycle – again, it is

understood that maintenance is a core part of the GeneXpert training curriculum and all future staff trained will be made aware of its importance.

- There is sufficient technical support available to stakeholders for the operation of the GeneXpert machines in case of failure – it is understood that such support will be available through Caroga later this year.
- The NTLP are aware of how Xpert MTB/RIF test results are reported, and how their reporting formats should be amended to adequately allow for these to be captured.
- Grantees are aware of suggested levels of utilisation for the GeneXpert machines.<sup>20</sup>
- A proactive procurement planning strategy for cartridges is in place, with the objective of reducing the amount of time spent redistributing unutilised cartridges.
- Stakeholders adequately plan to link patients detected with TB with the NTLP register for treatment, and are successfully treated.

To expedite the process of repairing broken machines, UNITAID should also explore with Cepheid the possibility of storing spare Xpert commodities, especially modules, at the country level.

### **Sustainability of project**

UNITAID should provide clear guidance to all TBXpert stakeholders on the intended length of its involvement in supporting GeneXpert machines, and what they expect from other stakeholders following this support. This guidance should ideally be provided in advance of the provision of funding. For example, this may include setting out an expected phasing out plan for UNITAID/ TB REACH support into the NTLP over a defined period.

To support the sustainability of the TBXpert project in the short term, UNITAID should consider providing a no cost extension to the country, which would allow the country to utilise the cartridges that were initially forecasted for but have not yet been used – this is likely to affect a significant number of cartridges (likely in excess of 10,000). UNITAID should also consider supporting the operating costs of the machines (i.e. warranty, calibration and cartridge costs) for an extended period of time to allow the country greater time to incorporate these costs into their budgeting processes.

UNITAID may also consider some form of leasing arrangement for the GeneXpert machines. This practice has been used for other diagnostic tests (e.g. CD4 point of care tests) and may offer more beneficial terms for countries – for example, this would remove concerns with warranties, and would allow countries to more easily upgrade the machines when they are out-dated. It may also provide stronger incentives to the manufacturer or leasing agent to ensure the machines are fully maintained and stay operational.

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<sup>20</sup> For examples, Tanzania aims to increase the utilisation of all machines in the country to 90%.



## List of country consultees

Table A5.2 presents the list of in-country stakeholders with whom consultations were held.

Table A5.2: Field visit consultee list

Stakeholder category	Organisation / Department	Name (position)
<b>MoHSW</b>	NTP	Dr. Beatrice Mutayoba (NTP Programme Manager)
	Central TB Reference Laboratory	Saidi Mfaume (Gene Xpert Focal Point)
<b>TB REACH Grantees</b>	MMRC	Dr Petra Clowes (ex-Project Coordinator for Operational Research and Interventions)
	MMRC	Dr Chacha (Project Coordinator for Operational Research and Interventions)
	UMB	Dr Abubakar Maghimbi (Clinical Technical Director)
	UMB	Dr SekelaMwakyusa (Country Medical Director)
	UMB	Dr Vincent Mashinji (Project Technical Lead)
	UMB	Daniel Lukamay (Community Engagement Officer)
<b>Amana project site</b>	Doctors	Two doctors
	Lab technicians	Three lab technicians
	Patients	Two patients
<b>Temeke project site</b>	Doctors	Two doctors
	Lab technicians	Three lab technicians
	Patients	Two patients
<b>Others</b>	FIND	Victoria Harris (Consultant support CTRL)
		Anna Ascorra (Consultant support CTRL)
	National Council of People Living with HIV/ AIDS (CSO)	Deogratius Peter (Chief Executive Officer)
	Tanzania Public Health Initiative	Jacob Kayombo (Director)
	Clinton Health Access Initiative	Dr. Esta Mtumbuka (Country Director)

## ANNEX 6 INDIA COUNTRY REPORT

### 1. Introduction

This annex presents key findings from the country visit to India, which was carried out by CEPA associate, Remi Verduin, during 10 – 13 February 2015.

The report is structured as follows: Section 2 presents some background information on the state of the TB epidemic, ongoing TB control efforts and the TBXpert project in India; Section 3 presents key findings from the field visits for each of the three evaluation dimensions (relevance, efficiency and effectiveness, and results and sustainability); and Section 4 provides a conclusion and some recommendations from the country experiences with Xpert. The list of country stakeholders consulted is included at the end.

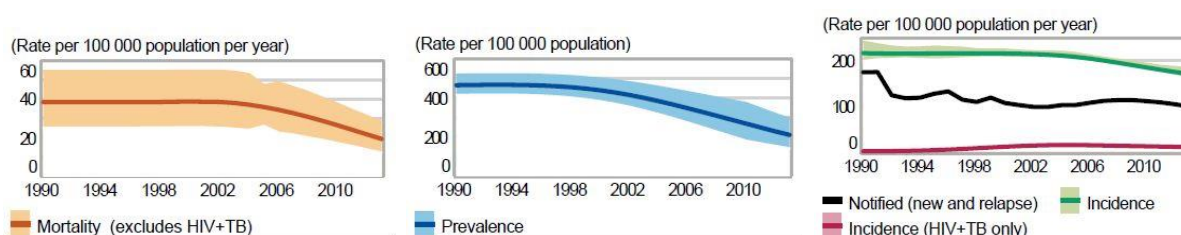
### 2. Background

This section provides a brief background on the status of TB and TBXpert project sites and roll-out in the country.

India is a vast sub-continent in Asia, with a population of 1.2 billion people in 2013, majority of which live in rural areas (69%). It comprises 36 States and Union Territories, divided into 712 District Units, approximately 6,000 Blocks; India has about half a million villages. Gross National Income per capita was US\$1,570 in 2013.

According to the 2014 WHO Global TB Report, India has 24% of the TB cases in the world and is thus one of the highest TB burden countries, also having the world's highest burden for MDR-TB. During 2013, the Revised National Tuberculosis Control Programme (RNTCP) notified 1,415,617 cases of all forms of TB, 621,762 bacteriologically confirmed new pulmonary TB and 23,506 MDR-TB cases. The WHO TB Report 2014 shows a gradual decline of mortality, prevalence, incidence and case notification in the last decade (Figure A6.1). Only 1.8% of TB patients are HIV positive (in Delhi ± 95% are tested).

Figure A6.1: Key trends in TB in India



The TB services under the RNTCP currently comprise 13,306 Designated Microscopy Centres (DMC), six National TB Reference Labs (NRL) and 62 Intermediate Reference Labs (IRL); of these, 50 carry out Solid Culture/Drug Sensitivity Testing (SC/DST), 24 Liquid Culture (LC/DST) and 50 Line Probe Assays (LPA).

RNTCP data show that there were at least 89 Cartridge Based-Nucleic Acid Amplification Test sites (CBNAAT is the RNTCP preferred generic name for the Xpert test) as of end 2014, mainly in the public sector and as part of donor support (USAID and PEPFAR funded projects through

FIND as well as from UNITAID). In addition, there are approximately 70 GeneXpert machines in the private sector through a programme managed by CHAI and IPAQT.

As part of the Programmatic Management of Drug-resistant TB (PMDT) plan, a laboratory expansion plan is being implemented since 2006, including ongoing quality assurance and annual proficiency testing (RNTCP accreditation). FIND and PATH, with funding from USAID, have provided crucial support for the roll-out of this PMDT plan, while UNITAID also provided essential equipment for a number of C/DST labs. A revised National Lab Scale-up Plan aims for further expansion to 120 IRLs (C/DST labs) and more than 950 Xpert machines, including 300 to be funded by the government, by 2017.

RNTCP in its National Strategic Plan for Tuberculosis Control 2012–2017 indicates that it wants to innovate to engage the private sector through public-private mix (PPM) initiatives to improve access to rapid testing, followed by TB treatment according to standards for TB care in India. Advocacy, Communication and Social Mobilisation (ACSM) will be used to increase demand.

The government of India has been increasing its funding for TB over the years, and currently plans to contribute about 50% of the funds for TB control in 2014<sup>21</sup>.

### **3. Evaluation findings**

This section presents key findings from the country visit on the three evaluation dimensions of: (i) relevance; (ii) efficiency and effectiveness; and (iii) results and sustainability.

#### **Relevance**

All stakeholders interviewed were of the view that the Xpert technology is a very useful innovation with high potential for diagnosing (pulmonary) TB in a quick and more reliable manner than any of the other currently available methods.

Xpert is included as part of the PMDT expansion plan (2012-17), with the RNTCP vision of including Xpert MTB-Rif in 950 sites at district labs and medical colleges by 2017. Criteria for referral of specimen for Xpert and DST have been developed to identify DR-TB patients, with a gradual expansion of target populations to be examined according to a set of well thought-out criteria and in line with the available lab capacity. By the end of 2014, all districts have expanded the target populations to match criterion C as shown in Figure A6.2 below.

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<sup>21</sup> <http://www.who.int/tb/data>, accessed January 6, 2015

Figure A6.2: MDR TB Suspect Criteria

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<b>A</b>	<b>(Failures &amp; Contacts of MDR-TB patients)</b>
<b>B – in addition to Criteria A:</b>	<b>(Sm+ve Re-treatment &amp; Follow Up cases)</b>
<b>C – in addition to Criteria B:</b>	<b>(Sm-ve Re-treatment &amp; HIV TB cases)</b>

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However, the Xpert test is considered expensive and viewed as an “add-on test”, and not as a replacement for sputum smear microscopy in the near future.

Diagnosing DR-TB can be quick with Xpert, but an additional test for Isoniazid (INH) resistance is needed to confirm MDR-TB using C/DST or Line Probe Assay (LPA) of first line drugs. In low MDR-TB risk groups the Xpert test may give a false positive result, demanding a repeat test. Chest X-ray has therefore been added as a priority screening test for selected groups of low TB risk populations, as its sensitivity is higher than sputum smear microscopy.

With Xpert MTB/RIF not being a Point of Care (POC) test, specimens have to be transported from a number of lower level health facilities to a central laboratory, thus implying limits to the extent to which the technology can be decentralised.

There was also some concern expressed that the Xpert technology is mainly located in the public sector, while the large majority of first-time healthcare seekers go to the private sector – thereby reducing its current relevance.<sup>22</sup> The RNTCP has instructed State and District TB coordinators to establish wider public private partnerships to offer the new diagnostic technology at the earliest.

### Efficiency and effectiveness

*Management and delivery of project (including timeliness, communication with partners, coordination with NTP and other in-country donors)*

All project partners and in-country donors interviewed stated that the UNITAID TBXpert project had been implemented well in country and communication had been very good, with key stakeholders being made aware of the roll-out process.

The project kicked-off with signing of the Letter of Agreement (LoA) on 10 May 2013. Given previous experience of the EXPAND-TB project, WHO was able to facilitate the process adequately. The 40 4-module GeneXpert machines were delivered in August 2013 and cleared from customs with WHO support in September 2013. Site selection was done by the RNTCP

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<sup>22</sup> The RNTCP has adopted a strategy of allowing private providers to refer all presumptive TB patients, especially those matching criteria A, B and C, to government facilities for free Xpert testing, where they are registered as “referrals” (if they give the referral note). The number of referrals reported until now (360) is very small, pointing to the fact that this form of intensified case finding has not yet expanded, though NTP staff expects that many are registered as a “new” TB case, with the result that these “indirect referrals” are thus not captured as private sector contribution.

in close collaboration with the States and other partners. Gradual installation was carried out by Cepheid depending on the speed of necessary adaptations made in existing laboratories by state governments as well as training of staff. The installation and training of lab staff took place between September and November 2013 in most states.

An adaptation was proposed by the RNTCP (and approved by UNITAID) to obtain three additional 2-module GeneXpert machines, to be located at different locations in the Andaman and Nicobar islands. After placing the order in 2014, the machines for the islands were delivered and three of the four were installed soon thereafter, one awaiting the site preparations to be completed.

The introduction and roll-out of the Xpert MTB/RIF technology was done with oversight from a consultant microbiologist, the TBXpert focal person appointed at the Central TB Division (CTD) on the request of WHO. This was coordinated with ongoing programmes on laboratory improvements being supported by WHO and PATH, with funding from USAID.

The large majority of sites started testing in December 2013, resulting in a limited number of tests performed in 2013 (3,900), but expanding quickly in 2014, preventing expiry by nearly exhausting the existing cartridge supply. Through expediting the next supply of Xpert cartridges by Cepheid and by re-allocating existing stocks from low-demand sites, the programme managed to avoid stock-outs.

Interview with the RNTCP and other partners emphasised that all donor support for Xpert had been provided in close consultation with RNTCP. However, there was some lack of clarity on the roll out in the private sector through CHAI and IPAQT as the number of functional GeneXpert machines differ per month (e.g. due to module failure) and not all the labs involved are notifying cases found to the Ministry. As a result, the RNTCP has not yet captured the latest numbers of tests and cases detected in their overall figures.

*Product implementation issues (module failure, maintenance and warranties, other implementation issues)*

We understand that the RNTCP implemented a pilot study in 2012 and 2013 to generate scientific evidence and to test the feasibility of using the Xpert technology in India, where the rate of module failure was very high, predominantly on account of the dust factor. As a result the Xpert locations were improved to avoid dust coming into the labs and Cepheid made a number of modifications to the platform design to reduce the extent of module failure. Under the UNITAID TBXpert project funded machines, there were 11 module failures amongst the 164 modules between July and December 2014, and another 9-10 module failures have been reported in 2015 already, following online calibrations. The reason for this type of failure is currently being looked into.

Maintenance of the GeneXpert machines is well organised by Cepheid (and its local subsidiary Labindia), in good and fast coordination with the state and central level NTP and to everybody's satisfaction. A first visit to assess the actual problem takes place within one or two days after Cepheid has been notified. Some module repairs can be done in-country and

may take a few days. Platforms and modules that can't be repaired in India are sent to France and it may take several weeks before repaired or new equipment is back in place.

We understand that state governments are supposed to ensure expanded warranty contracts or pay for repairs themselves after the present warranty period is over end 2015. However we are unclear in terms of whether specific budget allocations have actually been made for this to date.

Key issues with placing the GeneXpert was to ensure that the State Governments took responsibility for preparing the sites, including a dust-free room and reliable electricity supply using a UPS system; two have solar energy systems, reportedly costing USD 4,000 each.

#### *Cost of accessing the Xpert diagnostic test and test turn-around times*

No specific study results were available in the Indian context as evidence that the Xpert test turnaround time was short or that patient costs had reduced under the Xpert test. However:

- Patient interviews in Delhi and Rohtak confirmed that diagnosis of TB, including Xpert test, is free at the public facilities, except INR 5 (= US\$0.10) for registration for one patient. Non-medical costs (travel costs and food) ranged from INR 10 to INR 200, average INR 50 (just less than US\$1). Indirect costs (travel time, visit time, income forgone) had a wider range, from no costs for an elderly person to INR 400 (US\$6.5) for a sick young patient who had come accompanied by her mother, who couldn't work that day. Travel time in the cities was within one hour and patients usually didn't spend more than an hour waiting at the clinic. The two patients who had received their Xpert test result at the time of interview had received it the next day from testing.
- Patients visiting the private sector have to pay consultation fees, but private practitioners can refer presumptive TB patients to the public sector for a free Xpert test. Private health facilities collaborating under the IPAQT project have bought their own GeneXpert machines under the concessional pricing scheme and the cost for an Xpert test has contractually been limited to INR 1,700 (US\$27).
- Clinicians and laboratory staff at the locations visited noted much improvement in the time it takes to obtain a result of a DR-TB test compared to the past, when patients had to wait up to 5 months before the lab could report on the results of SC/DST.<sup>23</sup> Xpert MTB/RIF is enabling them to inform patients about the lab examination results quickly, often within a day after submitting sputum (this was confirmed by lab staff, nurses, clinicians and TB patients during interviews); a consequence to this rapid turnaround time is the higher enrolment rate for TB and MDR-TB treatment. In the public sector there was mention of a period of five to ten days before patients start

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<sup>23</sup> The solid (Löwenstein-Jensen, LJ) Culture and Drug Sensitivity Test (DST) can take between 2-5 months to identify MDR-TB. The use of liquid culture (LC) and DST has already reduced this period to 4-6 weeks. Use of LPA has reduced this further to 3-5 days, while Xpert theoretically can produce a same day test result, but with information on resistance to one drug (Rifampicin) only.

their MDR-TB treatment, especially as a result of rigorous clinical and laboratory examinations according to protocol. TB treatment is provided free of charge in 3,644 Tuberculosis Units and in 122 DR-TB Treatment Centres throughout India.

### *Procurement planning*

The Central TB Division at the MoHFW is responsible for planning and forecasting of Xpert cartridges under the UNITAID TBXpert project. So far, the programme has managed to avoid stock-outs by shifting cartridges from low to high demand settings, where staff sometimes works overtime to complete the number of tests each day. RNTCP foresees that the amount of cartridges approved under the TBXpert project may be insufficient in 2015 and intends to buy additional cartridges.

### **Results and sustainability<sup>24</sup>**

#### *Public health impact*

In terms of public health impact, the expectation would be that the introduction of Xpert MTB/RIF would lead to the detection of more TB cases than before, at an earlier stage in the disease, before having spread the infection to others. Following detection, immediate start of TB treatment with the correct regimen should take place (for both new pulmonary TB patients as well as for MDR-TB patients). We review the actual public impact achieved to date, given this expectation.

As noted above, testing with Xpert started at the end of 2013, with only 3,900 cartridges being used to test 3,686 presumptive (DR) TB patients, resulting in 570 Rifampicin resistant cases, 43 HIV+ TB patients and 386 new TB cases under the TBXpert project by the end of 2013.

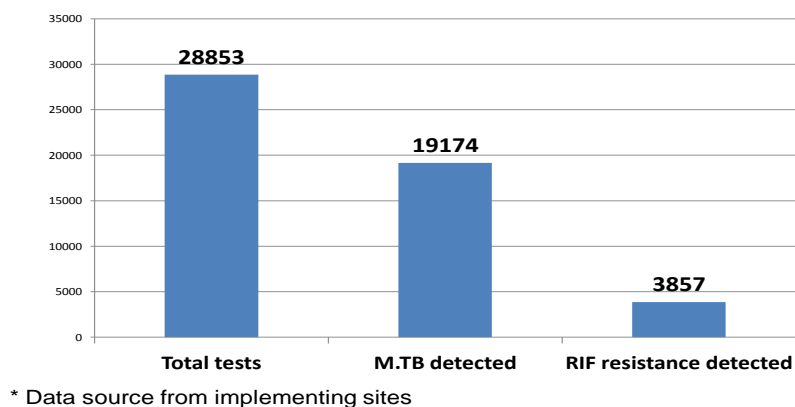
Figure A6.3 below shows the number of Xpert tests carried out in the first half 2014 at the UNITAID supported Xpert sites. The numbers are based on the latest report by RNTCP, with minimal difference from what was reported to UNITAID during 2014. Though there was a mix of target populations tested according the prevailing guidelines in various states where Xpert is located, the yield of detecting TB appears to be very high: total tests done 28,853; 1,974 tests had errors (7%), 26,879 individuals have a result; 19,174 tests were MTB positive (71% of 26,879), 6,793 were incident (new) TB cases and the remaining were relapse and failure cases (some 8,500); among the 19,174 there were 755 HIV+ TB cases; 3,857 TB cases with Rifampicin resistance (20% among the 19,174 MTB detected). This high proportion of MDR points to a logical focus on selecting known pulmonary TB cases like smear positive failure and re-treatment cases, the risk groups with the highest probability of MDR-TB.

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<sup>24</sup> Data included in this section has been provided by the NTP during the country visits.

Figure A6.3: TB cases detected at UNITAID supported sites

### Outcome of TBXpert Project (UNITAID) from 43 sites (January- June 2014)\*

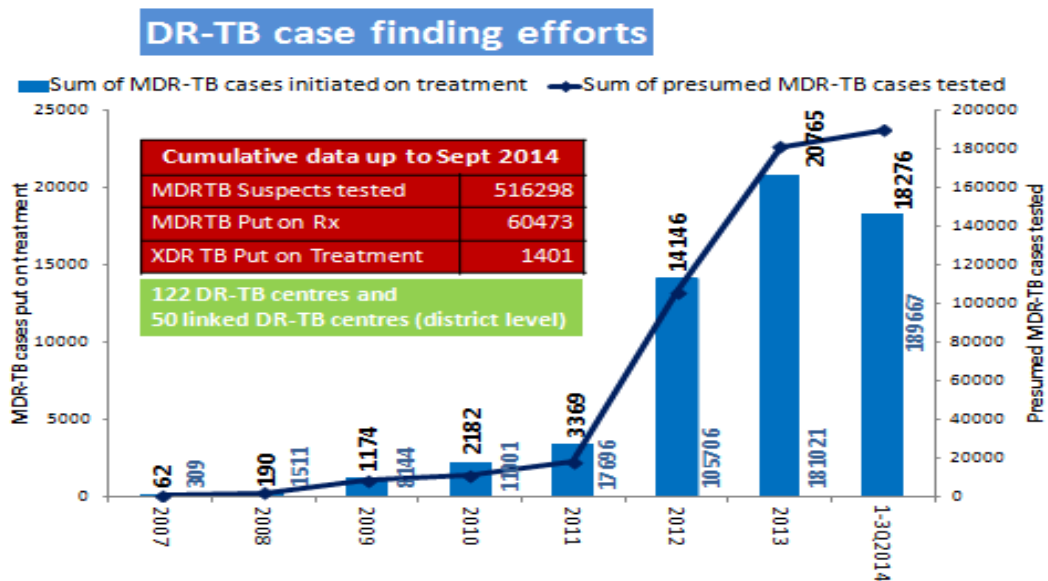


The expansion of Xpert testing among less high-risk populations reduces the yield of MDR-TB from 71% among failure cases to less than 2% among, for example, paediatric cases in Delhi. Also the reports on laboratory results from Rohtak show a similar trend, with a high yield initially due to new and backlog cases, which tapers off after one to two years.

Figure A6.4 presents summary data on MDR-TB case finding from 2007 to 2014 (first 3 quarters only), as presented by WHO/RNTCP. As can be seen from the figure, though data on the 4<sup>th</sup> quarter of 2014 are not yet included, the speed of the increase in MDR-TB case finding appears to be levelling off despite the expanded use of the Xpert test since 2014. The large increase in MDR-TB cases in 2012 and 2013 has been on account of substantial efforts on laboratory strengthening, improved sample collection and transport systems and introduction of liquid culture capacity and Line Probe Assays (LPA) for first line drugs. The “levelling off” in 2014 can be expected as the Xpert test is only partly replacing or preceding the LPA test and focussing on enhanced case finding in target groups with lower MDR-TB risk, like children and HIV patients. However we recognise that it is not possible to draw a strong conclusion based on this data as it is too early to review any trend changes in TB case detection in India on account of the introduction of Xpert.



Figure A6.4: Trends in MDR-TB case finding in India



Consultations with stakeholders during the field visit confirmed the above noted trends in MDR-TB case finding. As such therefore, the additionality of the use of Xpert (while difficult to assess at this stage) is at present likely to be less in finding MDR-TB cases than in identifying new (incident) TB cases in new or expanded target groups under enhanced case finding. However, as in 2013 only 23,000 of the 62,000 estimated MDR-TB patients were found, a further expanded, decentralised and fully functional network of GeneXpert machines could in the next few years lead to an additional increase in MDR-TB case finding.

In terms of broader public health impact we consider a number of issues such as strength of linkages with treatment and coordination with other health sectors. We note the following:

- There have been some improvements in terms of treatment access and success, however these are not yet fully adequate in relation to the need.
- The RNTCP Annual Report 2014 states that of the 23,289 MDR TB patients found in 2013, 20,763 were initiated on MDR treatment, leaving a 10% gap related to access barriers for patients who are facing a two year treatment duration. No shortages of FLDs or SLDs were mentioned during the visit.

Monitoring access to treatment is supported by the introduction of an electronic, individual patient based recording and reporting system for all TB patients (“NIKSHAY”), which is being implemented since July 2014, with in some places a 99% concordance with the paper-based system. Government stakeholders in Delhi indicated that there is a considerable backlog in data entry, making the system not yet suitable for analysis of case finding and treatment results. Our spot inspection of the laboratory registers suggests that they were neatly maintained.

There is improving coordination with HIV/AIDS control efforts in the country. The RNTCP mentioned that there is a strong collaboration with the National AIDS Control Organisation

(NACO). All TB patients are offered HIV tests and all HIV patients are offered TB tests through cross-referral mechanism. The HIV status of the patient is also recorded in the TB treatment card. RNTCP has also prioritised the use of Xpert MTB/RIF tests for PLHIV. Joint TB-HIV collaborative meetings are conducted where performance of both the programmes are reviewed. 30 Xpert machines are being placed in ART centres in four states in a joint project of the two programmes, funded by PEPFAR/USAID with technical assistance from FIND.

### *Market impact*

Our understanding of the expansion of the GeneXpert technology in India is as follows:

- The first GeneXpert platforms arrived in India for a feasibility study by RNTCP, WHO and FIND during March 2012 – December 2013, when 27 machines were introduced at 18 locations, funded by USAID.
- A further 10 sites received 12 machines under Expand TB (2013-Dec 2014).
- Under the UNITAID TBXpert, 43 GeneXperts were positioned at decentralised locations to scale up PMDT since December 2013, with 80,000 Xpert cartridges received and mostly used by the end of 2014.
- Six more GeneXperts were positioned at specialist hospitals in four major cities (till June 2014), to accelerate TB and DR-TB diagnosis in paediatric cases, under USAID and FIND support.
- Through PEPFAR/USAID a further 30 GeneXpert machines are being introduced (2014 till September 2015) for use at 30 Anti-Retroviral Treatment (ART) centres, with technical assistance from WHO country office for India.
- Under the IPAQT initiative by CHAI approximately 70 GeneXpert platforms have become accessible in the private health sector by end 2014.
- The GoI's CBNAAT expansion plan 2012-2017 aims to further scale-up Xpert use: in addition to the above mentioned about 150 GeneXpert machines, India is said to receive from Global Fund's Single Stream of Funding 600 GeneXpert machines between 2014 and 2016, with a further 300 to be bought by GoI (100 in 2014/2015 and another 200 in 2015/2016). Altogether India is scheduled to have more than one thousand GeneXpert platforms from 2017 onwards.

Though Xpert MTB/RIF will not fully replace sputum smear microscopy, there is already a considerable increase in the number platforms and test cartridges over time, suggesting market impact in terms of some degree of scaling up within the country.

### *Sustainability of project*

From the start of the UNITAID project, the GoI was clear that the Union and State governments have the responsibility for positioning and preparing locations of Xpert sites and ensuring continuity of the technology after the completion of UNITAID funding. The

preparation of Xpert sites by States has happened, sometimes leading to delays in deployment of the machines, but ensuring ownership.

During our interviews, the RNTCP mentioned that the GoI at either the national or state level “will step in” to fund all maintenance, consumables, supplies and staff. As noted, there is a plan for the state governments to take over funding of the warranties for the machines, although a clear budget allocation for this has not yet been made.

The RNTCP further stated that ensuring universal access to DST and DST-guided treatment across India, together with addressing factors associated with unfavourable treatment outcomes, will be the way forward in improving the quality of Drug Resistant TB diagnosis and treatment. This approach is being built into India’s revised PMDT scale up plan (2015-19), currently under development.

As per this transition plan of the RNTCP (which has been used to prepare India’s Global Fund Concept Note which was submitted on 27<sup>th</sup> of February 2015), the Xpert technology has been embraced by the NTP as an important innovation in TB case detection and a country-wide implementation is the aim: priority areas for deployment of Xpert MTB/RIF will be Medical Colleges with Drug Resistant TB Treatment Centres, ART centres, urban TB districts which are highly populated and other high workload districts.

Thus from a policy and planning point of view the future of the Xpert technology in India has been ensured. A positive sign can also be noted from the WHO 2013 country TB report, which shows that for 2014 the GoI has nearly doubled its budget for TB control, from US\$80m to US\$ 160m, 66% of the total estimated budget.

#### **4. Conclusion and recommendations**

The UNITAID TBXpert project came in India at an opportune moment, when a well-coordinated effort to roll-out the Xpert technology as part of a properly designed PMDT plan of the RNTCP was just starting. The project was designed and implemented as part of the country’s own plans, with a decentralised approach, supported by an effective specimen transport system. Therefore the UNITAID TBXpert project has been effective in offering expanded access to TB and DR-TB diagnostic services, well managed by the Central TB Division and State TB Officers, with close monitoring by the TBXpert focal person and WHO colleagues, the M&E showing good initial results.

To further improve the scope and usefulness of Xpert MTB/Rif technology, and the role UNITAID can play in this process, the following recommendations have been compiled, largely based on stakeholders feedback.

*For Cepheid:*

- The Cepheid Xpert remote monitoring tool should be finalised as soon as possible, to allow central monitoring at RNTCP of all the GeneXpert machines and their use on the Xpert dashboard.

- The Xpert test output software should be adjusted so results can automatically be incorporated in India’s Revised National TB Control Programme’s electronic register (NIKSHAY).
- Cepheid should look into the post-calibration module failures and solve the problem as soon as possible.

*For UNITAID:*

- A longer time frame for projects entailing introduction of new technology is required, especially to ensure sustainability.

*For the Government of India / RNTCP:*

- The improving economic conditions make it possible that GoI gradually takes more responsibility for funding the Xpert technology including related operating costs.
- Since the large majority of people with medical complaints including chronic cough consult doctors and other health care providers in the private sector first, the sector should be subsidised to screen widely for TB.

## List of consultations

Table A6.1 presents the list of in-country stakeholders with whom consultations were held.

*Table A6.1: Field visit consultee list*

Stakeholder category	Organisation / Department	Name and position
<b>RNTCP (TB REACH Grantee)</b>	Ministry of Health and Family Welfare / Central TB Division	Dr. Kuldeep S. Sachdeva, Additional Deputy Director General (TB), Deputy TB programme manager
		Dr. S. Anand, WHO RNTCP Consultant – Microbiologist, CTD
		Dr. Syed Imran Farooq, WHO RNTCP Consultant - DR-TB, CTD
		Dr. Jyoti Jaju, WHO RNTCP Consultant - DR-TB, CTD
	Delhi State	Dr. Shivani Chandra, WHO RNTCP Medical Consultant, Delhi State
Haryana State	Dr. Nath Dr Sudhi, State HQ Medical Consultant-DRTB, WHO	
<b>Delhi State RNTCP staff</b>	Doctors	Dr. Ashawani Khanna, State TB Officer, Delhi Dr. Hanif, Microbiologist, IRL Delhi

Stakeholder category	Organisation / Department	Name and position
		Dr. Chopra, Director, Delhi State TB Diagnostic Centre Dr. Anuj Bhatnagan, Rajan Babu Institute of Pulmonary Medicine and Tuberculosis (RBIPMT)
	Patients	Two, anonymous, at RBIPMT
	Lab technicians	Several
<b>Haryana State RNTCP staff</b>	Doctors	Dr. S.L. Verma, IRL Microbiologist & State Nodal Person for Xpert (CBNAAT) Project, Karnal Dr. P. K. Shridhar, APO, State TB Cell, Panchkula Dr. Aparna Parmar, Professor, PGIMS, Rohtak Dr. Akanaksha , Senior Resident, PGIMS, Rohtak Dr. Vikas Singh, MO District TB Centre, Rohtak
	Patients	Three, anonymous, at District Chest Diseases and TB Centre, Rohtak
	Lab technicians	Khem Chand, Lab Technician Medical College, PGIMS
<b>Others</b>	WHO / India	Dr. Malik Parmar, TB Advisor
	FIND	Dr. C.N. Paramasivan, head of TB programme, FIND India & South East Asia Dr. Umesh Alavadi, Medical Officer, SL DST and Labs North Dr. Rahul Thakur, Project Leader GF projects and Labs East Dr. Pravakar Adhikaree, Project manager EXPAND-TB and Labs South Dr. Manoj Toshniwal, Project Coordinator incl. PPM and all finance
	CEPHEID	Abhishek Gupta, Field Application Scientist
	USAID/Health Office	Dr. Reuben Swamickan, Advisor – Tuberculosis
	CHAI	Harkesh Dabas, Country Director
	GLRA/Delhi	Dr. Ashok, MDR-TB project Delhi

## ANNEX 7 INDONESIA COUNTRY REPORT

### 1. Introduction

This annex presents key findings from our field visit to Indonesia, which was carried out by CEPA associate, Remi Verduim and took place during 16-18 February 2015.

The report is structured as follows: Section 2 presents some background information on the state of the TB epidemic, ongoing TB control efforts and the TBXpert project in Indonesia; Section 3 presents key findings from the field visits for each of the three evaluation dimensions (relevance, efficiency and effectiveness, and results and sustainability); and Section 4 provides a conclusion and some recommendations from the country experiences with Xpert. The list of country stakeholders consulted is included at the end.

### 2. Background

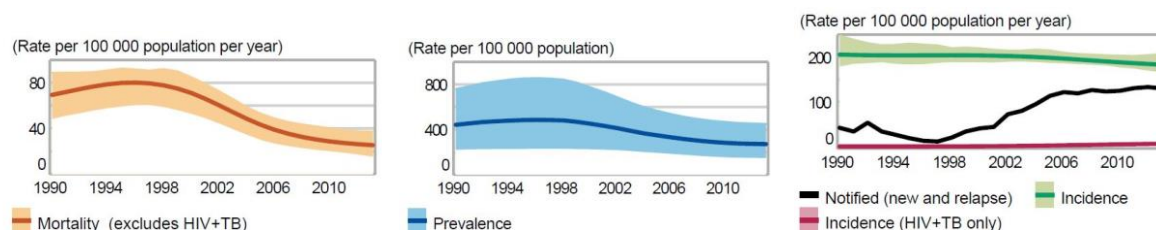
This section provides a brief background on the status of TB in Indonesia. It also provides a summary of the TBXpert project in the country.

#### Status of TB in Indonesia

Indonesia is a large country in South East Asia; an archipelago consisting of over 13,000 islands, ranging from large populous regions to many smaller uninhabited islands. The total population was 250 million in 2013, majority of which live in rural areas. Gross national income per capita was US\$3,580 in 2013.<sup>25</sup>

According to the WHO Global TB Report 2014, Indonesia belongs to the top ten TB incident countries in terms of absolute numbers of TB patients (with new pulmonary smear-positive patients being 196,310). The report also shows a very gradual decline in mortality, prevalence, incidence and case notification in the last decade (refer Figure A7.1), with an estimated incidence rate of 183 per 100,000 population (range 164-207), prevalence rate of 272 (range 138-450) and mortality rate of 25 (range 14-37), which is below the MDG target.

Figure A7.1: Key trends in TB in Indonesia



The total number of new and relapse TB cases notified in 2013 was 325,582. Of the new pulmonary TB cases, 60% are bacteriologically confirmed; and of relapse cases, 80% are bacteriologically confirmed. Treatment success of the 2012 cohort of new and relapsed TB cases was 86%.<sup>26</sup> The National TB Control Programme (NTP) has been working for the past

<sup>25</sup> [www.who.int/tb/data](http://www.who.int/tb/data), accessed 2015-01-06

<sup>26</sup> [www.who.int/tb/data](http://www.who.int/tb/data), accessed 2015-01-06

fifteen years with partners to improve the TB services country-wide, resulting in a considerable reduction of the gap between estimated and notified TB patients. However results of a recent prevalence survey may require an upward adjustment of the TB estimates (and hence entail a larger gap between estimated and confirmed cases).

HIV is a relatively small problem in Indonesia, with a minor proportion of TB patients tested for HIV (2%) and low focus on other TB/HIV collaborative activities. Attention on MDR-TB is increasing, with nearly 40% of the 8,000 re-treatment cases tested for Rifampicin resistance or MDR-TB in 2013 with different lab technologies. More than 900 cases of DR-TB were found, with approximately 800 put on treatment.

The Government of Indonesia contributed around 30% of the funds planned for TB control in 2014 (US\$55m). However, 57% of the overall NTP budget is unfunded (the gap is US\$72m). The Global Fund is the largest donor, but there are also grants from other donors e.g. from USAID through TB CARE I.

### **TBXpert support in Indonesia**

The UNITAID/TBREACH Wave 3 TBXpert project in Jakarta is entitled “*Detection of additional TB cases using mass screening, X-ray and GeneXpert MTB/RIF technology and a sustainable social enterprise in Indonesia*”. It was designed as an expansion of the social business model for enhanced TB case finding implemented by the International Research and Development (IRD) in Karachi and Dhaka.

The project is implemented by Project Inovasi Sehat Indonesia (PT ISI), which is a business consortium of four stakeholders: REMDEC (as the lead partner), Indonesian Society of Respiriology (ISR), Summit Institute of Development (SID) and Indonesia Association Against Tuberculosis (IAAT). The total amount for the project from TB REACH is US\$1,012,500 and UNITAID provides 25 GeneXpert machines and up to 100,000 cartridges for a two year period, ending November 1, 2015.<sup>27</sup> PT ISI has received 27,500 Xpert MTB/Rif cartridges to date (i.e. 27.5% of the target) and has used almost all of them by 31 December 2014.

In the process of the proposal development, various TB case finding interventions in different populations and target groups of Jakarta were included, leading to a fairly complex set of six similar but still different interventions to enhance and expand TB case detection. Our understanding is that actual project implementation has been quite different from that set out in the proposal. In particular, the PPM model is being implemented through the following strategies:

- *Strategy 1:* Active screening for presumptive TB patients is carried out through the following four interventions: (i) at three diagnostic centres for pulmonary disease; (ii) at up to 25 private hospitals and clinics; (iii) at some public health facilities in high risk

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<sup>27</sup> The Project Plan allocates a total of 165,000 cartridges for Indonesia, in line with that proposed for the other two PPM projects in Pakistan and Bangladesh. However the proposal from PT ISI and our consultations during the field visit state that the planned number of cartridges is 100,000.

settings; and (iv) in community settings like orphanages, nursing homes, workplaces and prisons. PT ISI originally planned to work with 180 screeners, but the number had to be reduced to 20-25 because of the high minimum wage in Jakarta province. Screeners use a mobile phone application for verbal screening of target populations on risk factors for TB, based on WHO guidelines. Sputum is collected on the spot and transported through a PT ISI organised courier service to a central location at one of the three diagnostic centres set up by PT ISI for Xpert testing. At present there are 18 GeneXpert machines located at these screening sites: 10 at PDPI, 6 at Abata and 2 at Taman Puring.

- *Strategy 2:* Under the fifth intervention, presently 7 of the planned 10 GeneXpert machines are located at selected private health facilities. From these seven hospitals, the test results are not sent to PT ISI automatically and require regular visits to the facilities. Access to patient information still being discussed with hospital management and clinicians.
- *Strategy 3:* The sixth intervention aims to check smear negative sputum samples from symptomatic patients from 42 *Puskesmas* (health centres); currently 41 *Puskesmas* collaborate with PT ISI and sputum samples are collected daily by couriers and brought to the diagnostic centres. This system works well and brings in the majority of the sputum samples for testing.

Training of lab staff on the use of the GeneXpert machines was facilitated by PT ISI staff after attending a Training of Trainers course and using materials from Webinars.

IRD has a contract with PT ISI to support the social business model, Information Technology (IT) related matters and also infection control for three sites where the GeneXpert machines are placed. There is one person employed by IRD as a manager in Jakarta to provide technical assistance and oversight. The IRD manager provides considerable technical assistance to meet the TB REACH M&E requirements, as well as technical assistance to the PT ISI M&E officers.

### **3. Evaluation findings**

This section presents our findings from the country visit on the three evaluation dimensions of: (i) relevance; (ii) efficiency and effectiveness; and (iii) results and sustainability.

#### **Relevance**

Based on the preliminary findings of a recent TB prevalence survey in Indonesia, there is a large gap between the number of TB patients estimated and detected. This warrants the expansion of TB case detection efforts, from passive to active case finding in wider target groups – for example, as is being carried out by PT ISI under the TBXpert project.

The capacity of Xpert MTB/RIF to identify *Mycobacterium tuberculosis* and Rif Resistance in sputum of symptomatic patients within two hours makes it a very relevant test, especially in view of the limited lab capacity for TB diagnosis in Indonesia. Relevance of the TBXpert project



is further demonstrated by a change in policy of the NTP, as a result of finding a high proportion (15%) of TB and DR-TB among symptomatic patients with a negative sputum smear test at health centres.<sup>28</sup> The NTP has revised its policy and algorithm to allow for such patients to have their sputum tested with Xpert MTB/RIF instead of waiting for the result of two weeks treatment with a non-specific broad-spectrum antibiotic followed by a repeat sputum smear test. Other national TB control documents such as the TB Strategic Plan, Programmatic Management of Drug-resistant TB (PMDT) plan, National Plan for Development of the Laboratory Network, guidelines, standards, SOPs and training modules are all being updated or are under revision to include the new molecular technology.

However, Xpert MTB/RIF is not expected to replace sputum smear microscopy any time soon due to its high cost, but is rather seen as an “add-on” diagnostic test, in cases where clinical suspicion for TB is high and sputum smear microscopy is not conclusive.

The project targets a range of vulnerable populations in Jakarta as described above. However due to low yield, the project has reduced its scope somewhat from targeting a range of risk groups to focusing on prisons alone.

## **Efficiency and effectiveness**

### *Timeliness*

Issues with the importation of three digital X-ray machines that were to be used to generate revenues under the project have prevented the set up of the social business model in Jakarta till today, but other TBXpert activities commenced since December 2013.

However, despite the delay in starting up, PT ISI has made a number of adjustments to its approach to facilitate “catching up”. For example, there was a focus on “efficient” case-finding, as a result of which some of the planned community activities for TB case finding such as door-to-door visits in high risk areas (e.g. low income and slum areas), were not carried out, and other strategies were given higher priority.

The intensified case finding approach has facilitated the increase in the number of cases detected; however these are below the planned targets as discussed below.

### *Coordination with NTP and other in-country donors*

A Central GeneXpert Advisory Team (CGAT) was established by the NTP and stakeholders in 2012 (comprising Ministry of Health (MoH) Department of Hospital Services and National TB Programme, National Reference Laboratories, professional organisations and partners) to discuss and advise on policy and operational issues related to Xpert MTB/RIF use. The CGAT’s view was that PT ISI has been very focused on implementation of the project activities, without sufficiently sharing key information on the design and purpose of the project, the choices made for location of sites and the approach to screening of presumptive TB patients.

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<sup>28</sup> Progress Report TB REACH III / Indonesia, 2014 by PT ISI

In general, collaboration with PT ISI has been a learning experience for both the NTP and PT ISI, given this is PT ISI's first experience of working with the government. Key challenges mentioned were:

- the use of algorithms not (yet) formally authorised by NTP;
- not using the NTP recording and reporting system for referrals; and
- insufficient attention to ensuring that TB patients found were put on treatment.

PT ISI's progress report and comments from NTP and TB partners indicate that a major shortcoming of project implementation is the weak linkage with the routine TB programme. Without a well-functioning referral system, around half of the new TB patients and the majority of the MDR-TB patients have not started treatment soon after detection, many even getting lost in the referral process.

Other issues are related to the fact that PT ISI works with hospitals and health facilities that fall under the responsibility of the Provincial Health Office (PHO), not the Ministry of Health (MoH). We learned that instructions from PT ISI staff are not always understood by health care providers; NTP and PHO staff mentioned that especially the *Puskesmas* staff need clear directions.

NTP and other TB partners/donors in the country are thus of the opinion that the UNITAID support for Indonesia has not been well coordinated. As such the PT ISI work is not yet well embedded in the wider NTP framework.

However, there has been some coordination with other donor support in the country – for example, TBCARE I with USAID funding organised a training of trainers course for laboratory and clinical staff and one PT ISI lab staff participated.

WHO Indonesia has supported the importation process, customs clearance and delivery of the 25 GeneXpert machines and Xpert MTB/RIF cartridges since November 2013, however have not been advised by WHO headquarters to engage extensively with the project.

#### *Module failure and warranties*

In the last six months of 2014, nine out of 32 modules in 8 GeneXpert machines have failed, with some having failed several months ago and not yet repaired/ replaced. The PT ISI IT manager has informed Cepheid and provided all necessary information, however Cepheid and its local subsidiary in Indonesia have not responded. PT ISI has therefore informed TB REACH as well. No further information has been received from Cepheid or TB REACH with regards to these module failures.

PT ISI staff is of the opinion that the warranty period offered by Cepheid is too short. Their view is that Cepheid and its local representative have not been providing the required level of services. We understand that Cepheid has appointed a new organisation (Medquest) as their representative in Indonesia from 2015, and have recently contacted PT ISI to resolve the module failure issues.

### *Other implementation issues*

For its system of screening for presumptive TB, PT ISI has used the information from Lönnroth/WHO.<sup>29</sup> The PT ISI algorithm for screening for TB has the following characteristics:

- *Red suspect: if a person has any of two major symptoms: cough for two weeks or more or haemoptysis*
- *Yellow suspect: at least two minor symptoms / risk factors, like diabetes, COPD, etc.*
- *Green (not suspect): only one or no minor symptom / risk factor.*

Both “red” and “yellow” TB suspects are proposed for an Xpert MTB/RIF test. The NTP policy environment has recently been updated with new TB Guidelines, including algorithms. This may need an adaptation of the mobile phone app used by screeners. In fact, a demonstration of the mobile phone app at the PT ISI office gave an unexpected result when our test person, not having mentioned one of the major symptoms, still had a score of ‘red suspect’. The explanation given was that the scoring system had been changed for higher standards for screening in prisons, following which there were some errors in the app scoring in other sites. This was already discussed with the IT Manager and PT ISI is still trying to solve the issue.

More generally, we understand there have been a number of challenges with the implementation of the Xpert technology in the country. For instance the knowledge of clinicians on candidate patients for testing is insufficient (and even after training, doctors are reluctant to change previous practices). There is thus low utilisation of the Xpert machines and MDR-TB detection is below expectation due to poor selection of presumptive MDR-TB patients, limitations in sample transport from health facilities to laboratories, patients refusing treatment, high rates of default and patient mortality.

There are also some challenges with reporting of results by PT ISI. From the seven hospitals that have their own GeneXpert system, the test results are not sent to PT ISI and data collection requires regular visits to the facilities. Given the inefficiency of this approach, we understand that at present an alternate more effective approach is being developed.

### *Cost of accessing diagnostic test and test turn-around times*

There was limited opportunity to interview TB patients during the country field visit. The one patient who could be interviewed in Jakarta made it clear that sputum smear and Xpert test are free of charge, while he had to pay IDR 180,000 (= US\$14) for a chest X-ray as additional medical costs and a small amount for transport. However, a patient costing study done in 2013 (KNCV/TBCARE I/USAID)<sup>30</sup> showed that on average presumptive TB patients pay during diagnosis around IDR 350,000 (=US\$28), irrespective of whether they have Rifampicin susceptible TB or MDR-TB.

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<sup>29</sup> The International Journal of Tuberculosis and Lung Disease, Volume 17, Number 3, 1 March 2013, pp. 289-298(10); Systematic screening for active tuberculosis: rationale, definitions and key considerations [State of the art series. Active case finding/screening. Number 1 in the series]

<sup>30</sup> Costs faced by MDR-TB patients during diagnosis and treatment\_report\_Indonesia\_Feb2014, TBCARE I/USAID

The patient interviewed had received the result of the Xpert test the next day via SMS. Based on interviews with staff at clinics and OPDs, it can be concluded that compared to culture/DST, the turn-around time of the Xpert test has reduced the waiting period tremendously. According to a study done in 2014, the quick diagnosis of Rifampicin resistance by Xpert MTB/RIF has reduced the time to start MDR-TB patients on second-line treatment from on average 81 to 15 days.<sup>31</sup> However, as noted above, for TB patients detected under the TBXpert project, especially the Rif resistant TB patients, there have been a number of challenges in terms of linkages with treatment. We understand that more than 50% of MDR-TB patients did not start treatment within three months.

#### *Experience with the PPM/SBM model*

Different models of collaboration with the private health care sector under PPM were considered in the application to UNITAID/TB REACH; for example several smaller clinics to be linked to a larger facility for Xpert testing, closer collaboration between public and private facilities (public-private partnership). According to the original plan, the PT ISI project would offer low cost or free services for middle and low income persons, and full cost services for higher income and insured persons. Examination of presumptive TB patients using Xpert is done free for all. Revenue would be generated through four streams:

- (i) X-ray fees for middle and high-income clients;
- (ii) fees for additional health services;
- (iii) insurance payments from government schemes covering poor persons; and
- (iv) corporate social responsibility grants from the private sector.

However, the foreseen income generation using digital X-ray machines has not materialised, because the equipment has not arrived in the country as a result of importation problems (as noted above). As such therefore, so far, revenue generation has not been as planned, with no revenue in 2013 and US\$29,433 between Q1 and Q4 of 2014. Further, the health insurance that is part of the government's Universal Health Coverage doesn't include TB screening or TB lab examinations yet, though this is being pursued by the NTP.

PT ISI staff mentioned that the choice of Jakarta for implementing the Karachi/Dhaka social business model appears less suitable than initially envisioned. A key reason was the difficulty in finding screeners at the minimum wage rate. As a result, PT ISI has focused on identifying presumptive TB patients in out-patient departments of larger and busier public and private hospitals and clinics, as well as on organising daily courier services for Xpert testing of sputum from smear negative symptomatic patients from 41 *Puskesmas*.

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<sup>31</sup> TB CARE | HSS Case Studies: Indonesia

### *Procurement planning*

There has been a significant difference between the planned cartridges of 100,000 for 2013 and 2014 and actual cartridges procurement of 27,500 as of end December 2014.

The 2013 Annual Progress Report indicates that there was a delay in processing the required delivery documentation, which led to a significant delay in ordering of GeneXpert equipment. Once ordered, delivery of instruments and cartridges took place on November 4, 2013 and items were released from customs on November 18 2013 (i.e. a relatively smooth experience).

### **Results and sustainability**

#### *Public health impact*

As Figure A7.2 below shows, there has been an increase in the use of cartridges over time, which has led to 4,036 MTB cases being detected, amongst a total of 23,967 patients tested (i.e. a high proportion of 16%). Among the MTB cases, 327 (8%) were found to be Rifampicin resistant – which is quite a high proportion given that PT ISI is focusing on finding new cases. It would thus appear that clinicians from the collaborating health facilities correctly include failure and retreatment cases for Xpert testing and therefore a higher proportion of MDR-TB is found than expected among just new TB cases. Of all 25,256 tests conducted since the start, 1,289 showed errors or failed tests; this implies a failure rate of 5.1%, which is in line with published information from other countries.<sup>32</sup>

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<sup>32</sup> Jacob Creswell et al. Results from early programmatic implementation of Xpert MTB/RIF testing in nine countries, BMC Infectious Diseases 2014, 14:2 doi:10.1186/1471-2334-14-2

Figure A7.2: Number of sputum tests with Xpert and the results, in relation to the number of operational GeneXpert machines between Q4 2013 and Q4 2014, TBXpert project, Indonesia

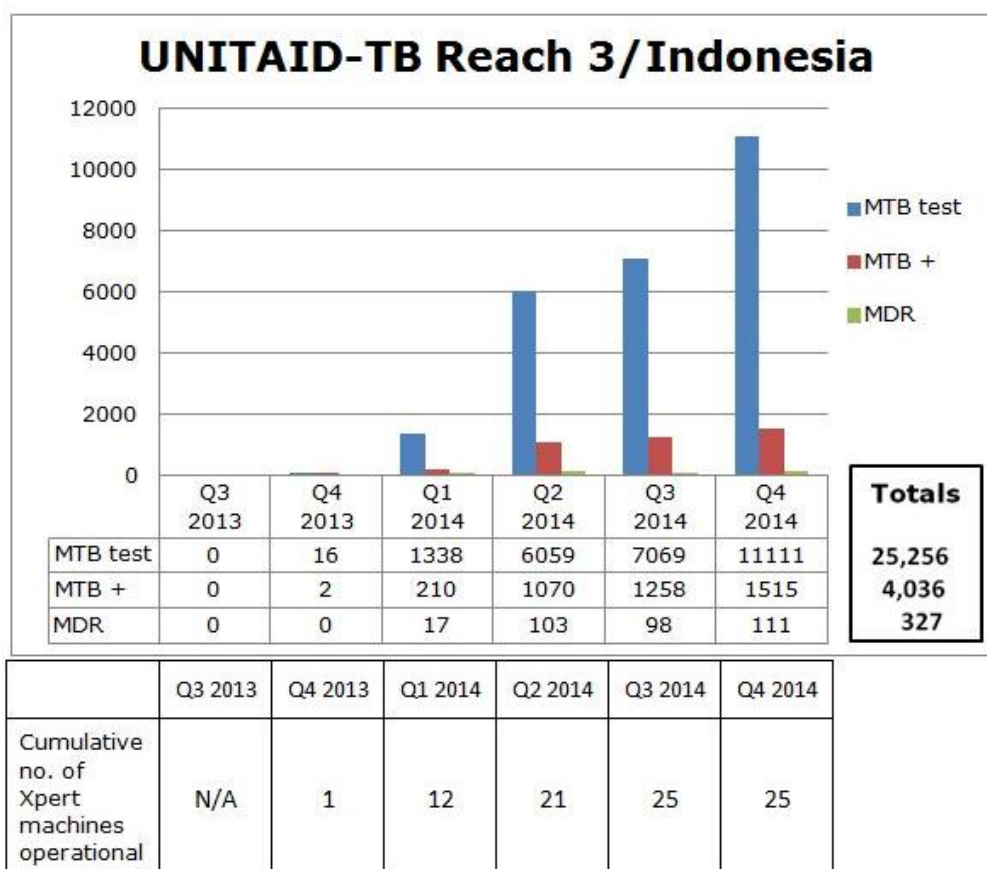


Table A7.1 below summarises diagnosis and treatment data from the 2<sup>nd</sup> and 3<sup>rd</sup> quarter of 2014 (for which the data is complete). As can be seen from the table:

- Strategy 3 appears to be yielding the most number of people to be tested and also cases detected.
- Strategy 1 and 2 are not working very well, as for strategy 1 there are much fewer than planned screeners and strategy 2 has issues given that the X-ray machines have not arrived and revenue generation is low.
- Given the wide variety of target populations included in the testing during Q2 and Q3 2014, a 19% MTB yield (i.e. (2,097+198)/12,011) is fairly high, making the project a relevant and useful intervention.
- However linkages with treatment are low for all three strategies. It should be noted however that during our visit we were informed in one hospital that the physician had referred several patients to another DR-TB treatment centre outside Jakarta (and not to the designated facility (Persahabatan) for Jakarta, due to limited bed capacity there (12 beds) and the expected delay in patient assessment). These patients are not captured in PT ISI's M&E system.

Table A7.1: Details on number of tests done, results and start of treatment, Q 2 and Q3 2014

	No. tested with Xpert	No. MTB susceptible	No. MTB susc. on treatment	% MTB susc. on treatment	No. MTB Rif Resistant	No. MTB Rif Res. on treatment	% MTB Rif Res. on treatment
Strategy 1	3,345	449	346	77%	48	22	46%
Strategy 2	1,366	375	114	30%	43	0*	0%
Strategy 3	7,300	1273	624	49%	107	9	8%
<b>Total Q2 + Q3</b>	<b>12,011</b>	<b>2,097</b>	<b>1,084</b>	<b>52%</b>	<b>198</b>	<b>31</b>	<b>16%</b>

The focus of PT ISI is on enhanced case finding rather than on finding MDR-TB. Of the 25,240 tests performed in the whole of 2014, 15,084 (60%) were done on sputum smear negative samples and still 2,299 MTB patients were found. In addition, 161 MDR-TB cases were detected among them. These TB patients are, to a large extent, additional cases that otherwise would have been found later or not at all.

However, a large proportion of cases, especially MDR-TB cases, detected had not started treatment yet, severely reducing the public health impact of the PT ISI project. Reasons given for the low treatment enrolment were that patients have to get the Xpert test results from the health facility that sent their sputum for Xpert testing.

Often the patient's phone number is not recorded on the Xpert test request form, hampering the feedback process and follow-up the patients. PT ISI facilitates sending the test result to the health facility, but patients still have to go to the health facility to either start first line TB treatment or to get a referral to the only hospital in Jakarta that can initiate second line treatment (Persahabatan), after further specimen for C/DST have been collected. Many patients get lost in this process, especially the presumed MDR-TB patients.

We have not received information regarding shortages of first and second line TB drugs in the government NTP system. In contrast, a TB CARE I HSS Case Study shows that in 2013 more than 1,000 MDR-TB patients were found under the NTP programme supported by TBCARE I, nearly 800 (72%) through testing by Xpert MTB/RIF, and nearly 80% of them had started MDR treatment.<sup>33</sup> In the first half of 2014, more than 600 (93%) MDR-TB cases were found with Xpert MTB/RIF, of which more than 80% had started MDR-TB treatment. The TBCARE I final report on Indonesia (Oct 2010-Dec 2014) mentions an "e-TB Manager", which is an electronic system that has brought significant improvements to second-line drug management. It enables monthly reviews and forecasting for each of the 23 PMDT sites in the country. Recently new functions on drug availability and quantification were added to the software, as well as on Xpert MTB/RIF cartridge transaction history, stock position, cartridge availability and monthly cartridge consumption, etc. Laboratories are required to update the data on all tests for treatment follow-up into the e-TB Manager. One of the main outcomes of utilising

<sup>33</sup> TB CARE I HSS Case Studies: Indonesia

e-TB Manager to strengthen logistics management was that there were no SLD stock-outs in any PMDT hospital from 2010 through 2014.

### *Market impact*

In 2012, KNCV/TBCARE I was the first to bring Xpert technology to Indonesia, using USAID funding, to improve diagnosis of TB and MDR-TB. These were 17 GeneXpert machines and a corresponding number of cartridges.<sup>34</sup>

In 2013, the NTP bought another 24 GeneXpert machines with Global Fund grants and TBCARE helped with further roll out in the provinces. By June 2014, a total of 11,843 Xpert MTB/RIF tests had been performed.

At the end of 2013, the UNITAID/TB REACH TBXpert project brought another 25 GeneXpert machines into the country. By the end of 2014 27,500 Xpert cartridges had been delivered and nearly 90% had been used.

While from PT ISI's point of view, the price of the Xpert technology is too high for the commercial health care market in Jakarta, the NTP's vision to expand the GeneXpert technology in each of the 500 districts of Indonesia by the end of 2019 offers good prospect for further gradual expansion.

### *Sustainability*

The TBXpert project in Indonesia was set up as an NGO-run activity, aimed at establishing a self-sustainable social enterprise. This hasn't materialised yet, and given the current status of the Xpert technology in the private health facilities, the prospects are not good.

For the Xpert technology to continue effectively, it will be important to embed the GeneXpert machines in the government system. Consultations indicated that discussions between the NTP, PT ISI and the PHO regarding a transition plan had taken place, but that no clear conclusions had been reached. The NTP has also explored the option of including funding for the maintenance of GeneXpert machines under the national health insurance programme, especially considering TB drugs and smear microscopy are part of it already. However, this process needs time, following official government procedures, eventually involving the Ministry of Finance to create an additional budget for the machines and the running costs. Private hospitals and clinics that have received the GeneXpert through UNITAID need to budget for maintenance, including calibration and warranty from the end of 2015, an issue which has also not yet been resolved.

PT ISI has not started developing transition plans yet. There has been no communication between WHO HQ/ TB REACH/ UNITAID and WHO Indonesia regarding the need to facilitate the transition of GeneXpert machines from PT ISI to others to ensure sustainability.

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<sup>34</sup> We understand that it took some time to collaborate with the MoH's Directorate of Laboratory Services (BPPM) for the approval of the Xpert technology in the country, which delayed project start-up. The machines were located at three National Reference Labs and 14 Provincial Hospitals engaged in PMDT. The Xpert roll-out started after a training of trainers course of laboratory staff.



TBCARE I/USAID and the NTP/MoH together with the hospital department of MoH have planned for future financing of the machines that came in under TBCARE I. Also Global Fund funding for Xpert supplies and maintenance is being planned, so it is expected that the government will supply Xpert MTB/RIF cartridges for government health facilities.

Embedding the Xpert technology brought into the country in the government programme is essential for continuity. A positive sign is that the TBXpert project has contributed to policy development and adjustments of algorithms in use. The National TB Guidelines were revised and completed last year and now include in the diagnostic algorithm the new guideline that “TB suspects” whose sputum is smear-negative should get access to the Xpert MTB/RIF test in facilities where the test is available instead of a course of non-specific antibiotics for two weeks followed by repeat sputum smear microscopy if not improved. Other national TB control documents such as the TB Strategic Plan, Programmatic Management of Drug-resistant TB (PMDT) plan, National Plan for Development of the Laboratory Network, guidelines, standards, SOPs and training modules are all being updated or are under revision to include the new molecular technology, as part of major planning efforts for the Global Fund application (the aim is for concept note submission in April 2015) and developing the Challenge TB (USAID funded) work plan for the US financial year 2014-2015.

A Health Technology Assessment by the Government of Indonesia is ongoing, aiming at further roll out Universal Health Coverage (UHC), together with a National Health Insurance. This effort might offer an opportunity to absorb Xpert MTB/RIF into routine health care services, further ensuring its sustainability.

#### **4. Conclusion and recommendations**

This section provides some conclusions and recommendations from the country visit, based on CEPA’s analysis of the suggestions made by the country stakeholders during the consultations.

The introduction of Xpert MTB/RIF under the UNITAID TBXpert project in Indonesia has accelerated diagnosis and treatment of DR-TB cases, but only to a limited extent, because the focus has been on intensified case finding. While the project has made important achievements in terms of quick expansion of case finding and appropriate use of the Xpert MTB/RIF test cartridges to diagnose TB and DR-TB patients, sufficient attention has not been paid to the treatment of detected patients. Without proper handover of the Xpert equipment, the continuity and sustainability of the 25 GeneXpert machines is at risk.

Our recommendations for PT ISI are as follows:

- Improve communication with the NTP and partners – for example, organise a partners meeting to create more awareness on the PT ISI project, achievements and challenges.
- More generally, strengthen collaboration, with national and provincial NTP, health facilities and partners.

- Ensure that TB patients detected are enrolled on treatment as soon as possible. Focus especially on patients referred for further MDR-TB assessment and possible DR-TB treatment initiation at Persahabatan Hospital.
- Actively engage with the NTP and other donors or private sector to ensure the sustainability of UNITAID GeneXpert machines.
- Focus attention on a few enhanced case finding interventions for effective performance/ results (rather than doing a mix of various interventions in one site or changing the strategy over time, which causes confusion).
- Critically appraise the functioning of the social business model and carry out detailed forecasts and projections to ascertain a suitable model that can be sustained given the specifics of the population and health systems in Jakarta. For example, as a start, a detailed mapping of the private health facilities in Jakarta is required, in terms of the number of daily consultations, including proportion of pulmonary cases. Such an analysis will inform the potential structure of an effective social business model in Jakarta.

Our recommendations for UNITAID/ WHO/ TB REACH are as follows:

- A project duration of two years is too short to introduce a new technology in a country, establish a social business model and at the same time make sure it is fully embedded and accepted in the country's PMDT plan. More time (whether through a project extension or additional support) should be given to grantees to ensure thorough learning and proper embedding of the TBXpert project into the country's PMDT approach.
- Support the government processes that have been initiated for takeover of the GeneXpert machines after UNITAID funding is completed. More generally, encourage sustainability/ transition planning from the start of a project.

### List of consultations

Table A7.2 presents the list of in-country stakeholders with whom consultations were held.

*Table A7.2: Field visit consultee list*

Stakeholder category	Organisation / Department	Name and position
NTP	Sub Directorate of Tuberculosis, DG DC & EH, Ministry of Health	Dr. Vanda Siagian, Deputy Programme Manager, Head of Standardization Dr. Triya Dinihari, Deputy Programme Manager, Head of Monitoring and Evaluation Dina Frasasti, Technical Officer MDR-TB Eka Sulistiany

Stakeholder category	Organisation / Department	Name and position
	Provincial Health Office	Ida Kurniawati, Provincial TB Programme Manager, Jakarta
<b>TB REACH Grantee</b>	Project Inovasi Sehat Indonesia (PT ISI)	Dr. Roy Tjiong, Director ISI Dr. Aditiawarman, MPH – Chief Operational Officer Dr. Sri Dhuny Asri, SpP (Pulmonologist) - Clinical Manager Dr. Enrico Rinaldi - Business Development & Networking Manager Dr. Yusie Permata, MIH - M&E Manager Asrilla Noor, Training Manager Ali Akbar, ST – IT Manager Desri M. Purba, SKM - M&E Staff Dinasti Mularsih, SKM – M&E Staff Dhevie Talumewo - Procurement & Logistic Officer
<b>Persahabatan Hospital, OPD TB, MDR-TB, C/DST lab</b>	Doctors	Dr. Heidy Agustin, Pulmonologist  Dr. Rinaldi, Microbiologist
<b>Diagnostic Centre PDPI</b>		Lab technician
<b>St. Carolus Clinic</b>	Nurse at OPD Patient ISI Screener	Explanation OPD procedures One anonymous patient interviewed Explanation screening and transport of specimen
<b>RSUD Pasar Rebo</b>	Doctors	Dr. Julaga Tobing, Vice Director; Dr. Subagyo, Pulmonologist; Dr. Aziza Ariyani, Head of Laboratorium
<b>Others</b>	WHO Indonesia	Dr. Muhammad Akhtar, Medical Officer Tuberculosis Programme; Dr. Setiawanjati Laksono (NPO), TB/PMDT Coordinator; Dr. Benjamin Sihombing, TB Coordinator; Mikyal Faralina (Ella), TB/PMDT staff
	Central TB reference laboratory	Andriansjah, PhD, Microbiology Lab of Faculty of Medicine, University of Indonesia (National Referral Lab for Molecular Technology)
	KNCV, Challenge TB	Dr. Jhon Sugiharto, Deputy Director Technical Services Roni Chandra, Senior Technical Officer Laboratory
	IRD	Dr. Fauziah Putri, Manager
	FHI360	Dr. Betty
	Harvard School of Public Health	Dr. Anuraj Shankar, Senior Research Scientist, Department of Nutrition

## ANNEX 8 ANALYSIS OF SELECT PROJECT PROGRESS INDICATORS

This annex supports the analysis in the main report, presenting additional analysis on the progress indicators reported in the available Annual and Semi-Annual Progress Reports. It is noted that at the time of the evaluation, 2014 annual data was not yet available, and not all indicators are reported in the Semi-Annual Report. Therefore, this analysis is principally of 2013 progress against targets, which we acknowledge provides only a small portion of the progress to date.

The following sections look at the indicator data on:

- Procurement
- Tests performed, number of individuals tested and case detection

### Procurement

*Indicator O1.3: “Median number of days between date of planned delivery of GeneXpert instrument order at port of entry and date of actual delivery at port of entry”.*

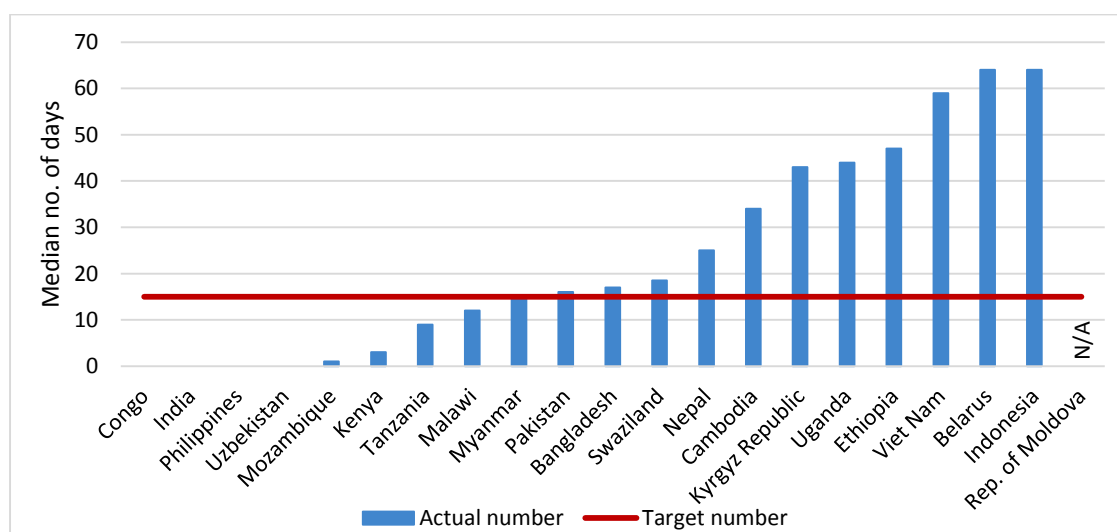
*Target: 15 days*

Figure A8.1 shows the median difference in days between planned and actual delivery of instruments in 2013, with countries exceeding the target shown as crossing the red line.

#### Key Points:

- 8 countries achieved the target, and Congo, India, Philippines and Uzbekistan reported a median number of days of 0 between planned and actual delivery of instruments in 2013.
- 12 countries exceeded the target of 15 days between planned and actual delivery.
- The worst performers in 2013 were Belarus and Indonesia who both reported a median delay of 64 days.

Figure A8.1: Median difference in days between planned and actual delivery of instruments in 2013.



Source: 2013 Annual Report

**Indicator O1.4: “Median number of days between date of planned delivery of Xpert MTB/RIF cartridges order at port of entry and date of actual delivery at port of entry”.**

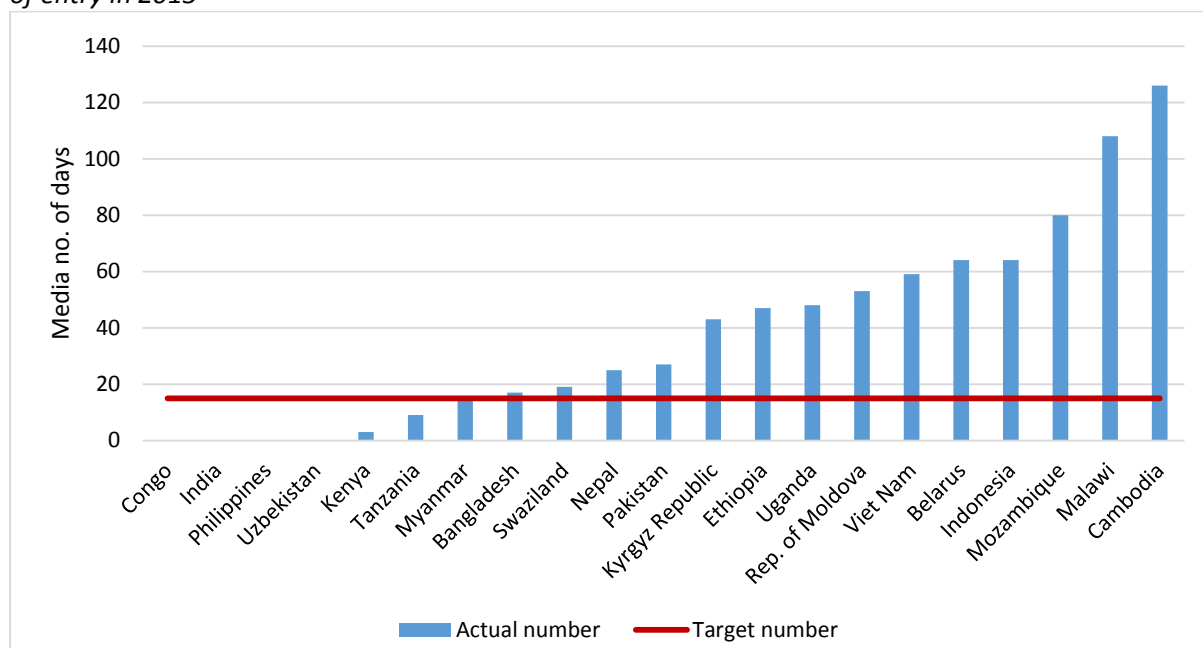
Target: 15 days.

Figure A8.2 shows the median difference in days between planned and actual delivery of MTB/RIF cartridges in 2013.

**Key Points:**

- 7 countries achieved the target, Congo, India, Philippines and Uzbekistan reported a median number of days of 0 between planned and actual delivery of instruments in 2013.
- 14 countries exceeded the target of 15 days between planned and actual delivery.
- The worst performers in 2013 were Cambodia and Malawi who both reported a median delay of 126 and 108 days respectively.

Figure A8.2: Median number of days between planned and actual delivery of order of cartridges at port of entry in 2013



Source: 2013 Annual Report

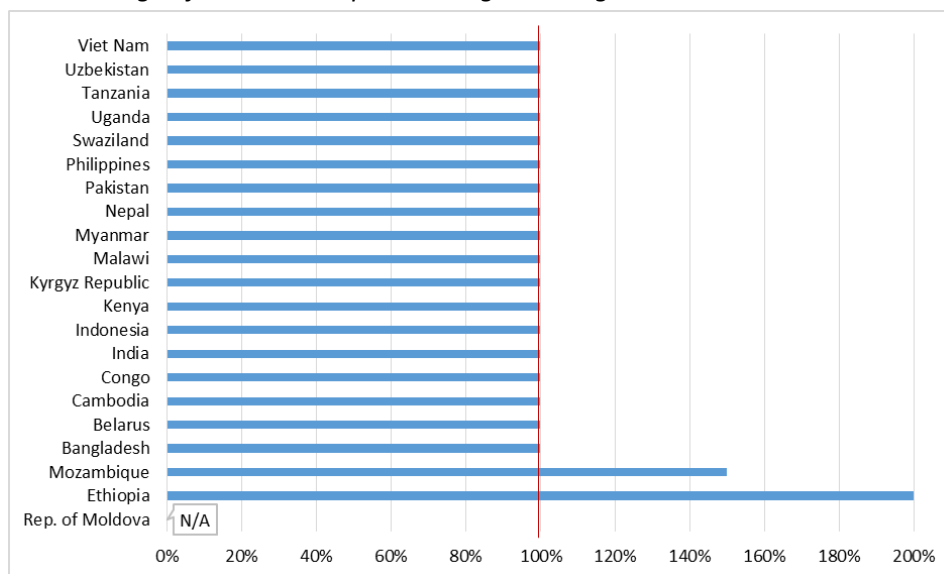
**Indicator O1.1 Number of GeneXpert instrument modules procured within framework of TBXpert Project**

Figure A8.3 presents the progress achieved by each of the project countries in procuring GeneXpert instrument modules in 2013.

**Key Points:**

- All project countries achieved their 2013 instrument procurement target.
- Moldova did not have targets for instrument procurement under the project framework.
- Mozambique and Ethiopia actually exceeded their target, each procuring and additional 16 instruments.

Figure A8.3: Percentage of instruments procured against targets in 2013



Source: 2014 Annual Report

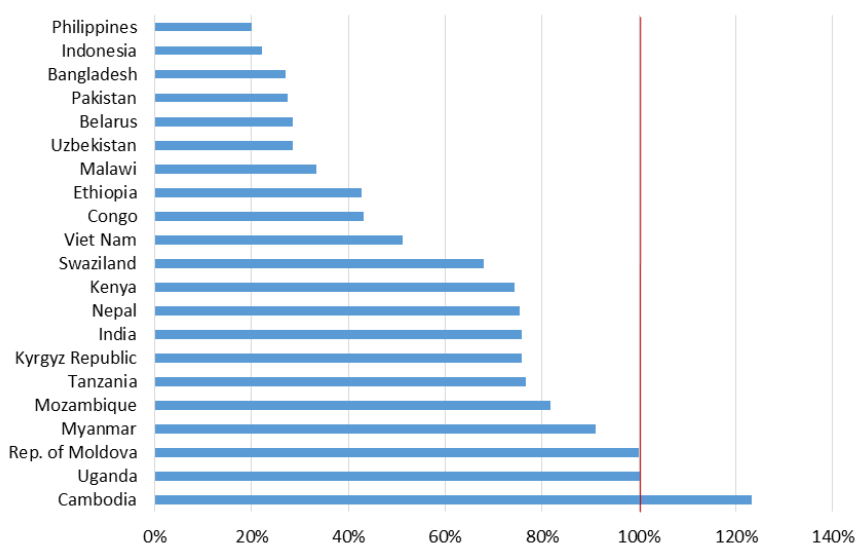
**Indicator O1.2 Number of Xpert MTB/RIF cartridges procured within framework of TBXpert Project**

Figure A8.4 presents the progress achieved by each of the project countries in procuring MTB/RIF cartridges in 2013.

**Key Points:**

- Cambodia, Moldova and Uganda each achieved their procurement targets, with Cambodia exceeding its target by 23%.
- Poor performers included Philippines, Indonesia Bangladesh, Pakistan and Uzbekistan, who all failed to reach 30% of their target.

Figure A8.4: Percentage of cartridges procured against targets in 2013



Source: 2013 Annual Report

## Tests performed, individuals tested and case detection

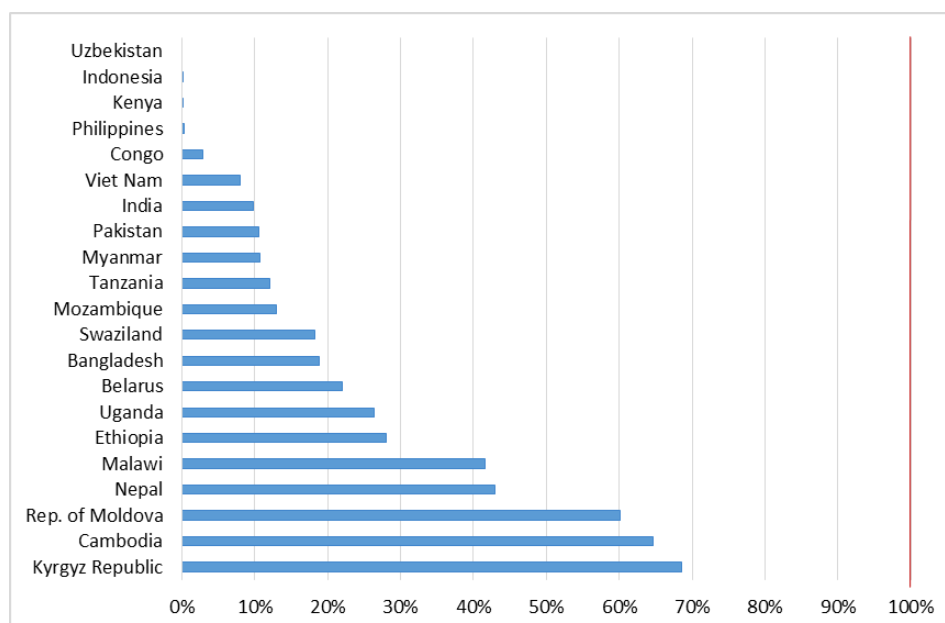
### Indicator O2.2 Cumulative number of Xpert MTB/RIF tests performed using TBXpert Project commodities

Figure A8.5 presents the progress achieved by each of the project countries in performing tests using the TBXpert project commodities in 2013.

#### Key Points:

- No country achieved its target in 2013. This may be a result of the delay in cartridge procurement, which meant that implementers were late in initiating testing in 2013.
- Uzbekistan, Indonesia, Kenya and the Philippines achieved very low testing rates.
- Kyrgyzstan, Cambodia and Moldova were the only project countries to achieve a target rate of 60% or above.

Figure A8.5: Percentage of cumulative number of tests performed against targets in 2013



Source: 2013 Annual Report

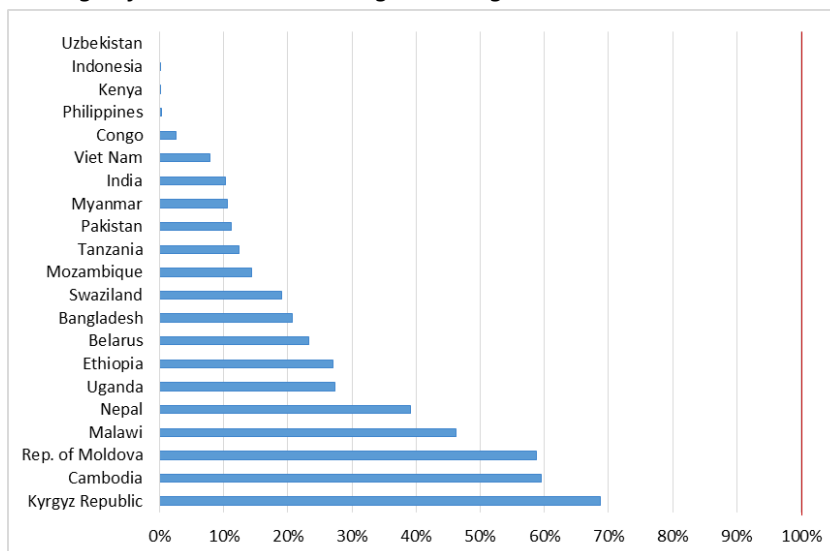
### Indicator O2.3 Number of individuals tested with Xpert MTB/RIF using TBXpert Project commodities

Figure A8.6 presents the progress achieved by each of the project countries in testing individuals using the TBXpert project commodities in 2013.

#### Key Points:

- No country achieved its target in 2013. Again, this may be a result of the delay in cartridge procurement, which meant that implementers were late in initiating testing in 2013.
- Country performance mirrors that of progress achieved in reaching O2.2 targets (see figure above).

Figure A8.6: Percentage of individuals tested against targets in 2013



Source: 2013 Annual Report

**Indicator G1.1: “Number of incident TB patients detected using TBXpert project commodities”**

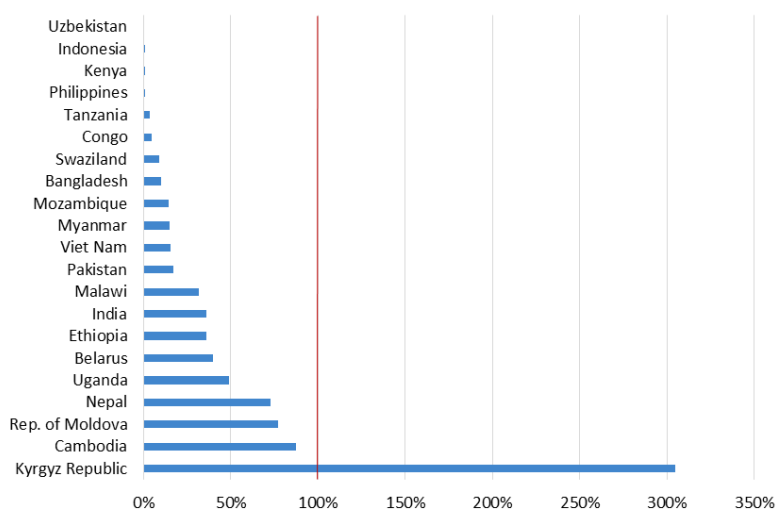
Target: 30,258 (20,441-40,075) in 2013 and 76,559 (51,744-101,373) in 2014, plus individual targets per country.

2013 target not achieved. Figure A8.7 shows the progress each of the project countries has made in achieving its G1.1 outcome target in 2013.

**Key Points:**

- Kyrgyz Republic exceeded its target by over 200%
- All other countries did not reach their targets, with the best performers being Cambodia, Nepal and Moldova who achieved 87%, 73% and 77% respectively.
- Uzbekistan and Indonesia did not report any detection of incident TB cases; this was due to fact that both countries did not start testing until January 2014.

Figure A8.7: Percentage of 2013 incident TB patient detection target reached



Source: 2013 Annual Report



**Indicator G1.2: “Number of incident HIV-positive TB patients detected using TBXpert project commodities”.**

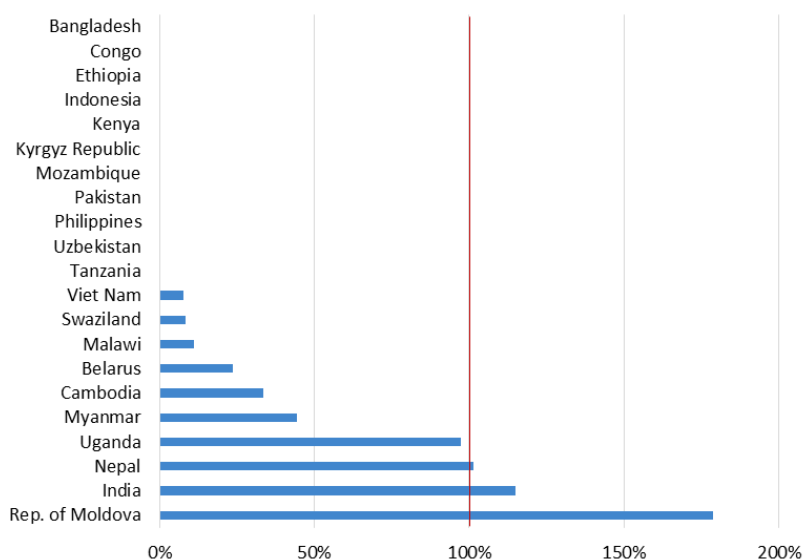
Target: 4,931 (3,136-6,725) in 2013 and 12,283 (7,837-16,729) in 2014, plus individual country targets.

2013 target not achieved. Figure A8.10 presents the progress achieved by each of the project countries in reaching their target of detecting HIV-positive patients with TBXpert commodities in 2013.

**Key Points:**

- India, Nepal and Moldova each achieved their target of HIV-positive TB case detection. India surpassed its target by 15% and Moldova by 79%.
- Performance amongst other countries was poor, with 11 countries achieving 0% of their target.

Figure A8.10: Percentage of 2013 HIV-positive TB patient detection target reached



Source: 2013 Annual Report

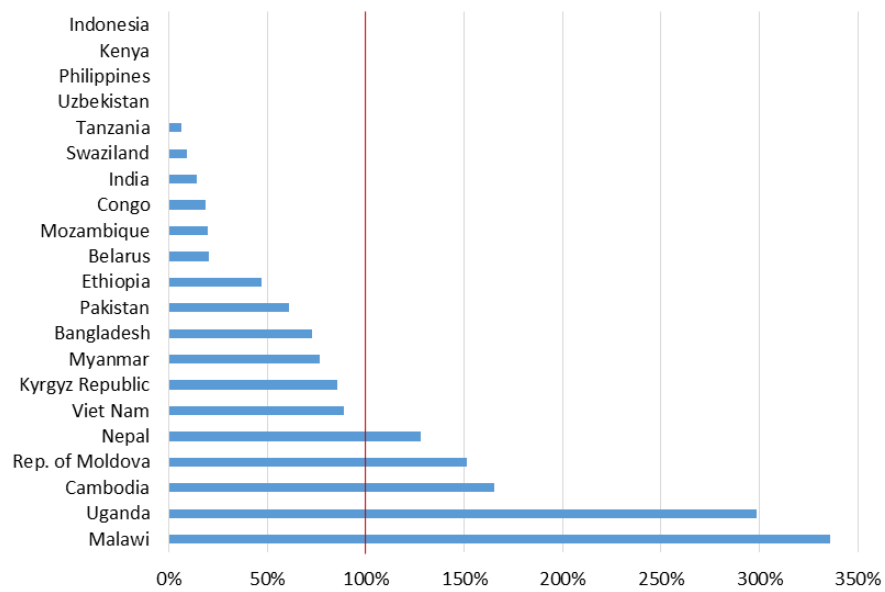
**Indicator G1.3 Number of incident rifampicin-resistant TB patients detected using TBXpert project commodities**

Figure A8.11 presents the progress achieved by each of the project countries in reaching its target of detecting RIF resistant TB patients with TBXpert commodities in 2013.

**Key Points:**

- Project countries performed better in detecting RIF-resistant TB cases during 2013.
- Cambodia, Malawi, Nepal, Moldova and Uganda all exceeded their targets for this output, and only four countries (Uzbekistan, Philippines, Kenya and Indonesia) failed to detect any RIF-resistant cases.

Figure A8.11: Percentage of 2013 rifampicin-resistant TB patient detection target reached



Source: 2013 Annual Report