

TECHNICAL HIGHLIGHT



Overcoming Maintenance Challenges Associated with GeneXpert Machines — Experience in Bangladesh

CTB Lab advisor replacing the defective module of a GeneXpert machine at CDC Kishoregonj

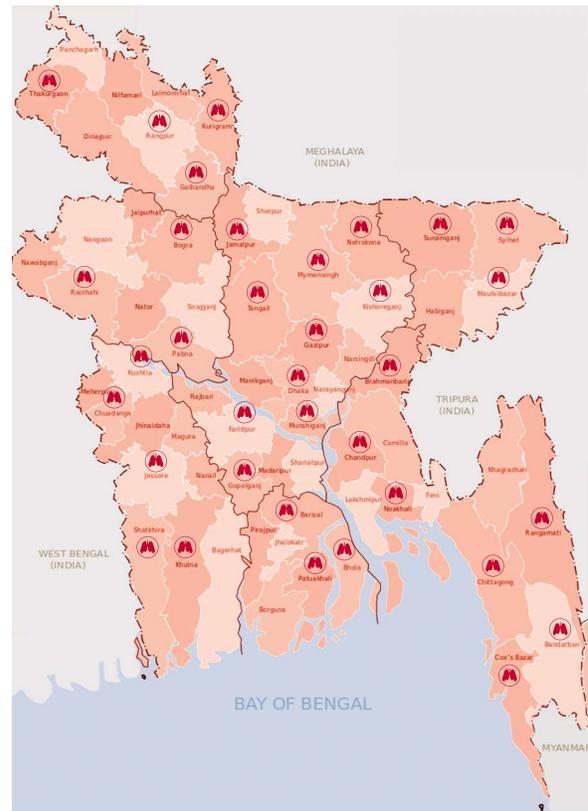
PROJECT CONTEXT

GeneXpert has revolutionized the diagnosis of tuberculosis (TB) and drug resistant TB (DR-TB) by effectively detecting *M. tuberculosis* in clinical specimens and RMP resistance in less than two hours without sophisticated laboratories. This enables patients to begin treatment for rifampicin resistant TB on the same day, rather than after several months of ineffective treatment.

Through the TBCARE II Project, USAID supported the expansion of NTP’s diagnostic capacity and installed 39 GeneXpert machines between 2012 and 2014. Most of the machines (23) were placed in district level Chest Disease Clinics (CDCs) across the country; the remaining 16 are in tertiary level hospitals in Dhaka City, including the Chest Disease Hospital-CDH, National TB Reference Laboratory-NTRL, Regional TB Reference Laboratories-RTRLs and specialized hospitals (Figure 1).

In April 2015, as the TB CARE II project phased out, Challenge TB Bangladesh, implemented by Management Sciences for Health (MSH), took responsibility for operationalizing the 39 GeneXpert machines (228 modules in a total) in 38 centers across the country.

FIGURE I. Geographic Distribution of GeneXpert



BANGLADESH

PROBLEM STATEMENT

In July 2015, an initial exploratory assessment of GeneXpert machines was conducted by the project and found nine non-functional machines (out of 39) in addition to multiple module failures among the GeneXpert network. During this time, CTB experienced significant maintenance challenges from lack of an implementation plan by the predecessor project and slow troubleshooting support from the manufacturer, Cepheid. There were no established mechanisms to support the module replacement

process, which included customs clearance of shipped modules and spare parts by NTP, module swap (exchange of defective module with new module between country and Cepheid EU), routine troubleshooting, and GeneXpert check run.

The GeneXpert check test (formerly called calibration) was not performed routinely, even though it is required by Cepheid to maintain the warranty and is also crucial to ensuring that the GeneXpert provides accurate results. The customs clearance was very complicated due to

bureaucracy and a weak monitoring system. Also, returning defective modules to Cepheid EU was a big challenge for NTP, as they don't have an established mechanism to pay shipment costs. Many maintenance issues were due to poor placement of the instruments in facilities and lab technicians' lack of knowledge to implement routine preventive maintenance practice. Also, the supply chain management was weak that led to chronic shortage of cartridges in 2015 leading to emergency procurements.

Dusty module at the beginning of the Challenge TB Bangladesh project



Dusty computers at the beginning of the Challenge TB Bangladesh project



PROJECT IMPLEMENTATION

There are 39 NTP-supported¹ GeneXpert machines in 38 sites across the country (six GX16 and 33 GX4 machines = 228 modules). Upon taking responsibility for improving and ensuring proper maintenance, CTB revived communications with Cepheid EU and the local Cepheid agency and renewed all 39 warranties (three years for each GX4 and one year for each GX16 machine). CTB began regular engagement with the local Cepheid agency to ensure timely maintenance support.

With CTB support, one member of the NTP's staff (M&E officer) and a CTB lab advisor were sent to Toulouse, France, to be trained on GX maintenance and troubleshooting. CTB calibrated

36 machines and replaced more than 100 broken modules since December 2015 in phases.

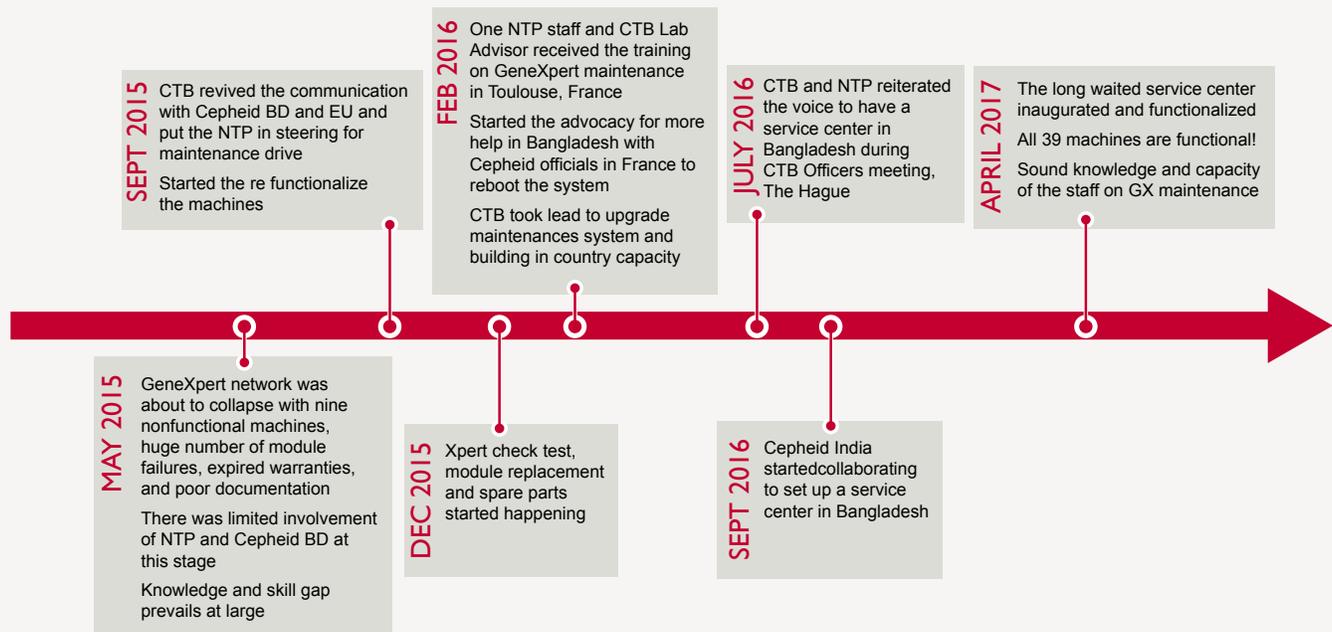
CTB also conducted feedback workshops on GeneXpert centers' performance in APA2 for the operators (medical technologists), CDC consultants/ lab coordinator/ lab focal person from partners, supportive supervision of GeneXpert sites to monitor the performance of the network.

CTB developed the monitoring standard operating procedures (SOPs), checklist, and implementation plan for NTP Bangladesh to address staff shortage, and provided training on routine GeneXpert maintenance.

CTB provided NTP with technical assistance to build regional pools of trained staff with onsite maintenance demonstrations of the GeneXpert during regular supervision and visits. The project also advocated at different international meetings to establish a GeneXpert service center in Bangladesh as a permanent solution for maintenance.

In November 2016, CTB introduced the GXAlert software to all GeneXpert sites (currently 32 covered) to monitor the machine's performance and data capture in real time and provide necessary feedback to improve the utilization, cartridges, consumable forecasting, and maintenances of the machines.

FIGURE 2. Timeframe for GeneXpert support in Bangladesh from Challenge TB.



¹ A few machines are managed within the NGO sector primarily with icddr,b, purchased through TB REACH. The icddr,b managed machines are in Dhaka (and soon Sylhet) and used for TB diagnosis among more affluent segments of the population who are able to pay for a chest x-ray, with free GeneXpert as follow-up if indicated.

RESULTS AND ACHIEVEMENTS

By initiating, re-engaging, and expanding communications among NTP, the local Cepheid agency, and other stakeholders, CTB has streamlined the process by which maintenance issues are addressed. Through these multi-pronged efforts, all 39 GeneXpert machines are now functional and have up-to-date GeneXpert check test statuses. While a few modules are pending intervention, more than 206 out of 228 (90%) modules are functional (Figure 3).

After persistent advocacy by CTB at international meetings and fora, Cepheid established a GeneXpert service center in Bangladesh by acknowledging the country’s needs. This has increased interest and enthusiasm among donors and partners for expanded availability and use of GeneXpert

As full functionality² of machines increased, this has resulted in more tests to diagnose TB and DR-TB cases as shown in Figure 4.

To mitigate a backlog, CTB trained and oriented the staff at all GeneXpert sites on basic maintenance.

The turnaround time for module replacement has been slashed from 5 -12 months down to two weeks. CTB devised a faster mechanism of customs clearance for NTP involving the Cepheid local agency. The inventory/shipment of spare parts/ modules is properly managed and

FIGURE 3. Status of GeneXpert Modules

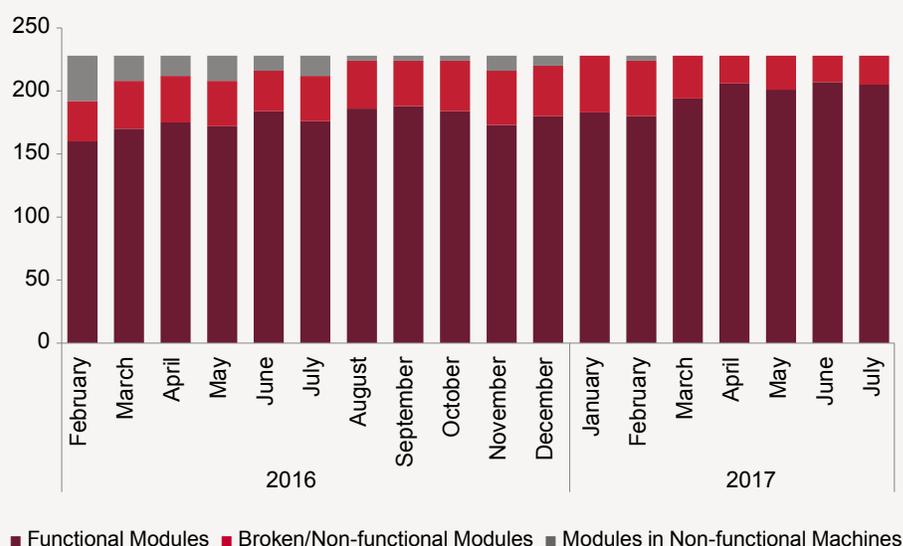
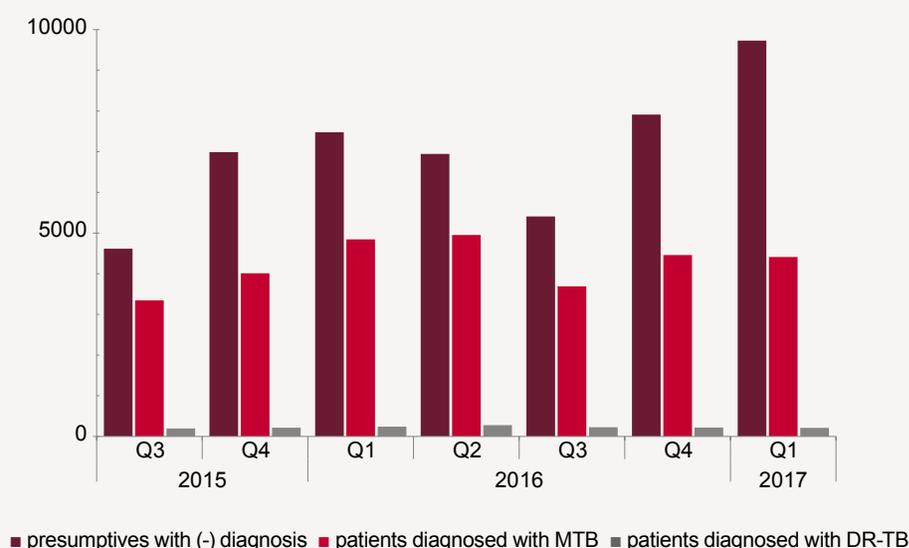


FIGURE 4. GeneXpert Testing for Presumptive TB



monitored and no lost cases have been reported. Warranties and other relevant information are now well documented

and NTP has created a position for a focal person to oversee the NTP-managed GeneXpert network.

² Functionality at 100% is not possible in most field settings because modules that become non-functional occur at random and replacement is not immediate.

Acknowledgements

Thank you to all of the staff from Challenge TB Bangladesh for their support in the development of this technical highlight.

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LESSONS LEARNED

GeneXpert maintenance remains challenging in many countries around the world. Proactive efforts by CTB Bangladesh, a strong relationship with NTP, partners, and Cepheid played a vital role in successfully strengthening the existing system. The complexity of decision-making and action in the Bangladeshi health system and inadequate maintenance support from manufacturer may not allow the complete benefit of the rapid diagnostic to be fully realized. Due to poor implementation, new technologies that can significantly change the way TB and MDR-TB are

diagnosed can be deemed not feasible and abandoned. In the absence of increased support, more robust diagnostic technology will be required for settings like Bangladesh to reach END TB targets. Therefore, it is critical to have proper support, placement, and buy-in of new technology by the country program before implementation. Establishing systems for maintenance and links to service providers is essential to sustain a TB diagnostic network.

WAY FORWARD

It will be critical to appoint a full time GeneXpert network manager to ensure optimum utilization of the machines. Additionally, NTP should enforce the GeneXpert implementation plan, monitoring tools, and SOPs and should take over the full responsibility of the network and secure the required funding to scale, strengthen and sustain the network and be prepared enough to take

over upcoming developments of the GeneXpert technology. This includes the introduction of GeneXpert MTB/RIF Ultra to better diagnose TB in children and people living with HIV, Omni to expand molecular diagnostic testing close to population as a point of care diagnostic tool, and C360 for real-time disease and system surveillance information.

The Global Health Bureau, Office of Health, Infectious Disease and Nutrition (HIDN), US Agency for International Development, financially supports this publication through Challenge TB under the terms of Agreement No. AID-OAA-A-14-00029 This publication is made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of Challenge TB and do not necessarily reflect the views of USAID or the United States Government.