TECHNICAL HIGHLIGHT

Institutionalizing a prefabricated Bio-Safety Level-3 laboratory: Lessons from Bangladesh

Performing MTB culture and DST (solid medium) in the BSL-3 lab (Photo credit: CTB)

BACKGROUND

The US Agency for International Development (USAID)-funded Challenge TB (CTB) Bangladesh Project worked with the National TB Control Program (NTP) to strengthen laboratory services and systems by improving laboratory capacity for diagnosis and treatment monitoring of tuberculosis (TB) and drug-resistant TB (DR-TB) patients. This includes improving and expanding the capacity of Regional TB Reference Laboratories (RTRLs) to provide quality lab services for increased detection of TB and DR-TB.

The TB laboratory network under the NTP represents a functional hierarchy, with the National TB Reference Laboratory (NTRL) of the National Institute of Diseases of the Chest and Hospital, Dhaka, at the top. Under the direct supervision of the NTRL, the NTP has RTRLs in Rajshahi, Khulna, and Chittagong. Based on identified need and in accordance with the NTP's Strategic Plan (2012–2017), Sylhet division, which includes many hard-to-reach districts and upazilas (sub-districts), was selected to install a new RTRL. Timely follow-up culture of DR-TB patients missed is poor this region, as mycobacterium tuberculosis (MTB) patients are referred to the NTRL or RTRLs in other divisions, far from Sylhet, or the sample is lost or has deteriorated when sent by courier.

Ensuring the appropriate infrastructure design and biosafety standards was challenging as old buildings were converted to NTRLs and RTRLs. Considering the geographical importance and patient benefits, the NTP decided to establish a high-quality regional TB laboratory that met international standards in Sylhet to expand the country's TB diagnostic capacity, and it selected a containerized approach to minimize cost and infrastructure challenges. A Bio-Safety Level-3 Laboratory (BSL-3 lab) in Sylhet would accelerate TB and DR-TB diagnosis and treatment management in the northeast region of the country. This BSL-3 lab, the highest level of safety of its type in Bangladesh, provides rapid and quality services. It has state-of-the-art diagnostic technologies that are particularly effective in testing for DR-TB. The laboratory can be used to perform solid culture and drug susceptibility testing (DST) for first- and second-line TB medicines and also provides support to the rapid diagnosis of rifampicin-resistant TB through GeneXpert and other novel diagnostic tools.

BANGLADESH

IMPLEMENTATION

The laboratory was planned by TB CARE II project in 2013- 2014. The laboratory was built in South Africa, and installed by CTB with support from the NTP; Divisional Director (Health) office, Sylhet; Civil Surgeon office, Sylhet; Public Works Department (PWD); and Sylhet City Corporation. The Global Fund supported renovating the site's infrastructure. PWD and PDB supported the renovation and setting up an electric substation. The NTP helped to identify and engage key stakeholders through consultative meeting and continuous advocacy efforts. The NTP also worked with government counterparts to ensure strong political commitment for the lab.

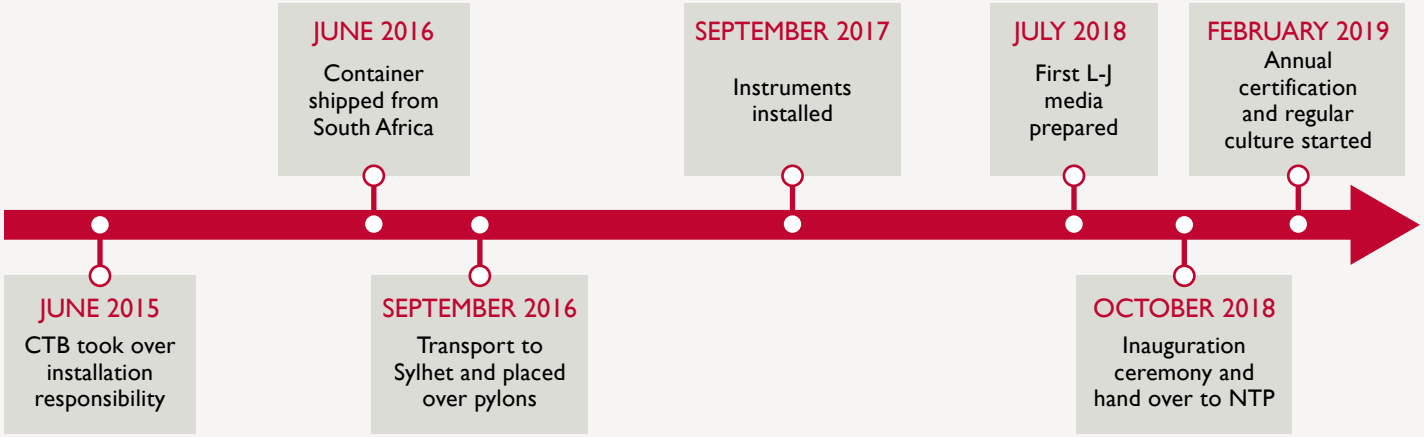
USAID provided the necessary funds to establish a containerized BSL-3 TB laboratory at Sylhet. The open space in front of the Chest Disease Hospital (CDH) was chosen as the site, by the NTP and the University Research Co., LLC (URC) TB CARE II Bangladesh Project started the process of establishing this laboratory in early 2015.

In spring 2015, the responsibility of completing the activities needed to establish this laboratory was handed over to CTB from TB CARE II Project. Numerous challenges were faced, including shipment of the lab from South Africa, paying VAT and taxes, transporting the containers from the port of Chittagong to the site, placement of the container over the pylon, and setting up the electric substation. Support came from the NTP, other related Government of Bangladesh (GoB) offices, donors, international experts, and the local authority, all of whom were eager to have the country's first containerized BSL-3 lab. CTB supported the NTP to complete several activities, such shipping the laboratory from South Africa, placing it on the site, and providing insurance and security services.

The Air Filter Maintenance Services (AFMS) team trained the BSL-3 lab team on how to operate the lab and provided standard operating procedures and biosafety guidelines developed by the CTB lab advisor.

Site preparation for placement of the BSL-3 lab (Photo credit: Sharmin Islam, CTB)

FIGURE 1. Timeframe for BSL-3 laboratory implementation



RESULTS AND ACHIEVEMENTS

CTB, with support from the NTP, had the BSL-3 lab shipped from South Africa and transported it to the site at Sylhet in September 2016. The project installed the lab and set up the equipment in September 2017, and it became operational in September 2018. The project handed over the functioning lab to the CDH under the Ministry of Health and Family Welfare (MoHFW) of Bangladesh in October 2018 along with a year's supply of selected consumables. At the inauguration ceremony, the Honorable Minister of Finance expressed his gratitude to USAID for supporting the creation of the BSL-3 lab in Sylhet.

CTB has been providing security services since October 2016. The laboratory has a built-in effluent decontamination system for environmental safety. As of March 2019, the lab team had performed L-J cultures on 165 DR-TB patients to monitor treatment. The GeneXpert machines have been used for 10,605 tests and confirmed 247 rifampicin-resistant patients. The lab passed its yearly calibration and certification, conducted by AFMS, in February 2019.

The Honorable Minister of Finance and a representative of USAID inaugurated the BSL-3 laboratory on October 18, 2018 (Photo credit: Samuel Murmur, CTB)

LESSONS LEARNED

Installing a prefabricated, containerized laboratory was a new experience for Bangladesh. Identifying and engaging key stakeholders and securing strong political commitment is crucial for establishing and institutionalizing such a lab in a resource-constrained country like Bangladesh. This type of sophisticated laboratory has several pre-installation steps, including securing permission from the Power Development Board; complying with regulatory bodies; and coordinating with the government for shipment, value-added tax, and other taxes. These activities should be planned at the beginning of the project. CTB gained valuable insight while implementing this project and involved key stakeholders through advocacy. An intense consultative process was followed to involve GoB counterparts, local health authorities, civil society organizations, and other implementing partner in establishing the lab.

Stakeholder engagement at times was complicated because of the wide range of stakeholders some of whom were beyond direct control of the MoHFW. The Ministry of Finance needed to be involved for customs clearances and taxes. The Public Works Department and Power Development Board were involved to develop the infrastructure

Entrance of the BSL-3 lab (Photo credit: CTB)

Control Panel of the BSL-3 lab (Photo credit: Samuel Murmu, CTB)

and connect the power supply. The government department of fire and environmental ministry were involved in the review of fire safety issues. The city corporation of Sylhet helped put a fence around the site. Civil society members in Sylhet worked to expedite the process. The project needed to engage all those actors to establish and operationalize the lab. Splitting the cost evenly between the GoB and CTB set a new precedence for cost sharing for the donor and implementers.

Inside the BSL-3 lab (Photo credit: CTB)

WAY FORWARD

The laboratory will serve as a center of excellence to provide TB and DR-TB diagnostic services, build staff capacity at the regional level, conduct operational research, and serve as a TB education center. It will ensure the highest level of safety for staff, equipment, and the environment. Multipronged efforts by the NTP and donors are needed to mobilize resources and sustain lab operations. Given the implementation experience, the scalability of a prefabricated BSL-3 lab would have low marginal cost to provide TB diagnosis services to vulnerable populations. Before initiating such sophisticated interventions, implementers should identify and engage key stakeholder through advocacy and highlight the benefits, ensure political commitment, orient manufacturers to the local context and potential delays in the implementation phase, train lab staff, and establish a strong monitoring system. Long-term sustainability of the laboratory will require NTP support of all operational and maintenance cost, human resources support, and ongoing safety and security consideration.

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