

# Critical Pathway Analysis for Introducing New Tuberculosis Diagnostics in Bangladesh

**Final report**

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## **Executive summary**

Bangladesh, a country in South Asia, has been classified by the World Health Organization (WHO) as a high TB-burden country and currently ranks 8th globally, with an annual incidence of 379,000 tuberculosis (TB) cases. Recognizing TB as a major public health threat, Bangladesh has pursued strong control policies since its independence through the National TB Control Programme (NTP). In 2015, the country adopted the WHO's End TB Strategy, which envisions a 95% reduction in TB-related deaths and a 90% reduction in TB incidence by 2035, aiming to lower the incidence rate from a projected 225 cases per 100,000 in 2015 to 10 cases per 100,000 or fewer.

While WHO standards guide the NTP's policies and strategies standards, systemic delays in the introduction of new TB diagnostics in the country undermine progress and strategic decisions. To better understand these challenges, Child Health Research Foundation, in partnership with McGill University, Canada, conducted a Critical Path Analysis (CPA) on introducing new TB diagnostics in both the public and private sectors of Bangladesh.

The CPA was conducted in the context of an unchanged TB incidence trend in the country. We reviewed existing literature, national TB reports, meeting notes, and policy papers, and conducted interviews with the key stakeholders in the country's TB control program to map the pathway of introducing TB diagnostics in Bangladesh, from regulatory approval to point-of-care use.

Our CPA analysis revealed that introducing a TB diagnostic in the public sector typically requires 3-6 years. Strong government commitment to the NTP and the robust community health networks serve as key enablers, while multisectoral engagement offers opportunities for the rapid scale-up. However, securing financing for TB diagnostics and obtaining WHO Prequalification (PQ)

certification remain critical, as limited public funding and donor dependency on WHO PQ slow down the progress. Other barriers include lengthy regulatory processes, shortage of trained personnel, and weak supply chain systems.

Stakeholder consultations further highlighted the need to integrate point-of-care diagnostics into TB programs through a demand-driven approach. Despite its significant role in healthcare delivery, the private sector remains underutilized in TB control. Stronger private sector engagement could play a pivotal role in accelerating progress toward End TB targets.

In conclusion, the CPA underscores the need to harmonize regulatory pathways to reduce approval delays, increase public financing, and foster collaboration among public and private stakeholders for coordinated action.

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## Critical pathway analysis for introducing new tuberculosis diagnostics in Bangladesh

### Background

Tuberculosis (TB), caused by *Mycobacterium tuberculosis*, is a centuries-old airborne disease that remains one of the world's deadliest infections, with 10.8 million new cases reported globally in 2023. Despite sustained efforts by governments, development agencies, donors, and technology partners, the number of active TB cases continues to rise, reversing the declining trend observed until 2020.<sup>1</sup>

Bangladesh, a country in South Asia, is ranked among the world's top eight high-burden countries for TB. In 2022, a total of 307,561 TB cases were identified in Bangladesh, corresponding to an incidence of 221 per 100,000 population.<sup>2</sup> Additionally, 18% TB cases in the country go undetected, posing serious challenges to TB control efforts in Bangladesh.<sup>3</sup> The TB incidence rate in Bangladesh has remained almost constant the last 10 years, (225/100,000 population in 2015 to 221/100,000 population in 2022, which makes it challenging to meet the target set by Bangladesh to reduce TB incidence by 90% reduction in tuberculosis incidence rate from 225 cases per 100,000 in 2015 to 10 cases per 100,000 or less by 2035.<sup>2</sup> The current TB scenario in Bangladesh is summarized in Table 1.

Table 1: Estimated population and TB Burden in Bangladesh 2023

Criteria	*Value
Population	171 million
Incidence rate	221 per 100,000 population
TB associate mortality rate	26per 100,000 population
Incidence of MDR/RR-TB	2.9 per 100,000 population

\*Global Tuberculosis Report 2024

Healthcare services related to TB in Bangladesh are mostly provided by the public sector and are operationalised through the National Tuberculosis Control Program (NTP), which has been effectively functional since 1965. The NTP is an entity under the Mycobacterial Disease Control (MBDC) Unit of the Director-General Health Service (DGHS). The NTP envisions ending the TB epidemic in the country and contribute in achieving a world free of TB, with zero deaths, disease, and suffering caused by TB. Its strategy is guided by four key principles: (i) strong government stewardship and accountability with robust monitoring and evaluation; (ii) building effective coalitions with civil society organizations and communities; (iii) safeguarding human rights, ethics, and equity; and (iv) adapting global targets to national contexts through international collaboration. The strategy is built on three interconnected pillars: (a) patient-centred care and prevention, including early diagnosis with universal drug susceptibility testing, systematic screening of contacts and high-risk groups; (b) bold policies and supportive systems, underpinned by strong political commitment, adequate resources, engagement of communities, civil society, and both public and private providers; and (c) research and innovation through the discovery, development, and rapid uptake of new tools and interventions.

With recent advancements in molecular diagnostics, the TB diagnostic landscape in Bangladesh has evolved. Alongside traditional low-sensitivity methods such as sputum smear microscopy, the introduction of WHO-recommended molecular tests like GeneXpert (in 2012) and Truenat (in 2020) has significantly enhanced the country's TB diagnostic capacity. However, an estimated 20% of all tuberculosis (TB) cases remain undiagnosed, highlighting critical gaps in TB case detection and reporting. Additionally, scaling up advanced molecular diagnostics such as GeneXpert has been hindered due to availability of supplies, equipment

maintenance challenges, and inequitable access, particularly for people in hard-to-reach areas.<sup>4</sup>

The introduction and scale-up of TB diagnostics in Bangladesh necessitate navigating complex systems that involve multiple stakeholders, regulatory hurdles, fragmented policies, logistical constraints, and community-level engagement.<sup>5,6</sup> Moreover, heavy reliance on donor funding further slows scaling of the diagnostics.<sup>7</sup> Therefore, private-sector diagnostic industry, often consider the TB market high-risk as a result, private investment in TB diagnostics in the country remains limited.<sup>8,9</sup>

Like many other LMICs, Bangladesh also has limited multisectoral collaboration and weak integration between the TB program and broader health and development sectors. Diagnostic gaps remain significant, particularly for children, extrapulmonary tuberculosis, rifampicin-resistant tuberculosis, and multidrug-resistant tuberculosis. Additional barriers, including dependence on imported diagnostic tools, delays in regulatory approval, and broader system inefficiencies, continue to hinder the timely introduction of innovative solutions in the country.

The Child Health Research Foundation (CHRF) in Bangladesh, in collaboration with McGill University, Canada, has conducted an in-depth assessment of the critical pathways for the introduction, early uptake, and scale-up of new TB diagnostics in Bangladesh to generate comprehensive qualitative insights for introducing and rapidly adopting new TB diagnostic tools in Bangladesh.

## **Aims and objectives**

The overarching goal of this project was to systematically analyse the critical pathways for introducing new TB diagnostics in Bangladesh and to identify key barriers that hinder their timely and effective adoption at scale.

### **Specific goals:**

1. To define the national TB diagnostic regulatory and approval pathways, including opportunities for regional regulatory harmonization to expedite the introduction of novel TB diagnostics.
2. To identify key challenges, including regulatory, financial, infrastructural, and sociocultural factors, that hinder the adoption and early implementation of new TB diagnostic tools.
3. To map the roles and perspectives of critical stakeholders (e.g., government agencies, private sector, international donors, and community actors) in facilitating or obstructing diagnostic introduction and scale-up.
4. To develop a country-specific roadmap for the early adoption and integration of new TB diagnostics into the existing health system, with consideration of health equity and sustainability.

## Methods

To achieve the project objectives, we have structured CPA work plan into four key workstreams (figure 1):

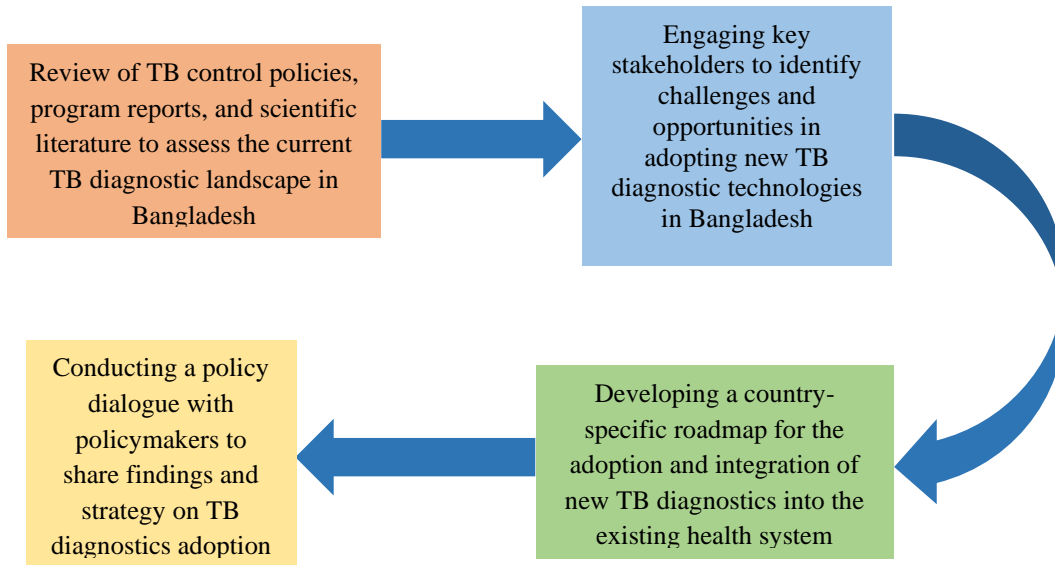


Figure 1: Conceptual Framework of CPA for adopting new TB diagnostics in Bangladesh

### 1. Review of Existing Literature and Program Reports

This stream involved a comprehensive review of TB control policies, program reports, and scientific literature to assess the current TB control landscape in Bangladesh. The goal was to identify crucial pathways for integrating new TB diagnostic tools into the NTP.

### 2. Identifying Key Stakeholders in the TB Control Program

This stream involved engaging with key individuals and organizations involved in TB control efforts in Bangladesh to gather insights into the existing challenges and opportunities for adopting new Tuberculosis Diagnostic Technologies.

### **3. In-Depth Interviews with the stakeholders**

This stream involved conducting in-depth discussions with a selected group of experts involved in TB control program in the country to gain insights into the barriers and facilitators influencing the introduction of new TB diagnostics in Bangladesh. To ensure consistency and comprehensive coverage of key themes, we used an interview guide to direct the discussions (Annexure 1). This qualitative approach allowed us to explore the perspectives and experiences of stakeholders directly engaged in TB control and provided a deeper understanding of the contextual, operational, and policy-related factors that influence the adoption of new diagnostic tools.

### **4. Plotting the Critical Pathway Analysis (CPA) for Future TB Diagnostics**

A high-level policy dialogue was convened with key stakeholders and policymakers to present the findings and develop strategies to streamline the adoption of TB diagnostics. The discussions contributed to the development of a comprehensive CPA framework aimed at expediting the introduction of new TB diagnostic tools in Bangladesh.

## **Results**

### **National Tuberculosis Control Program in Bangladesh**

The NTP in Bangladesh has evolved through several key phases. The NTP began operations in Bangladesh (then East Pakistan) in 1965, initially focusing on curative care through specialized TB clinics and hospitals. During the Second Health and Population Plan (1980–1986), TB services expanded to 124 Upazila Health Complexes, and in the Third Health and Population Plan (1986–1991), these services were integrated with leprosy control under the Mycobacterium Disease Control Unit of the Directorate General of Health Services. A major shift occurred during the Fourth Population and Health Plan (1992–1998) with the adoption of the Directly Observed Treatment Short-course strategy (DOTS) under the project “Further Development of TB and Leprosy Control Services.” In 2002, DOTS services were extended to Dhaka Metropolitan City, and by 2007, TB control services had been scaled up nationwide.

4,10

Recognizing the need for stronger surveillance and accountability, the Government of Bangladesh declared TB a mandatory notifiable disease in 2014, a policy that is currently being operationalized. Over the past decade, more than 2 million individuals with TB symptoms have been tested annually, resulting in the prevention of approximately 1 million deaths, with TB case detection rising from 26% in 2001 to 74% in 2018.<sup>4</sup>

To minimize exposure to tuberculosis in healthcare and congregate settings, the Government of Bangladesh (GoB) introduced national TB infection control guidelines in 2011, in line with the recommendations of the WHO. Despite the establishment of these guidelines, the extent of their implementation across healthcare facilities in Bangladesh remains low.<sup>11</sup> Additionally, there are persistent delays in diagnosis and treatment undermining control efforts. Therefore,

the TB burden in the country remains considerably high. Patient delay in healthcare seeking also affects the TB control program as delay in TB diagnosis and treatment leads to more severe complications and increases TB transmission in the community.<sup>12</sup> Earlier reports showed that a substantial proportion of patients in Bangladesh delay seeking appropriate medical care due to a lack of awareness regarding TB symptoms and the availability of treatment options. Diagnosis and treatment delays are primarily due to individuals not recognizing the TB symptoms and sought care from informal healthcare providers or drug vendors, who often lack the necessary training to diagnose and manage TB effectively. This reliance on informal healthcare providers further prolongs the time before accurate diagnosis and effective treatment can begin.<sup>13</sup> Weaknesses in diagnostic networks and a lack of coordination between TB services and other health programs also contribute significantly to these diagnostic delays.<sup>14</sup>

### **Landscape of TB Diagnostics in Bangladesh**

With the advances of TB diagnostic technologies globally, Bangladesh is using a set of tools to detect and manage TB cases. In Bangladesh, smear microscopy remains widely used because it is affordable and well-suited for point-of-care testing. In 2021, 1,119 laboratories across the country performed smear microscopy, and 3,797,978 samples were tested, with 161,997 presumptive TB cases identified.<sup>3</sup> In addition to smear microscopy, culture-based TB diagnosis was introduced in the country in 2007 and is currently available in 5 Regional TB Reference Laboratories across the country.<sup>3</sup>

To enhance TB diagnostics, Bangladesh is working on the phased replacement of microscopy by rapid molecular tests. Bangladesh introduced GeneXpert in 2010 through a research program and incorporated this detection method in the national program in 2012. However, scaling up of the GeneXpert technology was slow, requiring several years to become accessible to a larger population, and by 2024, 735 GeneXpert machines were in service nationwide (figure 2).

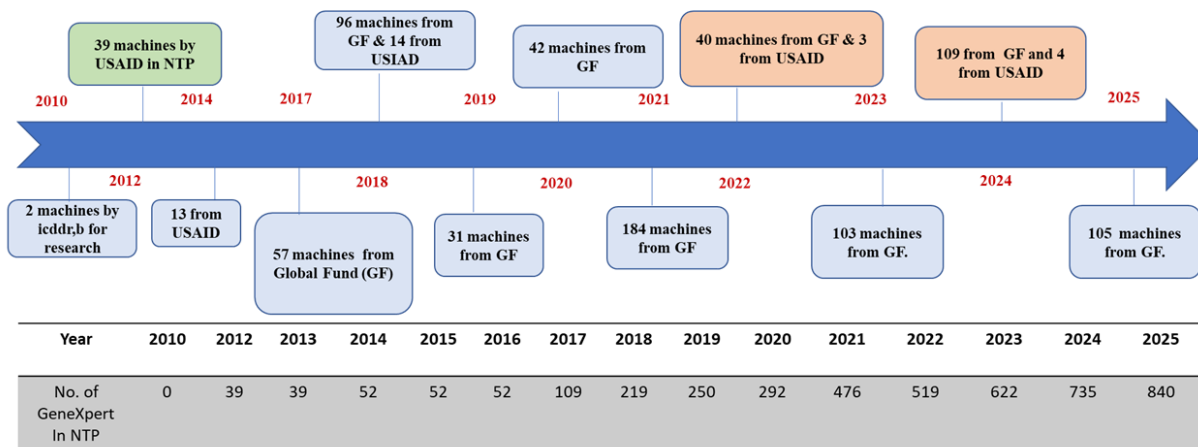


Figure 2: GeneXpert adoption in the Bangladesh National Tuberculosis Program

In 2022, Bangladesh incorporated Truenat into the TB diagnostic algorithm. As of 2024, 150 Truenat devices have been deployed across the country. This portable, battery-powered device is suitable for peripheral health facilities, making it an effective tool for decentralized TB diagnosis. Additionally, in 2023, the NTP, in collaboration with icddr,b, integrated digital chest X-ray with Computer-Aided Detection Technology into the national TB screening guidelines and is currently working in remote areas. Furthermore, some new devices, such as the Interferon-Gamma Release Assay, are being used in the country at a pilot scale to assess latent tuberculosis infection prevalence in eligible healthcare workers.

## **Stakeholders in the TB control program**

We reviewed the existing literature and consulted with experts to map the stakeholders involved in the TB control program of Bangladesh. The following institutions, civil society organizations (CSOs), and individuals were identified that play critical roles in TB control and, therefore, influence the introduction of TB diagnostics in the country.

### **1. Public Institutions**

- **Ministry of Health and Family Welfare (MoHFW)**

The Ministry of Health and Family Welfare (MoHFW) is a Bangladesh government ministry charged with health policy in Bangladesh. It provides overall leadership and direction for the health sector, including TB control. The MoHFW, primarily through its Health Service Division (HSD) and relevant directorates, supports key aspects of the program such as resource allocation, procurement and supply chain management, and strengthening the health workforce.

- **Directorate General of Health Services (DGHS)**

The Directorate General of Health Services (DGHS) is the Bangladesh government directorate under the Ministry of Health and Family Welfare responsible for delivering health services in Bangladesh. It oversees the implementation of health programs, including tuberculosis, through its various units and departments.

- **National TB Technical Committee**

The National TB Technical Committee is a working group within the MoHFW in Bangladesh to address the technical aspects of the TB program and facilitate decision-making. It provides technical guidance and support for the implementation of TB control strategies, the introduction of new diagnostic tools for TB, and other related activities.

- **[National Tuberculosis Control Program](#)**

The National Tuberculosis Control Program (NTP) in Bangladesh is the primary entity under the MoHFW responsible for the implementation of TB control activities in the country. The NTP implements TB diagnostics in the public sector.

- **[Directorate General of Drug Administration](#)**

As the principal drug regulatory authority under the MoHFW, the Directorate General of Drug Administration (DGDA) oversees the regulation of medicines, vaccines, medical devices, and other healthcare products in Bangladesh. Its mandate includes the import, production, storage, sale, and export of these products, ensuring they meet national quality and safety standards. In collaboration with the NTP, DGDA works to strengthen testing capacity and supports local manufacturers in producing quality-assured anti-TB medicines and a new tubercular diagnostic tool.

- **[Directorate General of Family Planning](#)**

In Bangladesh, the Directorate General of Family Planning (DGFP) supports the NTP mainly through information, education, and communication (IEC) initiatives. While the DGHS holds the primary responsibility for TB control, the DGFP plays a complementary role by raising public awareness about tuberculosis, organizing networking activities, and encouraging healthy practices.

## **2. International Organizations**

- **[World Health Organization \(WHO\)](#)**

The WHO supports global TB control programs by leading efforts to combat the disease, setting international standards, and offering technical and strategic support. Its work includes developing strategies, monitoring the epidemic, issuing guidelines for diagnosis and treatment, and promoting research and innovation for new tools. In Bangladesh, the

WHO provides technical assistance, guidance, and resources to strengthen TB control initiatives.

- [The Global Fund](#)

The Global Fund is a major contributor to the Global Tuberculosis Control Program, providing substantial financial and technical support, particularly to low- and middle-income countries. Its investments focus on prevention, diagnosis, treatment, and care, leading to significant reductions in TB cases and deaths. As of 2022, the Global Fund had signed grants totalling over US\$835 million with Bangladesh and disbursed over US\$700 million.<sup>15</sup> The Global Fund has played a pivotal role in expanding TB treatment coverage, enhancing case detection, and strengthening prevention efforts in Bangladesh.<sup>15</sup>

- **USAID**

In Bangladesh's TB control efforts, USAID was one of the key alliances and supported the "Combating TB in Bangladesh" project, which was focused on increasing TB case detection, improving treatment outcomes, and strengthening the national TB diagnostic network. Its contributions included funding, technical assistance, and capacity building for stakeholders involved in TB control. In addition, USAID supported various TB initiatives implemented by multiple partner organizations. However, the recent shift in the global funding landscape, particularly the cessation of USAID funding for TB may have a significant impact on the national TB program. While it is still too early to fully assess the scale of the consequences, initial reports suggest that tens of thousands of patients may have had their healthcare services interrupted.<sup>16</sup> In addition, the suspension of critical technology transfer has further constrained the continuity of TB services in the country.

- [icddr,b](#)

icddr,b, an international research organisation based in Bangladesh, contributes significantly to TB control in Bangladesh through its research, public-private partnerships, and the introduction of innovative diagnostic tools. The organization operates TB Screening and Treatment Centers (TBSTCs) and actively collaborates with the NTP to improve TB diagnosis, treatment, and overall management.

### 3. Non-Governmental Organizations

Various Non-Governmental Organizations (NGOs) collaborate with the NTP to implement TB control programs and raise awareness about TB in Bangladesh. Some of these organizations also conduct operational research to test the feasibility of using new TB diagnostics in the country.

[BRAC](#) provides support to Bangladesh's TB control program through its community-based approach, engaging *Shasthya Sebikas* (Female village health volunteers) in diagnosis and treatment, and collaborating with the NTP and the Global Fund. Its efforts prioritize increasing case detection, improving treatment success rates, fostering community engagement, and expanding access to modern diagnostic tools such as digital X-rays and GeneXpert machines.

[Health Education and Economic Development \(HEED\)](#) Bangladesh plays a vital role in the country's TB control program by conducting awareness campaigns, building capacity, and providing direct services under the NTP. As an NGO, it works closely with the government to deliver TB services, especially in hard-to-reach areas. The organization focuses on reaching vulnerable groups, such as communities in tea gardens and ethnic villages, aiming to improve case detection and treatment adherence. In doing so, HEED makes a significant contribution to the national goal of reducing the public health impact

of TB. Additionally, many other NGOs also contribute to TB control by providing services, mobilizing communities, and advocating for better care.

#### **4. Private Healthcare Providers**

Private healthcare providers are essential in delivering healthcare services in Bangladesh and are often the first point of contact for screening suspected TB cases, subsequently referring them to government-owned TB centers. Despite their significant involvement in TB screening, private healthcare providers are underutilized in the national TB control program, as TB diagnostics are primarily provided free of cost through the public sector. Therefore, Bangladesh has a substantial opportunity to engage private sector providers to enhance TB diagnosis and care. In recent days, some large private diagnostic centers have taken initiatives to expand the TB diagnosis program and started using advanced TB diagnostics to screen the TB patients.

#### **5. Patients**

In Bangladesh, out-of-pocket expenditure remains the dominant source of health financing, accounting for nearly 70% of the country's total health expenditure, giving patients considerable influence over healthcare services.<sup>17,18</sup> However, in the case of TB diagnostics, most care is delivered through the public sector, limiting patients' role in influencing TB diagnostic uptake. With the evolving global financing landscape for TB control programs, which anticipates increased private sector engagement, patients could emerge as a key driving force in the adoption and utilization of TB diagnostics in the country.

## **Critical Path Analysis country roadmap**

We engaged with a selected group of experts in in-depth discussions to explore the pathway/s for introducing new TB diagnostic tools in both public and private healthcare sectors in Bangladesh. Participants included representatives from the NTP, WHO TB Technical Committee, USAID, icddr,b, TB specialists, and policy advisors. The discussions highlighted critical challenges, policy gaps, and potential solutions for TB diagnosis, treatment, and program implementation, providing valuable insights into NTP's decision-making process for integrating innovative diagnostics.

Interviews revealed that the public sector is the largest user of TB diagnostics in Bangladesh, with a small proportion of diagnostics being utilized in the private sector. Thus, a public-private mixed model exists for TB diagnostics in the country. It is also worth noting that TB diagnostics in Bangladesh the country entirely rely on imported devices, as no indigenous products are currently being used in the field of TB diagnosis.

The NTP is the primary authority for introducing new TB diagnostics in the country. However, WHO, donor agencies, and CSOs play influential roles in shaping policy decisions, particularly for adoption in the public sector. The current strategic plan of the TB control program emphasizes the introduction and scale-up of rapid molecular diagnostics. Yet, funding constraints remain a major barrier: nearly 80% of the TB diagnostic program depends on donor financing, and accessing these resources requires meeting strict criteria, which is often lengthy and complex.

WHO prequalification plays a critical role in facilitating the adoption of TB diagnostics, as it enables access to external funding, strengthens institutional confidence, and accelerates regulatory approval. However, the process to secure prequalification and subsequent funding

is time-consuming. Approval for new diagnostics requires clearance from the TB Technical Committee, while the DGDA authorizes import licenses. The DGDA typically relies on approvals from international regulatory authorities such as the U.S. FDA or CE marking and considers evidence of use in other high-burden countries. Despite this, weak post-sale services, and inadequate needs assessments frequently hinder the scale-up of diagnostics.

Moreover, financial support for TB diagnostics is often limited to device procurement and utilization, with insufficient investment in staff training and community sensitization. Consequently, many healthcare providers remain unaware of new diagnostic tools or, when aware, lack clear guidance on appropriate patient referral pathways.

### **Pathway to introducing new TB diagnostics in the private sector**

The introduction of new TB diagnostics in Bangladesh is relatively straightforward in the private sector. Once the DGDA approves a device and listed in the medical device registration log, private entities can proceed with importing and distributing it to private institutions for use. The specific requirements and procedures for obtaining an import permit vary depending on the product type and are guided by the procedure laid down in the Drugs Act, 1940. In case the nature of the devices is such that the above procedure cannot be adopted, DGDA may take any other measure to verify the claim of the manufacturer or importer and/or the conformity of the device with the regulatory requirements. The process typically begins with the nomination of a local vendor authorized to import and distribute the devices. The vendor then needs to apply to the DGDA to have the devices listed in the official medical device registry and to obtain the necessary import permits. The vendor needs to provide a set of information along with a comprehensive dossier with the application for an import permit. This includes the availability of a CFS, certification from ISO 13485, and approval by a recognised

international regulatory body such as the FDA, CE. The details guidelines for applying for device registration to DGDA are available online. The requirement for the device registration is provided in Annexure 2. The procedure of the application to DGDA is given in Annexure 3. Importantly, in addition to getting approval from DGDA, if the device emits radiation (e.g., X-ray, MRI machine), the vendor must obtain permission from the relevant authority, such as the Bangladesh Atomic Energy Commission. Once submitted, the complete application undergoes an Expert Review, a process that typically takes 2–3 months. The expert opinions are then evaluated by the DGDA Technical Committee, which may either request additional supporting documents or issue a decision. If the Committee grants a favourable outcome, the DGDA provides a device registration certificate, authorizing import and use in the private sector. Although WHO endorsement is not mandatory for private-sector approval, it can significantly expedite the review and approval process. The basic requirement for DGDA approval and the tentative timeline to complete each step are listed in Table 2.

Once a medical device receives regulatory approval from the DGDA, the process shifts from licensing to actual acquisition and market introduction. This stage involves two key phases:

- Procurement Phase and
- Market Entry Phase

**Procurement Phase:** After receiving DGDA approval, the authorized local vendor arranges the purchase from the manufacturer or supplier abroad. Procurement can take 4 to 12 months, depending on:

- Manufacturer production schedules
- International shipping and customs clearance

- Volume of the order and negotiation timelines

Importantly, even after DGDA approval, the shipment must pass customs inspections to verify documentation, labelling, and packaging requirements.

Table 2: Requirements for DGDA approval and timeline for device registration

<b>Device Class</b>	<b>Type of Device</b>	<b>Required Documents</b>	<b>Administrative review time</b>	<b>Technical review time</b>	<b>Certificate Validity</b>
<b>Class A</b>	Low risk (e.g., swabs for TB specimen collection)	Certificate of Free Sale (CFS) from the country of origin	14 Days	4 – 6 months (new) 1 month (change)	No expiration date
<b>Class B</b>	Moderate low risk (e.g., syringes, infusion sets)	Certificate of Free Sale (CFS) from the country of origin	14 Days	4 – 6 months (new) 2 – 3 months (renewal) 1 month (change)	5 years
<b>Class C</b>	Moderate high risk (for instance, X-ray devices)	Certificate of Free Sale (CFS) from the country of origin, International Standard (e.g., ISO 13485) certification	14 Days	4 – 6 months (new) 2 – 3 months (renewal) 1 month (change)	5 years
<b>Class D</b>	high-risk (e.g., ventilators, implanted defibrillators)	Certificate of Free Sale (CFS) from the country of origin, International Standard (e.g., ISO 13485) certification	14 Days	4 – 6 months (new) 2 – 3 months (renewal) 1 month (change)	5 years

**Market Entry Phase:** Once imported, the vendor distributes the device to private hospitals, clinics, and diagnostic centers. For complex or high-risk devices, vendors often provide training for healthcare staff and maintenance plans to ensure correct usage. Since this pathway applies to private healthcare, procurement is typically funded by private entities or NGOs rather than government budgets.

From the initial application to full market availability, the process typically spans 1–2 years, depending on the type of device, the quality of the submitted documents, and the country’s willingness to adopt it for TB diagnosis (figure 3).

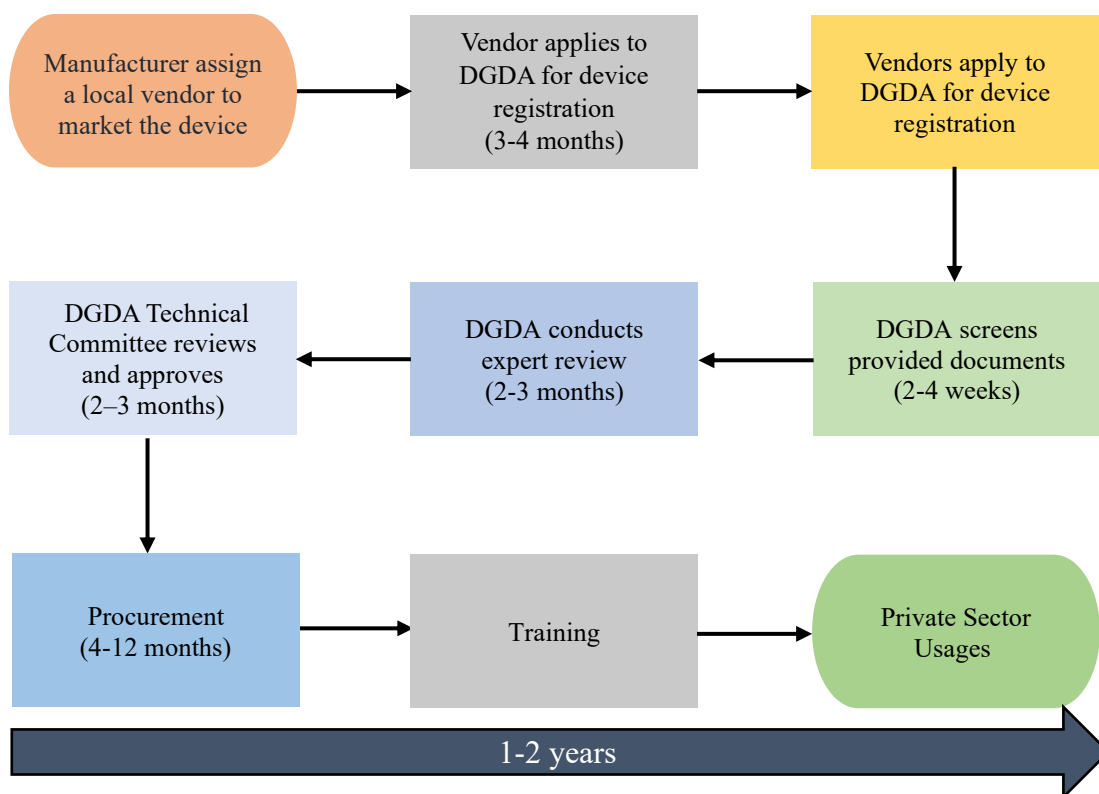


Figure 3: Adoption pathway of new TB diagnostics in private sectors of Bangladesh

Table 3: Processes and tasks involved in introducing new TB diagnostics in Bangladesh’s private sector

<b>A. Market demand creation</b>	
Tasks	<ul style="list-style-type: none"> <li>▪ Generating evidence on the test’s effectiveness, accuracy, and impact</li> <li>▪ Advocacy and awareness campaigns targeting policymakers, healthcare providers, and communities</li> </ul>
Actors/Stakeholders	<ul style="list-style-type: none"> <li>▪ Manufacturers, CSOs, Distributors</li> </ul>
Enablers	<ul style="list-style-type: none"> <li>▪ Low cost, minimal technical requirements, and rapid turnaround of results</li> <li>▪ Certifications from internationally recognized regulatory bodies, such as the FDA, CE, or ISO</li> <li>▪ WHO PQ certification</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Healthcare services related to TB are largely provided by the public sector free of charge, offering limited financial incentive for the private sector to invest.</li> <li>▪ Multi-purpose devices are more desirable, given the low demand for TB diagnostics in the private sector.</li> </ul>
Timeline	Unspecified
<b>B. Diagnostic Registration</b>	
Tasks	<ul style="list-style-type: none"> <li>▪ New diagnostics need be registered in the Bangladesh Medical Device Registration Log to obtain import permits and enable distribution.</li> </ul>
Actors/Stakeholders	<ul style="list-style-type: none"> <li>▪ DGDA and Distributor</li> </ul>
Enablers	<ul style="list-style-type: none"> <li>▪ Complete dossier detailing the product description and user guidelines</li> </ul>

	<ul style="list-style-type: none"> <li>▪ Free Sale Certification in the country of origin</li> <li>▪ FDA, CE, or ISO certification</li> <li>▪ Data from high TB burden countries,</li> <li>▪ Approval from other regulatory bodies, such as the environmental ministry</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Lengthy administrative processes</li> <li>▪ Lack of Free Sale Certificate</li> <li>▪ Distributor’s reluctance due to slow demand</li> </ul>
Timeline	12-18 Months
<b>C. Pricing</b>	
Tasks	<ul style="list-style-type: none"> <li>▪ There is no standard or fixed price that makes these tools universally attractive for NTPs to invest in. Optimal pricing is context-dependent and varies according to the specific diagnostic tool and its use case. Additionally, while the country has established a national health insurance program that currently includes and reimburses existing TB tests, the inclusion of new TB tests into the national insurance scheme is a phased process, prioritizing widely used tests. Furthermore, concessional pricing does not automatically cover the private health sector, and alternative mechanisms may be needed for private providers to access such pricing</li> </ul>
Actors/Stakeholders	Manufacturer, Distributor and Private investor
Enablers	<ul style="list-style-type: none"> <li>▪ Availability of Corporate Social Responsibility (CSR) Models based price</li> <li>▪ Availability of reagent rental (placement) contracts</li> <li>▪ Pack size</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Slow demand increases the operating cost</li> </ul>

Timeline	<ul style="list-style-type: none"> <li>▪ Unspecified</li> </ul>
<b>D. Procurement and Distribution</b>	
Tasks	Offering diagnostics at lower price for LMIC
Actors/Stakeholders	Manufacturer, Distributor, Private Operators
Enablers	<ul style="list-style-type: none"> <li>▪ Availability of CSR Models based price for reduced sale prices</li> <li>▪ Offering reagent rental (placement) contracts to reduce initial investment.</li> </ul> <p>In Bangladesh, most private healthcare providers acquire devices through reagent agreements, where the cost of the machine is offset by the purchase of reagents and associated logistics.</p>
Barriers	<ul style="list-style-type: none"> <li>▪ Often, most sales and support services are not available in the country during the early stages, which makes investors reluctant to invest at that time.</li> <li>▪ Selecting a well reputed distributors provide confidence in services</li> </ul>
Timeline	<ul style="list-style-type: none"> <li>▪ 4-6 months</li> </ul>

### **Pathway to introducing new TB diagnostics in Bangladesh’s public healthcare sector**

The process of introducing new TB diagnostic tools into Bangladesh’s public healthcare sector is a complex, multi-step pathway that requires regulatory compliance, programmatic alignment, stakeholder engagement, and procurement planning.

The pathway begins with the NTP conducting a needs assessment to evaluate the potential benefits of a new diagnostic tool, funding availability and implementation feasibility. In general, NTP prioritizes diagnostics that have received WHO PQ certificate, as this endorsement facilitates access to donor funding, particularly from the Global Fund. Additionally, for diagnostics with

WHO user guidelines already available for use in TB control programs, the NTP can directly proceed with planning their integration into the national TB control program. However, for diagnostics without user guidelines, NTP collaborates with CSOs to conduct operational research to assess their feasibility for use in the Bangladesh context. This operational research usually requires prior approval from both the DGDA and the BMRC, which together may take about 4–6 months to grant clearance. The operational research itself typically lasts 12–24 months.

Based on the needs assessment, operational research findings, or availability of WHO guidance, NTP initiates program planning to integrate the diagnostic tool. At this stage, advocacy and community sensitization activities are conducted to build public and stakeholder support. The integration plan is then submitted to the TB Technical Committee for review and approval, which generally requires 2–3 months. Following approval, NTP seeks funding to support implementation. Some of these processes may occur in parallel to reduce timelines.

Currently, the Global Fund is the main source of financing for TB diagnostics in the public sector in Bangladesh. To access this funding, NTP needs to submit a proposal to the Bangladesh Country Coordinating Mechanism (BCCM), which manages Global Fund operations in the country. The Global Fund also requires cost-sharing through domestic funding, which must be approved by both the Ministry of Health and the Ministry of Finance. This approval process typically takes 2–6 months.

Once financing is secured, NTP purchase the diagnostic in coordination with the national procurement and supply chain management system and coordinates with central medical service depot to distribute the devices for public sector use. The procurement process itself may take 6–18 months, depending on supply chain complexity and vendor engagement with the principal company for the availability of the diagnostics. Like the private sector, the public sector also

requires DGDA approval to import devices into the country. However, in many cases, upon request from the NTP or other relevant authorities, the DGDA issues a No Objection Certificate (NOC) to allow temporary import of the device while the application for listing in the Medical Device Registry is under review. Overall, the introduction of a new TB diagnostic tool in Bangladesh's public sector is a lengthy process, often requiring 3–6 years from initial assessment to full-scale adoption (figure 4).

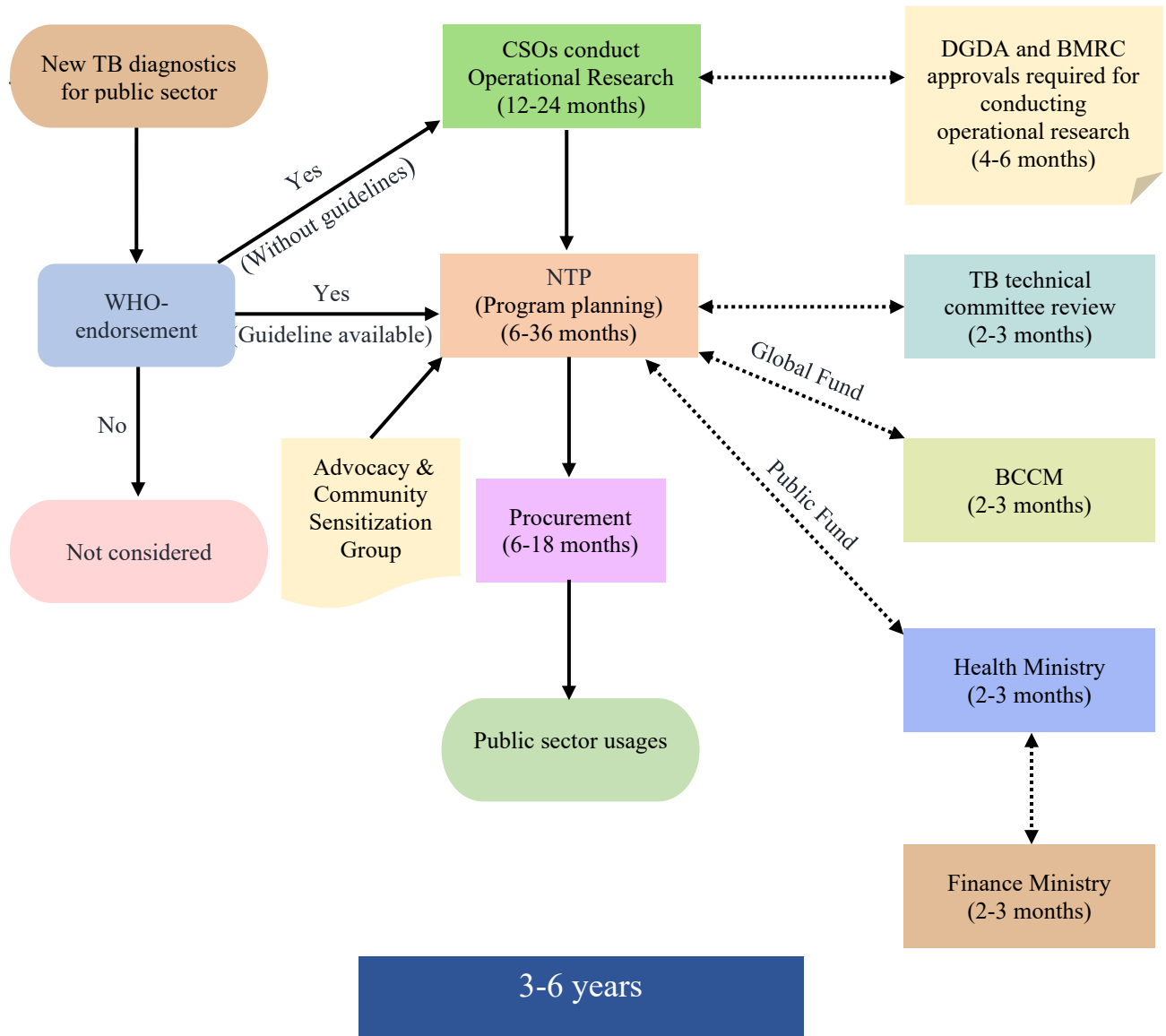


Figure 4: Adoption pathway of new TB diagnostics in public sector of Bangladesh

Table 4: Processes and tasks involved with introducing new TB diagnostics in the public sector of Bangladesh

<b>A. In-country need assessment regarding the introduction of the new TB diagnostics</b>	
Tasks	Identifying local gaps, priorities, and resources required for effective program implementation in connection with the adoption of the new TB diagnostics and scale-up
Actors/Stakeholders	<ul style="list-style-type: none"> <li>▪ The NTP is the primary body responsible for assessing local needs for adopting new TB diagnostics</li> <li>▪ CSOs, WHO, and Development Partners and support the NTP in conducting in-country needs assessments for new TB diagnostics in Bangladesh.</li> </ul>
Enablers	<ul style="list-style-type: none"> <li>▪ Low cost, minimal technical requirements, and rapid, reproducible results</li> <li>▪ WHO PQ is desirable as it facilitates a faster pathway for funding availability</li> <li>▪ Certifications FDA, CE, ISO, or other internationally recognized regulatory bodies</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Obtaining WHO PQ can be time-consuming and may delay diagnostic adoption into the NTP program</li> </ul>

- Absence of diagnostic implementation guidelines in the TB control program necessitates in-country operational research to assess the feasibility of device use
- To date, diagnostics without WHO PQ have not been introduced in the national TB program of Bangladesh

<b>Timeline</b>	Unspecified, continuous process that the NTP and CSOs are consistently working on
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**B. Program planning for new TB device adoption**

Tasks	<ul style="list-style-type: none"> <li>▪ Developing the adoption and scale-up plan for the diagnostic</li> <li>▪ Estimating the financial implications</li> <li>▪ Updating of the national guidelines and other normative tools</li> </ul>
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Actors/Stakeholders	National TB technical working group
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Enablers	<ul style="list-style-type: none"> <li>▪ WHO guidelines for program implementation</li> <li>▪ Positive findings from operational research</li> </ul>
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Barriers	<ul style="list-style-type: none"> <li>▪ NTP follows a three-year program planning cycle, which delays the adoption of new devices in a short time frame</li> <li>▪ Lack of donor support, as the implementation of TB diagnostics in Bangladesh is heavily dependent on foreign aid</li> <li>▪ High technical requirements for device implementation</li> <li>▪ Lack of supporting logistics</li> </ul>
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Timeline	6-36 months
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**C. TB technical committee review and approval**

Task	Providing policy guidance on the implementation of TB control program activities in Bangladesh and recommending the adoption of new initiatives on TB control activities
Actors/Stakeholders	National TB Technical Committee
Enablers	<ul style="list-style-type: none"> <li>▪ Positive findings from operational research</li> <li>▪ Supportive evidence from other high TB burden countries</li> <li>▪ Advocacy and community sensitization. The TB Technical Committee includes representatives from DGHS, NTP, NGO partners, WHO, research institutes, and donor agencies. Early sensitization of committee members about the device helps expedite the review process</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ The technical committee meets quarterly and sometimes delayed</li> <li>▪ Insufficient documentation may delay the approval process</li> </ul>
Timeline	4-6 months

#### **D. Bangladesh Country Coordinating Mechanism (BCCM)**

Tasks	The BCCM, a multi-sectoral national body mandated by the Global Fund, oversees the approval of Global Fund resource utilization in Bangladesh. Its functions include improving the performance of the Global Fund. The BCCM supports activities through stakeholder collaboration, ensuring efficient program implementation, and avoiding duplication by harmonizing efforts with other national programs.
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Actors/Stakeholders	<ul style="list-style-type: none"> <li>▪ The BCCM is represented by members from GoB, CSOs, research institutes, community representatives and development partners</li> </ul>
Enablers	<ul style="list-style-type: none"> <li>▪ WHO PQ certificates, and positive findings from operational research</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Accessing Global Fund support is time-consuming, as the Fund follows a three-year cycle for allocating resources to new initiatives</li> </ul>
Timeline	2-3 months if funds are available, otherwise, need to wait for the next funding cycle

#### **E. Approval by DGHS: Director General of Health Services/ Health Ministry**

Tasks	<ul style="list-style-type: none"> <li>▪ Review all processes undertaken, allocate public funds</li> </ul>
Actors/Stakeholders	<ul style="list-style-type: none"> <li>▪ MoHFW, Ministry of Finance</li> </ul>
Enablers	<ul style="list-style-type: none"> <li>▪ WHO prequalification certificates, FDA, CE or ISO certification</li> <li>▪ Data for other high TB burden countries</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Slow decision-making and stringent budget reallocation policies</li> </ul>
Timeline	<ul style="list-style-type: none"> <li>▪ 3-4 months</li> </ul>

#### **F. Procurement System Management**

Tasks	The CMSD is the designated government body responsible for procuring medical supplies and equipment, including TB diagnostic tools. It oversees the acquisition of new equipment and manages its distribution to laboratories and health facilities across Bangladesh.
Actors/Stakeholders	<ul style="list-style-type: none"> <li>▪ CMSD, NTP</li> </ul>

Enablers	<ul style="list-style-type: none"> <li>▪ Availability of funds for procurement</li> <li>▪ Availability of the device in the market</li> <li>▪ Inclusion of the device in the official medical equipment list</li> <li>▪ Availability of a No Objection Certificate (NOC) from the relevant department</li> <li>▪ Presence of a local vendor for importing the device into the country</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Slow action taken in developing the procurement plan</li> </ul>
Timeline	6-18 months, depending on the funding source and diagnostic availability in the market
<b>G. Arrival of the commodity and distribution to the appropriate centers</b>	
Tasks	<ul style="list-style-type: none"> <li>▪ Receipt of the commodity in the warehouse and then plan the distribution to the appropriate centers</li> </ul>
Actors/Stakeholders	<ul style="list-style-type: none"> <li>▪ CMSD, NTP, WHO</li> </ul>
Enablers	<ul style="list-style-type: none"> <li>▪ NOC from relevant authorities</li> <li>▪ Availability of supporting logistics</li> <li>▪ Approved plan for in-country deployment and use of the diagnostics</li> </ul>
Barriers	<ul style="list-style-type: none"> <li>▪ Slow action taken by the relevant officials and lack of supervision</li> </ul>
Timeline	<ul style="list-style-type: none"> <li>▪ 3-6 months</li> </ul>

## **Factors influencing the introduction of new TB diagnostics in the public sector of Bangladesh**

Bangladesh has a long-standing and well-functioning NTP, with a strong vision to adopt advanced diagnostic tools for rapid and improved case detection. However, the introduction of new TB diagnostics in public sector remains slow and complex due to several challenges. Our CPA analysis identified some influencing factors for slow adoption and integration of new TB diagnostic technologies in the country.

### **1. Lengthy administrative processes**

The approval pathway for new TB diagnostics is lengthy. Authorities rely heavily on external endorsements, such as WHO PQ, FDA, or CE approval, which can extend adoption timelines. Staff shortages at the government level often delay the processing applications for registering new technologies. Consequently, device registration and approval may delay.

### **2. Gaps in strategic planning**

In Bangladesh, Tb diagnostics are largely supported by development aids, thus the adoption of new TB diagnostics is often driven more by donor priorities than by the country's own epidemiological needs. Therefore, proper need assessment is overlooked which sometimes delays scale-up, and by the time diagnostics are widely deployed, the disease landscape may have already shifted. Moreover, high-cost diagnostics that are initially introduced through donor support face significant challenges in achieving nationwide expansion due to the absence of sustainable funding mechanisms.

### **3. Inadequate logistical support**

In Bangladesh, TB diagnostics are sometimes introduced without adequate logistical planning, which undermines their effective use. During stakeholder discussions, it was noted that GeneXpert machines had been deployed to sub-district facilities without ensuring a reliable backup power supply. As a result, frequent power outages left many machines non-functional. Moreover, repairing faulty GeneXpert modules required sending them abroad, a process that was costly, logistically challenging, and led to prolonged service disruptions.

### **4. Limited market availability**

It is evident that LMICs like Bangladesh often experience delays in the local availability of new diagnostics, which further slows implementation. For example, portable X-ray machines took a considerable amount of time to become accessible in Bangladesh, even after purchase orders had been placed. Ensuring the timely availability of new devices is therefore critical for accelerating service expansion in the LMICs.

### **5. Lack of community and clinician sensitization**

In some cases, TB diagnostics have been introduced in Bangladesh without adequate communication to end users, particularly clinicians. As a result, many clinicians remain unaware of the availability of these diagnostics and are unable to appropriately refer patients. Stakeholder discussions highlighted that the early rollout of GeneXpert lacked proper community sensitization, leaving clinicians unfamiliar with referral procedures and leading to significant underutilization of the service. Effective sensitization and training are therefore essential to ensure proper referral pathways and full integration of new TB diagnostics into routine care.

## **6. Absence of incentives for healthcare providers**

In Bangladesh, laboratory personnel in the public sector receive financial incentives for conducting paid pathological tests. However, TB diagnostic tests are offered free of cost at public sector, meaning staff receive no incentives for performing them. This lack of financial incentive often leads personnel to prioritize other procedures instead of promoting TB testing. Additionally, third-party actors sometimes direct patients toward unnecessary tests, further discouraging appropriate TB screening and limiting the optimal use of available TB diagnostics.

## **7. Shortage of skilled human resources and knowledge gaps**

Bangladesh is one of the countries with 'severe shortages' of health workers. Therefore, patients, especially the poor and the disadvantaged, mostly seek health care from the non-qualified providers in the informal sector which causes delay in appropriate TB care. Additionally, Bangladesh faces a shortage of adequately trained professionals capable of operating advanced diagnostic platforms or interpreting complex results. This gap is particularly evident in the diagnosis and management of childhood TB, where lack of specialized training undermines accuracy and timely care.

## **8. Fragmented public–private coordination**

With TB services largely concentrated in the public sector, collaboration with private providers remains limited. Since a substantial proportion of patients initially seek care in private facilities, strengthening public–private partnerships could accelerate the adoption of new diagnostics, as private providers often have more flexibility in procurement and implementation of TB diagnostics in a shorter timeframe.

## **Recommendations for accelerating TB diagnostic adoption in Bangladesh**

Despite that in the last decade, the world has witnessed formidable progress in the field of TB diagnostics, delayed and inaccurate diagnosis continues to hinder effective TB control in Bangladesh. The adoption of new, rapid, and accurate diagnostic tools is crucial for detecting TB earlier, improving treatment outcomes, and reducing transmission within communities.

### **1. Developer perspectives**

- Given the high TB burden and limited human resources in Bangladesh, stakeholders emphasized the need for high-quality point-of-care diagnostics to support nationwide TB program expansion. Manufacturers are therefore recommended to prioritize cost-effective, near point-of-care tests that integrate easily into care pathways and deliver results in short timeframe.
- Because TB testing is free at public facilities, private sector investment in TB diagnostics in Bangladesh has been limited. Although greater public–private partnerships are anticipated due to global financial shifts, private organizations remain reluctant to invest in single-purpose diagnostics. Therefore, manufacturers can consider prioritizing devices that are multipurpose or compatible with open platforms.
- Bangladesh continues to face limitations in health infrastructure, unreliable power supply, and a shortage of skilled personnel. As a result, user-friendly diagnostics that require minimal technical expertise and low maintenance are essential to ensure that healthcare workers at all levels can operate them effectively.

- Bangladesh often struggles to maintain TB diagnostic systems due to limited technical support and spare parts, leading to underutilization. Partnership of manufacturers with reliable local vendors to ensure ongoing support and timely spare parts availability will be beneficial.
- Bangladesh's regulatory authority often relies on international approvals for device registration. Securing approvals from recognised regulatory bodies in advance to expedite import permits is recommended.

## 2. **Government and other recipients' perspective**

- In Bangladesh, TB diagnostics are often introduced without context-specific assessment, limiting scalability. Conducting thorough needs and feasibility evaluations can ensure alignment with local priorities and support sustainable TB diagnostic adoption in Bangladesh.
- Devices without WHO guidance need operational research to assess feasibility. Early involvement of NTP officials and policymakers, updated national policies, and educational materials for providers and patients are essential for rapid and effective integration of new TB diagnostics.
- National health policies and guidelines should be updated to support rapid integration of new diagnostics, accompanied by educational materials for providers, patients, and the public to ensure proper understanding of their use, timing, and target groups.
- Public investment in TB diagnostics in Bangladesh is limited, relying mostly on development partners, which causes adoption delays. Increasing domestic funding would enable timely, context-appropriate decisions and reduce reliance on external donors.

### **3. Donor and WHO perspective**

- The NTP in Bangladesh primarily relies on WHO-approved diagnostics, as donor funding is mostly limited to WHO-prequalified devices. Broadening prequalification criteria for development assistance funding could accelerate policy decisions and the adoption of new diagnostics.
- Scaling up certain devices is challenging due to weak health infrastructure. Enhanced support from development agencies for context-specific market analyses could better inform Bangladesh's TB diagnostic needs and facilitate more effective scale-up.
- Investing in targeted training and education for device implementation, maintenance, and troubleshooting could speed up the adoption of new diagnostics in Bangladesh, where shortages of skilled health professionals and an imbalanced skill mix often delay their effective use.
- Obtaining WHO PQ certification is often time consuming, delaying the adoption of new diagnostics in the National TB Program. Revising WHO-PQ guidelines to provide more accessible pathways for innovative diagnostics could accelerate approval, introduction, and scale-up in Bangladesh and globally.
- Amid declining global health funding, advocacy by WHO for stronger political commitment and resource mobilization, promotion of adaptable tools for country-specific needs, and facilitation of coordinated data sharing and surveillance is expected to be helpful.

### **Conclusion**

The CPA for introducing new tuberculosis diagnostics in Bangladesh highlights a multi-step process spanning 3–6 years in the public healthcare sector and 1-2 years in the private healthcare sector, from regulatory approval to procurement. The successful implementation of TB diagnostics

depends on navigating both supporting factors and significant challenges. Key enablers include the presence of established regulatory frameworks, growing global attention to TB control, and potential funding opportunities from international donors. However, prolonged regulatory timelines, limited technical capacity, delays in funding disbursement, lack of public fund support, and procurement inefficiencies can hinder timely TB diagnostic adoption. Challenges also arise from fragmented coordination among stakeholders, inadequate laboratory infrastructure, and dependence on external funding. To overcome these obstacles, it is essential to enhance coordination among diagnostic manufacturers, the government, donors, and implementing partners, and to establish sustainable financing mechanisms. Additionally, adopting a phased introduction strategy, starting with high-burden areas, can accelerate impact while longer-term systems are built.

## **References**

1. Global tuberculosis report 2024. Geneva: World Health Organization; 2024.
2. National Tuberculosis Control Programme. Annual report 2023. Dhaka: Directorate General of Health Services, Ministry of Health and Family Welfare, Government of Bangladesh; 2023.
3. National Tuberculosis Control Programme. Annual report 2022. Dhaka: Directorate General of Health Services, Ministry of Health and Family Welfare, Government of Bangladesh; 2022.
4. National Strategic Plan for TB Control 2021-2025, National TB Control Programme, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh; 2020.

5. National strategic plan to end tuberculosis in Bangladesh 2024 - 2030, National Tuberculosis Control Programme, Directorate General of Health Services, Ministry of Health and Family Welfare, Dhaka , Bangladesh; 2023.
6. Zafar Ullah AN, Newell JN, Ahmed JU, Hyder MK, Islam A. Government-NGO collaboration: the case of tuberculosis control in Bangladesh. *Health Policy Plan* 2006; **21**(2): 143-55.
7. Hasan MZ, Ahmed S, Islam Z, et al. Costs of services and funding gap of the Bangladesh National Tuberculosis Control Programme 2016-2022: An ingredient based approach. *PLoS One* 2023; **18**(6): e0286560.
8. Hanrahan CF, Shah M. Economic challenges associated with tuberculosis diagnostic development. *Expert Rev Pharmacoecon Outcomes Res* 2014; **14**(4): 499-510.
9. Yerlikaya S, Broger T, Isaacs C, et al. Blazing the trail for innovative tuberculosis diagnostics. *Infection* 2024; **52**(1): 29-42.
10. National Tuberculosis Control Programme. Annual report 2016. Dhaka: Directorate General of Health Services, Ministry of Health and Family Welfare, Government of Bangladesh; 2016.
11. Nazneen A, Tarannum S, Chowdhury KIA, et al. Implementation status of national tuberculosis infection control guidelines in Bangladeshi hospitals. *PloS one* 2021; **16**(2): e0246923.
12. Noman MZI, Islam S, Aktar S, et al. Healthcare seeking behavior and delays in case of Drug-Resistant Tuberculosis patients in Bangladesh: Findings from a cross-sectional survey. *PLOS Glob Public Health* 2024; **4**(1): e0001903.

13. Sultana S, Salwa M, Towhid MII, Islam SS, Haque MA. Challenges for tuberculosis control at selected primary healthcare centers in Bangladesh: A mixed-method study. *Indian Journal of Tuberculosis* 2022; **69**(2): 134-40.
14. Insua M, Haumba S, Zannat F, Matji R, Smith-Arthur A. 2012. Reducing TB Delays: Evaluating the Frequency and Causes of Delays .Technical Report. Published by the USAID TB CARE II Project.
15. Rahman MF, Khan MSI, Huda MM, Mondal UK, Shiddiky MJ, Ross AG. The Global Fund's Bangladesh program. *IJID regions* 2025; **15**.
16. Fight against tuberculosis stalls in Bangladesh as U.S. cuts aid. Pulitzer Center, published on August 14; 2025. <https://pulitzercenter.org/stories/fight-against-tuberculosis-stalls-bangladesh-us-cuts-aid>.
17. Rahman MM, Islam MR, Rahman MS, et al. Forgone healthcare and financial burden due to out-of-pocket payments in Bangladesh: a multilevel analysis. *Health economics review* 2022; **12**(1): 5.
18. Serván-Mori E, Islam MD, Kaplan WA, Thrasher R, Wirtz VJ. Out-of-pocket expenditure on medicines in Bangladesh: An analysis of the national household income and expenditure survey 2016–17. *PLOS ONE* 2022; **17**(9): e0274671.

**Annexure 1: Stakeholders interviewed to map the country-level pathways for introducing new TB diagnostics**

	<b>Name</b>	<b>Designation</b>	<b>Organization Involved</b>	<b>Type of Organization</b>
1.	Dr. Shayla Islam	Program Manager (Tuberculosis Control program)	BRAC	Non-Governmental Organization (NGO)
2.	Dr. Anupama Hazarika	Medical Officer, Communicable Disease Surveillance	WHO, Bangladesh	Specialized agency of the United Nations
3.	Dr. M. A. Hamid Selim	Senior TB Global Fund Grant Advisor for NTP	Global Fund, Bangladesh	International Financing Organization
4.	Ms. Umme Tasnim Maliha	Microbiologist & laboratory expert	NTP, Bangladesh	Government Program for Tuberculosis
5.	Dr. Asif Mujtaba Mahmud	TB Specialist	Asgar Ali Hospital	Private Hospital
6.	Dr. Abu Jamil Faisel	Ex-Senior Technical Director	Challenge TB Project	International Public Health Project
7.	Dr. Sukumar Sarkar	Senior Policy Advisor	USAID	Government agency of the United States
8.	Dr. Najis Arefin Saki	National Professional Officer, Tuberculosis	WHO, Bangladesh	Specialized agency of the United Nations

Communicable Disease Surveillance				
9.	Kamrul Hasan	Assistant Director	Directorate General of Drug Administration (DGDA)	Government Regulatory Authority
10.	Dr. Shahriar Ahmed	Deputy Chief of Party, USAID's & Assistant Scientist	icddr,b	International Research Organization
11.	Dr. Pronab Modak	Ex-Deputy Program Manager	NTP, Bangladesh	Government Program for Tuberculosis
12.	Sarder Tanzir Hossain	Diagnostics Technical Director	FHI 360	Non-profit International Development Organization
13.	Dr. Sk. Nazmul Huda	Country Project Director (HS4TB)	Management Sciences for Health (MSH), Bangladesh	Non-profit International Public Health Organization
14.	Dr. Mahmudul Hasan Khan	Senior Manager	Social Marketing Company (SMC)	Non-profit Private Sector Social Enterprise
15.	Dr. Tapash Roy	Country Director	Interactive Research and Development (IRD), Bangladesh	Non-profit Research and Public Health Organization
16.	Md. Allimuzzaman	Chief Executive Director	Biotrade International	Local Distributor
17.	Md. Ariful Islam Bhuiya	Chairman	Kutub and Son's	Local Distributor

## Annexure 2: Required information/document for device registration in Bangladesh

SI	Required information
1	Name, address and communication details of the Manufacturer /Agent in Bangladesh
2	Authorization letter of the Authorized Agent
3	Name address and communication details of the manufacturer
4	Are the products already imported in Bangladesh, if so since when
5	Name of the product, including its generic name, if any
6	Device class and classification system followed. Attached conformity assessment certificate.
7	Details of the Confirmatory Assessment body
8	Since how long the device is being used commercially? Has clinical evaluation and safety issues been addressed for the device?
9	Principle use of the device
10	Is it a drug-device combination?
11	If the above is “yes”, is the drug a new drug
12	Is it a kit comprising of more than one device?
13	Sizes of the device
14	Is Device Master File submitted
15	Short description of the Manufacturing process

16	Procedure for sterilization
17	Procedure for release of the Device in the market
18	Name and qualifications of technical personnel for manufacture and quality
19	Layout plan of the premises accompanied by the floor plan.
20	Details of QMS and manual
21	Is the product tested before release, if yes, submit details; if no, specify criteria for release
22	Has the product been withdrawn due to any reasons? If yes please specify.
23	Recall procedure to be followed in case the product has to be withdrawn
24	Names of the countries where the device is exported.

### **Annexure 3: Application process for registration of medical devices for manufacture and import into Bangladesh**

#### **a. Procedure for application for registration of Medical Devices**

1. Application for registration of a Medical Devices shall be made by the authorized person or local authorized agent of the manufacturer, or foreign supplier in the prescribed form to the office of the DGDA.
2. Prescribed fees shall be paid along with the application.
3. Separate application and fees are to be paid for separate applications, separate manufacturing premises and separate products. Similar type of Medical Devices if manufactured in the same premises can be applied in the same application form (Example– All Stents – Similar type, All Intra Ocular Lenses – Similar type, All Catheters – Similar type, All Orthopaedic Implants – Similar type, All Sutures

Similar type etc.). However, an application shall not have more than 5 products and for more than 5 products separate applications shall be made. (To consider company placing product as a manufacturer)

**b. Product details to be submitted with application**

1. Name of the Device, including brand name and generic name, if any
2. Device Class as per GHTF classification
3. Device details and description
4. Device sizes
5. Principle use of the device
6. Device Master File, (required only in cases where the CE/US FDA approvals are not available) should include material of construction and details of quantitative analysis, if required
7. Short description of the manufacturing process. Multi-facility manufacturing details may be given, (Brief description of manufacturing process and accompanied with flow diagram)
8. Labelling and Packaging details,
9. Details of accessories required for using the product, if applicable
10. Details of any predicate/ substantially equivalent product, if applicable,
11. Standard of the product, (Prevailing International standards like ISO (International Organization for Standardization)/ASTM (American Society for Testing and Materials)/IEC (International Electrotechnical Commission)/AAMI (Association for Advancement of Medical Instrumentation)
12. Device user's manual /Direction for use, e-labelling if any (Example: e-Instruction for

Use)

**c. Marketing and Regulatory details to be submitted with the application**

1. Regulatory status in the country of manufacture and in other developed economies:
  - a) For class B Devices, FSC from country of origin,
  - b) For class C and D Medical Devices, CFS from any one of the countries (e.g., EU, USA, Canada, Australia and Japan) and CFS from country of origin.
2. Conformity assessment certificate or equivalent certificate has to be submitted.
3. List of countries where the device is marketed,
4. Details regarding any withdrawal / market recall initiated by the regulatory authority from the market for any reasons in the last two years.

**d. Combination devices**

1. The medical benefits of Drug-device combination products should be described in detail.
2. Drugs which are incorporated with the device and have action ancillary to device, data on the drug's safety has to be given,
3. Clinical trial data of devices containing new drugs have to be submitted. (Refer New Drug definition under Drug Act and Rules Bangladesh and make amendment if necessary)

**e. Sales and post marketing process details**

1. Sales, Service and Distribution model details of the product, (Example: Direct marketing/ Channel partners; Service support etc), procedure by applicant/ manufacturer
2. Post Marketing: Adverse report handling, Field Action, product recalls including re-export of the product and complaint management procedure by applicant/ manufacturer

#### **Annexure 4: Acceptance of Findings by Bangladesh National TB Programme**

The National Tuberculosis Control Programme of Bangladesh, Ministry of Health hereby acknowledges and accepts the content of the report as complete and satisfactory. By signing this report, the National TB Programme confirms that the findings may be relied on for the next steps in introducing novel TB diagnostics in the country.

*Handwritten signature*  
3/2/2026  
**Dr. Md. Anashan Habib**  
Medical Officer (MBDC)  
DGHS, MoHFW  
A-88781