Critical pathway analysis for introducing new tuberculosis diagnostics in Bangladesh

Final report

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Child Health Research Foundation
CHRF
Prevent Infections, Save Lives

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Executive summary

Bangladesh, a country in the 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 the NTP's policies and strategies are guided by WHO standards, systemic delays in the introduction of new TB diagnostics in the country undermine the 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 both in public and private sector of Bangladesh.

The CPA was conducted in the context of a 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 offer 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 week supply chain systems.

Stakeholder consultations further highlighted the need of integrating point-of-care diagnostics into TB programs through a demand deriving 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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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.[1]

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.[2] Additionally, 18% TB cases in the country go undetected, posing serious challenges to TB control efforts in Bangladesh.[3] 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.[2] 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 is mostly provided by the public sector and is 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-centered 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.[4]

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.[5,6] Moreover, heavy reliance on donor funding further slows scaling of the diagnostics.[7] 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.[8,9]

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

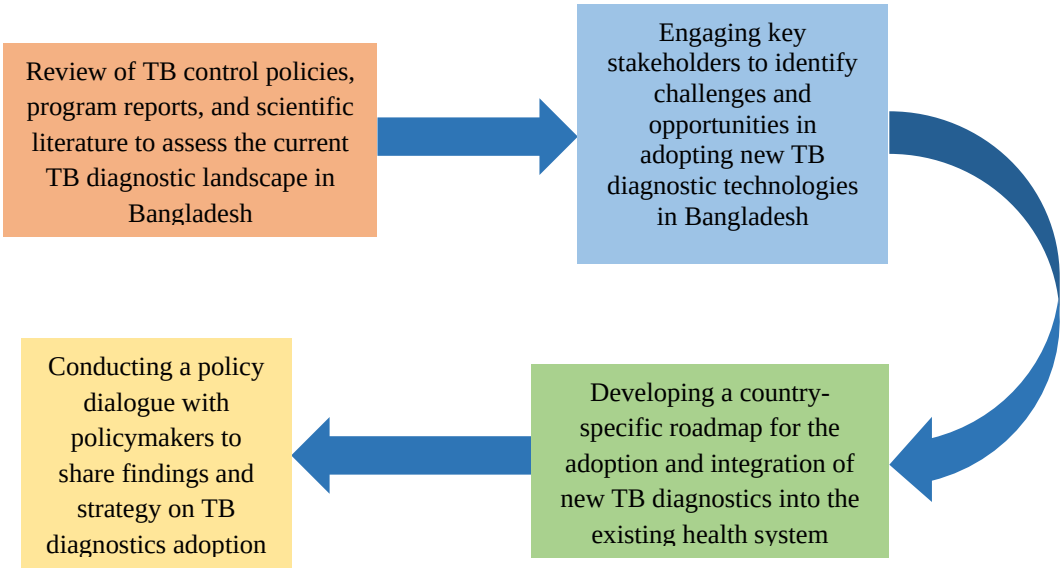


Figure 1: Conceptual Framework of CPA for adopting new TB diagnostics in Bangladesh

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

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 will be organized with stakeholders and policymakers to present findings and develop strategies for streamlining the adoption of TB diagnostics.

The outcome will help to draw a detailed 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.[10,11]

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 3 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.[11]

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

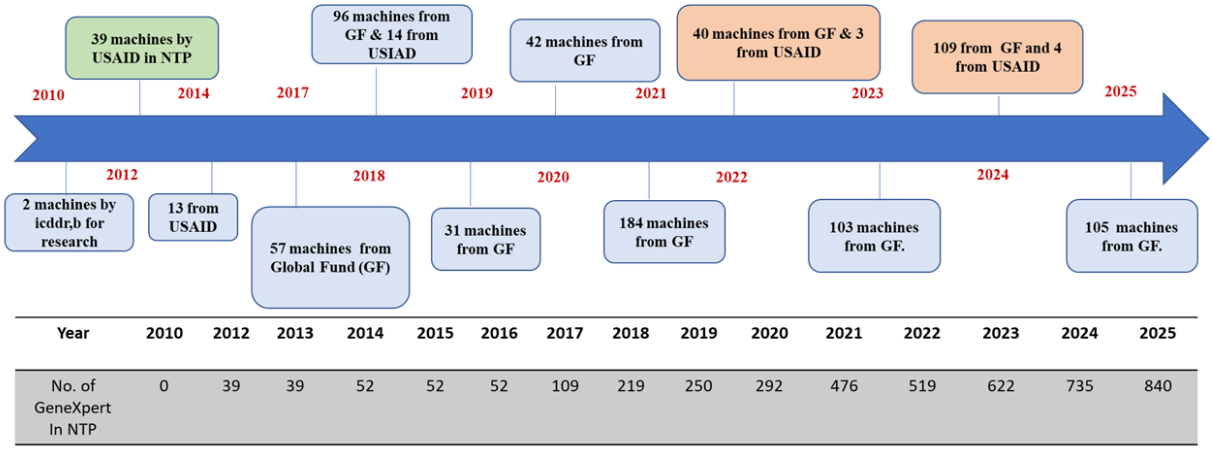
implementation across healthcare facilities in Bangladesh remains low.[12] Additionally, there is persistent delays in diagnosis and treatment undermining control efforts. Therefore, the TB burden in the country remains considerably high. Patient delay in healthcare seeking also affects the TB control program as delay in TB diagnosis and treatment leads to more severe complications and increases TB transmission in the community.[13] 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.[14] Weaknesses in diagnostic networks and a lack of coordination between TB services and other health programs also contribute significantly to these diagnostic delays.[15]

Landscape of TB Diagnostics in Bangladesh

With the advanced of TB diagnostic technologies globally, Bangladesh 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.[3] 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.[3]

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).[16]

Figure 2: GeneXpert adoption in Bangladesh National Tuberculosis Program



In 2022, Bangladesh incorporated Truenat into 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 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 which play critical roles in TB control and, therefore, influencing 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 implement 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.[17] The Global Fund has played a pivotal role in expanding TB treatment coverage, enhancing case detection, and strengthening prevention efforts in Bangladesh.[17]

- **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.[18] 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 in 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.[19,20] 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's is the largest user of the TB diagnostics in Bangladesh, with a small proportion of diagnostics are 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. Bureaucratic hurdles further delay adoption. 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, bureaucratic inefficiencies, 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

Device Class	Type of Device	Required Documents	Administrative review time	Technical review time	Certificate Validity
Class A	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
Class 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
Class C	Moderate high risk (for instance, X-ray devices)	Certificate of Free Sale (CFS) from the country of origin, International	14 Days	4 – 6 months (new) 2 – 3 months (renewal) 1 month (change)	5 years

		Standard (e.g., ISO 13485) certification			
Class D	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).

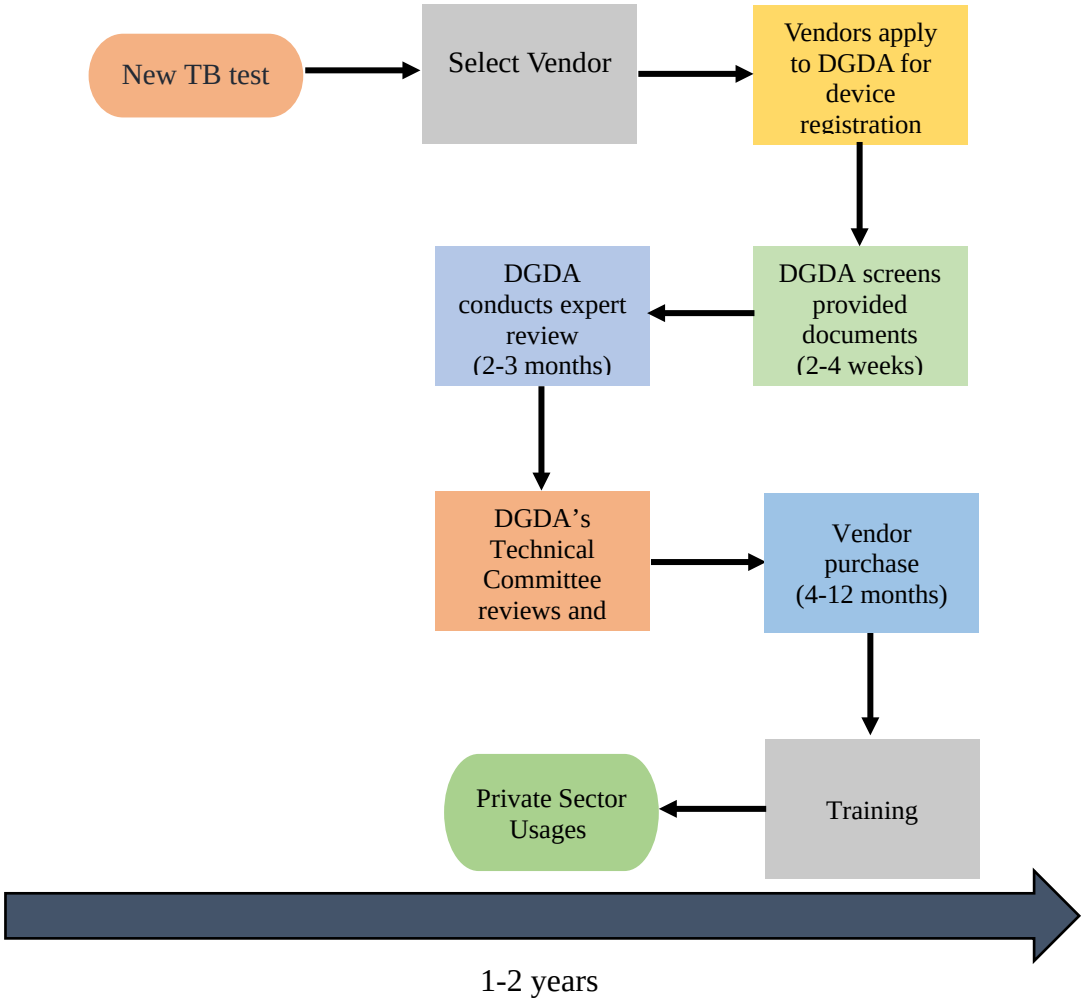


Figure 3: Adoption pathway of new TB diagnostics in private sectors of Bangladesh

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

A. Market demand creation	
Tasks	▪ Generating evidence on the test's effectiveness, accuracy, and impact ▪ Advocacy and awareness campaigns targeting policymakers, healthcare providers, and communities
Actors/Stakeholders	▪ Manufacturers, CSOs, Distributors
Enablers	▪ Low cost, minimal technical requirements, and rapid turnaround of results ▪ Certifications from internationally recognized regulatory bodies, such as the FDA, CE, or ISO ▪ WHO PQ certification
Barriers	▪ 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. ▪ Multi-purpose devices are more desirable, given the low demand for TB diagnostics in the private sector.
Timeline	Unspecified

B. Diagnostic Registration	
Tasks	▪ New diagnostics need be registered in the Bangladesh Medical Device Registration Log to obtain import permits and enable distribution.
Actors/Stakeholders	▪ DGDA and Distributor
Enablers	▪ Complete dossier detailing the product description and user guidelines ▪ Free Sale Certification in the country of origin ▪ FDA, CE, or ISO certification ▪ Data from high TB burden countries, ▪ Approval from other regulatory bodies, such as the environmental ministry
Barriers	▪ Lengthy bureaucratic processes ▪ Lack of Free Sale Certificate ▪ Distributor's reluctance due to slow demand
Timeline	12-18 Months
C. Pricing	
Tasks	▪ 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
Actors/Stakeholders	Manufacturer, Distributor and Private investor
Enablers	▪ Availability of Corporate Social Responsibility (CSR) Models based price ▪ Availability of reagent rental (placement) contracts ▪ Pack size
Barriers	▪ Slow demand increases the operating cost
Timeline	▪ Unspecified
D. Procurement and Distribution	
Tasks	Offering diagnostics at lower price for LMIC
Actors/Stakeholders	Manufacturer, Distributor, Private Operators
Enablers	▪ Availability of CSR Models based price for reduced sale prices ▪ Offering reagent rental (placement) contracts to reduce initial investment. 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.
Barriers	▪ 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. ▪ Selecting a well reputed distributors provide confidence in services
Timeline	▪ 4-6 months

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 deport 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).

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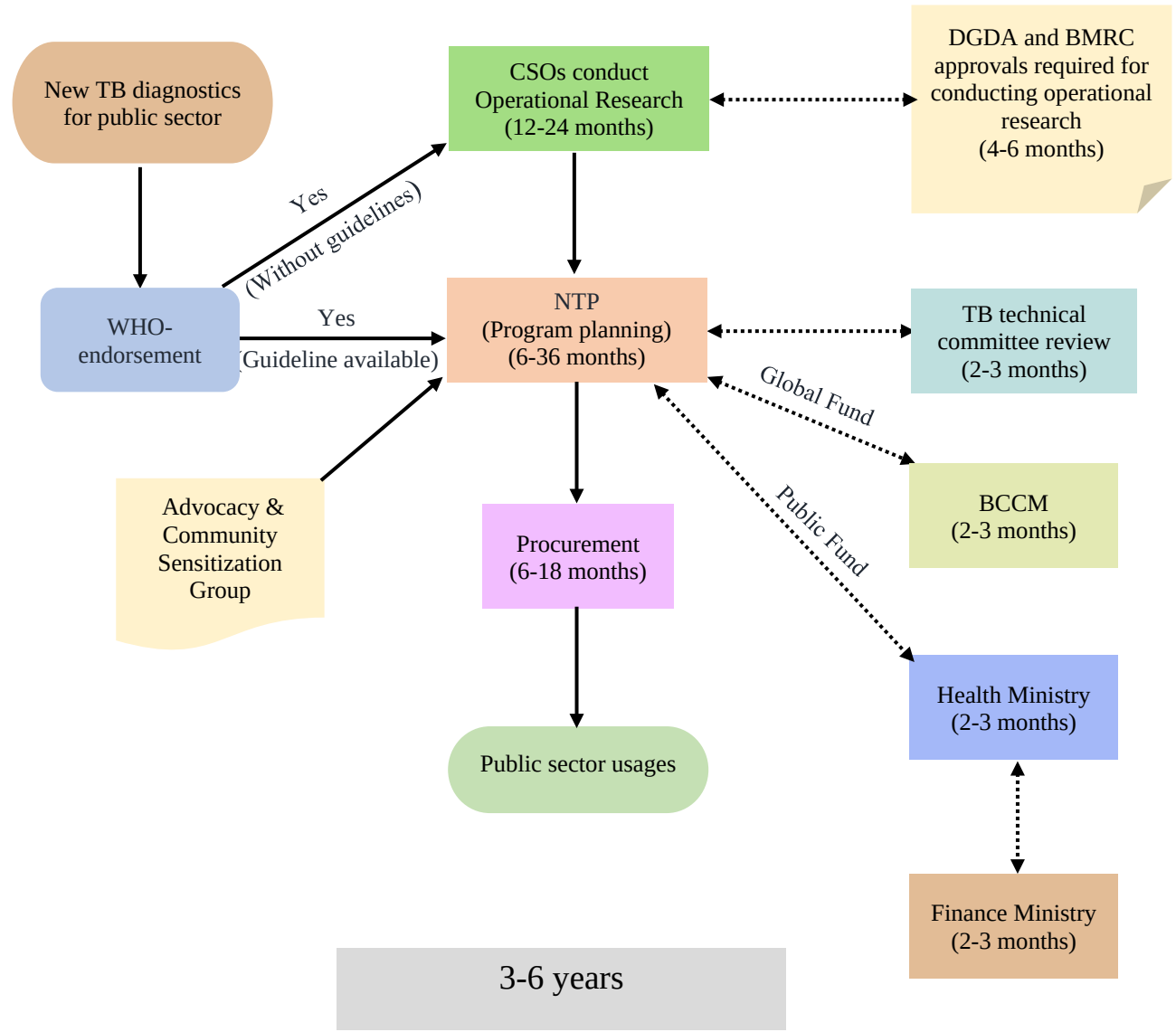

Figure 4: Adoption pathway of new TB diagnostics in public sector of Bangladesh

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

E. In-country need assessment regarding the introduction of the new TB diagnostics	
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	▪ The NTP is the primary body responsible for assessing local needs for adopting new TB diagnostics ▪ CSOs, WHO, and Development Partners and support the NTP in conducting in-country needs assessments for new TB diagnostics in Bangladesh.
Enablers	▪ Low cost, minimal technical requirements, and rapid, reproducible results ▪ WHO PQ is desirable as it facilitates a faster pathway for funding availability ▪ Certifications FDA, CE, ISO, or other internationally recognized regulatory bodies
Barriers	▪ Obtaining WHO PQ can be time-consuming and may delay diagnostic adoption into the NTP program ▪ 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
Timeline	Unspecified, continuous process that the NTP and CSOs are consistently working on
F. Program planning for new TB device adoption	
Tasks	▪ Developing the adoption and scale-up plan for the diagnostic ▪ Estimating the financial implications ▪ Updating of the national guidelines and other normative tools
Actors/Stakeholders	National TB technical working group
Enablers	▪ WHO guidelines for program implementation ▪ Positive findings from operational research
Barriers	▪ NTP follows a three-year program planning cycle, which delays the adoption of new devices in a short time frame ▪ Lack of donor support, as the implementation of TB diagnostics in Bangladesh is heavily dependent on foreign aid ▪ High technical requirements for device implementation ▪ Lack of supporting logistics
Timeline	6-36 months
G. 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	▪ Positive findings from operational research ▪ Supportive evidence from other high TB burden countries ▪ 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
Barriers	▪ The technical committee meets quarterly and often delays due to the bureaucratic process ▪ Insufficient documentation may delay the approval process
Timeline	4-6 months
H. 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.

Actors/Stakeholders	▪ The BCCM is represented by members from GoB, CSOs, research institutes, community representatives and development partners
Enablers	▪ WHO PQ certificates, and positive findings from operational research
Barriers	▪ Accessing Global Fund support is time-consuming, as the Fund follows a three-year cycle for allocating resources to new initiatives
Timeline	2-3 months if funds are available, otherwise, need to wait for the next funding cycle
I. Approval by DGHS: Director General of Health Services/ Health Ministry	
Tasks	▪ Review all processes undertaken, allocate public funds
Actors/Stakeholders	▪ MoHFW, Ministry of Finance
Enablers	▪ WHO prequalification certificates, FDA, CE or ISO certification ▪ Data for other high TB burden countries
Barriers	▪ Slow decision-making and stringent budget reallocation policies
Timeline	▪ 3-4 months
J. 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	▪ CMSD, NTP
Enablers	▪ Availability of funds for procurement ▪ Availability of the device in the market ▪ Inclusion of the device in the official medical equipment list ▪ Availability of a No Objection Certificate (NOC) from the relevant department ▪ Presence of a local vendor for importing the device into the country
Barriers	▪ Slow action taken in developing the procurement plan
Timeline	6-18 months, depending on the funding source and diagnostic availability in the market
K. Arrival of the commodity and distribution to the appropriate centers	
Tasks	▪ Receipt of the commodity in the warehouse and then plan the distribution to the appropriate centers
Actors/Stakeholders	▪ CMSD, NTP, WHO
Enablers	▪ NOC from relevant authorities ▪ Availability of supporting logistics ▪ Approved plan for in-country deployment and use of the diagnostics
Barriers	▪ Slow action taken by the relevant officials and lack of supervision
Timeline	▪ 3-6 months

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. **Complicated bureaucratic processes**

The approval pathway for new TB diagnostics is lengthy and often inefficient, largely due to limited regulatory capacity and bureaucratic delays. 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 create resistance in processing applications for registering new technologies. Consequently, device registration and approval are frequently delayed.

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 nonqualified 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 shortage of human resources in Bangladesh, rapid, affordable, and low-technology diagnostic devices are particularly desirable. Manufacturers should therefore prioritize developing TB diagnostics that are near point-of-care, cost-effective, and easily integrated into care pathways; meeting the strong demand for tests that provide results during the same visit.
    - Because TB testing is provided free at public facilities, private sector investment in TB diagnostics in Bangladesh is limited. Consequently, manufacturers should prioritize developing devices that are compatible with open platforms or designed for multipurpose use to better meet private sector needs.
    - Manufacturers should secure certifications from recognized regulatory bodies such as the FDA, CE, or ISO beforehand, as Bangladesh's regulatory authority largely depends on these approvals when issuing import licenses.

2. **Government and other Recipient perspective**

    - Conduct a thorough needs assessment before introducing new TB diagnostics to ensure alignment with local needs, national priorities, and global standards.

- Engage key stakeholders including CSOs, and research organizations and private practitioners to advocate for and support the adoption of new diagnostics.
- Engage NTP officials and policymakers early to build awareness and address system gaps.
- Train clinicians and healthcare workers on proper use of new diagnostics to ensure effective implementation and uptake.
- Increase public funding for TB diagnostics to support timely, context-driven decisions and reduce reliance on external donors.

3. Donor perspectives

- Support affordable and scalable diagnostics to ensure long-term sustainability and accessibility.
- Diversify prequalification criteria by recognizing regulatory approvals from trusted institutions such as the FDA, CE, ISO, and others.
- Facilitate context-specific market analyses to better understand in-country needs for TB diagnostics.
- Invest in training and education programs to build local capacity for device implementation, maintenance, and troubleshooting.
- Support local governments and CSOs in staying informed about critical pathways and processes for adopting new diagnostics

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.

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

	Name	Designation	Organization Involved	Type of Organization
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.	Dr. Asif Mujtaba Mahmud	TB Specialist	Asgar Ali Hospital	Private Hospital
5.	Dr. Abu Jamil Faisel	Ex-Senior Technical Director	Challenge TB Project	International Public Health Project
6.	Dr. Sukumar Sarkar	Senior Policy Advisor	USAID	Government agency of the United States
7.	Dr. Najis Arefin Saki	National Professional Officer, Tuberculosis Communicable Disease Surveillance	WHO, Bangladesh	Specialized agency of the United Nations
8.	Kamrul Hasan	Assistant Director	Directorate General of Drug Administration (DGDA)	Government Regulatory Authority
9.	Dr. Shahriar Ahmed	Deputy Chief of Party, USAID's & Assistant Scientist	icddr,b	International Research Organization

10.	Dr. Pronab Modak	Ex-Deputy Program Manager	NTP, Bangladesh	Government Program for Tuberculosis
11.	Sarder Tanzir Hossain	Diagnostics Technical Director	FHI 360	Non-profit International Development Organization
12.	Dr. Sk. Nazmul Huda	Country Project Director (HS4TB)	Management Sciences for Health (MSH), Bangladesh	Non-profit International Public Health Organization
13.	Dr. Mahmudul Hasan Khan	Senior Manager	Social Marketing Company (SMC)	Non-profit Private Sector Social Enterprise
14.	Dr. Tapash Roy	Country Director	Interactive Research and Development (IRD), Bangladesh	Non-profit Research and Public Health Organization
15.	Md. Allimuzzaman	Chief Executive Director	Biotrade International	Local Distributor
16.	Md. Ariful Islam Bhuiya	Chairman	Kutub and Son's	Local Distributor

Annexure 2: Required information/document for device registration with DGDA

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 than5 products separate applications shall be made. (To consider company placing product as a manufacturer)

b. Product details to be summitted 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