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REVIEW ARTICLE

SCALING UP QUALITY ASSURANCE FOR TB DIAGNOSIS IN INDIA: STRATEGIES AND OUTCOMES TO 2025

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ABSTRACT

India has taken a bold and ambitious step in committing to end tuberculosis (TB) by 2025, ahead of the global target of 2030. This commentary explores the strategies adopted for scaling up quality assurance (QA) in TB diagnostics, which forms the backbone of accurate, timely, and efficient case detection and management. It discusses political leadership, technological integration, private sector engagement, surveillance indicators, and economic support mechanisms, and analyzes how these strategies have improved the TB diagnostic landscape in India. It concludes with a reflection on key challenges and future directions required to sustain momentum in India's TB elimination efforts.

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INTRODUCTION

India contributes to approximately a quarter of the global TB burden (WHO, 2018). As such, the country's success in eradicating TB is pivotal to achieving global elimination goals. Recognizing this, the Government of India launched an ambitious National Strategic Plan (NSP) for TB Elimination (2017-2025), setting a deadline five years ahead of the United Nations Sustainable Development Goal (SDG) target of 2030 (MoHFW, 2017). Achieving this goal requires not only political will but a well-integrated system that ensures accurate diagnosis, consistent treatment, and robust surveillance. A core component of this elimination strategy is quality assurance (QA) in TB diagnostics. Effective QA systems ensure that laboratory services are accurate, timely, and reliable, forming the foundation of patient management, epidemiological surveillance, and programmatic interventions. This commentary presents a detailed overview of India's progress in scaling QA systems in TB diagnosis and evaluates the impact of this effort on national TB elimination goals.

Political Will and Programmatic Innovations
The political narrative around TB elimination gained traction with Prime Minister Narendra Modi's commitment during the One World TB Summit 2023 in Varanasi (TBC India, 2023). Launching initiatives like TB-Mukt Panchayat and acknowledging Ni-kshay Mitra for community involvement, he emphasized the role of collective effort. The Direct Benefit Transfer (DBT) scheme, through which nearly ₹2 lakh crore was distributed among 75 lakh patients, exemplifies India's dedication to patient-centric approaches. The onset of COVID-19 posed a major disruption to TB services, with notification rates dropping sharply in early 2020. However, by repurposing resources such as Nikshay Sampark and promoting bidirectional screening, the Central TB Division rapidly closed the gap, reaching pre-pandemic notification levels by December 2020 (TBC India Report, 2020).

Diagnostics Infrastructure: Building and Scaling Up
India's diagnostic ecosystem has expanded significantly, integrating multiple diagnostic technologies. A tiered laboratory network now spans National Reference Labs, Intermediate Reference Labs, and peripheral microscopy centers. Advanced molecular diagnostics such as CBNAAT (GeneXpert) and Truenat are available at sub-district and district levels.

As of 2022:

- 1,287 GeneXpert machines across 1,147 sites participated in external quality assurance (EQA) assessments; 97.82%

demonstrated satisfactory performance (India TB Report, 2018).

- 841 Truenat machines in 797 sites participated, with 90.84% passing EQA.
- Over 22.1 crore individuals were screened through active case finding (ACF); 19.5 lakh underwent diagnostic testing, resulting in 48,329 confirmed TB cases (TBC India, 2023).

This scaling effort was accompanied by training of laboratory staff, digital connectivity of diagnostic instruments, and performance-based monitoring (GLI Guide, 2016).

Universal Drug Susceptibility Testing and MDR-TB Management: Universal Drug Susceptibility Testing (UDST) has become a key priority under the NSP (MoHFW, 2017). It ensures that all diagnosed patients, particularly those with comorbidities or treatment irregularities, undergo testing for resistance to first-line anti-TB drugs. New regimens for MDR-TB have incorporated drugs like Bedaquiline and Delamanid, currently deployed in 7 states/UTs. These are provided under monitored conditions, and their rollout is aligned with WHO guidelines. India's laboratory network now includes Line Probe Assay (LPA) and liquid culture facilities, contributing to early detection and appropriate treatment initiation. Digital tools, including the Nikshay portal and connectivity software, have further enhanced data accuracy and availability. These systems support real-time monitoring, reduce diagnostic delays, and enable automated alerts for missed follow-ups (GLI Guide, 2016)[5].

Private Sector Engagement: Unlocking Hidden Burden
Despite handling over 75% of initial care-seeking in India, the private sector traditionally contributed minimally to TB notifications. Through the JEET (Joint Effort for Elimination of Tuberculosis) initiative and strategic partnerships, this gap is narrowing. Notification from private providers rose from 11% in 2017 to over 56% by 2023 (WHO, 2018)[6]. Incentives such as ₹500 for notifying TB cases and outcomes have encouraged reporting. Collaboration with bodies like the Indian Medical Association (IMA), FOGSI, and IAP has improved adherence to national guidelines. These efforts help identify cases that would otherwise be missed and bring uniformity in diagnosis and treatment protocols.

Social Protection and Economic Support Mechanisms
TB disproportionately affects the socioeconomically vulnerable. The National TB Prevalence Survey (2019-2021) revealed that TB treatment cost was ₹7,500 in the public sector and ₹20,000 in the private sector per patient (TBC India, 2023)[8]. The financial burden often leads to catastrophic health expenditure (CHE). To address this, schemes like Nikshay Poshan Yojana (NPY) provide ₹500 per month to support nutritional needs during treatment. Incentives for treatment completion and support for contact tracing further alleviate economic pressure.

Quality Assurance and Surveillance Metrics
India has institutionalized quality assurance through structured EQA programs, regular audits, and supervisory mechanisms. Indicators such as the Presumptive TB Examination Rate (PTBER) and Annualized TB Case Notification Rate (ACNR) are employed to track diagnostic efficiency (Nikshay Reports, 2023)[2].
Moreover, Joint Supportive Supervision Missions and regional reviews ensure accountability and corrective action. The TB Index, linked to Sustainable Development Goals, helps prioritize interventions in high-burden districts.

Challenges and Future Outlook: Despite significant gains, challenges remain. Pockets of under-diagnosis exist in remote and tribal regions. Diagnostic capacity must be equitably distributed, especially in low-resource settings. Adherence to diagnostic protocols and periodic retraining of healthcare personnel are needed. Integration with other public health initiatives like Ayushman Bharat, expanding digital innovations (e.g., AI-assisted radiology), and ensuring uninterrupted supply chains will strengthen outcomes. Enhanced community engagement and addressing TB-related stigma are also pivotal. India's experience demonstrates that a well-coordinated, quality-focused, and inclusive approach can yield transformative outcomes. The country is on a promising trajectory, but sustained political commitment, strategic investments, and constant vigilance will determine its success in eliminating TB by 2025.

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