ACCELERATING TUBERCULOSIS ELIMINATION IN INDIA THROUGH HIGH-IMPACT DIAGNOSTIC STRATEGIES

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Abstract:

India accounts for the largest share of the global tuberculosis (TB) burden, and diagnostic gaps remain a major barrier to elimination. Despite significant expansion of molecular testing and laboratory infrastructure under NTEP, delayed diagnosis, incomplete drug-resistance testing, underutilized platforms, inequitable access, and weak private-sector integration continue to undermine outcomes. This article highlights the central role of diagnostics in reducing transmission and improving survival, and proposes high-impact strategies including targeted screening, universal upfront molecular testing, baseline drug-resistance testing, decentralised point-of-care diagnostics, private-sector engagement, and adoption of future-ready tools. Strengthening diagnostics is essential to accelerate TB elimination in India.

1. Context and Rationale

According to the WHO Global TB report (2025), India bears the largest tuberculosis (TB) burden globally, accounting for over one-quarter of the world's TB cases. Despite sustained progress over the past decade, TB continues to impose a substantial public health, economic, and social burden, disproportionately affecting the poor, working-age adults, and vulnerable populations [1].

The National Strategic Plan (NSP) for TB Elimination (2023–2027) under the National Tuberculosis Elimination Programme (NTEP) places strong emphasis on early and accurate diagnosis, universal drug-resistance testing, rapid initiation of appropriate treatment, patient-centric and equity-focused care. Diagnostics are explicitly identified in the NSP as a foundational pillar for TB elimination, alongside treatment, prevention, and social support. This reflects a growing recognition that treatment success and transmission control are contingent on timely and accurate diagnosis. While India has expanded access to molecular diagnostics and strengthened laboratory networks, diagnostic gaps continue to limit the impact of programmatic interventions [2,3]

Achieving TB elimination will require a paradigm shift from selective testing to universal, high-quality diagnostic coverage, particularly at the first point of patient contact with the health system [4].

Why Diagnostics Are Central to TB Elimination

TB elimination is fundamentally diagnosis-dependent. Unlike many communicable diseases, where presumptive or syndromic management may interrupt transmission, TB transmission persists until infectious individuals are accurately diagnosed and effectively treated. Every missed or delayed diagnosis represents a continued source of community transmission[5].

Current programmatic experience highlights several diagnostic challenges that directly undermine elimination efforts:
·Diagnostic delays remain substantial, with patients often experiencing weeks to months between symptom onset and confirmed diagnosis, particularly when initial testing relies on low-sensitivity tools.
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Currently only 53% of bacteriologically positive TB cases are detected underlying the fact that 47% TB cases are bacteriologically-negative and the efforts to identify organisms remain sub-optimal. Only about 44% of estimated Drug-resistant TB (DR-TB) were detected; the cases are frequently identified late, after treatment failure or clinical deterioration, increasing both mortality and programmatic costs. In some settings, smear microscopy continues as the initial diagnostic test, despite limited sensitivity (~50–60%), resulting in false negatives, delayed diagnosis, and missed TB cases, particularly among vulnerable populations [6].

These diagnostic gaps contribute to ongoing community transmission, higher TB-related mortality, amplification of drug resistance and increased financial burden on households and the health system.

Conversely, strengthening TB diagnostics produces multiplicative public health benefits. Evidence from India and comparable high-burden settings demonstrates that early molecular diagnosis and upfront drug-resistance testing reduce the infectious period and secondary transmission, enable treatment initiation within days rather than weeks improving outcomes and survival, prevent the emergence and spread of drug-resistance and reduce long-term programmatic costs.

In economic terms, investments in diagnostics yield high returns, as the cost of early detection is substantially lower than the cost of treating advanced or drug-resistant disease. From a health systems perspective, diagnostics serve as the gateway intervention upon which all downstream TB control measures depend.

2. Current Diagnostic Landscape in India

Public Sector Diagnostic Network

Over the past decade, India has significantly expanded its tuberculosis diagnostic capacity, establishing one of the largest laboratory networks globally. This expansion has been driven by sustained investments in decentralized laboratory infrastructure and the adoption of WHO-recommended diagnostic technologies (WRD) [7]. The public sector diagnostic ecosystem currently comprises:

- Rapid molecular diagnostic platforms, including Truenat and CBNAAT, deployed across districts and high-burden blocks with 6,500 NAAT laboratories (approximately 4,800 Truenat and 1,700 CBNAAT),
- A wide network of 24,500 smear microscopy centres providing peripheral access
- About 84 Culture and drug-susceptibility testing (DST) laboratories, including reference laboratories for first- and second-line drug resistance

As a result of these efforts, the proportion of bacteriologically confirmed TB cases tested using molecular diagnostics has increased substantially in recent years, and India now performs tens of millions of TB diagnostic tests annually through the public health system. Molecular testing capacity has expanded to all districts, supporting early detection of TB and rifampicin resistance.

However, coverage has not uniformly translated into optimal utilization or impact. Persistent challenges include:

- Under-utilization of molecular platforms in some facilities due to workflow, staffing, or operational constraints. A total of 6.8 million tests were performed on ~ 6500 devices translating into an average utilisation of ~ 1000 tests per device per year indicating gross underutilisation of available capacity. These platforms also support multi-disease testing, including HIV, HCV, HPV, and dengue, offering opportunities for improved efficiency and return on investment through integrated use.
- Geographic inequities remain evident, especially in remote and tribal areas and the North-Eastern states and larger states reflecting challenges in specimen transportation. Available point of care platforms offers an ideal platform for scaling up decentralised testing in these areas.

In addition, while culture and DST capacity has expanded, turnaround times remain long (4 to 8 weeks), limiting their effectiveness for timely clinical decision-making. These gaps reduce the potential gains from existing investments and constrain progress toward elimination.

Private Sector Diagnostics

The private health sector plays a dominant role in TB care-seeking behaviour, with more than half of TB patients initially seeking diagnosis and treatment outside the public system. Private laboratories and hospitals therefore represent a critical but under-leveraged component of the national diagnostic landscape [8,9].

Despite this central role, significant gaps persist:

- Access to WRDs in the private sector remains inconsistent and often cost-dependent
- Diagnostic algorithms vary widely, with continued use of non-standard or low-sensitivity tests in some settings
- TB notification and data integration with national surveillance platforms remain incomplete, despite regulatory mandates
- The potential of Rural Health Care Providers (RHCPs) in adoption of near point-of-care (nPOC) diagnostic and screening technologies endorsed by NTEP, particularly in inaccessible, high-burden, and large rural populations is not realised.
- Community ownership of Active Case Finding (ACF) strategies remains poor.

These challenges contribute to delayed diagnosis, inappropriate treatment, and under-reporting of TB cases, undermining national surveillance and planning. While recent public–private mix (PPM) initiatives have improved engagement, diagnostic integration of the private sector remains partial and uneven across states.

Equity and Access Challenges

Despite overall expansion of diagnostic capacity, equitable access to quality TB diagnostics remains a major concern. Several population groups continue to face disproportionate barriers, including:

- Rural and tribal populations, where distance, transport costs, and limited facility readiness delay testing
- Urban poor and migrant populations, who frequently rely on informal or fragmented care pathways
- People living with HIV and other vulnerable groups, for whom TB diagnosis is often more complex and delayed

These inequities result in missed or late diagnoses, prolonged infectious periods, and poorer outcomes. From an elimination perspective, such diagnostic blind spots sustain transmission in precisely those populations where TB burden is highest.

3. Key Gaps and Challenges

Financing and Market Constraints

Sustainable financing remains a key challenge for TB diagnostics. Molecular testing depends on cartridge and consumable based platforms, creating recurrent, volume-driven expenditure. Given programme targets that require multiple screening tests for each confirmed TB case, at least one molecular diagnostic test for every presumptive patient, and additional testing among nearly 15% high-risk populations, the resulting national testing volume is estimated at 20–30 crore screening and diagnostic tests annually. This scale of testing creates substantial and sustained recurrent expenditure pressures for both state governments and NTEP [10,11].

At the same time, India's domestic diagnostic manufacturing capacity remains under-leveraged. Despite the availability of indigenous platforms, procurement and market-shaping strategies have not fully exploited economies of scale to reduce per-test costs, secure supply chains, and stimulate innovation. Addressing these constraints is essential to ensure affordable, resilient, and domestically financed diagnostic services at scale.

Technical Gaps in TB Diagnostics

Despite significant expansion of diagnostic infrastructure under the NTEP, important technical gaps continue to constrain impact. Smear microscopy remains the first diagnostic test in certain settings despite its well-documented low sensitivity. Reliance on smear-based algorithms contributes to missed diagnoses and prolonged infectious periods.

While rapid molecular diagnostics have been scaled nationally, upfront detection of drug resistance remains largely limited to rifampicin. Resistance to fluoroquinolones and other key drugs is often identified only after treatment failure or clinical deterioration. Given India's large burden of drug-resistant TB, delayed or incomplete resistance profiling increases the risk of amplification of resistance and poor treatment outcomes.

Additionally, non-sputum-based diagnostics remain limited (blood or saliva or stool), constraining effective diagnosis in children and extrapulmonary TB, which together account for a substantial proportion of notified cases. These technical gaps directly undermine early detection and effective case management [12,13].

Programmatic and Health System Gaps

Beyond technology availability, programmatic inefficiencies reduce the effectiveness of existing diagnostic capacity. Delays between diagnosis and treatment initiation remain common, particularly where diagnostic and treatment services are not co-located increasing the risk of loss to follow-up.

Diagnostic and treatment pathways are often fragmented across facilities, sectors, and levels of care, particularly at the public–private interface. This fragmentation leads to duplication of testing, inconsistent clinical decision-making, and avoidable patient costs. Furthermore, quality assurance systems across laboratories remain variable, with differences in adherence to standard operating procedures, external quality assessment, and data reporting.

Collectively, these system-level gaps dilute the potential benefits of advanced diagnostics and limit their contribution to elimination goals.

4. Strategic Policy Recommendations

Strategy 1: Screening and Active Case Finding

Screening population and Implementing targeted Active Case Finding (ACF) among high-risk and vulnerable populations using low-cost chest radiography (with digital or AI-assisted interpretation where feasible) followed by confirmatory molecular testing.

Currently, out of the 200 million population mapped for screening only 2.1 million (1%) are tested of which 35,000 (1.6%) are diagnosed with TB. To improve screenings, community-led ACF models should be explored and operationalized through convergence with the G RAM G scheme, leveraging the availability of nearly 12 crore active workers at the village level to support symptom screening, community mobilization, referral, and linkage to diagnostic services [14].

Usage of newer triage and diagnostic tool for community, increase the community screening from 1% of mapped population to 20% of mapped population will enable early identification of presumptive TB cases, reduce diagnostic delays, and optimize use of molecular diagnostics while maintaining affordability at scale.

Strategy 2: Universal Upfront Molecular Testing

Transitioning to molecular tests as the initial diagnostic test for all presumptive TB cases represents a critical policy shift. Replacing smear-first algorithms with rapid molecular testing would substantially reduce missed cases and diagnostic delays. The upfront molecular testing gap is 79%; under the programme of the 24.3 million presumptive TB cases tested only 5.1 million (21%) had molecular tests. A benchmark of 100% is proposed to achieve in next five years enabling earlier case detection, shorter infectious periods, reduced transmission, and improved treatment outcomes.

Strategy 3: Universal Baseline Drug-Resistance Testing

Mandatory reflex testing for first- and second-line drug resistance at the time of TB diagnosis would ensure that resistance profiles are known before treatment initiation. Out of the 64000 Rifampicin cases detected only 26000 (41%) were tested for second line TB resistance (Fluroquinolone). Decentralized rapid DST using molecular platforms can make this feasible at scale. This would result in reduced amplification of drug resistance, higher treatment success rates, and lower long-term programme costs.

Strategy 4: Decentralization and Point-of-Care Diagnostics

Expanding **point-of-care molecular diagnostic platforms at Sub-centres (SCs), Primary Health Centres (PHCs), and Community Health Centres (CHCs**) supported by **mobile diagnostic units and strengthened specimen transport networks** will help address geographic inequities and reduce patient-level diagnostic delays. India currently has approximately **182000 lakh Ayushman Arogya Mandirs, 32,000 PHCs, and 6,500 CHCs, while about 24,500 Designated Microscopy Centres (DMCs)** are largely concentrated at PHCs, CHCs, and tertiary facilities. A phased saturation approach is proposed, aiming to extend **molecular diagnostic coverage to 50% of AAM and 100% of PHCs and CHCs,** thereby decentralizing access, improving equity

Decentralization of TB diagnostics by expanding point-of-care molecular testing to achieve 50% coverage of Ayushman Arogya Mandir and 100% coverage of PHCs and CHCs, would lead to faster diagnosis, improved access in hard-to-reach areas, and greater equity in TB care.

Strategy 5: Private Sector Diagnostic Integration

Enable private sector use of WRDs through a co-financing model, whereby the programme covers up to 50% of test-kit costs, conditional on mandatory Nikshay notification and performance-linked reimbursement. Introduce a digital diagnostic voucher for presumptive TB patients diagnosed in the private sector, redeemable only for WRDs at empanelled laboratories. This will standardize diagnostic practices, strengthen surveillance, and reduce patient out-of-pocket expenditure while maintaining fiscal discipline. Engaging RHCPs extends diagnostic reach beyond formal health facilities, enabling early identification of presumptive TB cases, reducing first-contact delays, and improving access in settings with limited facility density

Strategy 6: Innovation and Future-Ready Diagnostics

Non-sputum-based diagnostics (blood, saliva, or stool), cough-based application, and genomic surveillance using next-generation sequencing (NGS) are critical to prepare India for **elimination-phase TB challenges** and emerging drug-resistance patterns. AI-assisted CXR triage has demonstrated the ability to screen **3–5 times more individuals per day** than symptom-based approaches, with **sensitivity exceeding 85–90%** in community and high-risk settings, enabling efficient identification of presumptive TB at low per-person cost.

Non-sputum-based diagnostics are particularly important for **children, extrapulmonary TB, and smear-negative disease,** which together account for an estimated **30–40% of TB** cases and are systematically under-diagnosed using sputum-dependent methods. In parallel, targeted use of **NGS for surveillance** can detect emerging resistance to key drugs and transmission clusters earlier than conventional methods; even **sentinel genomic surveillance covering 5–10% of DR-TB cases** can provide actionable insights for programme planning and drug policy.

5. Economic and Public Health Impact

Strengthening tuberculosis (TB) diagnostics yields high returns on investment because TB transmission and outcomes are diagnosis-dependent. With India reporting ~2.7 million TB cases annually, reducing diagnostic delays delivers substantial public health and fiscal benefits.

An untreated pulmonary TB patient may infect 10–15 individuals per year, whereas rapid molecular diagnostics enable confirmation within days and early treatment initiation. Evidence indicates that universal upfront molecular testing can reduce diagnostic delays by 30–50%, resulting in fewer secondary infections and lower future TB incidence.

The economic case is strongest for drug-resistant TB (DR-TB). MDR-TB treatment costs are approximately 10–15 times higher than drug-sensitive TB, require 18–24 months of therapy, and have poorer outcomes. In contrast, the incremental cost of universal baseline drug-resistance testing is relatively small. Preventing even 10–15% of MDR-TB cases through early resistance detection is sufficient to offset additional diagnostic expenditure, making diagnostic scale-up cost-saving over time.

Early diagnosis also reduces catastrophic health expenditure, which frequently exceeds 20–30% of annual household income due to repeated pre-diagnostic visits and income loss. As TB primarily affects the 15–59 year age group, early diagnosis preserves productivity and reduces long-term disability. Overall, economic analyses show that investments in TB diagnostics become cost-saving within a 3–5 year horizon, outperforming downstream spending on prolonged treatment and hospitalization.

Conclusion:

TB elimination cannot be achieved without a decisive strengthening of diagnostic strategies. Universal access to rapid, accurate, and affordable diagnostics across public and private sectors and at all levels of care must be positioned as a core national priority to translate political commitment into measurable elimination gains.
Diagnostics are the gateway intervention for TB elimination. India possesses the technological capacity, programmatic experience, and manufacturing strength to lead globally. Strategic policy action on diagnostics will determine whether TB elimination becomes a reality or remains an aspiration. Expanded TB diagnostics should be treated as a strategic investment, not a recurrent cost, delivering measurable health gains and long-term fiscal savings while accelerating progress toward TB elimination.

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