**The Unfinished Agenda: Critical Barriers and Research Priorities for Tuberculosis Elimination in India Towards and Beyond 2025**

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Abstract:

Background: India bears the highest global burden of tuberculosis (TB), accounting for an estimated 26-28% of global incidence. The National Tuberculosis Elimination Programme (NTEP) has set an ambitious target to eliminate TB by 2025, five years ahead of the United Nations Sustainable Development Goals (SDGs) target of 2030. This review critically synthesizes evidence to examine the NTEP's performance, highlighting successes, persistent challenges, and proposing evidence-based research protocols.

Methods: A comprehensive narrative review was conducted, drawing upon official government reports, the WHO Global Tuberculosis Report 2024, and peer-reviewed academic literature published between 2015 and mid-2024. Search terms included "tuberculosis," "India," "elimination," "challenges," "drug-resistant TB," "private sector," "stigma," "nutrition," and "diagnostics". The analysis focused on epidemiological trends, programmatic achievements, and persistent challenges.

Findings: While the NTEP has made notable strides in case notification, diagnostic expansion, and patient support, significant challenges persist. Key progress includes a 17.7% decline in TB incidence from 2015 to 2023 and a 24% reduction in mortality. However, critical problems include: the high burden of drug-resistant TB (DR-TB); a fragmented private sector leading to underreporting; deep-seated socio-economic barriers; diagnostic delays in vulnerable populations; and human resource shortages. Factual data confirms India is on a positive trajectory, but the ambitious 2025 target remains a formidable challenge.

Interpretation: Achieving TB elimination requires a data-driven, multi-sectoral approach that transcends biomedical interventions alone. Future strategies must prioritize intensified implementation research, strengthening public-private partnerships, empowering communities, and comprehensively addressing social determinants. Sustained political commitment and increased funding are crucial to accelerate progress toward a TB-free India beyond 2025.

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1. Introduction

Tuberculosis (TB) remains a formidable global health challenge, disproportionately affecting low- and middle-income countries. India, with its population exceeding 1.4 billion, shoulders the highest TB burden worldwide (1). The National Tuberculosis Elimination Programme (NTEP), launched in 2017 under the National Strategic Plan (NSP) 2017-2025, represents India's renewed commitment to ending TB as a national health priority (2). The program aims to eliminate TB by 2025 – defined as reducing TB incidence to less than 44 cases per 100,000 population, mortality to fewer than 3 deaths per 100,000, and ensuring zero catastrophic costs for affected households – an ambitious target five years ahead of the United Nations Sustainable Development Goals (SDGs) target of 2030 (1, 2).

The NTEP operates on four strategic pillars: Detect-Treat-Prevent-Build (DTPB), which fundamentally re-engineers the country's approach from management to elimination. Key initiatives include the use of advanced diagnostics, financial and nutritional support for patients, active case-finding campaigns, and multisectoral partnerships. Despite these comprehensive efforts, India still accounts for a disproportionate share of the global TB burden (1, 3).

This review article provides a critical, evidence-based assessment of the NTEP's performance, focusing on its successes and the critical challenges that threaten to derail the 2025 target. It integrates data and insights from recent national and international reports, identifying "burning problems" and proposing evidence-based research protocols to accelerate progress toward a TB-free India.

2. Methodological Approach

Our analysis is grounded in the most recent and credible data from both national and international sources. A systematic narrative review approach was employed, drawing evidence from official government reports, high-impact peer-reviewed journals, systematic reviews, and epidemiological studies up to mid-2024.

Primary sources include:

* India TB Report 2024 (Ministry of Health and Family Welfare, Government of India): This official report is the primary source for program data, offering key performance indicators and progress updates (2).
* WHO Global Tuberculosis Report 2024: This report provides an independent, external assessment of India's progress within a global context (1).
* Other relevant literature was identified through searches in electronic databases such as PubMed and Google Scholar. The search covered articles published between January 2015 and June 2024. Keywords included "tuberculosis," "India," "elimination," "challenges," "drug-resistant TB," "private sector," "stigma," "nutrition," and "diagnostics". Grey literature, including NTEP reports and World Health Organization (WHO) documents, was also considered. Studies were included if they provided original data or critical commentary on the operational, clinical, or social challenges of TB control in India.

3. Overview of the National Tuberculosis Elimination Programme (NTEP)

The NTEP's evolution from the Revised National Tuberculosis Control Programme (RNTCP) reflects a strategic shift from control to elimination, incorporating digital health tools like the Ni-kshay portal for real-time tracking of cases and direct benefit transfers (DBT) (2, 4). Under the Ni-kshay Poshan Yojana (NPY), patients receive INR 500 monthly for nutritional support, with over ₹3,202 crores disbursed to 1.13 crore beneficiaries in 2023 (2). The Pradhan Mantri TB Mukt Bharat Abhiyaan (PMTBMBA), launched in 2022, has mobilized over 160,000 Ni-kshay Mitras (community supporters) to provide nutritional aid to more than 1.14 million patients, addressing undernutrition – a key TB risk factor (2, 5).

The program has emphasized advanced diagnostics, including nucleic acid amplification tests (NAATs) like CBNAAT and Truenat machines (2, 6). Private sector engagement has surged, contributing 33% of all notifications in 2023, a massive increase from just 1.9 lakh in 2015, facilitated by mandatory reporting and incentives (2, 7, 8). Recent updates include the rollout of shorter MDR-TB regimens (6-9 months) incorporating drugs like bedaquiline and delamanid (9, 10), and pilots for AI-assisted X-ray screening [add ref 39, 41]. Vaccine development, including trials for M72/AS01E and BCG revaccination, is prioritized under the India TB Research Consortium (2).

4. Key Achievements and Progress

* India has demonstrated notable progress in its fight against TB:
* Epidemiological Gains: TB incidence declined by 17.7% from 2015 to 2023 (from 237 to 195 per 100,000), surpassing the global average. Mortality also fell by 24% (from 28 to 22 per 100,000) during the same period (1, 2).
* Increased Case Notifications: A record 26.07 lakh TB cases were notified in 2023, reflecting improved detection and a narrowing gap between estimated and reported cases (1, 2).
* Private Sector Contribution: The private sector's contribution to notifications rose significantly from 1.9 lakh in 2015 to 33% of all notifications in 2023 (2, 7).
* Improved Treatment Outcomes: The treatment success rate for new cases reached 88% in 2023, and 89% for drug-susceptible TB. For MDR-TB, success rates improved to 87% (2, 9).
* Patient Support: Over ₹3,202 crores have been disbursed to 1.13 crore beneficiaries under the Ni-kshay Poshan Yojana (2). The PMTBMBA has been transformative, with studies showing nutritional support lowering mortality by up to 50% in undernourished patients (2, 5).
* Diagnostic Expansion: 58% of diagnosed patients were offered a drug susceptibility test (DST) in 2023. The rollout of molecular diagnostics like CBNAAT and Truenat has been scaled up (2, 6). Newer, shorter all-oral regimens like BPaL-M have been approved and are being rolled out (9, 10).
* Prevention: India has national TB Preventive Therapy (TPT) guidelines for household contacts and people living with HIV (PLHIV) (2, 6, 11).

5. Analysis of Key Challenges

Despite these notable achievements, multifaceted challenges rooted in epidemiological, systemic, socio-economic, and operational factors continue to pose significant barriers to TB elimination:

5.1. The Crisis of Drug-Resistant TB (DR-TB)

* DR-TB, particularly MDR-TB and XDR-TB, remains the most critical and complex challenge (1, 6).
* High Burden: India accounts for a significant portion of the world's DR-TB cases, with an estimated 110,000 new MDR-TB cases occurring annually (1) 36.
* Treatment Complexity and Adherence: While newer, shorter all-oral regimens like BPaL-M offer hope, their widespread and effective implementation, ensuring patient adherence, and managing adverse events remain significant challenges (9, 10).
* Lack of Universal DST: Not all patients receive timely DST, leading to empirical treatment which fuels the spread of resistant strains. DST for critical drugs like fluoroquinolones and bedaquiline remains patchy (6, 12).
* Surveillance Gaps: A comprehensive, real-time understanding of drug resistance patterns across different regions is still a major gap (1, 3).

5.2. Delayed Diagnosis and "Missing" Cases

* A significant number of TB cases remain undiagnosed or unreported ("missing cases") (1, 3).
* Access to Advanced Diagnostics: Despite the scale-up of molecular diagnostics, their reach in remote, tribal, and conflict-affected areas is limited. An estimated 20-30% of cases are missed due to underreporting (3, 8).
* Paucibacillary and Extra-pulmonary TB: Diagnosing smear-negative, paediatric, and extra-pulmonary TB is still difficult with conventional methods (13).
* Diagnostic Delays: Delays from symptom onset to treatment average 7–9 weeks, with 44–59% of total costs incurred pre-treatment due to repeated visits and testing (14)34].

5.3. Socio-Economic and Behavioral Factors

* TB is deeply intertwined with socio-economic determinants (15, 16).
* Poverty and Malnutrition: Poverty, overcrowding, and undernutrition are both risk factors and consequences of the disease (15).
* Catastrophic Costs: Many households still face catastrophic out-of-pocket expenditures (affecting 7-32% of drug-sensitive TB patients and 68% of DR-TB cases), due to loss of wages and travel costs (14, 15) 38].
* Stigma: Stigma associated with TB leads to delayed care-seeking, hiding of diagnosis, and adversely affects treatment adherence (16).

5.4. Fragmented and Unregulated Private Sector Engagement

* A large proportion of TB patients in India seek care from private providers, a sector that is highly fragmented (7, 17).
* Suboptimal Reporting: Despite a rise in private sector notification, it still lags behind targets, undermining surveillance (7, 17).
* Inconsistent Care: This often results in inconsistent diagnostic practices, the prescription of non-standard drug regimens, and a failure to notify cases, contributing to the undiagnosed burden and fueling drug resistance (7, 8, 17).

5.5. Programmatic and System-Level Weaknesses

* The NTEP faces internal challenges related to human resources and data systems (18, 19).
* Human Resource Shortages: High workload, burnout, and vacancies among key staff affect program quality and follow-up (18).
* Data Quality and Use: Real-time data for actionable intelligence and dynamic resource allocation is underutilized. Gaps include incomplete contact investigation and delayed DBT linkage (19).
* Supply-Chain Resilience: Localized stock-outs of new drugs and lab consumables are reported (10).
* Comorbidity Integration: Weak bidirectional screening for comorbidities like diabetes and HIV persists (2).
* COVID-19 Pandemic Impact: The pandemic disrupted services, leading to an estimated 1.5 million missed TB diagnoses globally in 2020, with India heavily impacted (12).

6. Identification of Burning Problems

Based on current data and expert analyses, the most critical ("burning") problems posing immediate threats to progress and requiring urgent intervention include:

1. Multidrug-Resistant TB (MDR/XDR-TB) Prevalence and Treatment Access: High resistance rates and uneven uptake of newer regimens threaten epidemic control (1, 6, 9).
2. Delayed Diagnosis and Underreporting in Vulnerable Populations: Persistent gaps in active case finding among migrants, the urban poor, and remote communities sustain transmission (3, 8, 14).
3. Catastrophic Costs and Nutritional Deficits for Patients: The financial and nutritional burdens erode adherence and push vulnerable populations into poverty (14, 15).
4. Fragmented and Unregulated Private Sector: Its large share in care delivery coupled with variable notification quality contributes to "missing" cases and fuels drug resistance (7, 20).
5. Human Resource and Infrastructure Shortages: Staff vacancies, high workloads, and drug stockouts hinder program delivery (10, 18).
6. Stigma and Low Community Awareness: These behavioral barriers limit engagement and delay early detection (16).
7. Devised Research Protocols to Address Burning Problems

To generate evidence-based solutions, several research protocols are proposed, designed for feasibility within India's health infrastructure and leveraging existing NTEP data systems like Ni-kshay.

1. MDR/XDR-TB Prevalence and Treatment Access Protocols:

Effectiveness and Feasibility of Decentralized, Shorter, All-Oral Regimens: A prospective cohort study evaluating treatment success, safety, and adherence rates of newer all-oral shorter regimens like BPaL-M in district-level settings (9, 10).

Fast-track DST for All TB: A stepped-wedge study to evaluate if a reflex DST algorithm cuts time-to-effective regimen and improves outcomes (6, 8).

2. Delayed Diagnosis and Underreporting Protocols:

Blended Public-Private Partnership Model for Enhanced Case Detection: A cluster-randomized controlled trial (cRCT) assessing the yield of active case-finding using mobile CBNAAT vans and incentivized private providers (8).

Mobile AI Diagnostics: A mixed-methods study piloting mobile AI diagnostics for early detection in migrants and remote communities.

Paediatric TB Diagnostic Pathway Evaluation: A prospective diagnostic accuracy study to determine the incremental yield of non-sputum sampling in children.

3. Catastrophic Costs and Nutritional Deficits Protocols:

Impact of Comprehensive Social Support Package: A randomized controlled trial evaluating the effect of enhanced social support on treatment success and reduction in catastrophic costs among MDR-TB patients (14, 15).

Catastrophic Costs Sentinel Surveillance: A sentinel patient-cost survey combined with microsimulation of benefit packages to identify effective policy levers (14, 20).

4. Fragmented Private Sector Protocols:

Private-Sector Notification & Quality "Nudge-Bundle" Trial: A cluster randomized trial to assess if combined incentives + e-prescription improve complete notification and standard-of-care (7, 21, 22).

5. Human Resource Shortages Protocols:

Task-Shifting and Telemedicine Trial: A cluster-randomized trial evaluating task-shifting and telemedicine interventions to address staff vacancies (20).

Supply-Chain Readiness Audit: A cross-sectional audit to assess stockout risk for new drugs and lab consumables (15).

6. Stigma and Low Community Awareness Protocols:

Community-Led Anti-Stigma Campaigns: A qualitative action research study to develop and test community-led anti-stigma campaigns on health-seeking behavior (13).

8. Discussion: A Framework for a Future-Ready NTEP

India's journey toward TB elimination is a complex mix of commendable progress and persistent challenges. While the NTEP has successfully laid a strong foundation, the high burden of drug-resistant TB, the fragmented healthcare system, and deep-seated socio-economic barriers demand a more nuanced and aggressive approach (1, 3, 23). The official data confirm that while the country is on the right track, the ambitious 2025 target requires a significant acceleration of efforts and is unlikely to be fully met (3, 23).

To accelerate progress, a multi-pronged, "person-centered" framework is essential:

Adopt a Person-Centered Care Model: Shift from a disease-focused to a patient-focused model, integrating nutritional support, mental health counselling, and patient-friendly drug regimens into standard care.

Universal Access to Next-Generation Diagnostics: Accelerate the rollout of molecular point-of-care tests to the primary health centre level.

Deepened Private Sector Integration: Move beyond engagement to full integration through innovative financing models and streamlined reporting.

Aggressive Preventive Therapy: Scale up TB Preventive Therapy (TPT) for all household contacts of TB patients and high-risk groups.

Leverage Data as a Strategic Asset: Transform Ni-kshay from a reporting tool into a decision-support system to identify "hotspots" and predict outbreaks (19).

9. Limitations of the Review

This review has limitations. Firstly, the reliance on published literature may miss unpublished programmatic data or local challenges. Secondly, the rapid evolution of NTEP guidelines means some cited challenges may be in flux. Finally, as a narrative review, it does not include a formal meta-analysis.

10. Conclusion and Future Directions

India's fight against TB is at a critical juncture. The path to elimination requires a holistic strategy that simultaneously addresses the biological, social, and structural determinants of the disease. This entails significant political will, increased domestic financing, and a commitment to health equity. While 2025 may be aspirational, sustained efforts guided by targeted operational research can achieve substantial reductions by 2030. Future actions must prioritize implementation research, health systems research, and rigorous evaluation of social protection models. By adopting this comprehensive framework, India can transform its TB elimination goal from a lofty ambition into a tangible reality.

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