**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 from national and international reports and high-impact academic journals to examine the NTEP's performance, highlighting successes, persistent challenges, and proposing evidence-based research protocols. **Methods:** A comprehensive review was conducted drawing upon official government reports such as the India TB Report 2024, the WHO Global Tuberculosis Report 2024, and academic literature published between 2015 and mid-2025. Search terms included "tuberculosis," "India," "elimination," "challenges," "drug-resistant TB," "private sector," "stigma," "nutrition," and "diagnostics". The analysis focused on epidemiological trends, programmatic achievements, persistent challenges, and proposed research protocols. **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 (from 237 to 195 per 100,000) and a 24% reduction in mortality. Notifications reached a record 26.07 lakh cases in 2023. However, critical problems identified include: **the high burden of drug-resistant TB (DR-TB)**, particularly Multidrug-Resistant (MDR) and Extensively Drug-Resistant (XDR) TB; **the fragmented and often unregulated private sector** leading to underreporting and inconsistent care; **deep-seated socio-economic barriers** such as poverty, malnutrition, and catastrophic costs; **delayed diagnosis and underreporting in vulnerable populations**; and **human resource and infrastructure shortages**. Factual data confirms India is on a positive trajectory, but the ambitious 2025 target remains a formidable challenge and is unlikely to be met. **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, addressing social determinants comprehensively, and leveraging data as a strategic asset. Sustained political commitment, increased funding, and adaptive strategies are crucial to accelerate progress toward a TB-free India beyond 2025. **Funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. **Keywords:** Tuberculosis, Elimination, India, NTEP, MDR-TB, Diagnostic Delays, Catastrophic Costs, Private Sector, Research Protocols, Public Health Policy.

**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. 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. 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.

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.

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 review approach was employed, drawing evidence from official government reports, high-impact academic journals, systematic reviews, programmatic reports, and epidemiological studies up to September 2025.

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.
* **WHO Global Tuberculosis Report 2024**: This report provides an independent, external assessment of India's progress within a global context.
* Other relevant literature was identified through searches in electronic databases such as PubMed, Scopus, Google Scholar, and relevant Indian journals. The search covered articles published between January 2015 and February 2024, with some sources extending to mid-2025. 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). 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. 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.

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

**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 of 8.3%. Mortality also fell by **24%** (from 28 to 22 per 100,000) during the same period.
* **Increased Case Notifications**: A record **25.5 lakh TB cases were notified in 2023**, with 26.07 lakh cases reported in 2023, reflecting improved detection and a narrowing gap between estimated and reported cases.
* **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**.
* **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%, and for XDR-TB, to 68%.
* **Patient Support**: Over **₹3,202 crores** have been disbursed to 1.13 crore beneficiaries under the Ni-kshay Poshan Yojana, providing crucial nutritional support. The PMTBMBA has been transformative, with studies showing nutritional support lowering mortality by up to 50% in undernourished patients.
* **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. Newer, shorter all-oral regimens like BPaL-M have been approved and are being rolled out, with early program use growing.
* **Prevention**: India has national TB Preventive Therapy (TPT) guidelines for household contacts and people living with HIV (PLHIV).

**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.

* **High Burden**: India accounts for a significant portion of the world's DR-TB cases, with an estimated 400,000 new cases of MDR/RR-TB globally in 2023, a substantial number of which are in India. An estimated 110,000 new MDR-TB cases occur annually, with 10-15% progressing to XDR-TB.
* **Treatment Complexity and Adherence**: Conventional DR-TB treatment regimens are long, toxic, expensive, and often ineffective, leading to high patient dropout rates. While newer, shorter all-oral regimens like BPaL-M offer hope and are being rolled out nationally, their widespread and effective implementation, ensuring patient adherence, and managing adverse events (AEs) remain significant challenges.
* **Lack of Universal DST**: Not all patients, especially in the private sector, receive timely and necessary tests to determine drug resistance upfront, leading to empirical, often ineffective, treatment which further fuels the spread of resistant strains. DST for critical drugs like fluoroquinolones, bedaquiline, and rifapentine remains patchy.
* **Surveillance Gaps**: A comprehensive, real-time understanding of drug resistance patterns across different regions and populations is still a major gap.

**5.2. Delayed Diagnosis and "Missing" Cases** A significant number of TB cases remain undiagnosed or unreported ("missing cases"), often in the private sector and vulnerable populations.

* **Access to Advanced Diagnostics**: Despite the scale-up of CBNAAT and Truenat, their reach in remote, tribal, and conflict-affected areas is limited, leading to delays in diagnosis. An estimated 20-30% of cases are missed due to underreporting.
* **Paucibacillary and Extra-pulmonary TB**: Diagnosing smear-negative, paediatric, and extra-pulmonary TB is still difficult with conventional methods, leading to under-diagnosis in these groups. AI-CXR pilots exist but are not standardized.
* **Diagnostic Delays**: Delays from symptom onset to treatment average 7–9 weeks, double the acceptable 4 weeks, with 44–59% of total costs incurred pre-treatment due to repeated visits and testing.

**5.3. Socio-Economic and Behavioral Factors** TB is deeply intertwined with socio-economic determinants, exacerbating the epidemic.

* **Poverty and Malnutrition**: Poverty, overcrowding, and undernutrition are both risk factors and consequences of the disease, weakening immune systems and delaying care-seeking.
* **Catastrophic Costs**: Despite the Ni-kshay Poshan Yojana, 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, travel costs, and complementary medicines. Cash transfer delays and adequacy of ₹500/month threaten adherence.
* **Stigma**: Stigma associated with TB leads to delayed care-seeking, hiding of diagnosis, social isolation, and adversely affects mental health and treatment adherence. Low community awareness further limits engagement and early detection.

**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 and largely unregulated.

* **Suboptimal Reporting**: Despite a rise in private sector notification, it still lags behind targets, undermining surveillance.
* **Inconsistent Care**: This often results in inconsistent diagnostic practices, the prescription of non-standard drug regimens, and a failure to notify cases to the NTEP, contributing to the undiagnosed burden and fueling drug resistance.

**5.5. Programmatic and System-Level Weaknesses** The NTEP faces internal challenges related to human resources and data systems.

* **Human Resource Shortages**: High workload, burnout, and vacancies (exceeding 20% in rural facilities) among key staff like Senior Treatment Supervisors (STS) and Tuberculosis Health Visitors (THVs) affect program quality and follow-up.
* **Data Quality and Use**: While Ni-kshay is a robust platform, data entry is often seen as a burden. Real-time data for actionable intelligence, predictive analysis, and dynamic resource allocation is underutilized. Gaps include incomplete contact investigation, deduplication, and delayed DBT linkage.
* **Supply-Chain Resilience**: Localized stock-outs of new/repurposed drugs (pretomanid, rifapentine), cartridges, and lab consumables are reported.
* **Comorbidity Integration**: Weak bidirectional screening and tailored adherence support for comorbidities like diabetes, HIV (2% co-infection), and tobacco use persist.
* **Regional Disparities**: State-level variations highlight persistent higher burdens in northern states and deprived areas, masking national progress.
* **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, further widening the gap between targets and achievements.

**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 as of September 2025 include:

1. **Multidrug-Resistant TB (MDR/XDR-TB) Prevalence and Treatment Access**: High resistance rates and uneven uptake of newer, shorter regimens like BPaL-M threaten epidemic control and risk reversing gains.
2. **Delayed Diagnosis and Underreporting in Vulnerable Populations**: Persistent gaps in active case finding among migrants, the urban poor, and remote communities sustain transmission and lead to missed opportunities for early intervention.
3. **Catastrophic Costs and Nutritional Deficits for Patients**: The financial and nutritional burdens erode adherence and push vulnerable populations into poverty, worsening outcomes.
4. **Fragmented and Unregulated Private Sector**: Its large share in care delivery coupled with variable notification quality and inconsistent standards contributes to "missing" cases and fuels drug resistance.
5. **Human Resource and Infrastructure Shortages**: Staff vacancies, high workloads, and drug stockouts hinder program delivery, particularly in rural facilities.
6. **Stigma and Low Community Awareness**: These behavioral barriers limit engagement, delay early detection, and impact adherence.

**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. Ethical oversight from bodies like the Indian Council of Medical Research (ICMR) is essential.

1. **MDR/XDR-TB Prevalence and Treatment Access Protocols**:
   * **Effectiveness and Feasibility of Decentralized, Shorter, All-Oral Regimens**: A **prospective cohort study** or **RCT** evaluating treatment success, safety, and adherence rates of newer all-oral shorter regimens like BPaL-M in district-level settings compared to centralized DR-TB centres. This would involve 1,000-2,000 newly diagnosed DR-TB patients across diverse states, with outcomes tracking treatment success, ADRs (e.g., anemia, neuropathy, hepatotoxicity), and cost-effectiveness over 6-24 months.
   * **Fast-track DST for All TB**: A **stepped-wedge study** across 30 labs to evaluate if a reflex DST algorithm (Truenat/CBNAAT → reflex FQ & Bdq DST) cuts time-to-effective regimen and improves outcomes.
2. **Delayed Diagnosis and Underreporting in Vulnerable Populations Protocols**:
   * **Blended Public-Private Partnership Model for Enhanced Case Detection**: A **cluster-randomized controlled trial (cRCT)** in urban slum clusters or high-burden cities assessing the yield, cost-effectiveness, and feasibility of active case-finding (ACF) using mobile CBNAAT vans, incentivized private providers, and community health workers. This could detect cases, DR-TB cases, and time to treatment initiation.
   * **Mobile AI Diagnostics**: A **mixed-methods study** piloting mobile AI diagnostics (e.g., AI-assisted X-rays) for early detection, with geospatial analysis to identify underreporting zones in migrants and remote communities.
   * **Paediatric TB Diagnostic Pathway Evaluation**: A **prospective diagnostic accuracy study** to determine the incremental yield of non-sputum sampling (stool, NPA), ultrasound-guided FNAC, and CAD-CXR in children.
   * **Migrant-Aware Care Cascades**: A **longitudinal cohort study** of 3,000 PwTB tagged as migrants to identify cascade losses, focusing on treatment interruption, transfer-out, and success, compared to non-migrants.
3. **Catastrophic Costs and Nutritional Deficits Protocols**:
   * **Impact of Comprehensive Social Support Package**: A **randomized controlled trial** evaluating the effect of enhanced social support (additional nutritional kits, travel vouchers, counselling) on treatment success and reduction in catastrophic costs among MDR-TB patients.
   * **Bridging the DBT Gap**: A **cluster-randomized trial** to determine if auto-triggered, same-day DBT releases (via Nikshay-PFMS API) and a helpline reduce delays and improve adherence, measuring median days to first DBT credit, missed doses, and weight gain.
   * **Catastrophic Costs Sentinel Surveillance + Policy Simulation**: A **sentinel patient-cost survey** (using WHO tool) in 12 states combined with microsimulation of benefit packages (e.g., higher NPY, travel vouchers, sick-leave wage replacement) to identify effective policy levers.
4. **Fragmented and Unregulated Private Sector Protocols**:
   * **Private-Sector Notification & Quality "Nudge-Bundle" Trial**: A **cluster randomized trial** to assess if combined incentives + e-prescription + pharmacist linkage improve complete notification and standard-of-care from private chest physicians and pharmacies. Outcomes include proportion of cases notified within 7 days, DST completion, and treatment success.
   * **Public-Private Partnership Model for Universal DST**: A **cluster randomized controlled trial** to evaluate a novel PPP model in ensuring universal drug susceptibility testing for all presumptive TB cases, integrating private practitioners into Ni-kshay and providing incentives for notified cases.
5. **Human Resource and Infrastructure Shortages Protocols**:
   * **Task-Shifting and Telemedicine Trial**: A **cluster-randomized trial** evaluating task-shifting (e.g., training community health workers) and telemedicine interventions in 20 districts to address staff vacancies, measuring case notification rates and drug stockouts via routine NTEP data.
   * **Supply-Chain Readiness Audit**: A **cross-sectional structured audit** of 100 facilities and qualitative key-informant interviews to assess stockout risk, reorder thresholds, and vendor performance for new drugs (pretomanid, rifapentine, bedaquiline, delamanid), linezolid, moxifloxacin, and lab consumables.
6. **Stigma and Low Community Awareness Protocols**:
   * **Community-Led Anti-Stigma Campaigns**: A **qualitative action research study** with pre/post surveys to develop and test community-led anti-stigma campaigns (e.g., media campaigns via local influencers) on health-seeking behavior in stigma-prone areas.

**Cross-Cutting Methods and Operational Details (for all protocols)**:

* **Sampling & Power**: Utilize cluster-level coefficients from prior NTEP operational research (ICC 0.01–0.05) and account for conservative attrition (10–15%).
* **Data Systems**: Integrate with Ni-kshay for case IDs/outcomes, use REDCap/ODK for study CRFs, and leverage PFMS webhooks for DBT timing where allowed.
* **Ethics**: Ensure independent EC and state TB office nodal approval, with adverse event reporting aligned to CTD Pv SOPs.
* **Economics**: Conduct provider costing (ingredients method) and patient costing (WHO tool), presenting cost-per-additional-success and budget impact.
* **Equity Lens**: Pre-specify subgroup analyses for sex, age, migrant status, urban slum residence, caste/tribe, and wealth quintiles.
* **Dissemination**: Provide interim dashboards to district/state TB cells quarterly and develop "policy briefs" with one-page recommendations per study.

**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 with increased case notifications and patient-centric initiatives, the high burden of drug-resistant TB, the fragmented healthcare system, and deep-seated socio-economic barriers demand a more nuanced and aggressive approach. The official data and external analysis 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. The analysis reveals that the barriers to elimination are not merely technical but are deeply embedded in the country's health system and socio-economic fabric.

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. Decentralizing DR-TB management to the district level with adequate support is crucial.
* **Universal Access to Next-Generation Diagnostics**: Accelerate the rollout of molecular point-of-care tests to the primary health centre level and invest in R&D for non-sputum-based biomarkers for childhood and paucibacillary TB.
* **Deepened Private Sector Integration**: Move beyond engagement to full integration through innovative financing models, streamlined reporting apps, and accredited social health activists (ASHAs) acting as bridges between private providers and the NTEP.
* **Aggressive Preventive Therapy**: Scale up TB Preventive Therapy (TPT) for all household contacts of TB patients and high-risk groups, tackling stigma and strengthening counselling to ensure uptake and completion.
* **Leverage Data as a Strategic Asset**: Transform Ni-kshay from a reporting tool into a decision-support system to identify "hotspots," predict outbreaks, and dynamically manage stocks of drugs and diagnostics.

Global lessons, such as Vietnam's rapid diagnostics scale-up, could inform adaptations. Equity-focused approaches are crucial for vulnerable groups, and forecasting models predict 28.36 lakh cases in 2025 without acceleration of efforts.

**9. Limitations of the Review** While this review provides a comprehensive overview, certain limitations must be acknowledged. Firstly, the reliance on published literature and grey literature may miss unpublished programmatic data or local challenges that are not well-documented. Secondly, the rapid evolution of NTEP guidelines and the introduction of new policies (e.g., shorter regimens, newer diagnostics) mean that some of the cited challenges may be in flux, and the most recent operational data may not yet be reflected in the literature. Finally, as a scoping review, it does not include a formal meta-analysis, which limits our ability to quantitatively pool data on the prevalence of certain barriers.

**10. Conclusion and Future Directions** India's fight against TB is at a critical juncture. The path to elimination requires acknowledging that a pathogen-centric strategy alone is destined to fall short. The next phase of the NTEP must be bold and holistic, simultaneously addressing the biological, social, and structural determinants of the disease. This entails significant political will, increased domestic financing (to 2.5% of GDP), and a commitment to health equity. While 2025 may be aspirational, sustained efforts can achieve substantial reductions by 2030.

Future actions must be guided by targeted operational research. Key priorities include:

* **Implementation Research**: Studying the most effective models for decentralizing DR-TB care and integrating mental health support into routine TB services.
* **Health Systems Research**: Developing and testing innovative solutions for human resource constraints, such as task-shifting and optimized workload management.
* **Interventional Studies**: Rigorously evaluating the impact of enhanced social protection packages (beyond nutritional support) on treatment outcomes and catastrophic costs.
* **Public-Private Mix Models**: Designing and scaling sustainable, incentive-compatible models for deep and meaningful private sector engagement.

By adopting a comprehensive framework that combines cutting-edge technology with people-centered care and strong community engagement, India can transform its TB elimination goal from a lofty ambition into a tangible reality, setting a global precedent. Generating indigenous evidence through such operational research is crucial for policy refinement, optimizing resource allocation, and ultimately achieving the ambitious goal of a TB-free India. The key is to move these research findings from publication in journals to integration into policy and practice.

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