Special Article

NTEP : A Historical Overview and Vision for the Future of Tuberculosis Elimination

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Abstract

Background : In 1962, the Government of India launched the National TB Programme (NTP), initially focusing on District TB Centres with BCG vaccination and treatment. The elimination of Tuberculosis (TB) in India is hindered by deep-rooted and persistent challenges. Decades of unchecked transmission have left a large proportion of the population with latent TB infection, which can reactivate at any point. A staggering percentage of the population is undernourished - 35% of adults and nearly half of children - compromising their immune systems and increasing the risk of TB reactivation. Additionally, a host of risk factors, including diabetes, indoor air pollution from cooking stoves and smoking, exacerbate the problem.

Key words : Tuberculosis, India, TB Control Programme, TB Infection, Latent TB Infection.

In 1962, the Government of India launched the National TB Programme (NTP), initially focusing on District TB Centres with BCG vaccination and treatment.In 1993, the Revised National Tuberculosis Control Programme (RNTCP) was first tested in a population of 2.4 million in Delhi, Gujarat, Kerala, Maharashtra and West Bengal. By 1995, it reached 13 million people and by 1996, 20 million[1]. The programme followed the DOTS strategy, which is a globally accepted method for controlling Tuberculosis. This approach focuses on diagnosing TB using sputum smear microscopy, directly observing treatment, using standard treatment regimens, carefully recording and reporting cases and evaluating treatment results, all with strong political support. In 1997, RNTCP became a nationwide programme with plans for gradual expansion, incorporating the internationally recognized DOTS strategy and expanding nationwide by 2006[2]. In 2007, the Programmatic Management of Drug-Resistant TB (PMDT) was launched to address drug resistance, achieving full coverage by 2013. RNTCP aligns with the National Health Policy 2017, WHO's End TB Strategy, and the UN's SDGs[2].

Recently, the focus has shifted to a patient-centric approach, offering comprehensive care and support.

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Editor's Comment :

- India has made significant progress in its fight against TB by improving diagnostic tools and treatment strategies.
- Challenges such as drug resistance, the complexity of diagnosis, and the need for more community involvement remain critical obstacles to achieving the goal of TB elimination.

The Ministry of Health and Family Welfare (MoHFW) launched the National Strategic Plan for Tuberculosis Elimination (2017-2025), aiming to eliminate TB five years ahead of the global target[3].

This plan outlines transformative actions to reduce TB incidence, prevalence and mortality, building on past efforts. India's trajectory in TB control illustrates both the progress made and the ongoing challenges in combatting TB, especially in the face of drug resistance and the need for more advanced technologies to reach underserved populations. The NTEP's focus on a holistic and patient-centred approach shows promise in achieving the ambitious goal of eliminating TB by 2025.

The NSP 2017-2025 objectives include[3] :

- Expanding early detection of Tuberculosis and testing for drug resistance.
- Ensuring effective treatment to prevent drug resistance and interrupt transmission.
- Strengthening surveillance and monitoring of TB trends.
- Preventing TB onset and the progression of Latent Tuberculosis Infection (LTBI).
- Achieving full Tuberculosis elimination in India.

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By 2020, it became clear that the NSP 2017-2025 would not meet these ambitious targets. As a result, the revised NSP India 2025 was introduced to address these gaps and accelerate progress toward TB elimination. This updated plan focuses on urgent actions needed to speed up the national response to Tuberculosis.

The Government of India launched NIKSHAY in June 2012 to monitor and track Tuberculosis (TB) patient data across the country. NIKSHAY, a web-based platform developed by the Central TB Division and the National Informatics Centre (NIC), ensures universal access to TB patient data for all stakeholders. It was mandated that all private healthcare institutions report details of TB patients to the NIKSHAY database through a gazette notification issued by the Government of India[4].

The TB Mukt Bharat Abhiyaan, launched by the Government of India, is a bold and unwavering initiative aimed at eradicating Tuberculosis (TB) from the country by 2025 - five years ahead of the WHO's global target. India, with its large population, has long been burdened with the highest TB incidence in the world, significantly contributing to global TB cases. Despite decades of efforts, the disease remains a major public health issue, particularly affecting the most vulnerable, worsening poverty and hindering progress. The TB Mukt Bharat Abhiyaan is a call to action for every citizen, healthcare provider and organization to unite and combat this threat with urgency and determination.

The Abhiyaan focuses on several key pillars to achieve its goal. First, it prioritizes increasing awareness and early detection, particularly in rural and underserved areas, to dispel misconceptions about TB and encourage timely testing and treatment. The program also ensures universal access to free, high-quality treatment for all TB patients, regardless of financial constraints. Technological advancements are incorporated to improve diagnosis, treatment and monitoring, while research and drug development are emphasized to ensure new tools and therapies are available. Additionally, the campaign relies heavily on community engagement, empowering local health workers, volunteers and communities to raise awareness, identify patients, and provide support to those in need, ensuring sustainable and inclusive progress in the fight against TB.

The battle against TB requires unyielding commitment, uncompromising resolve and the mobilization of resources at all levels. The TB Mukt Bharat Abhiyaan is a clarion call to fight this war on all fronts: through awareness, early detection, quality treatment, innovation and grassroots engagement[5].

The elimination of Tuberculosis (TB) in India is hindered by deep-rooted and persistent challenges. Decades of unchecked transmission have left a large proportion of the population with latent TB infection, which can reactivate at any point. A staggering percentage of the population is undernourishe - 35% of adults and nearly half of children - compromising their immune systems and increasing the risk of TB reactivation. Additionally, a host of risk factors, including diabetes, indoor air pollution from cooking stoves, and smoking, exacerbate the problem. Many individuals who have received subpar TB treatment, particularly from private providers with limited capacity, are at high risk of relapse. While public sector treatment offers a better chance of success, a significant proportion of patients - one-third - are lost to follow-up before achieving a cure.

Urban overcrowding further accelerates TB transmission, with densely packed populations acting as hotspots for the spread of the disease. Infectious TB cases easily transmit the disease to family members and the wider community, perpetuating an unrelenting cycle. Despite these barriers, other nations have demonstrated that TB can be controlled with early diagnosis and proper treatment. However, India faces a critical challenge in timely diagnosis, plagued by inadequate diagnostic services and a shortage of trained medical professionals. The burden of multi-drug-resistant (MDR-TB) and extensively drug-resistant TB (XDR-TB) remains a major issue, with many cases undiagnosed and continuing to spread the disease. When diagnosed, patients are often subjected to lengthy, toxic and expensive treatments with low success rates and many fail to complete their regimens, worsening the situation.

Advancements in Tuberculosis Diagnosis : A Comprehensive Evolution in India's Diagnostic Paradigm

India's TB program has made significant strides in improving diagnostic services, with a focus on expanding free laboratory services for both public and private sector patients. By 2021, 80 laboratories were equipped with liquid culture systems, enhancing the capacity for First-Line and Second-Line Drug Susceptibility Testing (DST)[6]. The program has also adapted to emerging drug-resistant strains by

incorporating new drugs like Linezolid and Clofazimine into the testing process. The adoption of the Line Probe Assay (LPA), a critical molecular diagnostic tool. It is a rapid diagnostic method based on Polymerase Chain Reaction (PCR), utilized to detect Mycobacterium Tuberculosis (MTB) complex and assess drug resistance to Rifampicin (RPM) and Isoniazid (INH)[6].

Innovations like Machine Learning-based Annotation Tools for LPA interpretation and the expansion of National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited labs underline the program's commitment to enhancing diagnostic precision and integration within the national health infrastructure.

The Active Case Finding (ACF) strategy, launched nationwide in 2017, plays a crucial role in identifying individuals with active TB, especially in high-risk groups such as those with diabetes or chronic diseases. The National Tuberculosis Elimination Programme (NTEP) has also deployed 81 Mobile TB Diagnostic Vans to facilitate TB detection in remote areas, ensuring that geographical barriers do not impede timely diagnosis and treatment[6].

The TrueNat™ testing system (Molbio Diagnostics, Goa, India) is a rapid, portable, and battery-operated diagnostic tool designed for the quick detection of Mycobacterium Tuberculosis Complex (MTBC) and rifampicin resistance. It is particularly valuable in peripheral laboratories with limited infrastructure. According to WHO recommendations, TrueNat MTB or MTB Plus should be used as the initial diagnostic test for Tuberculosis on sputum samples, replacing smear microscopy or culture for both adults and children[7].

The Cartridge-based Nucleic Acid Amplification Test (CB-NAAT/GeneXpert)[8] is an automated molecular diagnostic method that detects Mycobacterium Tuberculosis and rifampicin resistance in just two hours using a cartridge system. The WHO has endorsed CB-NAAT as the preferred diagnostic test for TB, especially in children, including those with pulmonary and specific extra-pulmonary forms of the disease, as well as in adults and children with HIV or suspected multidrug-resistant TB (MDR-TB). CB-NAAT has also expanded its use to cover all types of extra-pulmonary samples in paediatric patients.

The Line Probe Assay (LPA) is a fast diagnostic method that utilizes Polymerase Chain Reaction (PCR) to detect MTB Complex and evaluate resistance to Rifampicin (RPM) and Isoniazid (INH). This is used to diagnose drug-resistant Tuberculosis in a programmatic setting. LPA testing is performed exclusively on sputum samples that are smear-positive for Acid-fast Bacilli (AFB)[9].

Emerging Diagnostic Technologies in Tuberculosis : Advancements in Accuracy and Precision

(1) Whole Genome Sequencing (WGS) :

Whole Genome Sequencing (WGS) has emerged as a groundbreaking tool in the diagnosis of Tuberculosis (TB). This technology provides an in-depth analysis of the Mycobacterium Tuberculosis (MTB) genome, offering valuable insights into its genetic structure. With a remarkable concordance with traditional culture-based Drug Susceptibility Testing (DST), WGS significantly enhances the accuracy of detecting resistance, especially for Multidrug-resistant Tuberculosis (MDR-TB). It allows for the identification of genetic resistance to a broad range of TB medications, enabling doctors to tailor treatment plans based on the pathogen's specific genetic characteristics. WGS improves diagnostic precision and is crucial for managing more complex and resistant forms of TB[10].

(2) Computer-Aided Detection for Chest Radiographs (CAD):

In high-burden areas where time, cost, and infrastructure are often limiting factors, new and scalable diagnostic tools are needed to enhance TB detection. One such advancement is the use of Computer-Aided Detection (CAD) software to analyze Chest Radiographs (CXR), a key method for TB screening. In resource-limited settings, the ability to digitally assess Chest X-rays and assign a likelihood score for TB is invaluable. CAD4TB, the most widely studied and deployed software, now in its sixth version, analyzes radiographic images to produce a risk score that indicates the probability of TB[11].

In conclusion, the strides made in diagnostic technologies and methodologies, combined with a robust and multi-pronged strategy for active case finding, mark a significant advancement in India's battle against Tuberculosis. These innovations reinforce the nation's determination to not only eradicate TB by 2025 but also to relentlessly enhance diagnostic capabilities to tackle the ever-evolving challenges posed by the disease.

Diagnosing Tuberculosis (TB) presents significant challenges despite technological advancements in tools like CB-NAAT and LPA. These tools, while valuable, are often costly, prone to errors, and lack the sensitivity or accuracy required for reliable results, particularly in remote, underserved areas where such tools are most needed. Existing diagnostic methods - combining molecular detection, culture and microscopy - are limited, especially for detecting latent TB or in children unable to produce sufficient sputum. Additionally, many of these methods rely on a stable power supply and skilled technicians, resources scarce in low-income settings. Diagnosing Extra-pulmonary TB (EPTB) adds another layer of complexity, requiring invasive biopsies and facing challenges like low bacillary load and varying clinical presentations. The WHO emphasizes early and accurate diagnosis as essential to TB control, underscoring the need for more affordable, rapid and accurate diagnostics, particularly in rural regions.

Tuberculosis is a reportable disease in India and since May 2012, it has been mandatory to notify TB cases at the time of diagnosis. This means that whenever a person is diagnosed with TB or begins treatment, the relevant public health authority must be informed.

Programmatic management of Drug-resistant Tuberculosis (DR-TB) in India (PMDT) - The growing threat of Drug-resistant Tuberculosis (DR-TB) has led to the swift expansion of the Programmatic Management of Drug-Resistant Tuberculosis (PMDT) services in India. Initially endorsed by the WHO in 2002, India adopted PMDT in 2007, achieving nationwide coverage by 2013. Since then, PMDT has been regularly updated to address the evolving needs of DR-TB diagnosis and treatment. The WHO has recently redefined extensively Drug-resistant Tuberculosis (XDR-TB) and introduced the concept of pre-XDR-TB, emphasizing the severity of these TB forms. This reclassification is based on resistance to key drugs and was supported by the WHO's 2019 interim guidance, which categorized anti-DR-TB drugs into three groups (A, B and C), with Group-A drugs forming the backbone of new PMDT regimens. In response, India's PMDT-2021 update has incorporated these changes, removing the emphasis on Second-line Injectable Drugs (SLIDs) and redefining Pre-XDR and XDR-TB. Pre-XDR-TB is now characterized as MDR/RR-TB with Fluoroquinolone (FQ) resistance, while XDR-TB includes resistance to Bdq and/or linezolid. These new definitions aim to improve reporting, monitoring, and surveillance of DR-TB and push for the development of better treatment strategies. PMDT-2021 also highlights ongoing challenges with current DR-TB diagnostic tools in India.

All samples that test positive in TrueNat are subsequently tested with TrueNat MTB-Rif Dx to check for rifampicin resistance. To detect isoniazid or fluoroquinolone resistance, second-line LPA (SL-LPA) is used, which currently takes at least two to three days for results. The advanced version of CBNAAT, Xpert-Mtb/XDR, can detect resistance to isoniazid, fluoroquinolones, SLIDs, and ethionamide, and is set to be progressively introduced across India. This will not only reduce turnaround times but also ease the burden on centres performing SL-LPA for large areas.

Treatment :

(1) Drug Sensitive TB – 6-month 2HRZE / 4HRE

(2) Drug Resistant TB[12]

(A) H Mono Regimen – (6-9 month) Lfx REZ

(B) B PaL M Regimen – (26 – 39 weeks) B PaL M

Recent trials of new oral treatments for drug-resistant Tuberculosis (TB) have shown promising outcomes, though challenges like toxicity and cost still exist. The NIX-TB trial demonstrated a 90% success rate with a combination of Bedaquiline (Bdq), Pretomanid (Pa), and Linezolid (Lzd) [BPaL] in patients with Pre-XDR-TB and MDR-TB who were either intolerant to or not responsive to standard treatments. Despite the high success rate, Lzd (1200 mg) caused considerable toxicity, with 81% of patients experiencing peripheral neuropathy and 48% suffering myelosuppression, often requiring dose adjustments or treatment pauses. Trials like TB Practecal and ZeNix further supported BPaL's effectiveness, recommending a reduced daily Lzd dose of 600 mg for a 91% success rate with fewer toxic effects. The BPaLM regimen (Bdq, Pa, Lzd 600 mg, Moxifloxacin) achieved an 88.7% success rate, with fewer adverse events (19.4%) compared to the WHO standard. The modified BPaL (mBPaL) trial also showed similar efficacy and manageable toxicity, including anemia and peripheral neuropathy. Cost-effectiveness studies indicate that BPaL-based regimens save costs, improve clinical outcomes for MDR-TB patients, and reduce the burden on healthcare systems. The Indian Council of Medical Research (ICMR) suggests these regimens could

enhance treatment adherence and success rates. Data from South Africa further support replacing Eto with Lzd in MDR/RR-TB treatment, showing comparable efficacy and safety. In children, Bdq has been confirmed to be safe, with no specific cardiac safety concerns for those under six. WHO reviews also affirm that Delamanid (Dlm) carries no significant cardiac safety risks in children, recommending its use for those under three with appropriate dosing.

For MDR/RR-TB patients aged 14 years or older, the 26-39 weeks BPaLM regimen is the preferred first-line treatment. For those under 14, the shorter 9-11 month oral MDR/RR-TB regimen should be prioritized, subject to the eligibility criteria for both the BPaLM and the 9-11 month shorter oral regimens.

(C) 9-month shorter oral MDR/RR-TB regimen

(2) Lzd (4-6) LfxCfz Z E H^h (6-9) Bdq (5) LfxCfz Z E

(4-6) LfxCfz Eto Z E H^h (6-9) Bdq (5) LfxCfz Z E

(D) Longer Oral M/ XDR- TB regimen

Bdq (6 or 9 month) + LfxLzdCfz Cs (18-20)

Advancements in treating drug-susceptible Tuberculosis (TB) have been significant, but the rise of multidrug-resistant (MDR-TB) and extensively drug-resistant TB (XDR-TB) has led to more difficult, often fatal cases. Surgery is being reconsidered, especially for cavitary MDR/XDR-TB with chemotherapy failure. Surgical options are categorized as emergency, urgent and elective and are considered when the disease is localized, surrounding tissue is TB-free and the patient can tolerate surgery. Pulmonary resection, combined with pre- and postoperative anti-TB treatment, has shown success rates of 88-92%, even in challenging cases[13].

Treatment Adherence Initiatives, Incentives and Support Systems :

To encourage adherence to TB treatment, various financial incentives have been put in place. The Government of India, through the Ministry of Health and Family Welfare, has launched the “Nikshay Poshan Yojana” (NPY) to offer nutritional support to all diagnosed TB patients. Under this scheme, Rs 1000 per month is directly transferred to each notified TB patient for the duration of their treatment, ensuring they receive the required nutrition during their recovery. All TB patients will now receive a nutritional support of Rs 3,000 to Rs 6,000 under NPY. Government has introduced Energy Dense Nutrition Supplementation (EDNS) for all underweight patients with BMI below 18.5 kg/m^2 at the time diagnosis for initial 2 months of treatment[14].

In addition to Tuberculosis (TB) patients, Nikshay Mitras will also adopt the household contacts of TB patients for the distribution of food baskets, aiming to enhance the immunity of the family members of those affected by TB.

Future Vision for Tuberculosis Control in India

India faces the highest Tuberculosis burden in the world, with a significant number of new cases each year and a large number of related deaths. The economic toll in terms of lost productivity and workdays is significant. In response, the Ministry of Health and Family Welfare (MoHFW) has launched the National Strategic Plan to meet the 2025 Sustainable Development Goal (SDG) target of ending TB. The scale of this challenge requires a comprehensive, district-specific approach, coordinated with local authorities, addressing the social factors contributing to TB.

In addition to existing initiatives like the National Tuberculosis Elimination Programme (NTEP), which provides free diagnostics, medication and nutritional support (Nikshay Poshan Yojana), there is a pressing need for increased community engagement. This includes improving living and working conditions and expanding access to treatment and diagnostic services. While the government’s progress is significant, societal involvement is critical to addressing the social determinants of TB. Greater collaboration with corporate bodies, NGOs, political representatives, and other stakeholders is essential to complement government efforts and accelerate progress toward TB elimination in India.

Conclusion

India has been a leader in the fight against Tuberculosis (TB) for over 50 years, but TB continues to be one of its most serious health challenges. Despite this, India is now better equipped than ever to tackle the disease with advanced diagnostic, treatment and care technologies. The National Strategic Plan (NSP) for 2020-2025 aims to make transformative changes in TB care, building on previous successes.

Significant achievements have been made under earlier NSP phases, including mandatory TB case

notifications, integration of TB services with general health services, expanded diagnostic capabilities, and improved management of drug-resistant TB. The introduction of services for TB-HIV co-infected patients and the establishment of national drug resistance surveillance have also strengthened the program. However, there is still a need for more extensive efforts to reduce TB incidence significantly. The NSP 2017-2025 outlines bold steps to eliminate TB by 2025. Despite progress, continued commitment, innovation, and multi-sectoral collaboration are essential to achieving a TB-free India.

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