

Paving a Way for "TB Mukt Bharat": A Snapshot of India's TB Elimination Program

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Indographics 2024;3:27-32.

Abstract

Keywords

- ► TB elimination
- ► National TB **Elimination Program**
- ► WHO End TB Strategy
- ► TB diagnosis
- ► TB treatment
- ► TB prevention
- TB notification

Tuberculosis (TB) remains a significant global health challenge, particularly in countries like India, where it is a leading cause of mortality. This article provides an overview of India's efforts to combat TB through its national TB programs, tracing their evolution from the National TB Program in 1962 to the current National TB Elimination Program (NTEP) launched in 2020. The NTEP aims to eliminate TB by ensuring universal access to high-quality diagnosis and treatment services. The program emphasizes prevention, detection, treatment, and capacity building, aligning with global initiatives like the World Health Organization's End TB Strategy. Key components of the NTEP include free diagnostic services, treatment regimens for drug-sensitive and drug-resistant TB, and TB preventive therapy. The program also includes robust patient support systems, such as incentive schemes and transport support, to improve treatment outcomes. Through these comprehensive strategies, India seeks to achieve its goal of a TB-free nation by 2025, aligning with global Sustainable Development Goals.

Introduction

Tuberculosis (TB), an airborne communicable disease, is the world's leading cause of death from a single infectious agent. According to the estimates for 2021, there were 1.4 million TB deaths among human immunodeficiency virus (HIV)-negative people and an additional 187,000 deaths among the people living with HIV/acquired immunodeficiency syndrome (AIDS) (PLHA). As per the Global TB Report 2023, 7.5 million people were newly diagnosed with TB worldwide in 2022. According to geographical distribution, 87% of the world's TB cases in 2022 and two-thirds of the global total was in eight countries; highest in India (27%), Indonesia (10%), China (7.1%), and Philippines (7%).¹ Also, the estimated incidence rate of TB in India was 196/ lakh population in 2022.² Hence, a robust national program must be required to handle this huge health care burden. The

> DOI https://doi.org/ 10.1055/s-0044-1787985. ISSN 2583-8229.

Government of India has led from the front in this regard with various national programs being in place. In 1962, the Government of India initiated its inaugural effort to tackle TB with the launch of the "National TB Program (NTP)." Initially focusing on BCG (bacille Calmette-Guérin) vaccination and TB treatment through a district TB center model, this program addressed the pressing public health issue posed by TB.

Evolution of the National Program

In 1997, recognizing the need for a more comprehensive approach, the NTP underwent a significant transformation and was renamed the "Revised National Tuberculosis Control Program" (RNTCP). This revision aligned with the globally endorsed directly observed treatment short-course (DOTS) strategy, which was implemented nationwide by 2006.³

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In 2007, the government further fortified its efforts with the introduction of the "Programmatic Management of Drug Resistant TB" (PMDT) to combat the emergence of drug-resistant strains. By 2013, PMDT achieved complete geographical coverage, strengthening the nation's response to this evolving threat.

RNTCP's evolution was closely aligned with broader health sector strategies such as the "National Health Policy 2017," as well as global initiatives including the World Health Organization's (WHO) "End TB Strategy" and the Sustainable Development Goals (SDGs) set forth by the United Nations. This integration ensured that India's efforts against TB were in harmony with international best practices and commitments to global health objectives.

In 2020, the "National TB Elimination Program" (NTEP) superseded the RNTCP, aiming to eradicate TB by ensuring universal access to high-quality diagnosis and treatment services within the government health system nationwide. With the ambitious goal of creating a "TB-free India," NTEP places significant emphasis on early detection, prompt treatment, and comprehensive patient support, including financial and nutritional assistance.

Aligned with the National Strategic Plan (2017–2025), NTEP operates on four core pillars: prevention, detection, treatment, and build.⁴ These pillars embody a holistic strategy designed to effectively address the challenges of TB elimination. Through proactive measures, robust diagnostic methods, prompt treatment protocols, and capacity-building initiatives, NTEP strives toward achieving its ultimate objective of eliminating TB from India.

The details of the various programs with their goals and year of implementation have been provided in **-Table 1**.

What is Meant by TB Elimination?

Elimination of TB is defined as the achievement of an incidence of less than 1 case of infectious TB disease per million population or reducing the prevalence of latent TB infection to less than 1%. The TB elimination phase is defined as an incidence of fewer than 20 cases per 100,000 population. Although we may seem far from achieving this target, robust strategies have been put in place to ensure that this vision becomes a reality soon.

Goals

The goals for our NTEP include:

- 1. 80% reduction in TB incidence as compared with the 2015 baseline
- 2. 90% reduction in TB mortality as compared with the 2015 baseline
- 3. 0% out-of-pocket health expenditure

On March 13, 2018, a clarion call was made by the Hon'ble Prime Minister of India to achieve the abovementioned goals by 2025—five years ahead of the global SDG target of 2030.

In pursuit of the overarching vision of a TB-free India (TB Mukt Bharat), India is partnering with the WHO to launch project GATIMAN. This initiative aims to bolster technical support in various crucial areas such as public-private partnerships, TB surveillance, knowledge dissemination, implementation research, drug-resistant TB management, TB infection control, and advocacy and communication efforts spanning across states and union territories.

Furthermore, in a concerted effort to address the challenge comprehensively, WHO-India has identified and prioritized 100 challenging and neglected districts for targeted interventions to accelerate the elimination of TB within the country. These districts represent areas where TB control efforts are particularly challenging due to various socioeconomic factors and limited access to health care services. Through focused attention and strategic interventions in these areas, India endeavors to make significant strides toward achieving its goal of eradicating TB.

Uncovering the Invisible: How Does the Program Help in the Diagnosis of Tuberculosis?

Providing free-of-cost laboratory services to patients attending public health facilities and those referred from the private sector is one of the fundamental objectives of the NTEP, as shown in **-Table 2**. The diagnosis of TB has to be made based on clinical, radiological, and microbiological features.

Clinical suspicion of TB is based on symptoms such as prolonged fever, cough, significant weight loss, hemoptysis, and night sweats.

Program	Year	Goals
National TB Program (NTP)	1962	BCG vaccinationTB treatment
Revised National Tuberculosis Control Program (RNTCP)	1997	 Introduction of Directly Observed Treatment Short-course (DOTS) Expansion of DOTS across the country (2006) Control of tuberculosis in India
Programmatic Management of Drug Resistant TB (PMDT)	2007	 To combat drug-resistant TB Achieved full geographical coverage by 2013
National TB Elimination Program (NTEP)	2020	 Universal access to free, quality diagnosis and treatment services Robust patient support Elimination of tuberculosis in India

Table 1 A brief history of the evolution of India's national program against TB

Abbreviations: BCG, bacille Calmette-Guérin; TB, tuberculosis.

Serial No.	Diagnostic modality	Specific tests available under the program free of cost
1.	Microscopy	Ziehl-Neelsen staining/light-emitting diode fluorescence microscopy (LED-FM) using Auramine-O dye
2.	Molecular testing	Xpert MTB/RIF assay working with GeneXpert instrument system (CBNAAT) $^{\rm a}$ and TrueNAT MTB $^{\rm b}$
3.	Culture	MGIT 960 (mycobacterial growth indicator tube)
4.	Drug susceptibility testing (DST)	Phenotypic DST (both first and second line drugs) FL-LPA, SL-LPA (line probe assay, first and second line)
5.	Radiology	Chest X-ray

Table 2 Tests being done free of cost under the NTEP program in DOTS (directly observed treatment short-course) centers across

 India

Abbreviation: NTEP, National Tuberculosis Elimination Program.

^aThe Xpert MTB/RIF assay, is performed on the GeneXpert instrument systems and is also known as CBNAAT(cartridge-based nucleic acid amplification test). It is a semiquantitative test based on the nested real-time polymerase chain reaction (PCR) technology. It is an in vitro diagnostic test for the detection of mycobacterium tuberculosis complex deoxyribonucleic acid (DNA) in raw sputum or concentrated sputum sediment prepared from induced or expectorated sputum and can also be used to detect the same in extrapulmonary specimens. In those specimens where mycobacterium tuberculosis complex (MTB-complex) is detected, the Xpert MTB/RIF assay can also detect mutations in the rpoB gene, which confer resistance to rifampicin. It is developed by Cepheid Diagnostics, USA and is one of the WHO-recommended rapid molecular tests for diagnosis of tuberculosis.

^bTrueNat MTB is an indigenous rapid molecular test platform developed by the Indian Council of Medical Research (ICMR). It is a platform which utilizes real-time polymerase chain reaction (PCR) technology built into micro-PCR chips.

Microbiological confirmation tools encompass microscopy, molecular techniques and culture with drug susceptibility testing of cultured isolates which are provided free of cost under the program.

It is important to note that serological tests are not currently endorsed in NTEP for the diagnosis of active TB.

In-house real-time polymerase chain reactions are not recommended for diagnosis of TB as they have a high rate of false positives and discrepancies have been reported in the results. While significant advances have been made in diagnosing pulmonary TB, extrapulmonary TB (EPTB) diagnosis and management remain a considerable challenge. EPTB, which can involve almost any system of the body, causing significant complications, along with the ambiguity regarding clinical management, has made itself a formidable enemy in the war against TB. Clinical manifestations of EPTB are nonspecific and mimic many other diseases. Moreover, due to the paucibacillary (lower organism load) nature of extrapulmonary specimens and sample collection often requiring invasive procedures, diagnosis of EPTB is often delayed. Varying responses to treatment and its duration further compound the management of EPTB. Presumptive EPTB cases undergo simultaneous testing for nucleic acid amplification tests (NAATs), culture, and line probe assay (LPA), with a preference for NAAT if available. In the absence of NAAT, samples are directly sent for culture and LPA. If the liquid culture is negative and clinical suspicion persists, alternative diagnostic modalities are employed. The NTEP's comprehensive approach, in line with the National Strategic Plan (2017-2025), emphasizes timely detection and treatment of TB, utilizing advanced diagnostic tools to combat the disease and achieve its elimination goals in India.

The Department of Medicine at All India Institute of Medical Sciences (AIIMS), New Delhi, India—a WHO collaborating center and National Centre for Excellence in Extrapulmonary TB—led the development of INDEX TB guidelines in 2016,⁵ enhancing EPTB care in India and Southeast Asia. The department has collaborated with WHO and various other stakeholders to come up with a comprehensive EPTB training module (tbcindia.gov.in)⁶ which integrates expertise from various specialities and aims to standardize care and aid primary care physicians in timely referrals and management decisions.

The Journey to Recovery: Role of the National Program in the Treatment of Tuberculosis

To contribute to universal health care, reduce out-of-pocket expenditure, and ensure zero catastrophic costs to patients, the NTEP provides free diagnostic and treatment services. With the widespread use of molecular diagnostics to test for resistance, the programmatic management has become more simplified. Earlier categorization of treatment based on prior exposure to antitubercular therapy, severe, or nonsevere form has been replaced by two categories, that is, drug-sensitive or drugresistant TB. The program has shown flexibility in embracing and adjusting to the newer medications and approaches to treatment. In recent years, the country has made considerable progress in the management of TB. The various treatment options for drug-sensitive and drug-resistant TB are summarized in **-Table 3**. EPTB treatment regimen and duration are contingent upon the affected site and drug-susceptibility pattern: Drug-susceptible EPTB (DS-EPTB) or drug-resistant EPTB (DR-EPTB). For DS-EPTB the standard injection-free combination of four oral drugs treatment regimen is implemented across the country for 6 months. However, the regimen and duration of treatment could vary according to the affected site and at the clinician's discretion as shown in ► Table 4. DR-EPTB is managed by all oral H mono/poly DR-TB regimen, shorter oral bedaquiline containing multidrug resistant/rifampicin-resistant (MDR/RR-TB) regimen, and longer oral MDR/RR-TB regimen as per drug susceptibility test results.

Table 3 Treatment regimens according to drug susceptibility

Type of TB	Regimen
Drug-sensitive pulmonary TB	(2) HRZE + (4) HRE
H mono-resistant/poly drug-resistant TB	(6–9) Lfx REZ
MDR TB (shorter regimen) ^a	(4–6) $Bdq_6 Lfx Eto Cfz ZEH + (5) Z E Lfx Cfz$
MDR TB (longer oral regimen) ^a	(18–20) Bdq ₆ Lfx Lzd Cfz Cs

Abbreviations: Bdq, bedaquiline; Cfz, clofazimine; Cs, cycloserine; E, ethambutol; Eto, ethionamide; H, isoniazid; Lfx, levofloxacin; Lzd, linezolid; MDR, multidrug resistant; R, rifampicin; TB, tuberculosis; Z, pyrazinamide.

Note: The numbers in the brackets indicate duration of treatment in months.

^aFor shorter and longer regimen, Bdq₆ indicates treatment with bedaquiline for 6 months, while rest of the drugs are given for the duration of months given in the brackets, respectively.

Table 4	Usual	duration	of EPTB	regimens ^a
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Site of disease	Initial regimen (initiation phase + continuation phase)	Duration
Lymph node TB Pleural TB Pericardial TB Hepatobiliary TB Intestinal TB Urinary TB Genital TB (male or female) Cutaneous TB	(2) HRZE + (4) HRE	6 mo
Ocular TB Ear, nose, and throat TB	(2) HRZE + (4–7) HRE	Usually 6–9 mo
TB otitis media	(2) HRZE + (7) HRE	Minimum of 9 mo
CNS TB Bone and joint TB	(2) HRZ + E/S + (10) HRE (2) HRZE + (10) HRE	Minimum of 12 mo
Spine TB	(2) HRZE + (10–16) HRE	Usually 12–18 mo

Abbreviations: CNS, central nervous system; E, ethambutol; EPTB, extrapulmonary tuberculosis; H, isoniazid; R, rifampicin; S, streptomycin; TB, tuberculosis; Z, pyrazinamide.

^aSome patients may require a longer course of treatment depending on their clinical response.

Building a Stronger Defense: Prevention of TB

Prevention stands as a foundational pillar within the National Strategic Plan (2017–2025), crucial for achieving the ambitious goal of ending TB in India by 2025. The focus lies on thwarting the emergence of TB within the nation's vulnerable populations. In 2021, the NTEP took a significant stride forward by broadening its policies to encompass the provision of TB preventive therapy (TPT). This expansion aims to accelerate the prevention efforts and drive a decline in TB incidence over the coming years.

Under this enhanced policy, TPT will be extended to all household contacts (HHCs) of index pulmonary TB patients, as well as other at-risk groups, extending beyond the previous focus solely on PLHA and HHCs aged under 5 years, as shown in **-Table 5**. By widening the scope of preventive measures, NTEP endeavors to fortify its approach toward preventing the transmission and spread of TB, thus advancing the nation's journey toward TB elimination.

According to current program guidelines, HHCs of patients with EPTB are presently not eligible for TPT. To determine eligibility for TPT, an assessment is conducted to rule out active TB, considering the balance between risks and benefits. A primary strategy for expanding TPT coverage in India involves the systematic tracing of HHCs and other vulnerable populations.

Under the NTEP, various tests such as tuberculin skin test, interferon-gamma release assays, or Cy-Tb test are employed for TB infection diagnosis. However, in regions where testing services are not yet available, TPT may be considered after excluding active TB based on symptom screening, chest Xray, and NAAT results.

NTEP personnel actively coordinate and facilitate a range of concurrent public health interventions to advance TB elimination efforts. These include contact tracing and the provision of TPT, bolstering support for patients accessing care in the private sector, enhancing surveillance mechanisms, promoting treatment adherence, managing TB comorbidities, conducting routine follow-ups, and providing incentives for patient support.

Patient Support Systems

Below is a list of schemes currently ongoing under the program and **-Table 6** enumerates the beneficiaries and the extent of benefits under each scheme.

1. Ni-Kshay Poshan Yojana (NPY): It is an incentive scheme launched in April 2018 under the National Health Mission

Target population	Strategy
People living with HIV/AIDS	Provide TPT after confirming the absence of active TB
Infants < 12 months with HIV in contact with active TB	Provide TPT after confirming the absence of active TB
Household contacts (HHC) below 5 years of age of pulmonary TB ^a patients	Offer TPT after ruling out active TB disease
Household contacts (HHC) 5 years and above of pulmonary TB ^a patients ^b	Provide TPT among TB infection (TBI) positive individuals after ruling out TB disease
Individuals on immunosuppressive therapy, having silicosis, on anti-TNF treatment, on dialysis, preparing for organ or hematologic transplantation	Offer TPT among TB infection (TBI) positive individuals after ruling out TB disease

Table 5 TB preventive therapy (TPT) implementation strategies (Adapted from National TB Program document)

Abbreviations: AIDS, acquired immunodeficiency syndrome; HIV, human immunodeficiency virus; TB, tuberculosis. ^aBacteriologically confirmed pulmonary TB patients.

^bChest X-ray (CXR) and TBI testing is offered whenever and wherever available, but TPT must not be deferred if they are unavailable.

Table 6 Patient support schemes under NTEP

Schemes	Beneficiary	Benefit amount
(1) Ni-Kshay Poshan Yojana (NPY)	Confirmed TB patients: • DS-TB and DR-TB • Public sector patients • Private sector patients	INR 500 per month till treatment is completed
(2) Tribal Support Scheme	Confirmed TB patients residing in tribal territory	INR 750 (one time)
(3) Treatment Supporter Honorarium	Treatment supporter	 INR 1,000 for DS-TB patients INR 5,000 for DR-TB patients
(4) Incentive for Notification and Outcomes	 Private health facilities: Practitioner /clinic, etc. (single) Hospital/clinic/nursing home, etc. (multi) Laboratories/Chemists 	 INR 500 as informant or notification incentive INR 500 for outcome declaration

Abbreviations: DR-TB, drug-resistant tuberculosis; DS-TB, drug-susceptible tuberculosis; NTEP, National Tuberculosis Elimination Program.

by the Central TB Division of the Ministry of Health and Family Welfare (MoH&FW) for TB patients who are under treatment and have registered/notified themselves on the NIKSHAY portal.

- Transport support for TB patients in notified tribal areas: To provide access to diagnosis and treatment centers for people in the tribal areas, NTEP initiated transport support for TB patients in notified tribal areas in 2019. Transport support is available for patients receiving treatment from both private and public sectors.
- 3. Honorarium for treatment supporters: This scheme was launched in 2019. Any registered staff in NIKSHAY can act as a treatment supporter. Treatment supporters are given an honorarium of INR 1,000 for DS-TB patients and INR 5,000 for DR-TB patients if the treatment outcome of the patient they are supporting has been declared either "cured" or "treatment complete."
- 4. Notification and treatment outcome incentive for private sector providers: Under this scheme launched in 2018, private sector providers are given incentives for notifying TB patients to the NIKSHAY portal and also for declaring treatment outcomes. A patient may also be considered an informant and incentivized.

The Final Word: TB Notification

Starting from March 16, 2018, the Government of India made a significant move by declaring TB a notifiable disease, compelling the reporting of each TB case for public health reasons. Health care providers are mandated to notify all TB patients to local public health authorities, while pharmacies dispensing antitubercular medications are required to report patient details. To ensure comprehensive treatment support, patients are encouraged to self-notify.

The seriousness of TB reporting and management is underscored by legal provisions: nonnotification and failure to take public health action are punishable under IPC (Indian Penal Code) sections 269 and 270. This highlights the government's commitment to effectively address TB by enforcing stringent measures for reporting and managing cases, thereby safeguarding public health interests.

The following are the available modes of TB notification:

- (1) NIKSHAY portal: https://www.nikshay.in/
- (2) Call center NIKSHAY Sampark: 1800116666
- (3) Physical pro forma
- (4) District nodal officers

Steps for TB Notification via the NIKSHAY Portal

TB notification is the first step in ensuring proper calculation of burden and monitoring the progress with respect to the control and elimination of the disease. Through the central notification NIKSHAY portal, the process has become a simple one as described below:

- Step 1. Log In with your respective Login ID and password through this link https://www.nikshay.in/
- Step 2. Click for new enrolment on the dashboard
- Step 3. Select the patient type from dropdown menu
- Step 4. Add basic details of the patient
- Step 5. Deduplicate the patient enrolled if intimated
- Step 6. Add residence details (Note: This information can be filled by paramedical staff, not necessary to be filled by clinicians only)
- Step 7. If there is no duplication, then select Tuberculosis Unit (TU) and Peripheral Health Institute (PHI)
- Step 8. Add demographic details
- Step 9. Add emergency contact details
- Step 10. Add case and notify the case

Conclusion

India's NTEP has made significant progress in combatting the disease through the implementation of robust strategies for detection, treatment, and prevention. While India moves steadily toward its goal of a "TB-free nation," there is a crucial need to shift focus toward addressing EPTB cases. The diagnosis and management of EPTB pose significant challenges and act as a bottleneck in achieving TB elimination.

To overcome this challenge, there is a pressing need for a more stringent and uniform reporting system for EPTB cases. Additionally, increasing research mandates toward the diagnosis and management of EPTB can facilitate better understanding and management of the disease.

With the rapid advancements in artificial intelligence (AI) and genomics, there is an imminent paradigm shift in how TB is diagnosed and treated. Newer diagnostic modalities such as whole-genome sequencing, already in use in developed countries, hold promise for revolutionizing TB diagnosis. Moreover, the development of innovative software utilizing AI can aid in interpreting chest radiographs and detecting acid-fast bacilli in microscopy, enhancing diagnostic accuracy and efficiency.

By continuing to prioritize innovation, fostering collaboration, and allocating resources effectively, India is poised to achieve its goal of a TB-free nation. These efforts ensure a healthier future for all, marking a significant stride toward eliminating TB from the country.

Authors' Contributions

C.R. and M.M. have conceptualized and written the manuscript. The manuscript has been verified and proofread by N.N., S.V., and A.R.

Funding

None.

Conflict of Interest None declared.

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