Please share your comments/suggestions on this task force separately on an individual page by 20th June 2024 on email Id: umeshkapil@gmail.com.

सत्यमेव जयते

DRAFT

NATIONAL ACADEMY OF MEDICAL SCIENCES (INDIA)

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

REPORT OF TASK FORCE

ON

TUBERCULOSIS IN INDIA

2023

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REPORT OF TASK FORCE

ON

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We are grateful to all the clinicians and academicians who contributed to the development of this document.

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Preface

Tuberculosis is both curable and preventable. The cost of diagnosis and treatment of TB is free for patients. Despite this, women, men, children, and babies are still becoming ill and dying from TB every day.

TB is a public health scourge, a health security threat and a development challenge. Integral to the commitment to End TB by 2025, India has launched a dramatically accelerated fight against tuberculosis (TB) and for those most affected by it: the poorest, most vulnerable, socially marginalized and inequitably served. However, the speed of progress is not sufficient to reach the SDG and the End TB Strategy goals. Activities required to speed up development towards global targets for reducing the burden of TB disease include closing the incidence–notification gaps, increasing the proportion of notified cases from public and private sectors that are bacteriologically confirmed, monitoring to ensure that people are correctly diagnosed and started on the most effective short and safe treatment regimen as early as possible and the implementation of follow up guidelines for those who are under treatment.

The much-neglected areas of contact tracing, active case finding, TB preventive therapy and air borne infection prevention measures need to be strengthened.

With aims of Safe, Effective, Patient-centred, Timely, Efficient, and Equitable care for TB patients this Task Force has made a sincere attempt to look at the gaps in current program and suggested recommendations to bridge the same.

List of Abbreviations

3HP	Three Months of Weekly Rifapentine Plus Isoniazid
4R	Four Months of Daily Rifampicin
6H	Six Months of Daily Isoniazid
6Lfx	Six Months of Daily Levofloxacin
1HP	One Month of Daily Rifapentine Plus Isoniazid
ACF	Active TB Case Finding
AIDS	Acquired Immunodeficiency Syndrome
ALT	Alanine Aminotransferase
ANC	Antenatal Care
ART	Antiretroviral Treatment
ARV	Antiretroviral Drugs
BRICS	Brazil, Russia, India, China and South Africa
BCG	Bacille Calmette-Guérin (vaccine)
Bdq	Bedaquiline
CAD	Computer Aided Detection
C(A)LHIV	Children (And Adolescents) Living with HIV infection
CBME	Competency – BASED MEDICAL EDUCATION
C DST	Culture and Drug Susceptibility Testing
CHW	Community Health Worker
CLHIV	Children living with HIV
CMSS	Central Medical Services Society stores
CTD	Central Tuberculosis Division
CXR	Chest X-ray or chest radiography
DMCs	Designated Microscopy Centres
DMP	Depot Medroxyprogesterone acetate
DR-TB	Drug-Resistant Tuberculosis
N/DDR TB	Nodal/ District Drug resistant TB Centre
DSD	Differentiated HIV service delivery
DST	Drug Susceptibility Testing
DS-TB	Drug-Sensitive Tuberculosis

DTG	Dolutegravir
E	Ethambutol
ELISA	Enzyme-Linked Immunosorbent Assay
EPTB	Extrapulmonary
FLLPA	First Line Line Probe Assay
FDC	Fixed-Dose Combination (Medicines)
FDC	Fixed-Dose Combination
GDF	Stop TB Partnership Global Drug Facility
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment, Development and Evaluation
H	Isoniazid
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEPA	High-Efficiency Particulate Air
HF	Health Facility
HHC	Household Contact
HIV	Human Immunodeficiency Virus
HRG	High Risk Group
Hr-TB	Isoniazid-Resistant, Rifampicin Susceptible TB Disease
HWC	Health And Wellness Centre
KSP	Knowledge Sharing Platform
ICCM	Integrated Community Case Management
ICMR	Indian Council of Medical Research
IGRA	Interferon-Gamma Release Assay
IMCI	Integrated Management of Childhood Illness
INSTIS	Integrase Strand Transfer Inhibitors
IPD	Individual Patient Data (Or Dataset)
IPT	Isoniazid Preventive Therapy
IRL	Intermediate Reference Laboratory
JMM	Joint Monitoring Mission
LAMP	Loop-Mediated Isothermal Amplification
LFT	Liver Function Test

LFX	Levofloxacin
LIMS	Laboratory Information Management System
LPA	Line-Probe Assay
M	Moxifloxacin
MDR-TB	Multidrug-Resistant Tuberculosis
MERM	Medical Event Reminder Monitoring
NAATs	Nucleic Acid Amplification Tests
NABL	National Accreditation Board for Testing and Calibration Laboratories
NGO	Non-Governmental Organization
NIRT	National Institute for Research in Tuberculosis
NPA	Nasopharyngeal Aspirate
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
NRL	National Reference Laboratories
NSP	National Strategic Plan
NTEP	National Tuberculosis Elimination Programme
NTLP	National TB and Leprosy Control Programme
NTP	National Tuberculosis Programme
PBCT	Pulmonary bacteriologically confirmed Tuberculosis
PHC	Primary Health Care
PIs	Protease Inhibitors
PLHIV	People Living With HIV
PMTPT	Programmatic Management Of Tuberculosis Preventive Treatment
POC	Point-of-Care
PPD	Purified Protein Derivative
PPSA	Patient Provider Support Agency
PTB	Pulmonary Tuberculosis
PWU	People Who Use Drugs
R	Rifampicin
RAL	Raltegravir
RCT	Randomized Controlled Trial
RNTCP	Revised National Tuberculosis Control Programme

RR	Relative Risk
RR-TB	Rifampicin-Resistant Tuberculosis
SAGE	Strategic Advisory Group of Experts on Immunisation
SAM	Severe Acute Malnutrition
SDGs	Sustainable Development Goals
SL-LPA	Second-Line Line-Probe Assay
SL LCDST	Second Line Liquid Culture and Drug Susceptibility Test
SNRL	Supra – National Reference Laboratories
SSRI	Selective Serotonin Reuptake Inhibitor
TB	Tuberculosis
TBI	Tuberculosis Infection
TBM	Tuberculous Meningitis
TDF	Tenofovir-Disoproxilfumarate
TDF-DP	Tenofovirdiphosphate
TNF	Tumour Necrosis Factor
TPT	Tuberculosis Preventive Treatment
TST	Tuberculin Skin Test
UNGA	United Nations General Assembly
UNHLMT	United Nations High Level Meeting on Tuberculosis (2018)
US FDA	United States Food and Drug Administration
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis
Z	Pyrazinmide

Operational definitions of terms used in the report

Active (tuberculosis) case-finding-Provider-initiated screening and testing in communities by mobile teams, often using mobile X-ray and rapid molecular tests. The term is sometimes used synonymously with "systematic screening".

Adherence-Extent to which a person's behaviour (e.g. taking medicines, following a particular diet, changing lifestyle) corresponds with agreed recommendations from a health care provider.

Advanced HIV disease-For adolescents and children aged 5 years and over, this is defined as a CD4 cell count below 200 cells/mm3 or a WHO clinical stage 3 or 4 event at presentation for care. All children aged under 5 years living with HIV should be considered as having advanced disease at presentation.

Adverse event-Any untoward medical occurrence that may present in a person with TB during treatment with a pharmaceutical product but that does not necessarily have a causal relationship with the treatment.

Age groups

Infant: aged under 1 year (12 months).

Child: aged under 10 years.

Young child: aged under 5 years.

Adolescent: aged 10–19 years (inclusive).

Young adolescent: aged 10–14 years.

Older adolescent: aged 15–19 years.

Adult: aged 20 years or over.

Background HIV and tuberculosis drug resistance prevalence-Settings with high HIV prevalence are defined as those in which the HIV prevalence is 1% or higher among adult pregnant women, or 5% or higher among people with TB. WHO does not intend to establish thresholds for low, moderate or high levels of prevalence of isoniazid resistance. National TB programmes will establish definitions for their own countries.

Bacteriologically confirmed tuberculosis-TB diagnosed in a biological specimen by a WHO-approved rapid test such as Xpert® MTB/RIF or LF-LAM, smear microscopy or culture.

Catastrophic cost - Defined as the total cost of tuberculosis care exceeding 20% of the annual income of the household, and it denotes the financial hardships faced by a patient/family.

Contact-Any person exposed to a person with TB.

Contact investigation-Systematic identification of people, including children and adolescents, with previously undiagnosed TB disease and TB infection among the contacts of an index TB patient in the household and in comparable settings in which transmission occurs. It consists of identification, clinical evaluation and/or testing and provision of appropriate TB treatment (for people with confirmed TB) or TB preventive treatment (for people without TB disease).

Decentralization-Depending on the standard in the research settings used for the comparator, this includes provision of, access to or capacity for child and adolescent TB services at a lower level of the health system than the lowest level where this is currently routinely provided. In most settings, decentralization applies to the district hospital (first referral level hospital) level and/or primary health care level and/or community level. Interventions for decentralization include capacity-building of various cadres of health care workers, expanding access to diagnostic services, ensuring availability of TB medicines for children and adolescents, and follow-up of children and adolescents with TB or on TB preventive treatment.

Differentiated HIV service delivery model-Person-centred approach to simplify provision of HIV services across the cascade in ways that better serve the needs of people living with HIV and reduce unnecessary burdens on the health system.

Drug susceptibility testing (DST)-In vitro testing using either molecular genotypic techniques to detect resistance-conferring mutations, or phenotypic methods to determine susceptibility to a medicine.

Extensive (or advanced) pulmonary tuberculosis disease-Presence of bilateral cavitary disease or extensive parenchymal damage on chest radiography (CXR). In children aged under 15 years, advanced disease is usually defined by the presence of cavities or bilateral disease on CXR.

Extensively drug-resistant tuberculosis (XDR-TB)-Pre-XDR-TB: TB caused by Mycobacterium tuberculosis strains that fulfil the definition of multidrug-resistant TB (MDR-TB) or rifampicin-resistant TB (RR-TB) and that are also resistant to any fluoroquinolone. (The fluoroquinolones include levofloxacin and moxifloxacin as currently recommended by WHO for inclusion in shorter and longer regimens.)

XDR-TB: TB caused by M. tuberculosis strains that fulfil the definition of MDR/RR-TB and that are also resistant to any fluoroquinolone and at least one additional Group A medicine. (Group A medicines are currently levofloxacin or moxifloxacin, bedaquiline and linezolid; therefore, XDR-TB is MDR/RR-TB that is resistant to a fluoroquinolone and either bedaquiline or linezolid (or both). Group A medicines could change in the future. Therefore, the terminology "Group A" is appropriate here and will apply to any Group A medicines in the future.)

Extrapulmonary tuberculosis -Any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs (e.g. pleura, peripheral lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges).

Family-centred, integrated care-Family-centred models of care refer to interventions selected on the basis of the needs, values and preferences of the child or adolescent and their family or caregiver. This can include health education, communication, material or psychological support. Integrated services refer to approaches to strengthen collaboration, coordination, integration and harmonization of child and adolescent TB services with other child health-related programmes and services. This can include integration of models of care for TB screening, prevention, diagnosis and treatment with other existing service delivery platforms for maternal and child health (e.g. antenatal care, integrated community case management, integrated management of childhood illnesses) and other related services (e.g. HIV, nutrition, immunization). Other examples include evaluation of children and adolescents with common comorbidities (e.g. meningitis, malnutrition, pneumonia, chronic lung disease, diabetes, HIV) for TB and community health strategies integrating child and adolescent TB awareness, education, screening, prevention and case-finding into training and service delivery activities.

Grading of Recommendations Assessment, Development and Evaluation (GRADE)-System for rating quality of evidence and strength of recommendations. This approach is explicit, comprehensive, transparent and pragmatic.6

High tuberculosis transmission setting-Setting with a high frequency of people with undetected or undiagnosed TB disease, or where people with infectious TB are present and there is a high risk of TB transmission. People with TB are most infectious when they are untreated or inadequately treated. Spread is increased by aerosol-generating procedures and by the presence of highly susceptible people.

Household contact-Person who shared the same enclosed living space as the index case for one or more nights or for frequent or extended daytime periods during the 3 months before the start of current treatment.

Index case (index patient) of tuberculosis-Initially identified person of any age with new or recurrent TB in a specific household or other comparable setting in which others may have been exposed. An index case is the person on which a contact investigation is centred but is not necessarily the source case.

Inpatient health care setting-Health care facility where people are admitted and assigned a bed while undergoing diagnosis and receiving treatment and care, for at least one overnight stay.

Integrated treatment decision algorithm-Flowchart allocating evidence-based scores to microbiological, clinical and radiological features that allow clinicians to make decisions regarding starting TB treatment in children.

Interferon-gamma release assay (IGRA)-Blood test used to test for Mycobacterium tuberculosis infection by measuring the body's immune response to TB bacteria.

Multidrug-resistant tuberculosis (MDR-TB)-TB caused by Mycobacterium tuberculosis strains that are resistant to at least both rifampicin and isoniazid.

New case- Newly registered episode of TB in a person who has never been treated for TB or has taken TB medicines for less than 1 month.

Non-severe pulmonary tuberculosis for the purpose of determining treatment duration for drug-susceptible tuberculosis

Intrathoracic lymph node TB without airway obstruction; uncomplicated TB pleural effusion or paucibacillary, non-cavitary disease confined to one lobe of the lungs and without a miliary pattern.

Number needed to screen-Number of people who need to undergo screening in order to diagnose one person with TB disease.

Operational research or implementation research-In the context of this document, applied research that aims to develop the critical evidence base that informs the effective, sustained and embedded adoption of interventions within a health system to improve health or patient outcomes. Such research deals with the knowledge gap between efficacy, effectiveness and current practice to produce the greatest gains in disease control. Operational research also

provides decision-makers with information to enable them to improve the performance of their health programmes.

Outpatient health care setting-Health care facility where people are undergoing diagnosis and receiving treatment and care but are not admitted for overnight stays (e.g. ambulatory clinic, dispensary).

Passive case-finding-Patient-initiated pathway to TB diagnosis involving a person with TB disease who experiences symptoms that they recognize as serious; the person having access to and seeking care, and presenting spontaneously at an appropriate health facility; a health worker correctly assessing that the person fulfils the criteria for presumptive TB; and successful use of a diagnostic algorithm with sufficient sensitivity and specificity to diagnose TB.

People who use drugs-People who engage in the harmful or hazardous use of psychoactive substances that could impact negatively on their health, social life, resources or legal situation.

Presumptive tuberculosis-Person who presents with symptoms or signs suggestive of TB.

Previously treated-People who have previously received 1 month or more of TB medicines. Previously treated people may have been treated with a first-line regimen for drug-susceptible TB or a second-line regimen for drug-resistant forms.

Programmatic management of tuberculosis preventive treatment-All coordinated activities by public and private health caregivers and the community aimed at scaling up TB preventive treatment to people who need it.

Pulmonary tuberculosis (PTB) (classification)-Any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. Following a WHO expert consultation in September 2021, intrathoracic lymph node TB(mediastinal and/or hilar, without radiographic abnormalities in the lungs) is now classified as pulmonary TB in children. Miliary TB is classified as PTB because there are lesions in the lungs. A person with both PTB and extrapulmonary TB should be classified as having PTB.

Rifampicin-resistant tuberculosis (RR-TB)-TB caused by Mycobacterium tuberculosis strains resistant to rifampicin. These strains may be susceptible or resistant to isoniazid (i.e. MDR-TB) or resistant other first-line or second-line TB medicines. In these guidelines and elsewhere, MDR-TB and RR-TB cases are often grouped together as MDR/RR-TB and are eligible for treatment with an MDR-TB regimen.

Rifampicin-susceptible, isoniazid-resistant tuberculosis-TB caused by Mycobacterium tuberculosis strains resistant to isoniazid and susceptible to rifampicin.

Serious adverse event-Adverse event that can lead to death or a life-threatening experience, to hospitalization or prolongation of hospitalization, to persistent or significant disability, or to a congenital anomaly. Serious adverse events that do not immediately result in one of these outcomes but that require an intervention to prevent such an outcome from happening are included. Serious adverse events may require a drastic intervention, such as termination of the medicine suspected of having caused the event.

Severe acute malnutrition-Presence of oedema of both feet or severe wasting (weight-for-height/length less than −3 standard deviations/Z-scores or mid-upper arm circumference less than 115 mm).

Severe extrapulmonary tuberculosis-Presence of miliary (disseminated) TB or TB meningitis. In children and young adolescents aged under 15 years, extrapulmonary forms of disease other than lymphadenopathy (peripheral nodes or isolated mediastinal mass without compression) are considered to be severe.

Source case-Person with TB disease who infected others in a new setting. This could be the index patient or another person who was not identified.

Systematic screening for tuberculosis disease-Systematic identification of people at risk for TB disease in a predetermined target group by assessing symptoms and using tests, examinations or other procedures that can be applied rapidly. For those who screen positive, the diagnosis needs to be established by one or several diagnostic tests and additional clinical assessments. This term is sometimes used interchangeably with “active tuberculosis case-finding”. It should be distinguished from testing for TB infection (with a TB skin test or interferon-gamma release assay).

Treatment outcomes and relapse-Categories for treatment outcomes used in this document and the term “relapse” were applied according to the definitions agreed for use by TB programmes, unless otherwise specified.

Tuberculin skin test (TST)-Intradermal injection of a combination of mycobacterial antigens that elicit an immune response (delayed-type hypersensitivity), represented by induration, which can be measured in millimetres. TST is used to diagnose TB infection.

Tuberculosis (TB)-Disease state due to Mycobacterium tuberculosis. In this document, it is commonly referred to as “TB disease” to distinguish it from “TB infection”.

Tuberculosis infection-State of persistent immune response to stimulation by Mycobacterium tuberculosis antigens with no evidence of clinically manifest TB disease. This is referred to as “TB infection” as distinct from “TB disease”. There is no gold standard test for direct identification of M. tuberculosis infection in humans. Most infected people have no signs or symptoms of TB but are at risk for TB disease. The term “latent TB infection” has been replaced by the term “TB infection” .

Tuberculosis preventive treatment (TPT)-Treatment offered to people considered at risk of TB disease to reduce that risk. Also referred to as “treatment of TB infection” or “TB preventive therapy”.

Underweight-Among adolescents, this usually refers to a body mass index below 18.5. Among children aged under 10 years, it usually refers to a weight-for-age Z-score below −2 standard deviations.

Executive summary

If India is to achieve its End tuberculosis (TB) targets by 2025, it is important that transmission of infection is prevented; all patients are identified; appropriate treatment regimens initiated; and treatments completed. There are gaps at each step of the TB care cascade that are unique to the varied rural and urban setting of India. Challenges include lack of awareness, continuing stigma, lack of coordination between various sectors to address issues such as migration, inadequate capacities of community level functionaries and structures, and a need for focus on quality in private sector health providers. India also has about half a million "missing" cases every year that are not notified, mostly remaining either undiagnosed or unaccountable, and inadequately diagnosed and treated by private providers.

The strategy of the National TB Elimination Program (NTEP) is to prevent, detect, treat, and build resistance to TB to achieve its ambitious goals. Prevention and Quality of care are the weakest link. There is suboptimal awareness about TB in the general population and meagre understanding of the disease among patients and their families. Implementation of the communication strategy is suboptimal and does not employ available modes of communication extensively. Stigma continues to be hugely prevalent and contributes to delays in seeking care. Prevention of airborne infections is another area that will require attention to achieve prevention of the disease.

a) *TB burden*-India's TB incidence for the year 2021 is 210 per 100,000 population – compared to the baseline year of 2015 (incidence was 256 per lakh population); there has been an 18% decline which is 7 percentage points better than the global average of 11%.The year 2021 witnessed a 19% increase from the previous year in TB patient notification—the total number of incident TB patients (new and relapse) notified during 2021 were 19,33,381 as opposed to that of 16,28,161 in 2020, despite the brief decline in TB notifications observed around the months corresponding to India's two major COVID-19 waves showing the sound principles on which the National TB Elimination Program (NTEP) is based. Still, a lot needs to be done as the rate of decline is not fast enough to realise THE END TB goals. New, comprehensively-deployed interventions are required to accelerate the rate of decline of incidence of TB many folds, from around 2% to more than 10-15% annually.

b) *TB diagnostics, treatment, active case finding and prevention*-The program effectively adheres to protocols of diagnosis and treatment. There was a substantial increase in universal drug sensitivity testing (UDST) from 2018 to 2019. It needs to be scaled up further urgently. However, areas requiring further strengthening are contact screening and ensuring prophylactic treatment for patients on antiretroviral treatment (ART) and children below 5 years of age. Scaling up TPT would be key to hasten the rate of decline in TB incidence from 2.5% at present to 10% required annually. Rigorous, expansive and accountable "TB contact tracing and investigation" for secondary TB patient detection and treatment coupled with active screening for TB among HRGs and TPT is one of the key activities that needs to be strengthened. The implementation of Active case Finding, Contact Tracing for Pulmonary Bacteriologically Confirmed TB and TB Preventive Therapy is in very early stages and needs to be scaled up urgently in the next three years leading to 2025.Diagnostic services have increased in the past year but, more infrastructure in terms of more laboratories for molecular diagnosis and DST, more mobile X ray units, more manpower (both technical and ground level- for delivering door step facilities to patients) and widespread adoption of digital technologies is needed to cover the country's vast population. The program has rapidly adopted injection free regimen for DSTB. Newer and shorter regimen with newer and repurposed drugs have also been incorporated in the program but has not yet covered the entire country. There is also shortage of newer drugs. The program has not been particularly strong enough in care cascade of MDR TB, XDR TB, other forms of DRTB, paediatric TB, extrapulmonary TB and TB in key populations. It has been suggested that health systems neglect children with TB because children are less contagious than adults (stopping the spread of TB is a priority), and TB is difficult to diagnose in children with currently available tools (The Union,2018). Same may be the case with EPTB. Isoniazid and rifapentine, a 3-month, once-weekly regimen for TB prevention; and Bedaquiline and Delamanid, two new drugs to treat TB, remain mostly inaccessible to children and no data are available on the performance and safety of the shorter MDR-TB regimen in children. Moreover Child friendly formulations (Syrups, Dispersible tablets) are still not available for many drugs. At present, migrants are not connected to public health facilities and are being captured in a limited manner during active case finding events. Efforts to reach migrants are limited. There is need for migrant strategies and projects to reach vulnerable populations with not only TB care but also improved access to overall health care for these communities. The NTEP will need to

consider comprehensive migrant strategies, including migrant projects to identify the missing cases.

c) *Supervision and monitoring* -Field-level supervision exercises over the past two years have been significantly impacted in the wake of the COVID-19 pandemic. Consequently, to identify the technical and administrative challenges faced by the States/ UTs and provide course-correction, a nationwide Joint Supportive Supervision Mission (JSSM) was conducted across 34 States/UTs. Furthermore, the programme division is strengthening the Nikshay portal by incorporating advanced analytical tools to provide regular feedback to the States on important indicators, which will help take necessary and timely actions. The universal uptake of this Nikshay surveillance system should be geared up urgently. Similarly, the notification of patients on TB Preventive Therapy is yet very poor and needs to be strengthened. Lack of personnel especially for Active Case Finding (ACF) and surveillance activities can be addressed by involving the already existing AFP (acute flaccid paralysis) network.

d) *Private sector engagement*-The last year has seen an increased engagement of the government with the private sector to ensure quality care and decrease catastrophic costs of TB patients visiting the private sector. The efforts in this direction needs to further strengthened by ensuring regular sensitisation and training of private providers and pharmacists. The engagement of interphase agencies in the form of Patient-Provider Support Agency (PPSA) to promote private sector engagement has also been scaled up to more than 170 districts.As significant percentage of drug resistant TB cases are being treated by the private sector, it would be wise that government should think of making Bedaquiline and Delamanid available with all the necessary steps to avoid their misuse. Regular and compulsory training of private providers in the optimal treatment of DSTB and DR-TB and when to refer should be held periodically.

e)*Patient support systems* -Direct Benefit Transfer (DBT) into the beneficiary's bank account under the NTEP continued its exemplary reach in 2021. Approximately INR 1488 crores have been paid to 57.33 lakh TB patients under NikshayPoshan Yojana (NPY) from April 2018 to February 2022.A few more remarkable steps have been taken by the GOI (Government of India) for strengthening the patient support system like launch of Nikshaymitra.

f) *Advocacy, Communication, and Community Engagement* -Sinceits inception, Advocacy, Communication, and Community Engagement (ACSM) have been bolstering the

programme's foundation by solidifying the measures across all aspects of TB care. The year 2021 saw the highest political commitment towards TB Mukt Bharat Abhiyaan by Hon'ble Governors at the 51st Conference of Governors chaired by the President of India—a first of its kind and juxtaposed with the lowest administrative unit—exemplified by the inclusion of the TB module in the Gram Pradhans induction for mobilising TB Free Panchayats. "Guidance Document on Community Engagement" has been developed to guide the States/ UTs in planning, designing, and monitoring the activities under community engagement. A strategy document to incorporate stigma reduction across all TB interventions "Strategy on Addressing Stigma Associated with Tuberculosis" was released in 2021.

However continued focus on mass awareness is vital. Sustained National campaign for cough hygiene and TB awareness programs by involving mass media, educational institutions, religious leaders, celebrities, politicians etc. should be done on a regular basis.

g)*TB Research*-Research is the third pillar of NSP 2017-2025. To that end, NTEP is collaborating with various national entities towards augmenting the development of new tools, reinforcing not only the rapid uptake of available tools and products but also to expedite our battle to end TB. Multi-state validation study of C-Tb skin test, multi-country project on "Epidemiological impact and intersection of the COVID-19 and tuberculosis pandemics in Brazil, Russia, India and South Africa" (IMPAC19TB) are a few notable examples. Furthermore, many initiatives have been taken up as pilot projects to employ Artificial Intelligence (AI) for improving healthcare delivery, increasing diagnostic accuracy, and screening for disease. Similarly many digital technologies are being studied, some of which are in pilot phase for improving patient compliance and tracking. These technologies should be rapidly made available to the whole country based on their performance in pilot studies. More research needs to be done in area of quality TB care, paediatric TB, DRTB and Extrapulmonary TB. Research on newer drugs, shorter regimens, newer point of care diagnostics and new vaccines taking in context the needs of our country, should be encouraged and funded. A test that predicts progression from infection to TB disease should be researched. Also research focusing on tackling Anti Microbial Resistant TB is crucial.

To achieve the goal of ending TB by 2025, the NTEP will have to reassess its strategies to reach the missing cases. Integrating vertical national health programs, strengthening referral pathways, and developing and implementing standards of quality of care will need to be

addressed. Also, India must reinforce international collaborations and capacities for antibiotic resistance prevention, surveillance, and infection control with countries worldwide.

It is hoped that this report and its recommendations can contribute to developing responsive strategies for a stronger and rapid response to the TB epidemic.

Contents

1. Introduction

Tuberculosis (TB) is a communicable disease that is a major cause of ill health and one of the leading causes of death worldwide. Until the coronavirus (COVID-19) pandemic, TB was the leading cause of death from a single infectious agent, ranking above HIV/AIDS and Malaria.

India has been engaged in Tuberculosis control activities for more than 50 years. Despite this, the magnitude of India's tuberculosis crisis is staggering. India is one of the 22 high-burden countries for TB. India has more than 26% of the world's burden of TB with an estimated 2.6 million cases, and an estimated half a million Indians die every year due to TB, making it the number one infectious disease killer in the country. Nearly 0.5 million people with TB disease remain missing and are likely in the private sector or the community. Among those who are found, almost one third of the patients are lost along their journey between care-seeking and successful cure. India bears 27% of the global burden of multi-drug resistant TB (MDR-TB).

According to global TB report 2022, there are 10 countries that account for about 70% of the global gap between the estimated global incidence of MDR/RR-TB each year and the number of people enrolled in treatment in 2021, India being one of them. Most of these are undetected and continue to transmit disease. Even those who are detected will have to endure long, toxic, and costly treatments only to have reduced odds of treatment success, along with a high drop-out rate and loss-to-follow-up.

High TB mortality, the large number of missing TB cases, the emergence of severe forms of drug resistance and the slow decline in TB incidence indicate that merely expanding the coverage of TB services is insufficient to end the epidemic.

In 2020, the RNTCP was renamed the National Tuberculosis Elimination Program (NTEP) to emphasize the aim of the Government of India to eliminate TB in India by 2025, five years ahead of the global target by WHO. The National Strategic Plan (NSP) for 2017-2025 proposes bold strategies with goal to achieve a rapid decline in burden of TB, morbidity and mortality while working towards elimination of TB in India by 2025. It is a welcome initiative and bold commitment from the government. The NSP for TB elimination has essentially four pillars to address the major challenges for TB control, namely, "Detect, Treat, Build and Prevent." However similar programs in the past have only succeeded in partially

attaining their set targets. The JMM 2015 observed that the implementation of the NSP for 2012-2017 did not achieve the projected increase in case detection by the RNTCP.

In strict sense, TB elimination is defined as less than one incident case per million population. The World Health Organization (WHO) END TB Strategy adopted by World Health Assembly in 2014 with aim to end the global TB epidemic serves as a blueprint for countries to reduce TB incidence by 80%, TB deaths by 90%, and to eliminate catastrophic costs for TB-affected households by 2030. It also sets targets to reduce TB incidence by 90% and TB deaths by 95% by 2035.

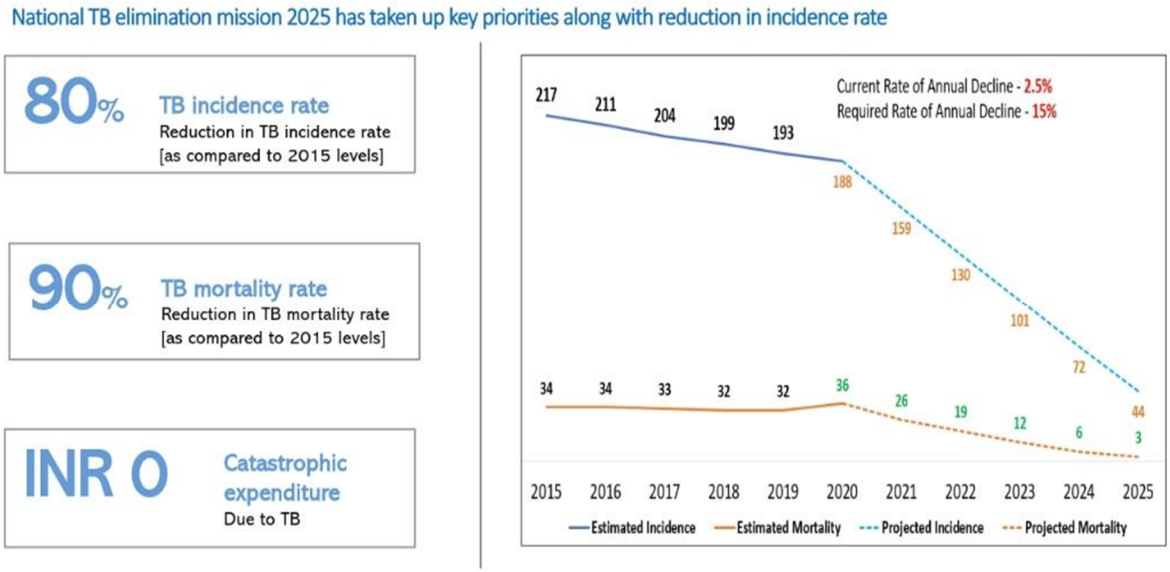
The NSP 2017-25 had targeted 80% reduction in TB incidence rate and 90% reduction in TB mortality rate and achieve zero catastrophic cost for affected families due to TB by 2025 as compared to 2015 baseline levels; five years earlier than the global target set by WHO.

As per the Global TB Report 2022, the only country in which a national TB prevalence survey has been completed since 2019 is India; the survey was started in 2019 but was interrupted for several months in 2020 due to the COVID-19 pandemic and then completed in 2021. This survey has informed interim estimates of TB incidence published as part of this report. The estimated incidence of all forms of TB in India for the year 2021 was 210 per 100,000 population and the estimated mortality rate among all forms of TB was 35 per 100,000 population in 2021against the targeted incidence of 142 per 100,000 and mortality rate of 15 per 100,000 respectively aimed by NSP 2017-2025 for the year 2022.The goal to achieve zero catastrophic cost due to TB by 2020 could also not be fulfilled. This could be attributed largely to the Covid 19 pandemic which had affected the measures of TB control programmes impacting care-seeking, treatment services, household income and cost incurred to the affected household.

The total number of incident TB patients (new & relapse) notified during 2021 was 19,33,381 which was 19% higher than that of 2020 (16,28,161). This shows the strength of the programme which had been able to catch-up with the dip in TB notifications that was observed around the months when the two major Covid 19 waves happened in India (TB annual report 2022).

There is a high-level political commitment for TB elimination but more needs to be done at the ground level to make real progress. Issues of overcrowding, poverty, malnutrition, smoking and alcohol intake etc. continue to propound the challenges to deal with. The current

rate of annual decline in TB incidence is 2.5% which is too slow to achieve the target of TB elimination by 2025 for which an annual decline rate of 15% will be required.



With the hope to bridge the gap between ambition and reality, this report tries to identify the major gaps in implementation of the NSP and suggests some recommendations to address them.

2. Background

"The struggle to end TB is not just a struggle against a single disease. It is also the struggle to end poverty, inequity, unsafe housing, discrimination, and stigma and to extend social protection and universal health coverage." These words by Tedros Adhanom Ghebreyesus, Director-General, WHO precisely emphasize that TB is not just a health problem but is also a serious social, economic, equality and human rights related problem.

India has a little less than 20 percent of the world's population, but has more than 25 percent of the total TB patients of the world which is a matter of grave concern. Most of the people affected by TB come from the poor section of society making it a humanitarian crisis.

The COVID-19 pandemic has reversed gains and set back the fight against TB by several years. As per the Global TB report 2022, the most obvious and immediate damaging impact of the pandemic was a large global drop in the reported number of people newly diagnosed with TB. From a peak of 7.1 million in 2019, this fell to 5.8 million in 2020 (–18%), back to the level last seen in 2012. In 2021, there was a partial recovery, to 6.4 million (the level of

2016–2017). Reductions in the reported number of people diagnosed with TB in 2020 and 2021 suggest that the number of people with undiagnosed and untreated TB has grown, resulting first in an increased number of TB deaths and more community transmission of infection and then, with some lag-time, increased numbers of people developing TB. Also, the number of people provided with treatment for drug resistant TB and TB preventive treatment dropped significantly. Through the implementation of the rapid response plan to mitigate the impact of Covid-19 pandemic on TB services, the NTEP was able to regain momentum in 2020-2021 and was successful in improving the coverage near to the pre-pandemic level. However, we still need to move forward with double the efforts and investments to urgently close the remaining gaps.

The cascade of TB care in India has been leaky, with long diagnostic delays, complex care pathways, poor quality of TB care in public as well as private health sectors and high TB case fatality. Tests, medicine refills and medical consultations are essential activities for patients but are greatly compromised due to lack of transportation, an overwhelmed health system, poor supply chain and lack of awareness in public and lack of motivation in health personnel. Even for those who are seeking care, the quality of TB care in both the public and private sectors falls short of international standards.

Patients are often deterred from seeking treatment by social stigma and poor access to quality services in the public sector. Most patients opt for treatment from formal or informal providers in the private health system. But, because this sector is largely unregulated and data gathering is poor, tracking patients throughout their course of treatment is difficult.

Drug-resistant TB threatens our ability to treat and control TB. Mumbai is one of the highest burden cities for drug-resistant TB in the world. The need to identify and address key gaps in DRTB care including improving TB infection control, improving TB laboratory quality, diagnostic and treatment services and treatment adherence to improve treatment outcomes cannot be over emphasized.

TB often has the worst outcomes amongst the most vulnerable. The Global Plan defines key populations to whom it is essential to reach out to for ending TB as they have increased exposure to TB, limited access to quality TB services, or are at increased risk of developing TB disease once infected, due to biological or behavioural factors that compromise their immune system (Stop TB Partnership & UNOPS, 2015). Focusing on key populations at high risk of TB who are underserved and marginalised means not conducting business as usual.

Costs of care-seeking for TB to patients and their households can be catastrophic, especially for the poorest who spend proportionately more on care-seeking than the less poor.

The staggering costs faced by patients when seeking TB diagnosis and treatment, can put families in poverty and undermine economic gains and stability. According to a cost analysis done by P Sinha et al published in Sep 21, patients with drug-susceptible TB paid a mean of US$46.8 in direct costs and US$666.5 in indirect costs.(In this study, costs were adjusted for inflation using an online calculator (www.statbureau.com) to December 2018 Indian rupees (INR) and then converted to $US using the conversion rate of US$1 = INR70). Cost for the treatment of drug-resistant TB was considerably higher. The location of patients, their use of private sector services, and need for hospitalization, among other factors, determine costs. Indirect costs constituted a striking 93.3% of the costs. Studies largely defined indirect costs as lost wages due to TB in addition to staff absenteeism and lost productivity. Treatment in the private sector can result in costs up to six-fold higher than in government facilities. As many as one in three TB patient in India experience catastrophic costs.

Efforts to end TB are a best buy—reaping $43 return for every $1 invested. Thus, while TB has a severe economic toll, efforts to end TB are one of the best investments for improving India's health, security and economic development.

Challenges regarding this illness in India include poor primary health-care and infrastructure in rural areas; unregulated private health care; HIV induced TB cases; lack of hygiene facilities and widespread malnourishment and poverty. The main variables that help understand tuberculosis transmission are rapid unplanned urbanization, overcrowding, poor airborne infection control, poor nutrition, HIV, diabetes and tobacco use. Marginalized sections are at the highest risk because of inadequate healthcare systems and lack of access to tuberculosis treatment centres in remote, unreached areas.

The lack of effective partnerships with private providers and limited participation of urban local bodies in the smaller cities adversely impacts the control efforts in the urban areas. Partnership with civil society and communities affected by TB is crucial to transform policies and practice, help mobilise resources and stimulate and support local action. There are certain good examples in the area of private provider involvement like the Global Fund project (Joint Effort for Elimination of Tuberculosis [JEET]), but it has yet not been scaled up to the entire country. The Central TB Division has scaled up the learning and institutional funding mechanisms of such partnerships through domestic sources; however, the wider engagement

of the private sector remains a challenge. Tracking patients put on treatment, especially the migrant urban slum dwellers, has also remains a challenge.

The Airborne Infection Control Unit (AICU) helps healthcare facilities implement TB infection control best practices to reduce healthcare-associated transmission of TB. Unfortunately, this has been not uniformly implemented throughout the country and continues to be a weak link in TB.

Although sufficient insight and expertise exists to inform TB programme decision-making, these resources have often been underutilized in terms of meeting the needs of policy makers for quantitative analysis and improvements in TB control policy and implementation.

The Honourable President of India, Smt Draupadi Murmu virtually launched the Pradhan Mantri TB Mukt Bharat Abhiyaan on September 9, 2022 to make this campaign a mass movement and with a vision to bring together all community stakeholders to support those on TB treatment. This shows India's commitment to accelerate the country's progress towards TB elimination and to realize this dream, we must address TB urgently to ensure a safer and healthier India. In this context, the expressed need by NAMS for identifying gaps and suggesting recommendations for TB elimination has been fulfilled vide this document.

3. Terms of reference (TORs) for the Task Force

The executive council of National Academy of Medical Sciences had assigned the following terms of reference for the Task Force on Tuberculosis in April 2022:

1. To identify the current status in the area of Tuberculosis.
2. Identify the deficiencies which needs to be addressed.
3. To recommend its prevention to make improvements in the area of Tuberculosis.

4. Methodology

The Task force conducted focused group discussions and zoom meetings along with expert members co-opted by the Chairperson. The meetings were conducted as and when required. The relevant technical documents, published papers, reports like JMM 2019, NSP 2017-25, data from TB prevalence guidelines were used as reference materials. The key recommendations were arrived at by consensus of the members based on their expertise and experience.

5. Observation/Critical review

5.1 Current situation in the country

To manage the TB situation in India, the RNTCP was established in 1992 replacing the earlier NTP, in vogue since 1962. The entire country was covered under the RNTCP by March 2006. Much progress has since been made and the country has pledged to End TB by 2025 five years ahead of the global SDG (Sustainable Goal Target), following the announcement of the Honourable Prime Minister of India in 2018.To give a thrust to this end, RNTCP was changed to NTEP since January 2021.

In 2021, the vision of the National Strategic Plan for Elimination of Tuberculosis (NSP 2017-25) permeated to state and district levels yet again to encompass more objectives. Eighteen States have committed to Ending TB by 2025 by formally implementing state specific Strategic Plans and have gone a step ahead to devise a District-specific Strategic Plan, which shall serve as a guiding tool for the programme managers and staff at the district and sub-district level towards the elimination of Tuberculosis.

TB Incidence: As per the Global TB Report 2022, the estimated incidence of all forms of TB in India for the year 2021 was 210 per 100,000 population (178-244 per 100,000 population). The total number of incident TB patients (new & relapse) notified during 2021 was19,33,381 which was 19% higher than that of 2020 (16,28,161). The programme had been able to catch-up with the dip in TB notifications that was observed around the months when the two major Covid-19 waves happened in India by introducing bidirectional screening for TB-Covid, doorstep delivery of services as well as earned gains on the behaviour change of people in terms of respiratory etiquette, which in the long run is expected to have an impact on reducing the transmission of TB as well as other respiratory infections.

Estimates of TB Burden, 2021, (Global Tuberculosis Report, 2022)

Estimates of TB Burden	Number	Rate per 100,000 Population
Incidence of TB cases (includes HIV + TB)	3 million	210
Incidence (HIV+TB only)	54,000	3.9
Lab confirmed MDR/RR-TB*	58,800	

Lab confirmed cases -Pre-XDR-TB or XDR-TB*	10,900	

**Includes cases with unknown previous TB treatment history*

Paediatric TB- About 31% of the global cases of TB in children are in India. Over the last decade, children consistently constitute 6-7% of all the patients treated under NTEP annually, pointing to a gap of 4-5% of total notification against the estimated incidence.

There is a dearth of Paediatric DR-TB data which remains a challenge both globally and nationally.

Extrapulmonary TB-In 2021, 5.06 lakh cases of extrapulmonary TB were diagnosed.

TB Prevalence-The result of the current National TB prevalence survey (2019-2021)are as follows:-

1) The prevalence of microbiologically confirmed PTB in population >15years age was 316 per one lakh population (95% Confidence Interval:290-342) in the country.
2) The prevalence of microbiologically confirmed PTB was higher in males and in the 55 years and above age group. An increasing trend of microbiologically confirmed PTB prevalence with increasing age was observed in both the genders.
3) Among the 20 state groups used in the survey, the lowest prevalence of microbiologically confirmed PTB was observed in Kerala with 115 per lakh and the highest was observed in Delhi with 534 per lakh population.
4) TB prevalence of India after adjusting for all forms of TB and Paediatric age group was 312 per lakh population (286 to 337) for the year 2021.The highest prevalence of all forms of TB among all age groups was 747 per lakh (510-984) in Delhi and the lowest was 137 (76-198) in Gujarat.
5) The prevalence of TB infection in India among population aged ≥ 15 years was 21.7 percentage (19.4-23.9) (model by robust standard error).
6) Higher prevalence of PTB was observed in older age group, males, malnourished, smokers, alcoholics and known diabetics.
7) The National smear and/or CBNAAT P:N ratio (Prevalence to Notification ratio) was 2.84 (2.61 - 3.07). The highest was observed in Chhattisgarh and lowest was observed in Gujarat.

8) Among participants who were interviewed for health seeking behaviour, 36.4% sought care for their symptoms, and 63.6% did not seek care for their symptoms.
9) Among those who did not seek care for their symptoms, 68.6% had ignored the symptoms of TB, 1633 18.1%) had not recognised the symptoms as illness, 11.63% had self-treated for their symptoms, and 1.67% could not afford to seek care.
10) Among the survey participants who were currently on TB treatment the median cost for diagnosis was Rs.2500, the median cost for treatment was Rs.5000, and the median indirect cost involved was Rs.2000.
11) The median Total cost for TB diagnosis and treatment was Rs.6000 ranging from Rs.1000 to Rs.28,000. The median cost for diagnosis, treatment and indirect cost was less among the public hospitals (Median Rs.5500), higher in NGO/Trust hospitals (Rs.9500) and highest in private hospitals (Median Rs.11,000).

TB Mortality: As per the Global TB Report 2022, the estimated HIV negative TB mortality rate for all forms of TB was 35 per 100,000 population (31-40 per 100,000 population) in 2021. Number of TB deaths in 2021 was 506 000 (one person every minute). This is an increase by 5.1 % from 2020 (481 000 in 2020).

In absolute numbers, the total number of estimated deaths from all forms of TB excluding HIV, for 2021 was 4.94 lakhs (4.31-5.62 lakhs) in the country. TB case fatality ratio (estimated mortality/estimated incidence) was 17% for the year 2021.

As per Nikshay, 76,002 (4.3%) DS-TB patients notified in 2020 were reported dead. This is just 15.4% of the estimate for the country, thus emphasising the importance of establishing a "TB Death Surveillance and Response" system in line with the maternal mortality surveillance to improve the coverage and real time resolution of lacunae including the system related factors.

Estimates of TB mortality, 2021,(Global Tuberculosis Report, 2022)

	Number	Rate per 100,000population
HIV-negative TB mortality	494,000	35
HIV-positive TB mortality	11,000	0.81

TB case notifications-India is one of the top three countries with the largest gaps between notifications of new and relapse (incident) TB cases and the best estimates of TB incidence as per the Global TB report 2022.

TB case notifications, 2021	
Total new and relapse	1,965,444
% tested with rapid diagnostics at time of diagnosis	22%
% with known HIV status	95%
% pulmonary	75%
% bacteriologically confirmed (Pulmonary cases only)	66%
% children aged 0-14 years	6%
% women(aged ≥15 years)	37%
%men(aged ≥15 years)	57%
Total cases notified	2,116,976

(Global TB Report, 2022)

Estimates of Catastrophic Costs due to TB-To date, there has been no nationally representative study of catastrophic costs for TB in India (Target is 0% of people with TB facing catastrophic costs by 2020). A recent systematic review (2020) by Chandra et al estimating the direct and indirect patient costs of drug-sensitive and drug-resistant TB care in India found that 7 to 32 % of DS-TB patients and 68% of DR-TB were experiencing catastrophic costs for TB care in India.

To plan, advocate and implement strategic interventions, which are evidence-based there is a need for a cost survey either separately or combined with health surveys at national and state level to understand the new baseline burden in the affected households, thereby aiding in tracking the progress towards the goal of achieving zero catastrophic cost due to TB.

TB Treatment Coverage-As per the Global TB report 2022, TB treatment coverage (notified/estimated incidence) of India in 2021 was 67%. DS-TB performance analysis of 2021 (India TB report 2022)

- In 2021, among 21,35,830 patients diagnosed, 20,30,509 (95%) patients were put on treatment.
- 61% were male and 39% were female among the patients put on treatment.
- Among the total notification, 6% patients were in Paediatric age group.
- Among 17,51,437 TB patients notified in 2020, 83% were successfully treated while 4% died during treatment.
- Disaggregated treatment success rate of patients notified from public and private sector are 83% and 82% respectively.

Drug-resistant TB care, 2021-India is one of the 10 countries that account for about 70% of the global gap between the estimated global incidence of MDR/RR-TB each year and the number of people enrolled in treatment in 2021.

Drug-resistant TB

% of bacteriologically confirmed TB cases tested for rifampicin resistance-New Pulmonary cases	76%
% of bacteriologically confirmed TB cases tested for rifampicin resistance - Previously treated Pulmonary cases	73%
Laboratory-confirmed cases - MDR/RR-TB	58,837
Patients started on treatment - MDR/RR-TB	53,037
Laboratory-confirmed cases - pre-XDR-TB or XDR-TB	10,937
Patients started on treatment - pre-XDR-TB or XDR-TB *	9780
MDR/RR-TB cases tested for resistance to any fluoroquinolone	19752

(Global tuberculosis report, 2022) DR-TB performance analysis of 2021 (India TB report 2022)

- In 2021, 48,232 MDR/RR-TB patients were diagnosed and 43,380 (90%) were put on treatment.

- 8455 Pre-XDR-TB, 376 XDR-TB and 13724 H mono/poly patients were diagnosed and 7562 (89%), 333 (89%) and 12008 (87%) were put on treatment respectively.
- A total of 1939 patients were initiated on shorter oral Bdq-containing MDR/RR-TB regimen, 23,889 on longer M/XDR-TB regimen and 25,235 patients were initiated on shorter injection containing MDR-TB regimen.
- The cohort of DR-TB patients initiated on treatment in 2019 reported 57% treatment success rate (34,535/60,873). This includes 39,358 of patients on shorter MDR-TB regimen (inj-containing) with 59% treatment success rate and 1280 of patient on longer oral regimen with 70% treatment success rate. This cohort also includes 11,791 patients put on old conventional MDR-TB regimen that has reported 49% treatment success rate.

TB preventive treatment-As per the Global TB Report 2022, only 24% of children < 5 years with household contacts of bacteriologically-confirmed TB cases were put on preventive treatment in the year 2021.People started on TB preventive treatment in 2021 was 423 706 which is a reduction by 3% as compared to 2020 (437 311).

In 2021, the eligibility for TPT has been expanded to all HHC of pulmonary TB, prioritizing in PBCT (pulmonary bacteriologically confirmed Tuberculosis) patients irrespective of age and other risks. High TB transmission settings (such as health care workers, prisons, mines, slums, tribal, migrant labourers etc) are being prioritized for TPT interventions guided by differential TB epidemiology by the State TPT Committee.

To overcome the challenges a long treatment entails, a new shorter TPT regimen with three months of weekly Rifapentine and Isoniazid (3HP) has been recommended as an alternative to six months of daily life Isoniazid regimen (6H) and has been made available in some of the states. The whole country is expected to be covered by March, 2023 by this shorter TPT regimen.

In 2021, more than 2 lakh PLHIV on active care and 1.20 lakh HHC of pulmonary bacteriologically confirmed TB patients were initiated on TB Preventive Treatment. The programme has introduced TPT in contacts of DR-TB patients in 12 States. (Andhra Pradesh, Telangana, Delhi, Gujarat, Himachal Pradesh, Karnataka, Kerala, Maharashtra, Meghalaya, Odisha, Punjab, and Assam)

5.2 Current infrastructure/facilities

TB Diagnostic Services-TB Laboratory Network in NTEP in 2021 (India TB Report,2022)

Level of facility in the health system		Testing modalities available
National Reference Laboratory	6	Microscopy, NAAT, LPA, Liquid Culture, LCDST
Intermediate Reference Laboratory (State Level)	34	Microscopy, NAAT, LPA, Liquid Culture, LCDST
C&DST Laboratory (in Medical Colleges & Private Sector)	58	Microscopy, NAAT, LPA, Liquid Culture, LCDST
District & Sub District Level	3760 NAAT	Microscopy, Rapid Molecular Test (NAAT), CBNAAT, TrueNat
Peripheral Sub District Level	21820 – DMCs	CBNAAT, TrueNat

NTEP has the largest network of TB diagnostic laboratories globally.

- By the end of 2021, 80 laboratories are equipped to support liquid culture system, of which 60 are certified for First-Line Liquid Culture Drug Susceptibility Testing (FL LCDST), and 49 are certified for Second Line Liquid Culture Drug Susceptibility Testing (SL LCDST). Moreover, Liquid culture-based DST has been expanded to include Linezolid and Pyrazinamide.
- 74 Laboratories are certified for FL LPA and out of these, 61 are additionally certified for SL LPA.
- In 2021, Liquid culture-based DST is expanded to include Linezolid and Pyrazinamide. NRL- NIRT, Chennai and NITRD, New Delhi are certified for DST to Bedaquiline, Delamanid and Clofazimine.
- NAAT facilities in the country were increased from 3147 in 2020 to 3760 in 2021.
- An in-built routine system has been designed for conducting External Quality Assessment (EQA) through WHO Supra National Reference Laboratories (SNRL), NIRT, Chennai and the coordinating SNRL Antwerp, Belgium.

Active Case Finding-In 2021, a total of 2.23 crore persons were screened, 17,52,903 samples tested for TB and 73,772 additional TB patients identified through Active Case Finding.

The NTEP has made 81 Mobile TB Diagnostic Vans available to the States for conducting ACF in remote and hard-to-reach areas.

Air-Borne Infection (AIC) Control Measures at Health Care Facilities

National Guidelines on Air-borne Infection Control in Healthcare and Other settings is being implemented at high-risk centres such as DR-TB centres, ART centres and C&DST laboratories. As per the district reports, 432 N/DDR-TBC are AIC compliant out of total 785 N/DDR-TBC.

Treatment Services-Treatment services are provided free of cost under the programme. Treatment for drug-sensitive and drug-resistant TB are aligned with global guidelines by national experts. Key highlights on treatment are given below-

- Injection-free treatment regimen for DS-TB was implemented across the country.
- Introduction of differentiated TB care package of services to reduce mortality.
- Engagement of Ayushman Bharat – Health and Wellness Centres (AB-HWC) in last mile service delivery for better access and quality care to TB, DR-TB patients, and their close contacts.
- Guidelines for Programmatic Management of Drug-resistant TB (PMDT) in India - 2021 released by Hon'ble Union Health Minister.
- In 2021, shorter oral Bdq-containing MDR/RRTB regimen was introduced to replace shorter injection-containing MDR-TB regimen in a phased manner with the aim to complete the transition by April 2022. Initially, it was started in eight states (namely Andhra Pradesh, Delhi, Gujarat, Himachal Pradesh, Karnataka, Maharashtra, Punjab, Telangana) in 3rd quarter of 2021 and gradually it was expanded to other states. By the end of 2021, 1939 (7%) patients were put on shorter oral Bdq-containing MDR/RR-TB regimen.
- Use of Bdq expanded to children from five years of age onwards and weighing 15 kg and above, pregnant women, in select patients beyond six months and its combined use with Delamanid introduced.
- Access to free drugs including newer drugs to patients seeking care in the private sector.

- NITRD, New Delhi in collaboration with Central TB Division and National Task Force (NTF) for Medical Colleges have initiated "Difficult to Treat TB Clinic (DT3C)" at National level. By the end of 2021, 47 difficult-to-treat TB patients were managed through this mechanism. This was further decentralized in 2021 to 26 states/UTs that have established State level – Difficult to-Treat TB Clinic (S-DT3C) in accordance with the Guidelines for PMDT in India 2021.
- As part of corporate sector involvement, DR-TB Centre established in Medanta Hospital, Gurugram, Haryana.
- By the end of 2021, 290/565 (51%) of medical colleges are providing services to DR-TB patients. Guidance has been given by NMC on mandatory establishment of DR-TB centres in all the medical colleges.
- DR-TB treatment services were decentralized to district DR-TB centers. By the end of 2021, 776 DR-TB centres were functional, which include 162 Nodal DR-TB centres. This helped to minimize the gap between diagnosis and treatment initiation, reduce cost of travel, and expedite early care of MDR/ RR-TB patients within their respective district.

TB Prevention-The Guidelines of PMTPT in India (2021) were released by the Hon'ble Union Health Minister on 6th August 2021.

- All 36 states/UTs have completed the training of state-level master trainers while cascade training at district levels and sub-district levels are ongoing.
- The Central TB division with support of WHO India introduced an excel based PMTPT tool to prepare district wise plans for PMTPT expansion to achieve national coverage up by mid-2022.
- ICMR has completed the C-TB feasibility study and results are encouraging and the same would be dedicated to the country on World TB Day 2022.

TB Co-morbidities and Special Situations-Many new cases of TB are attributable to five risk factors: undernourishment, HIV infection, alcohol use disorders, smoking (especially among men) and diabetes. The Global TB report, 2022 clearly shows that undernutrition is the most important and widespread risk factor associated with TB.

a) *TB and Malnutrition*

Through NikshayPoshanYojna, the Government is supporting the nutritional requirement of all TB patients through direct benefit transfer(DBT) of INR 500/month into the bank account of the beneficiary (TB patient) for the entire duration of TB treatment.

"Guidance document on nutritional care and support for patients with TB in India" has been developed and disseminated. The annual 'PoshanMah' is observed in the month of September to address malnutrition at population level. The Nutrition-TB App (N-TB app) has been developed by the CTD. This mobile-based application tool for healthcare workers simplifies assessment, counselling, and support for undernourished adult patients with tuberculosis. It is available for free from Google and the iOS app stores. Collaboration of NTEP and Ministry of Women and Child Development (MoWCD) has been established to address malnutrition in women and children.

b)*TB and Substance use (alcohol and tobacco)*

Information on alcohol use by TB patients is being captured in Nikshay. Services for alcohol users include counselling, linkages to de-addiction centres, and social support systems.

The TB Tobacco cessation service programme is being implemented in all States/UTs of the country and collaboration with NTEP is being strengthened .

c)*TB and Diabetes*

Intensified TB case finding is conducted in the Non communicable disease (NCD) clinics to screen TB cases using four-symptom complex. The TB symptoms identified at the NCD clinics are referred to the NTEP facilities for TB diagnosis and further management. Similarly, all TB patients are tested for blood sugar and, if found to be diabetic, are linked to the NCD clinic for management of diabetes. Nearly 93% of the TB Detection Centres have blood sugar testing facilities. Among the NCD clinic attendees with diabetes, about 7% have been screened for tuberculosis and referred for TB testing.

d)TB and HIV

Nearly 95% of TB Detection Centres (TDCs) have co-located HIV testing facilities. Single window TB and HIV services are being implemented through existing ART centers. For early detection of HIV among presumptive TB patients, Provider Initiated Testing and Counselling (PITC) is being implemented across the country. TB screening among ART centre attendees using '4 symptoms screening tool'. Based on the evaluation, PLHIV is being offered TB treatment or TB preventive therapy by ART.

e)TB and Covid-19

Bi-directional screening for TB and COVID–19i.e., COVID-19 screening for all diagnosed TB patients and TB screening for all suspected and confirmed COVID-19 patients is being done. Provision of Home sample collection services of sputum samples in COVID-19 containment zones.

f)Pediatric TB

NTEP has mandated upfront molecular diagnostics for all paediatric TB samples. The programme has child-friendly formulations of drugs for the management of Pediatric drug-sensitive TB and is procuring child-friendly formulations for DR TB.

Bedaquiline is approved for use in children above five years of age. NTEP has acquired the 20mg dispersible tab of Bedaquiline through the Japanese Grant of STOP TB Partnership.

The NTEP is collaborating with Child Health and Adolescent Health programmes of the Ministry of Health and Family Welfare (MoHFW), Rashtriya Bal SwasthyaKaryakram (RBSK), and Rashtriya Kishor SwasthyaKaryakram (RKSK) for better detection and management of Pediatric TB.

Paediatric Centre of Excellence: The NTEP has established a network of Centre of Excellence (pCoE-TB). These centres are organised at National, Regional, State, and District levels. The regional pCoE-TB has initiated too.

Patient Support Systems-

- NikshayPoshan Yojana (NPY). Rupees 500/month given to confirmed TB Patients, DSTB & DRTB, and Public + Private Sector Patients.
- Transport support of Rs 750 (one time) for confirmed TB patients residing in notified tribal areas.
- Honorarium for Treatment Supporters of Rs 1,000 for DS TB patients and Rs 5,000 for DR TB patients.
- Notification & Treatment Outcome Incentive for Private Sector Providers. Rupees 500 as Informant or Notification Incentive and Rs. 500 for Outcome declaration is being given.
- President Draupadi Murmu recently launched ‘Pradhan Mantri TB Mukt Bharat Abhiyan’ to eliminate TB by 2025 on September 9, 2022.

- The Nikshay Mitra initiative was also launched alongside to ensure additional diagnostic, nutritional, and vocational support to those on TB treatment, and encouraged elected representatives, corporates, NGOs, and individuals to come forward as donors to help the patients complete their journey towards recovery. The Nikshay 2.0 portal (https://communitysupport.nikshay.in/) will facilitate in providing additional patient support to improve treatment outcome of TB patients, augmenting community involvement and leveraging Corporate Social Responsibility (CSR) opportunities.

Partnerships for the Private Sector Engagement

More than 50% of patients regardless of their financial capability, seek TB care from the private sector and the private provider is their first point of contact. In 2001 CTD developed the first guidelines on partnerships especially on engagement of non-governmental organizations (NGO) and private providers which subsequently underwent revisions in 2008, 2014 and 2019 to ensure that quality services are provided to the TB patients in private sectorleading to decrease in the transmission of TB, mortality, comorbidity, drug resistance, and reduction in out-of-pocket expenditures for the TB care in the private sector.

IQVIA Consulting and Information Services India Private Limited

In India, IQVIA has one of the largest public health practices with over two decades of service devoted to the public sector and actively engaging with all aspects of the healthcare ecosystem including TB.

In 2021, IQVIA was part of the following key initiatives and projects:

National Technical Support Unit (NTSU): IQVIA was appointed as the National Technical Support Unit (NTSU) to the Central Tuberculosis Division for ensuring successful implementation of innovative interventions by supporting nine high priority states (viz. Uttar Pradesh, Maharashtra, Bihar, Rajasthan, Madhya Pradesh, Karnataka, West Bengal, Assam, and Tamil Nadu) and building their capacity in areas such as strategic purchasing, private sector engagements, Direct Benefit Transfers, and multi-sectoral collaboration.

Key activities undertaken under NTSU:

- Orientation and capacity building of onboarded (State Technical Support Units) STSUs.
- PPSA Payment Tracker and Partnerships Landscape

In most States, the private sector engagement is done by implementation of Patient Provider Support Agency (PPSA) and engaging with private labs/NGOs/ agencies under various partnership options. Since implementation of PPSA, the TB notification rate increased from 72 percent in 2018 to 81 percent in 2020.

DEFEAT TB Project: IQVIA is one of the seven consortium partners of iDEFEAT TB Project - USAID India's flagship TB project for drug Resistant TB and institutional strengthening for TB and DR-TB care led by The Union.

Major activities supported by IQVIA are strengthening of STDCs, engagement of private sector laboratories for TB diagnostic care and transforming conventional training approaches by building strategy and institutional systems for e-learning.

*Foundation for Innovative New Diagnostics (FIND):*FIND in partnership with the National TB Elimination Program (NTEP) continues to complement Government of India's efforts towards TB elimination. In 2021, FIND undertook the following activities:

a) Enhanced capacity for DR –TB diagnosis : Under Global Fund, FIND is establishing 20 LC&DST laboratories across India. Seven TB LC&DST laboratories were upgraded, validated and handed over to the NTEP. Upgradation work is underway for the remaining 13 laboratories. FIND supported 70 TB LC DST labs, by providing required consumables and reagents and maintenance services for 18 different types of nearly 4,100 essential lab equipment.
b) Scaling up CBNAAT External quality assessment (EQA) to all public and private sites in India.
c) Laboratory Information Management System (LIMS) : LIMS is designed to provide TB results, track samples, and test workflows inside the lab. Besides providing data analytics, it also monitors HR availability, training, equipment maintenance, sample storage and bio medical waste management, including a call centre service to resolve issues. As of November 2021, 53 C&DST labs were actively using LIMS. , LIMS 2.0 was integrated into NIKSHAY and will now be deployed across all C&DST laboratories in India.
d) Technical assistance to upgrade C-DST Labs.
e) Networks for Optimized Diagnosis to End TB (NODE-TB): It establishes dataset to guide NTEP in network planning and optimization – including optimal placement of

existing and new diagnostic technologies - and designing efficient sample referral mechanisms.

f) JEET (Joint Effort for Elimination of TB): FIND is one of the three partners, implementing project JEET across six states - Andhra Pradesh, Telangana, Karnataka, Punjab & Chandigarh, West Bengal & Himachal Pradesh - in 21 PPSA & 80 PPSA lite districts. The project has catalyzed private sector engagement by deploying a Hub & Spoke model to engage private health care providers, conduct CME trainings, support sample transport & linkages with DST facilities, and conduct active patient follow-ups, ensuring continuum of TB care. Successful outcomes were reported for 84% of patients diagnosed.

g) JEET 2.0: To improve access to TPT to all contacts (children and adults) of TB cases across 21 states in India.. The key activities include contact tracing, screening for active TB, counselling, TPT initiation and follow up. In September 2021, over 7000 household contacts were screened and more than 2000 initiated on treatment.

h) Women Empowerment to End TB (WE END TB): It engages women-led, Self-help Affinity Groups (SAGs) to increase access to TB services, treatment, linkages to micro-finance/skilling programs, and socio-economic schemes in rural Karnataka .

*Global Coalition Against Tuberculosis (GCAT):*The GCAT is a multi-partisan political forum that has worked to raise the political discourse on TB since 2012. Under the leadership of Dr Dalbir Singh, the forum has brought together over 35 Members of Parliament (MPs) and 20 renowned public health experts to regularly discuss the challenges to TB elimination in the country and support the ministry in gathering independent expert guidance and galvanizing political support at all levels of governance, to support the Government of India's efforts of eliminating TB.

*World Health Partners (WHP):*WHP, a non-profit Indian organization has been providing operational, technical and analytical support to address the TB burden through various projects in select districts of Gujarat, Jharkhand, Bihar, Punjab and Odisha.

Closing the Gaps in TB Care Cascade (CGC)

CGC is a four-year (2020-2024) project funded by the United States Agency for International Development (USAID) In 2021, the CGC project focused on

- Increasing case finding by engaging with private health care providers (iSMART X-ray).

- Improving adherence management with Digital Adherence Technology (DAT).
- Improving treatment outcomes with effective mental health and wellness interventions.
- Implementation of post-treatment follow-up.
- Centralised Control Center (CCC)- For tele-consultation, counselling and referral services. This model is particularly useful for populations that require aggressive follow-up over long periods as in tuberculosis, mental health, antenatal care etc. During the Year 2021, the CCC has provided its services to over 100,000 callers for tele-counselling and tele-consultations.
- Patient Provider Support Agency (PPSA)- Implementing PPSA project with the extensive government support in 11 districts of three states – Bihar, Punjab and Odisha .

USAID – Mukti Pay For Performance: Mukti is the World's First Pay-for-Performance program designed to improve the nutritional status and treatment outcomes of TB patients. It was designed in consultation with the MP State Government to address the issue of undernutrition which is attributable to 55% of the annual TB incidence.

*Program for Appropriate Technologies in Health (PATH):*Under the BMGF funded Complementary Grant, PATH has been spearheading the work in building partnerships under NTEP and transitioning donor supported partnerships to government funded as per the partnership guidance document.

PATH has provided technical assistance and support to the State TB Cell, to strengthen the private sector engagement efforts of NTEP.

PATH is implementing "99 DOTS lite" pilot project in selected districts to improve the treatment adherence among DSTB and DRTB patients in both public & private.

Next Generation Sequencing (NGS)- With funding from Rockefeller foundation, PATH is partnering with NIRT- Chennai to carry out gene sequencing using Oxford Nanopore for genotyping of tuberculosis. The objective is to utilize Next Generation Sequencing using Minion for drug resistance prediction of 1st line, 2nd line and newer drugs. This support will enable the first Indian report on genotyping of M. tuberculosis drug resistance using direct sputum samples for targeted NGS.

Trace TB-PATH has partnered with Wadhwani AI under USAID's Trace-TB grant for the evaluation of public health impact and scalability of AI solutions and its integration with Nikshay 2.0.

REACH (Resource Group for Education and Advocacy for Community Health):Strengthening a community-led response to TB in India

The Accountability Leadership by Local communities for Inclusive, Enabling Services (ALLIES) Project

Through the ALLIES project supported by USAID and implemented in 15 districts of Chhattisgarh, Jharkhand, Odisha and Tamil Nadu, trained TB Champions work in close coordination with the NTEP to implement a Community Accountability Framework (CAF), to understand and improve the Quality of Care (QoC) and Quality of Services (QoS) offered to people with TB.

Everwell Health Solutions- An enterprise based out of Delhi and Bangalore has been partnering with the NTEP under the guidance of CTD to support India's Digital TB strategy.

TBPPM-Learning Network India- The Tuberculosis (TB) Public Private Mix Learning Network (TBPPM-LN) India. Its goal is to create, nurture and maintain a dynamic global exchange of expertise and best practices in the area of private provider engagement in TB. The India chapter was spearheaded in early 2021.

John Snow India (JSIPL)

JSI is a part of Supply Chain Management Strengthening (SCMS) Project for TB Drugs. The aim of the project is to strengthen the technical capacity of the Central TB Division (CTD), State TB Cells (STC) to design, manage and monitor supply chains for improved access and availability of high-quality TB drugs, diagnostics and other commodities across India.

The project intends to work towards increasing the usage of NikshayAushadhi, the electronic Logistics Management System cross last mile facilities.

Centers for Disease Control and Preventio: The U.S. Centers for Disease Control and Prevention (CDC) India continued to support the Government of India's (GOI) tuberculosis (TB) elimination efforts in 2021 by expanding its efforts to support the NTEP.

The End DR-TB project in Dharavi slum of Mumbai supported by CDC aimed to improve treatment outcomes among DR TB patients by monitoring for ADR(Adverse drug reactions) using point-of-care technology, reducing lostto-follow-ups (LTFU) by tracking migration,

and diagnosing tuberculosis earlier through active case finding among household contacts of DR TB patients.

Axshya Plus: Supported by The International Union Against Tuberculosis and Lung Disease, South-East Asia ,it is an initiative to strengthen preventive care for contacts of TB Patients and create a suitable environment by collaborating with various stakeholders.

TISS :-TISS will continue supporting NTEP through Saksham Pravaah project to strengthen DRTB treatment and adherence support through psychosocial counseling services and other social protection and nutrition linkages in four States i.e. Maharashtra, Gujarat, Karnataka and Rajasthan.

-Another crucial component of project is to transition counselling services to NTEP staff (STS and TBHV) through their capacity building by creating a pool of Master trainers across the Country.

William J. Clinton Foundation (WJCF):-Partnered with TATA-1MG, a digital healthcare platform, with the aim to improve quality of service delivery and increase access to government Fixed-Dose Combinations (FDC) in the private sector.

-Deploying Medicine Event Reminder Monitor (MERM) and 99 DOTS Sticker for TB patients in the private sector

- Project ADITYA – A technology augmented, low HR PPSA modehas deployed a one-of-its-kind patient management system to enable chemists and informal providers to offer free X-ray to any symptomatic patient.

SWEET (System for Workplace Engagement to Eliminate TB) Kerala

Objective

- To promote awareness on TB prevention, screening and treatment across selected workplace
- To advocate for and facilitate an environment that minimizes and prevents TB transmission across selected workplace
- To support and facilitate early and free TB diagnosis across workplaces
- To facilitate and ensure access to free TB drugs and adherence to all workers
- To ensure care and support to all workforce post the completion of treatment
- To advocate and facilitate a stigma free environment for accessing TB associated services

Current Status -Advocacy, Communication and Community Engagement

The Ministry of Health and Family Welfare (MoHFW) launched the TB-Mukt Bharat Abhiyaan – A Jan Andolan to eliminate TB from India by 2025. TB module included in the Gram Pradhan induction material in Uttar Pradesh.

NikshayPatrika Newsletter- It is the quarterly newsletter of National Tuberculosis Elimination Programme. In the past few months, it has not only widened the coverage but also carries informative articles on diverse themes and topics. This reaches out to a steadily growing community involving NTEP staff, partner organisations working in the field and sharing educative and informative updates, learnings and reflections on a quarterly basis.Click or tap here to enter text.

More than 3500 TB survivors were trained as TB Champions across the country.The National TB Forum was reconstituted with civil society and ICMR representatives as co-chairs. Equal representation was ensured from line ministries, namely, Ministry of Rural Development, Ministry of Panchayati Raj, Ministry of Social Justice & Empowerment, Ministry of Health & Family Welfare, departments, civil societies, affected community, academician, media, subject experts, etc. By the end of 2021, all States had formed TB Forums, while 711 districts had District TB Forums in place. Most of the States and Districts also reported convening their meetings and discussing relevant issues.

5.3 Current Research and technologies

A substantial technological breakthrough will be necessary to dramatically accelerate the rate at which tuberculosis incidence reduces relative to previous levels. Therefore "Intensified research and innovation" are the third pillar of the End TB Strategy.

As per TB Annual report 2022, Key research activities undertaken in the year 2020-21 are as follows:

1. *Diagnostics*

- Validation studies for a few diagnostic equipment viz., TB detection kit, TB sample concentration and transport kit, TB DNA extraction kit etc., which are aimed at conducting point of care tests to address challenges in sample transport.
- A multi-state validation study of C-TB skin test to detect TB infection.
- Blood based triage test (POC)- Supported by Department of Biotechnology.

- Module for real time tracking of patient sample from time of collection till reporting has been developed under STRIDES partnership and pilot study initiated.
- Programme Division with technical support from Wadhwani Institute for Artificial Intelligence, has developed an Annotation tool for LPA result interpretation through Machine Learning (ML). Results obtained from Annotation tool is being compared with the results from panel of expert microbiologists.
- C-TB skin test feasibility study for TB infection has been completed by ICMR and results are encouraging and the same would be dedicated to the country on World TB Day 2022.
- IMPAACT4TB Study: A multicentric feasibility study is being undertaken through 6 ART centres by NIRT, Chennai. The evidence will be available by the end of 2022.
- Undertaking sentinel surveillance for drug resistant TB using Whole Genome Sequencing (WGS)- Protocol for the surveillance has been developed by SNRL-NIRT, Chennai, in coordination with CTD, UNION, FMR and WHO to be initiated in 2022.

2. Therapeutics
    - HICON-R study- High dose of Rifampicin (25mg/kg) in comparison to the conventional regimen of 10 mg/kg.
    - BEAT (Building Evidence for Advance treatment against Tuberculosis) study – using Bedaquiline, Delamanid, Linezolid and Clofazimine, to reduce XDR TB treatment to 6 – 9 months from the current duration of 18 months.
    - Modified BPaL regimen (BDQ, Pretomanid and Linezolid), a three-year study was initiated in October 2021 as a pilot in 10 sites across the country.
    - End TB trial – is a multi-country trial on shorter (6-9 month) regimen for MDR-TB.
    - The Central TB division with support of WHO India introduced an excel based PMTPT tool to prepare district wise plans for PMTPT expansion to achieve national coverage up by mid-2022.
    - Launch of self-learning module for the medical officers, private practitioners, and others on Guidelines for PMDT in India – 2021 with the aim to allow participants to learn at their own convenience and pace was developed on Swasth e-Gurukul platform and launched by the Hon’ble Union Health Minister in October 2021.

3. Vaccines

A study on the utility of r-BCG for prevention of disease among household contacts was initiated by ICMR. At the end of one year of follow up, the safety of both vaccines has been established.

4.Implementation Research

The Science & Engineering Board, DST (SERB-DST) is supporting NTEP in mathematical modelling for TB and for the various studies being undertaken on the basic biology and other research studies.

5. Artificial Intelligence (AI)

a. *Automated reading of Chest X ray*: The CTD in collaboration with NIC and ICMR is developing this AI solution to detect TB related changes from X-Ray images.

b. *Automated reading of LPA strips*. The solution is in the final stages of development and work is in progress towards integration into Nikshay with the support of Wadhwani Institute of Artificial Intelligence (WIAI).

c. *An AI solution is being developed to screen for TBand* also detect TB from cough sounds and voices with the support of WIAI. This will support the front-line staff to objectively triage patients for further diagnosis. The protocol for data collection and development of proof of concept has been approved by CTD and the data collection is expected to be initiated across the country by Jan'2022.

d. *Prediction of Lost to follow up:* An AI algorithm is being developed to identify patients who are potentially at risk of not being able to complete the full course of treatment. This can allow the health system/ treatment supporters to focus more on such patients right from treatment initiation, thus assisting implementation of Differentiated TB care.

e. *Chatbot:* A chatbot has been developed in collaboration with NIC for providing information on TB, Treatment of TB and available TB services under NTEP.

The India TB Research Consortium-The India TB Research Consortium (ITRC), an initiative led by the Indian Council of Medical Research (ICMR) was launched in August 2016in partnership with Tata Trusts, WHO and The Union with aims to develop new drugs/shorter drug regimens; rapid, cost effective indigenous diagnostic tools; efficacious vaccine and implementation and operational research for effective programmatic implementation. The progress so far of ITRC in various research portfolios is as follows-

4.Diagnostics-

- *For TB/MDR-TB*: New effective indigenous molecular diagnostic kit TrueNat for TB/MDR-TB & one [TrueNat (rif)] for MDR-TB was developed and validated. Test found at par with Xpert and has been recommended for use under RNTCP. Govt. of Telengana introduced under Programme in October, 2018 and the GOI has also started the process of procurement for use of TrueNAt under national Programme.
- Validation ongoing for TrueNat for EPTB and Paediatric TB.
- *For M/XDR-TB:* Low cost indigenous IGS culture based kit for M/XDR-TB detection has completed validation, revised final report is awaited.
- *For TB:* Improved smear microscopy kit i.e TB detect kit for TB diagnosis completed validation studies and results showed that the new microscopy is better for detecting smear TB.

5. *Therapeutics-*

For XDR-TB: A 6-9 months 4 drug Shorter regimen with all oral drugs (Delamanid + Bedaquiline+ Linezolid+ Clofazimine) for XDR-TB ongoing.

Study Repurposing of econazole and adding to WHO shorter regimen for reducing the treatment duration of MDR-TB

For MDR-TB: A clinical trial with the shorter 4 drug oral regimen for 6-9 months as compared to shorter WHO regimen, approved and will be initiated shortly.

Pk studies on 2nd line ATT sanctioned.

Observational study of inhaled gaseous nitric oxide (gNO) for adults with drug resistant pulmonary TB approved.

6. For Drug sensitive TB: Following clinical trials with regimen for improving efficacy and early culture conversion initiated:

- Repurposed drug metformin along with ATT for better cure rate and prevention of relapse.
- Repurposed drug Varapamil along with ATT for better cure rate and prevention of relapse.
- High dose rifampicin (25mg/kg and 35mg/kg as compared to 10 mg/kg) for better and early cure rate

Repurposing Clofazimine: Phase II Clinical trial with repurposed drug Clofazimine by replacing ethambutol as part of the first-line anti-TB regimen in order to shorten the overall duration of treatment in DS-TB from 6 months to 4 months by replacing ethambutol for treatment of DS-TB is ongoing.

Phase I study to evaluate the safety and pharmacokinetics of single dose of PLG encapsulated-ATD nanoparticles: and dose escalation study Nano-formulations of the standard anti-tb drug: Initiated

EBA study with Feropenam approved and has been initiated.

Animal studies with Inhalational Rifabutin and INH ongoing completed and showed early clearance of bacilli from the animals as compared to standard treatment arms. Study with shorter duration proposed.

New anti-TB molecule: Transitmycin a new drug molecule discovered by NIRT in collaboration with IIT, Madras and Periyar university. A promising anti-Tb against MDR-TB with anti HIV activity molecule is undergoing animal study.

Clinical trial with Risorine [Rifampicin (450 mg and 600mg) and Piperine (225 mg)] for DS-TB for improving efficacy and early culture conversion approved and would be initiated soon.

For latent TB: Clinical trial with Rifapentine for latent TB sanctioned

Vaccines-Most advanced vaccine candidates (MIP and VPM1002) shortlisted after detailed landscape analysis. Capacity building of 7 centers with 5 subcenters done for undertaking clinical trials. A Phase III prevention of disease vaccine trial with 2 lead TB vaccine candidates (Mw(MIP) and VPM1002).

Implementation research-5 projects have been initiated.

• National TB prevalence survey in all states and UTs across India in collaboration with CTD & WHO initiated in TN in June 2019. Pilot initiated in WB, Maharashtra and UP. 25 Buses equipped with Molecular test and X-ray used in survey. 5000 population surveyed till now. Rest of the states survey to be initiated.

• Two projects are targeting high risk population groups for intensified pulmonary TB case finding; They are- Active case findings in (malnourished children admitted to NRCs) ongoing. Active case finding in select groups in Institutional settings in secondary care hospitals, sanctioned.

• Study on acceptability of ready to use therapeutic food (RUTF) in contacts of TB patients for prevention of TB in contacts completed and found that the RUTF is acceptable by the patient population and have negligible side effects.

• RATIONS (Reducing Activation of Tuberculosis by Improvement Of Nutritional Status) study: A cluster randomized trial of nutritional support (food rations) to reduce TB incidence in household contacts of patients with smear positive PTB in communities initiated in 28 TU of Jharkhand.

New Technologies for tackling TB

• Automated smear reading tool approved for validation.

• Projects on use of AI for X-ray diagnosis of TB.

• New app for improving self-reporting of Tb by patients/suspects approved in principle for validation.

• Use of technology for integrated case management for assisting patients towards TB care using current peripheral health care system approved in principle.

5.4 Current policies

a) Policies for Diagnosis*:*
   a. Policy for Drug-Sensitive TB (DS TB)
      - Patients with Pulmonary TB are diagnosed using sputum smear microscopy and/or Chest- X ray and Nucleic Acid Amplification Tests (NAAT).
      - Sputum Smear replacement by CBNAAT/TRUNAAT is introduced in the programme.
      - Response to DS TB treatment is monitored using sputum smear microscopy.
   b. Policy for Drug-Resistant TB (DR TB)
      - Microbiologically confirmed TB patients are offered NAAT for determining resistance to Rifampicin. Line Probe Assay (LPA – First Line) is offered to patients with Rifampicin Sensitive (RS) TB.
      - First and Second Line LPA is offered to Rifampicin-resistant (RR) and Isoniazid (H) resistant TB patients.
      - Liquid Culture (LC) & DST is performed for determining amplification of resistance to drugs used for managing DR TB.
      - LC is used for monitoring response to DR TB treatment.

b) Policies for Case finding:
   a. Passive Case Finding
      - Patients with symptoms of TB voluntarily seek health care
      - The Medical Officer follows diagnostic algorithm for evaluating TB patients.
   b. Intensified Case Finding
      - Provider-initiated screening of OPD/IPD attendees for symptoms of TB.
      - Tuberculosis screening for patients attending health facilities with comorbidities.
   c. Active Case Finding
      - Searching for TB patients among population at higher risk of TB in the community.

c) Policy for treatment
      - Treatment of drug-sensitive TB and drug-resistant TB: All diagnosed TB patients are to be put on standard first-line anti-TB regimen in the form of Fixed Dosage Combination (FDC) after ruling out at least rifampicin resistant status (when

biological sample available) and to be initiated on treatment within three days of diagnosis.

5.5 Current programs

- The Ministry of Health and Family Welfare (MoHFW) launched the TB-Mukt Bharat Abhiyaan - A Jan Andolan to eliminate TB from India by 2025.
- The Ni-kshay Mitra initiative was also launched alongside TB-Mukt Bharat to ensure additional diagnostic, nutritional, and vocational support to those on TB treatment.
- Ministry of Health and Family Welfare (MoHFW) and Ministry of Tribal Affairs (MoTA) have signed a Joint Action Plan for Elimination of TB, following which the Tribal TB Initiative was launched in March 2021 to achieve India's vision for 'Ending TB with priority focus on TB hotspots of tribal areas.
- As per the programme guidelines, there are management protocols in the form of algorithm available for DS-TB, DR-TB, and TB infection. With the aim to simplify and integrate these algorithms, a "Comprehensive Clinical Management Protocol of Tuberculosis" was developed by the programme and released by the Hon'ble Union Health Minister in October 2021.
- Active case finding among risk groups as defined in the National ACF guidelines which includes diabetes, chronic kidney and liver disease, patients on immunosuppressants, etc., was conducted in January 2021. TB services were largely affected due to COVID -19 and to detect the missing cases, a special ACF drive (from 2nd September 2021 to 1st November 2021) was launched by the Hon'ble Minister for Health & Family Welfare.
- The Central TB Division had issued a policy guidance in June 2021 based on the recommendations of NTEG for initiating the preparations for expansion of TPT coverage to the additional population.
- The Guidelines of PMTPT in India (2021) were released by the Hon'ble Union Health Minister on 6th August 2021. National Task Force for guideline development prepared these guidelines of TPT as per the recommendation of National Technical Working Group (NTEG) .
- The TB Tobacco cessation service programme is being implemented in all States/UTs of the country.

- Implementation of the protocol "Clinical guidance for management of adult COVID-19 patients", released by MoHFW on 14th January 2022, across the States/UTs to ensure the successful outcome of COVID-19 treatment and early identification & management of TB. While doing so, the following has been recommended:
- COVID-19 patients with active TB to be managed as per protocol.
- If cough persists after 2-3 weeks, to be tested for TB.
- Follow up COVID-19 patients post-treatment and periodically screen for TB.
- Involvement of Panchayati Raj Institution for TB Elimination

While encouraging larger inter-departmental participation to promote multi-sectoral approach towards TB elimination in Uttar Pradesh, the State TB Cell involved Panchayati Raj Institution (PRI) representatives especially newly elected Gram Pradhans in TB programmes.

Sub-National Certification of Disease-Free Status:

Timelines of implementation of interventions for ending TB across country may vary from district to district and some districts are in an advanced stage of progress towards disease elimination.

Hence the government has proposed to incentivize and reward well performing States/Districts for achieving target that are within their control and capacity. This will not only motivate States/Districts to prioritize and undertake implementation of these programs in elimination mode, but will also generate a sense of healthy competition among States/Districts. Accordingly, it is considered to have sub-national level disease elimination status documented and "Awards" be presented to respective State/Districts upon achievement of such status.

Surveillance

National Institute for Research (NIRT) has been roped in to strengthen TB surveillance under National Tuberculosis Elimination Programme by undertaking District Level Annual Survey (DLAS) and District Level Sentinel Survey (DLSS). The project aims to provide sub national level measure of TB burden of newly diagnosed bacteriological pulmonary cases, level of underreporting and annual trend of TB prevalence and incidence. NIRT through DLAS will also support the CTD in verification of State/district claims for awarding a National Certification of progress towards TB free status.

5.6 Current Budget

The NTEP budget more than doubled since the launch of the NSP (2017-2025). Government of India has engaged with World Bank project- Program Towards Elimination of Tuberculosis (PTETB) and availed an International Bank for Reconstruction and Development (IBRD) loan of USD 400 million to advance progress toward priority outcomes of the NSP 2017-25.

IBRD financing is US$400 million or 30 percent of the total program cost estimate of US$1.334 billion. The GOI will finance the remaining 70 percent. The full GOI request for IBRD financing for the period 2019 to 2025 is US$500 million and the remaining US$100 million requested by GOI will be considered by the World Bank by March 2022.

Financial Performance of NTEP (India TB Report 2022)

Description	2016-17	2020-21	2021-22
Budget requested	1000.00	3554.00	3628.85
Budget Estimates/ Approved Budget	640.00	3109.93	3409.94
Total Releases to States	533.17	629.71	480.35
Total Expenditure	677.78	3097.98	1811.91

*Till 11th March 2022 *(Rs in crore)*

The programme has identified and utilized Innovative and results-based financing for high impact NSP interventions (i.e. private sector scale-up and DBT). Over the period of NSP 2017-25, the NTEP has spent over 90% of the allocated resources (Rs 8127 Cr expended against an allocation of Rs 8964 Cr during 2017-20).

The electronic Public Financial Management System (PFMS) was rolled out to all the districts to improve the efficiency of district-level accounting and financial management.

The Global Fund to fight AIDS, Tuberculosis and Malaria has allocated USD 200 million grant to Central TB Division for next three years i.e. from April, 2021-March, 2024, under Payment for Result modality (PfR), allowing high degree of flexibility for the National Program to focus on impact and achievement of results, and autonomy to focus on health outcomes. The entire grant is tied with three Disbursement Linked Indicators related to achievement of MDR/RR TB-notification and treatment outcome; and increase in presumptive TB testing through rapid molecular diagnostics against the set targets.

6. Key Gaps and Suggested Recommendations

6.1 TB Diagnostic Services/Active Case Finding/surveillance

Key Gaps-

- People may not have access to TB diagnostic tests like marginalized populationsor internally displaced or due to geographical distance. Eg- Tribals
- Unavailability of diagnostic facilities in rural areas (especially for EP-TB).
- Insufficient referral mechanism at community-based facilities (Insufficient system and enablers in place)
- People may not seek care with a diagnostic facility due to lack of awareness regarding TB or due to challenges in navigating between health facilities or due to stigma/confidentiality issues.
- Many patient seek care from quacks initially especially in peripheries.
- Patients do not get a complete diagnosis of TB, despite reaching health facilities due to-

a) Non-availability of doctors/lab-technicians
b) Inadequate knowledge and skills of HCPs about TB diagnostic tests
c) Use of suboptimal diagnostic tests
d) Poor quality of diagnosis with limited capacity of laboratories
e) Different policies at the private health facilities
f) Poor adherence to diagnostic algorithms for the diagnosis

- Wide variability in the implementation of Xpert MTB/RIF.
- Lack of specialist services in health facilities for EP-TB
- Sub-optimal engagement of private health facilities for TB control.
- Individuals with a higher risk of missed diagnosis- PLHIV, immunosuppressed(for other reasons), children, people previously infected with TB and contacts of TB patients.

Recommendations-

1. Increasing and ensuring the availability of TB services in areas that are unconnected to health facilities using health extension workers.

2. The collection, storage, and transportation of samples for Xpert/CBNAAT, providing report to patients and notification should be done by health workers (anganwadi workers and ASHA) removing the burden from patients. Private agencies can be hired for the same.
3. Ensuring effective referral mechanism at community-based facilities.
4. Upfront Xpert MTB/RIF assay.
5. U-DST for all presumptive cases must be strictly implemented (current coverage of RDTs is 22%).
6. Use of appropriate diagnostic algorithms uniformly both in public and private sector.
7. Frequent trainings of both public and private sector HCPs in diagnostic algorithm and management.Training programs for all medics and paramedics for expertise in sample collection including pediatric and extrapulmonary cases.
8. Capacity and skill-building of HCPs with responsive behaviour to the patients
9. Engaging the private sector, including informal providers.
10. Tools such as Xpert MTB/RIF, line probe assays and liquid cultures must be scaled-up to reach more patients, in both public and private sectors.
11. Community awareness programmes using all forms of media, politicians, religious leaders and celebrities for improving care-seeking behaviour and remove stigma.
12. Active screening at camps. These camps can be conducted in schools, colleges and in workplaces.
13. Multifaceted and innovative interventions to improve ACF.
14. Proper review system for increasing TB testing rates.
15. Public-private collaborations or provision of incentives to support HCPs.
16. Using more sensitive new TB diagnostic tests (LED microscopy or automated nucleic acid molecular diagnostics).
17. Facilitating the identification of DR-TB via rapid susceptibility testing.
18. Improving the public healthcare system (use of rapid, accurate diagnostics and algorithms).
19. Systematic screening of high-risk populations and contacts to be conducted.
20. One of the key challenges identified in ACF has been the access to X-rays and NAAT. The program should make available hand-held X-ray devices equipped with Artificial Intelligence to aid automated reading which would improve access in hard-

to reach areas. Additionally, ensuring availability of molecular testing platform at the block levels will improve the yield during ACF.

21. Lack of personnel especially for Active case finding, Screening of high risk population, contact tracing, ensuring follow up and for surveillance activities can be addressed by involving the already existing AFP(Acute flaccid paralysis) network.

6.2 Current Policy

Key gaps-

1. The fallacy in diagnosis of sputum negative Tuberculosis is that NAAT determines resistance to Rifampicin at first instance and totally ignores resistance to Isoniazid which is not tested.
2. In treatment failure, LPA is done to assess Isoniazid resistance which is generally late detection now with a gap of 2- 3 months of treatment failure. Such issues are particularly relevant in EPTB as no sample may be available for any LPA or NAAT.

Recommendations-

1. New generation Xpert MTB/ XDR which detects mutation associated with resistance towards Isoniazid, Fluroquinilone, Second line injectibles and Ethionamide in a single test can be used and upgradation of the existing CBNAAT machines can be done all over the country in a phased manner.
2. Liquid culture which is a gold standard recommended by WHO must be used for Pulmonary and Extrapulmonary TB cases (whether sputum positive or negative). This will help in early detection of resistance for all drugs including INH. Hence strengthening of Liquid culture and DST must be done all over the country.
3. The Department of Microbiology of every Medical College must have Liquid culture facilities.

6.3 Treatment Services

6.3.1 Key Gaps and Recommendations, DSTB

Key gaps-

High pill burden and long treatment regime leads to non-compliance and poor treatment outcome.

Recommendations -

The new WHO recommendation of a 4-month regimen composed of rifapentine, isoniazid, pyrazinamide, and moxifloxacin (2HPMZ/2HPM) and another 4-month regimen(2HRZ(E)/2HR) for treatment of children with non-severe drug sensitive TB should be explored to further improve the treatment outcome.

6.3.2 Key Gaps and Recommendations, DRTB

Key gaps-

a)The use of standardized regimens without drug susceptibility testing in DRTB.

b) Medication stock outs and irregular supply of drugs.

c) Lack of access to newer and repurposed medications, including bedaquiline, delamanid and linezolid.

d) High rates of adverse events coupled with inadequate monitoring and management. Limited access to monitoring and management of adverse events.

e) No data available on burden of DRTB patients in private sector and their outcomes. Private providers may utilize sub-standard treatment approaches, including persons trained in other types of medical practices (homeopathy, Ayurvedic).

f) Variable availability of SLDs across the states and unavailability of Pediatric friendly SLD formulations.

g) The quality of patient care in various aspects such as counselling, laboratory investigations, treatment adherence, adverse events monitoring and management, follow up examinations and patient support is concerning.

h) Depression, anxiety and stress of DR-TB treatment along with discrimination and social stigma is often faced by these patients but get no/poor support.

Recommendations-

a) Targeted therapy based on drug susceptibility testing to allow for the use of effective drugs and avoidance of ineffective drugs which only cause toxicity. DST should be the rule with 100% coverage for deciding treatment regimen
b) Shorter and safer regimens to ensure compliance and completion of treatment.
c) Regular visit by health worker/anganwadi worker should be made at patients home to ensure compliance and completion of treatment .
d) Digital Adherence technologies (DAT) like 99 DOTS to be scaled up to entire country

e) Home delivery of drugs for remote areas.
f) More frequent forecasting and ordering of medications used to treat DR-TB.
g) Ensure adequate supplies of DR-TB medications are procured and evaluate access to them (percentage of people needing them who receive them) as part of program monitoring and evaluation.
h) Basic packages of services should be offered as an essential part of DR-TB care, with reporting on access to these types of support in addition to routine TB program outcomes. Pharmacovigilance programs must stress quality management of adverse events, with incentives for those who meet them.
i) Improve treatment literacy and support network for people living with DR-TB.
j) Train private providers in the optimal treatment of DR-TB. As significant percentage of drug resistant TB cases are being treated by the private sector, the government should consider making Bedaquiline and Delamanid available in private sector with all the necessary steps to avoid their misuse.
k) Ensure strict adherence and monitoring of Schedule H1 drugs. Prescription audit from the private sector.
l) Significant increase in lab capacity for CB-NAAT, LPA and DST for the new and repurposed drugs is required. This will also help in reducing turn around time (TAT).
m) Two year post treatment follow up of successfully treated DR-TB patients to detect relapse at an early stage should be implemented. Similarly Two year follow up of contacts should be considered.
n) Whole Genome sequencing should be applied appropriately to understand the drivers of DR-TB in India and for surveillance activities. Also its role needs to be explored for clinical management of DR-TB.
o) Capacity building and institutional strengthening and their training.
p) Tracking, monitoring and supporting patients both in public and private sectors from timely diagnosis including DST, prompt initiation of the optimal treatment regimes, to completion of treatment with appropriate follow-up during and after treatment. Monitoring and management of adverse drug reactions.
q) Strict measures should be taken to ensure that the quality of care in every aspect meets international standards.

r) Provide supportive counselling and services as routine DR-TB care. Consider options for outsourcing supporting services. Successful models of outsourced supporting services like 'Saksham' by Tata Institute of Social Sciences (TISS) should be scaled up in entire country. **Saksham Pravaah** provides psycho-social counselling for TB in 4 states viz Maharashtra, Gujarat, Karnataka and Rajasthan. It has successfully linked TB patients and their family members to various State and Central Government Social Protection Schemes ranging from Old Age pension, Women and Child Welfare schemes, Schemes for the Differently abled and Health Aid schemes.

s) Collaboration with IMA (Indian Medical Association), API (Association of Physicians of India), NCCP (National college of Chest Physicians), Indian Chest Society to ensure better involvement of Private Sector.

6.3.3 Paediatric TB-TB in a child indicates ongoing transmission and missed opportunities for prevention. It is important to prioritize children to achieve the goal of TB elimination in India.

Key Gaps-

a. Limited health personnel capacity for case detection.
b. Difficulty in obtaining samples especially sputum samples from younger children leading to underdiagnosis or late diagnosis.
c. Lack of sensitive point of care diagnostics.
d. Inconsistent availability of child friendly anti-TB drug including DR-TB formulations.
e. Lack of consistent availability of supply of pediatric FDC drugs.
f. Inadequate numbers of trained healthcare workers to suspect, investigate, diagnose pediatric TB and for quality pediatric care.
g. Very poor coverage of Bdq containing drug regimes in children with MDR TB.
h. Inadequate infection control measures at health facilities and within households.
i. Poor implementation of TPT and sub optimal completion rates.
j. Less emphasis on measures to protect children and adolescents from TB related stigma and discrimination.
k. No Proper guidelines on medical and social rehabilitation of patients with sequalae/disability.

l. Lack of robust data about the burden of DSTB and DRTB in pediatric population making planning of programs tailored for pediatric needs difficult.

Recommendations –

a. Build capacity of staff by providing pre-service and in-service training. Eg-Training programs on Pediatric TB diagnosis and management and training for expertise in collecting gastric aspirate samples etc. Consider increasing the number of centres of excellence for Pediatric TB to build core capacity for trainers. These centres should be identified urgently in high burden states.
b. Fast track child friendly TB formulations (Syrups/ dispersible tablets) for DS-TB, MDR-TB and TPT and ensure their regular supply.
c. Implement sensitive point of care diagnostics which are non-sputum based.
d. Training and provision of supplies for implementation of AIC measures at household, community and health facilities.
e. Mass awareness programs that all household contacts < 5 years need TPT, if they do not have active tuberculosis
f. Reverse contact tracing in all cases to identify the source case.
g. Prospective evaluation using Xpert MTB/RIF and Ultra for the detection of pulmonary and extrapulmonary TB in children (including urine and stool samples)
h. More studies are required in all areas of Pediatric TB - burden estimation, studies exploring non sputum based POC diagnostic tests, studies exploring shorter regimes for treatment and prophylaxis, and researches exploring more effective vaccine.
i. Collaboration with Indian Academy of Pediatrics (IAP) to have better engagement with private sector.

6.3.4 Extrapulmonary TB

Key Gaps-

a) Diagnosing EPTB remains challenging because clinical samples obtained from relatively inaccessible sites and are usually paucibacillary, thus decreasing the sensitivity of diagnostic tests.
b) Because smear microscopy or culture is not available to monitor patients with EPTB, clinical monitoring is the usual way to assess the response to treatment making monitoring subjective and expertise based.

c) Various methods that include needle biopsy, excision, endoscopy, laparoscopy, and biopsies under guidance of ultrasound, computed tomography (CT), or endoscopic ultrasound depending on the organ involved are employed to ascertain the diagnosis and often require Surgical expertise. The expertise, laboratory and radiological setup for above is not available especially in periphery.

d) Poor data available on burden of extrapulmonary TB. The program's major focus being Pulmonary TB, less emphasis and research done on Extrapulmonary TB.

Recommendations-

a) Health workers should be trained in suspecting EP TB.
b) Expertise and laboratory set up to diagnose and treat EPTB should be developed in all CHCs and District hospitals.
c) All suspected patients of EPTB should be promptly referred to higher centres to ensure timely diagnosis and treatment.
d) Facilities for transport to higher centre should be made available to patient.
e) All testing and their reports along with drugs should be made available to patients at their home.
f) Regular visit by health worker/anganwadi worker should be made at patients home to ensure compliance and completion of treatment.
g) More research needs to be done on EPTB especially on non sputum based diagnostics and diagnostics that do not require expertise.

6.4 Key Gaps and Suggested Recommendations in TB Preventive Services

Key gaps-

a. Low coverage of TPT among PLHIV and household contacts.
b. Shorter regimen of TPT is not available/implemented widely.
c. Lack of reliable tests to differentiate latent TB infection(LTBI) from disease.
d. Non-existent contact investigations for TB patients detected and notified from private sector.
e. Lack of policy to fast track coughers in waiting areas in secondary and tertiary care hospitals.
f. Lack of implementation of AIC interventions at health facilities.

Recommendations-

a. Compulsory screening of all the household contacts.
b. Human resources to be increased to support the TPT efforts, supervise and monitor implementation, ensure prompt action and management of the adverse events. Existing AFP surveillance network can be employed for the same.
c. Digital adherence technologies (DAT) must be used to ensure TPT compliance.
d. Explore TPT for contacts of DR-TB patients based on drug susceptibility patterns of index case.
e. Explore and implement shorter TPT regimen.
f. Ensure availability of Pyridoxine to prevent common adverse events associated with the use of Isoniazid.
g. Ensure implementation of AIC in health facilities.
h. Sustained National campaign for cough hygiene by involving mass media, awareness programmes in education institutions, involvement of religious leaders etc.
i. Strengthening measures to protect HCWs by implementing mandatory screening as a part of overall health check-ups at recruitment, annually and as needed.
j. Fast tracking validation and roll out of LTBI diagnostic tests like C-TB, NGS and IGRA.

6.5 Gaps and recommendations in current financial inputs

Key gaps-

a) Insufficient, incomplete and untimely release of NTEP budgets to State/UTs.
b) Continued gaps in coordination with the National Health Authority (NHA) to better implement AB-PMJAY schemes to ensure free and accessible outpatient and inpatient treatment for TB patients.
c) Inefficacies in monitoring budget and expenditures.
d) Lack of proper staff for implementing and monitoring important financial systems. For example, technical staff (i.e. Senior TB Treatment Supervisor (STS), Senior TB Laboratory Supervisor (STLS), etc.) are responsible for accounting entries and DBT transactions.
e) Delays in effective auditing processes. For example, untimely submission of audit reports by State and delayed appointment of auditor firms by NHM persists.

f) No system in place to monitor out-of-pocket and catastrophic health expenditures for TB.
g) Insufficient budget allocated for TB research.

Recommendations-

- NTEP should receive funding commensurate with the scale of India's TB epidemic.
- Budget for TB research and surveillance to be increased. Surveillance will require periodic prevalence surveys, nationwide TB drug-resistance surveillance, improved public health informatics, better tracking of TB deaths, and implementation science to identify and treat missing TB patients.
- Sufficient budget should be provided to medical colleges including those in non metropolitan cities for operational and basic science research.

6.6. Key Gaps with respect to the governance and management of NTEP as per the NSP

Key Gaps-

a) Top level governance recommendations of NSP 2017-2025 are not yet completely implemented and this includes the National TB Policy and TB Bill, and the institutional structures proposed.
b) Surveillance units at NTI and CTD not yet established.
c) Multiple expert groups are in place but planned restructure/ expansion ofCentral TB division (CTD) as outlined in NSP 2017-2025 is not undertaken as yet.

Recommendations-

a) Recommendations of NSP 2017-2025 should be implemented and including the National TB Policy and TB Bill, and the institutional structures proposed.
b) Establishment of surveillance units at NTI and CTD
c) Planned restructure/ expansion of Central TB division (CTD)
d) Establishment of surveillance units at NTI and CTD
e) Planned restructure/ expansion of Central TB division (CTD). The Central TB division needs re-strengthening with more manpower and technical experts.
f) The program needs periodic and more frequent review by a group of experts in the field.

6.7 Gaps in Medical education

Gaps-

Doctors especially those in private sector are usually not aware of the latest guidelines for diagnosis and management of TB, which results in the emergence of drug-resistant TB.

A study conducted by Revathi R et al in Chennai to assess the knowledge of TB diagnosis, national guidelines, and treatment among undergraduate students, found that the level of knowledge was not consistently adequate. There is limited opportunity for students to participate meaningfully in patient care during their undergraduate careers. Every Indian medical graduate should obtain the knowledge and the skill to diagnose and manage TB patients in the field.

Recommendations –

- Education on Tuberculosis is not adequate in undergraduate curriculum which needs to be addressed by NMC on priority basis.
- Rather than just theory lectures, advanced skill-based teaching such as Directly Observed Practical Skill, Demonstration-Observation-Assistance-Performance (DOAP), Video Demonstrations, Role Play, and Group interaction should be used as teaching tools.
- Program Based Teaching and Learning should be implemented in all medical colleges.
- Need to enhance the information regarding newer guidelines of tuberculosis detection and elimination amongst Non-government stake holders including family physicians and local practitioners.

6.8. Key gaps and recommendations in Quality Care

There is less emphasis on giving quality of care consistent with international standards. The Lancet Global Health, Sep 2018 published a landmark report entitled High-quality health systems (HQSS) in the Sustainable Development Goals era: Time for a revolution. In this HQSS Commission report, the authors suggests that by using already existing tools and improving quality of care (QI, Quality improvement) we can avert 50% of all TB deaths.

- There is a definite need to incorporate QOL (quality of Life) assessment as adjunct outcome measures in tuberculosis control programs. One must deviate from the

traditional indicators of disease severity and treatment response to capture the overall health status, with a greater emphasis on patient's, rather than clinician's, perspective of disease.

- A TB helpline should be considered to help the patients and their family members to get help for any concerns in diagnosis, treatment etc.

6.9 Key gaps and recommendations in TB research

Key Gaps-

- Available funding for TB research falls short of what is needed to have a major impact on the TB epidemic.
- Inadequate data on the burden of TB infection and disease (including drug-resistant TB) and treatment outcomes among children and adolescents at national level.
- Research on Extrapulmonary TB has been modest compared to PTB.
- Identify strategies for effective management of child contacts of parents/caregivers with drug-resistant TB in the intensive phase of treatment.

Recommendations-

- Increase domestic funding, collaborative networks, and international research partnerships.
- Facilitate and invest in Basic science research- Some of the most urgent areas for basic science research include understanding more about how TB infection progresses to disease, how to predict the risk and stages of disease progression based on biomarkers and how to more reliably and easily know when a person has been cured through treatment.
- Develop new drugs with lesser side effects, shorter regimes, diagnostics and vaccines, keeping in mind the specific problems of India.
- Operational research in order to understand how to optimally implement new tools within specific regional and local contexts. To be sustainable, operational research capacity needs to be more routinely embedded within NTPs, with resources allocated through annual budgets.
- Basic and clinical research for the development of affordable diagnostic tests with improved performance and predictive value for progression of LTBI to active TB; and safer and shorter duration treatments that can cure LTBI.

- Research on diagnostic tests with improved performance and predictive ability to measure reactivation of LTBI to active disease are critically needed.
- Programme-based epidemiologic and clinical surveillance is needed to monitor the risk for bacterial resistance to the drugs used in LTBI treatment.
- Separate research designed to meet the specific needs of children.
- Research on POC diagnostic modalities for EPTB.
- Research focusing on tackling Anti-Microbial Resistant TB.

7. Way forward

1. Introduction of rapid, affordable, easy to use point-of-care tests for diagnosing TB and detecting drug resistance.
2. Optimise the prevention and care of drug resistant TB.
3. Shorter and safer drug regimens for treating drug-sensitive, drug-resistant and latent forms of the disease should be researched and explored.

   The shortest prevention regimen available today is 1HP, a daily dose of rifapentine and isoniazid taken for four weeks. A Phase III clinical trial involving 3,000 participants over the age of 13, all of whom were living with HIV, found that 1HP performed just as well as nine months of isoniazid, which has long been the standard for TB preventive therapy.
4. Address the most vulnerable and hard to reach groups eg Tribals and migrant populations.
5. A new universally applicable, effective vaccine for pre-exposure and post-exposure prophylaxis.
6. Enhancing efforts towards rapid implementation of TB preventive treatment in the country.
7. Whole genome sequencing (WGS), the next generation sequencing (NGS) based technology has been successfully applied for the routine characterization of the organism, drug susceptibility testing, genotyping and epidemiological investigation of tuberculosis. Decentralization of next-generation sequencing (NGS) for affordable, scalable and rapid tb drug-susceptibility testing (DST) must be considered.
8. Fujifilm's SILVAMP TB LAM, or FujiLAM, is the first of a new generation of LAM tests for detecting TB. Testing is done using a urine sample, which is easy to collect from people of all ages. Further testing is needed to assess FujiLAM's potential as a POC diagnostic test for TB. The test's greatest potential is in serving individuals who have difficulty producing sputum, particularly children, health facility inpatients and people living with HIV who are more severely ill.
9. Volatile Organic Compound (VOC) test in TB patients has future diagnostic potential. eNose test is one of such device.

10. Invest in research and new tools- Taking into account the time it takes to develop and test diagnostic, drug, and vaccine candidates increased investment is required today to ensure new tools will be available as early as possible.
11. Separate research designed to meet the specific needs of children is critical to end Pediatric TB epidemic. Most of the previous research on Pediatric TB have focused mostly on finding out how to apply existing tools to diagnose, treat and prevent Pediatric TB. However children have different needs than adults. For example, children have difficulty producing sputum, making them poor candidates for diagnosis using the rapid diagnostic test Xpert MTB/RIF, which tests sputum. Gastric aspirates can be used but require expertise for sample collection. Research should be done to develop sensitive and specific diagnostic tests using easily available samples like stool, urine, nasal and oral swabs.
12. Monitoring and pharmacovigilance for new TB medicines to assure that we can appropriately treat patients and detect the emergence of resistance to new TB medicines, and that practical approaches to the development of standardized, laboratory and point of care (POC) DST can be implemented.
13. Incorporate and scale up more and more digital and Artificial intelligence (AI) techniques to TB diagnostics, therapeutics and patient care. AI for image recognition has a number of potential applications in TB, specifically for reading chest X-rays and in other areas where reading is done by humans. There are multiple benefits of using AI to read chest X-rays, including the ability to standardize scoring, savings on the costs of GeneXpert testing, and improved detection when using chest X-ray as a triage test. Using AI to read chest X-rays can be especially helpful in places where there is a lack of trained human readers and high screening throughput. Implement and scale up use of AI to identify ‘hotspots’ for TB screening campaigns or to help health care workers recognize.
14. A test that predicts progression from infection to TB disease should be researched. A more sensitive point-of-care non sputum-based test to replace smear microscopy for detecting pulmonary TB that is easy to perform and has limited operational requirements should be studied.
15. Facilitate holistic, patient-centric TB care and prevention through resource mobilisation and integrated actions.

16. Seriously tackle key determinants of TB, especially poverty, undernutrition and tobacco smoking, which have been clearly linked with TB and mortality due to TB. This will require intersectoral collaboration between multiple ministries, agencies and civil society. There is also significant opportunity for inclusion of TB in social protection programmes, which can focus on prevention as well as protect patients from impoverishment.
17. India must invest in research and surveillance. Research will need to focus on development and/or validation of new tools, including rapid point of care diagnostics, new TB drugs and vaccines. Surveillance will require periodic prevalence surveys, nationwide TB drug-resistance surveillance (as part of a more comprehensive antimicrobial resistance surveillance programme), improved public health informatics, better tracking of TB deaths and implementation science to identify and treat missing TB patients.
18. TB advocacy and patient groups in India need to be more active and empowered, and the RNTCP needs to engage further with civil society. Pressure from civil society and patient groups can help keep the spotlight on TB and help the Ministry of Health garner more resources. Advocacy will also help tackle stigma, delayed care seeking and other barriers that patients face.
19. Transform the global TB research agenda through increased domestic funding, collaborative networks, and trans-national research partnerships.

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Annexure 1

Results framework (impact and outcome indicators and targets), (NSP 2017-2025)

	Baseline		Target	
IMPACT INDICATORS	**2015**	**2020**	**2023**	**2025**
1. To reduce estimated TB Incidence rate (per 100,000)	217 (112-355)	142 (76-255)	77 (49-185)	44 (36-158)
2. To reduce estimated TB prevalence rate (per 100,000)	320 (280-380)	170 (159-217)	90 (81-125)	65 (56-93)
3. To reduce estimated mortality due to TB (per 100,000)	32 (29-35)	15 (13-16)	6 (5-7)	3 (3-4)
4. To achieve zero catastrophic cost for affected families due to TB	35%	0%	0%	0%
OUTCOME INDICATORS				
1. Total TB patient notification	1.74 mil	3.6 mil	2.7 mil	2 mil
2. Total patient Private providers notification	0.19 mil	2 mil	1.5 mil	1.2 mil
3. MDR/RR TB patients notified	28,096	92,000	69,000	55,000
4. Proportion of notified TB patients offered DST	25%	80%	98%	100%
5. Proportion of notified patients initiated on treatment	90%	95%	95%	95%
6. Treatment success rate among notified DSTB	75%	90%	92%	92%
7. Treatment success rate among notified DRTB	46%	65%	73%	75%
8. Proportion of identified targeted key affected population undergoing active case finding	0%	100%	100%	100%
9. Proportion of notified TB patients receiving financial support through DBT	0%	80%	90%	90%
10. Proportion of identified/eligible individuals for preventive therapy / LTBI s - initiated on treatment	10%	60%	90%	95%

Annexure 2

TB Key population

People who have **INCREASED EXPOSURE** to TB due to where they live or work	Prisoners, sex workers, miners, hospital visitors, health care workers and community health workers **PEOPLE WHO:** • live in urban slums • live in poorly ventilated or dusty conditions • are contacts of TB patients, including children • work in environents that are overcrowded • work in hospitals or are health care professionals
People who have **LIMITED ACCESS TO QUALITY TB SERVICES**	Migrant workers, women in settings with gender disparity. children, refugees or internally displaced people, illegal miners, and undocumented migrants **PEOPLE WHO:** • are from tribal populations or indigenous groups • are homeless • live in hard-to-reach areas • live in homes for the elderly • have mental or phyiscal disabilities • face legal barriers to access care • are lesbian, gay, bisexual or transgender
People at **INCREASED RISK** to TB because of **biological or behavioural factors** that compromise immune function	**PEOPLE WHO:** • live with HIV • have diabetes or silicosis • undergo immunosuppressive therapy • are undernourished • use tobacco • suffer from alcohol-use disorders • inject drugs