



Ministry of Health & Family Welfare
Government of India



REPORT OF THE JOINT MONITORING MISSION

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

November 2019



#TBHaregaDeshJeetega



Central TB Division, New Delhi



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**REVISED NATIONAL TUBERCULOSIS
CONTROL PROGRAMME**

November 2019

The 2019 Joint Monitoring Mission (JMM) for the Revised National Tuberculosis Control Programme (RNTCP), India was jointly organized by the World Health Organization (WHO) Country Office (WCO) for India and the Central Tuberculosis Division (CTD) and led by Dr. Kenneth Castro. The TB mini-epidemiology review conducted just ahead of the JMM was led by Dr. Patrick Moonan. At the conclusion of the JMM field visits and thematic team deliberations, team leads presented respective executive summaries with top-line recommendations to senior officials from Ministry of Health and Family Welfare (MoHFW), Government of India, including Mr. Sanjeeva Kumar, Dr. Arun Kumar Panda, Ms. Vandana Gurnani, Mr. Vikas Sheel, Dr. KS Sachdeva; senior officials from WHO including Dr. Soumya Swaminathan, Dr. Tereza Kasaeva, Dr. Henk Bekedam; and a wider international, national and state audience. The MoHFW officials shared their reflections and commitments for action while the WHO officials followed by representatives from Global Coalition of TB Activists, Stop TB Partnership, Medecins Sans Frontieres, and Alliance India also shared their reflections and expressed their continued commitment to support India in ending TB by 2025.

The JMM (TB), India 2019 report was prepared by a writing group led by Kenneth Castro, with contributions from the thematic and state team leads (alphabetically) – Amy Piatek, Anand Date, Annabel Baddeley, Anuj Bhatnagar, Anurag Bhargava, Avinash Kanchar, A Venkatraman, Blessina Kumar, Daksha Shah, Dawran Faizan, DCS Reddy, Diana Weil, Douglas Fraser Wares, Erika Vitek, Kirankumar Rade, Lal Sadasivan S, L S Chauhan, Malik Parmar, Manoj Jain, Marion Grossmann, Miruna Mosincat, Mohammed Yasin, Mukta Sharma, Nevin Wilson, Patrick Moonan, Puneet Dewan, Rajendra Prasad, Rajesh Solanki, Ranjani Ramachandran, Rebecca Gupta Lawrence, Richard Cunliffe, Rohit Sarin, Ronald Mutasa, Rupak Singla, Sangeeta Sharma, Senait Kebede, SK Sharma, Sreenivas A Nair, Suvanand Sahu, Thomas M Shinnick, Urvashi Singh, Varinder Singh, Vineet Chadha, William Wells, Wilson Lo and Yamuna Mundade.

Overall planning, organization, technical assistance, report compilation and coordination was led by the WCO for India (TB team) – Ranjani Ramachandran, Kirankumar Rade and Malik Parmar.

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Contents

Acknowledgements	I
Acronyms	II
Executive Summary	1
1. Introduction	5
1.1 Objectives	5
1.2 Methodology	6
1.3 Background: Epidemiology, Surveillance, Supervision, Monitoring and Evaluation	7
2. Findings and Recommendations	20
2.1 Build	20
2.1.1 Partnerships and Private Provider Engagement	20
2.1.2 Multisectoral Engagement and Accountability	29
2.1.3 Health System Strengthening	32
2.1.4 Tuberculosis in Urban Populations	38
2.1.5 Patient Support Systems	41
2.1.6 Community Engagement, Advocacy, Communication, and Social Mobilization	45
2.1.7 Research and Innovation	48
2.1.8 Technical Assistance to End Tuberculosis in India	55
2.2 Prevent	56
2.2.1 Preventive Services	56
2.3 Detect	62
2.3.1 Case Finding, Diagnostics and Laboratory Services	62
2.4 Treat	69
2.4.1 Treatment Services for Drug Sensitive Tuberculosis	69
2.4.2 Programmatic Management of Drug-resistant Tuberculosis	73
2.4.3 Commodities and Childhood Tuberculosis	82
2.4.3a Childhood TB	89
Annexes	95
3.1 State Level Reports	95
3.1.1 Assam	95
3.1.2 Chhattisgarh	103
3.1.3 Kerala	113
3.1.4 Rajasthan	125

3.1.5	Tamil Nadu	132
3.1.6	Uttar Pradesh	146
3.2	List of Participants	161
3.2.1	Thematic Groups	161
3.2.2	Field Visit Teams	168

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level tuberculosis (TB) cells, in the six states visited (Assam, Chhattisgarh, Kerala, Rajasthan, Tamil Nadu, Uttar Pradesh) welcomed the members of JMM with meticulous schedules and opportunities for field visits to enable JMM participants to gain an understanding of the successes, challenges, and ongoing efforts of the respective TB program activities. Members of this JMM extend their collective gratitude to all the participating state and district level TB programs, WCO, and RNTCP/MoHFW/GoI for their painstaking preparation and hospitality.

Acronyms

AB-PMJAY	Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana
ACSM	Advocacy, Communication, and Social Mobilization
ACF	Active Case Finding
ADR	Adverse Drug Reaction
ADSM	Active Drug Safety Monitoring and Management
AE	Adverse Events
AFB	Acid-fast bacillus
AI	Artificial Intelligence
AIC	Airborne Infection Control
Am	Amikacin
AMC	Annual Maintenance Contract
ART	Antiretroviral Therapy
ARTI	Annual Rate of TB Infection
ASHA	Accredited Social Health Activist
ATT	Anti-tubercular Treatment
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy
BCG	Bacille Calmette-Guerin vaccine
BDQ	Bedaquiline
BDQ-CAP	Bedaquiline Conditional Access Programme
BK+	Bacille de Koch (or Koch bacillus) positive smear
BMI	Body Mass Index
BRICS	Brazil, Russia, India, China, and South Africa
CB-NAAT	Cartridge-based Nucleic Acid Amplification Test
CBO	Community-based Organization
CDS	Clinical Decision Support
CDST	Culture and Drug Sensitivity Testing
CFZ	Clofazimine

CHC	Community Health Center
CME	Continuing Medical Education
CMSS	Central Medical Services Society
CPT	Cotrimoxazole Preventive Therapy
Cs	Cycloserine
CSO	Civil Society Organization
CSR	Corporate Social Responsibility
CTD	Central Tuberculosis Division
CXR	Chest X-Ray
DBT	Direct Benefit Transfer
DDS	District Drug Stores
DLM	Delamanid
DM	Diabetes mellitus
DMC	Designated Microscopy Center
DoP	Department of Post
DOT	Directly Observed Therapy
DOTS	Directly Observed Therapy, Short-course
DR-TB	Drug Resistant Tuberculosis
DRS	Drug Resistance Surveillance
DST	Drug Susceptibility Testing
DS-TB	Drug-Sensitive Tuberculosis
DTC	District Tuberculosis Center
DTO	District Tuberculosis Officer
E	Ethambutol
EPTB	Extrapulmonary Tuberculosis
Eto	Ethionamide
EQA	External Quality Assurance
FDC	Fixed-dose Combination
FIND	Foundation for Innovative New Diagnostics
FLD	First-line Drugs



FQ	Fluoroquinolone
FY	Fiscal Year
GoI	Government of India
GDF	Global Drug Facility
GeneXpert	Xpert MTB/RIF cartridge-based nucleic acid amplification test to detect <i>M. tuberculosis</i> and rifampin resistance
GF (or Global Fund)	Global Fund Against HIV/AIDS, Tuberculosis, and Malaria
H	Isoniazid
Hh	Isoniazid High Dose
HD	High Dose
HR	Human Resources
HS	Health Systems
HSS	Health Systems Strengthening
IC	Infection Control
ICF	Intensified Case Finding
ICMR	Indian Council of Medical Research
ICT	Information and Communication Technologies
ICTC	Integrated Counseling and Testing Center
IDAT	Integrated Digital Adherence Technologies
IEC	Information, Education, and Communication
IGRA	Interferon-Gamma Release Assay
IHME	Institute for Health Metrics and Evaluation
IMA	Indian Medical Association
IP	Implementing Partner
IRL	Intermediate Reference Laboratory
ITRC	India Tuberculosis Research Consortium
IVA	Independent Verification Agency
JEET	Joint Effort for Elimination of Tuberculosis
JMM	Joint Monitoring Mission
Km	Kanamycin



KPI	Key Performance Indicator
LF-LAM	Lateral Flow Urine Lipoarabinomannan Assay
Lfx	Levofloxacin
LIMS	Laboratory Information Management System
LPA	Line-probe Assay
LT	Laboratory Technician
LTBI	Latent Tuberculosis Infection
LZD	Linezolid
M&E	Monitoring and Evaluation
MAF-TB	Multisectoral Accountability Framework for Tuberculosis
MCH	Maternal and Child Health
MDG	Millennium Development Goal
MDR	Multidrug Resistance
MDR-TB	Multidrug Resistant Tuberculosis
MERMs	Medication Event Reminder Monitors
Mfx	Moxifloxacin
MoHRD	Ministry of Human Resource Development
MoHUPA	Ministry of Housing & Urban Poverty Alleviation
MO	Medical Officer
MoD	Ministry of Defence
MoHFW	Ministry of Health and Family Welfare
MOTC	Medical Officer Tuberculosis Control
MOU	Memorandum of Understanding
MoUD	Ministry of Urban Development
MPHW	Multipurpose Health Worker
MoWCD	Ministry of Women & Child Development
NAAT	Nucleic Acid Amplification Tests
NACO	National AIDS Control Organization
NACP	National AIDS Control Program
NCD	Noncommunicable Disease



NDRS	National Anti-Tuberculosis Drug Resistance Survey
NGO	Non-governmental Organization
NGS	Next-Generation Sequencing
NHA	National Health Authority
NHM	National Health Mission
NIKSHAY	Web-enabled electronic TB case notification/ monitoring system
NIRT	National Institute for Research in Tuberculosis
NITRD	National Institute of Tuberculosis and Respiratory Diseases
NPCDCS	National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases, and Stroke
NPY	NIKSHAY Poshan Yojana (nutritional support to TB patients)
NRHM	National Rural Health Mission
NRL	National Reference Laboratory
NSP	National Strategic Plan
NSS	National Sample Survey
NTCP	National Tobacco Control Programme
NTI	National Tuberculosis Institute
NTSU	National Technical Support Unit
NUHM	National Urban Health Mission
NVHCP	National Viral Hepatitis Control Program
OOP	Out-of-pocket expenditures
OpASHA	Operation ASHA
OR	Operational Research
OSE	On-Site Evaluation
OTC	Over-the-counter drugs
Pa	Pretomanid
PDS	Public Distribution System
PFMS	Public Financial Management System
PHC	Primary Health Center
PHI	Peripheral Health Institution



PIP	Project Implementation Plan
PLHIV	People Living with HIV/AIDS
PMDT	Programmatic Management of Drug Resistant Tuberculosis
PP	Private Practitioner
PPE	Private Provider Engagement
PPM	Public-Private Mix
PPSA	Patient Provider Support Agency
PR	Principal Recipient of grant from the Global Fund Against HIV/AIDS, Tuberculosis and Malaria
PRI	Panchayati Raj Institution
PSM	Procurement and Supply Management
PTB	Pulmonary Tuberculosis
PVPI	Pharmacovigilance Programme of India
QA	Quality Assurance
R	Rifampicin
RBSK	Rashtriya Bal Swasthya Karyakram (initiative for early child screening and intervention services)
RBRC	Random Blinded Re-checking
RCT	Randomized Controlled Trial
RCH	Reproductive and Child Health
RNTCP	Revised National Tuberculosis Control Program
RR-TB	Rifampicin-Resistant Tuberculosis
SDS	State Drug Stores
SHG	Self-help Group
SLD	Second-line Drugs
SL-DST	Second-line Drug Susceptibility Testing
SLI	Second-line Injectable Drugs
STC	State Tuberculosis Cell
STCI	Standards for Tuberculosis Care in India
STDC	State Tuberculosis Training and Demonstration Center
STR	Shorter Treatment Regimen for drug-resistant TB



STLS	State Tuberculosis Laboratory Supervisor
STO	State Tuberculosis Officer
STS	Senior Treatment Supervisor
TA	Technical Assistance
TAT	Turnaround Times
TB	Tuberculosis
TBHV	Tuberculosis Health Visitor
TOG	Technical and Operational Guidelines
TOR	Terms of Reference
TueNat MTB	Chip-based nucleic acid amplification test to detect <i>M. tuberculosis</i>
TrueNat MTB-RIF Dx	Chip-based nucleic acid amplification test to detect rifampicin-resistant <i>M. tuberculosis</i>
TSG	Technical Support Group
TST	Tuberculin Skin Test
TSU	Technical Support Unit
TU	Tuberculosis Unit
UATBC	Universal Access to Tuberculosis Care
UDST	Universal Drug Susceptibility Tests
UHC	Universal Health Coverage
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNHLM	United Nations High-level Meeting
USAID	United States Agency for International Development
UVGI	Ultraviolet Germicidal Irradiation
WCO	World Health Organization Country Office
WHO	World Health Organization
WHP	World Health Partners
XDR-TB	Extensively Drug Resistant Tuberculosis
YLL	Years of Life Lost
Z	Pyrazinamide



Executive Summary

This is the seventh World Health Organization (WHO) - Government of India (GoI) Joint Monitoring Mission (JMM) on tuberculosis (TB) since the launch of the Revised National TB Control Program (RNTCP) in India 21 years ago. Members of the 2019 JMM applaud India's commitment to end TB by 2025, and the [National Strategic Plan for Tuberculosis 2017-25: Elimination by 2025 \(NSP\)](#).

In 2017 the Honorable Prime Minister Narendra Modi enthusiastically endorsed the implementation of India's NSP, which has been underway since then. Prime Minister Modi has repeatedly committed to the nation and the world to reach the 2030 United Nations (UN) Sustainable Development Goals (SDG) Target to End the TB Epidemic by 2025¹. Furthermore, India committed at the 2018 UN High-Level Meeting on ending TB, which is critical to ending the epidemic globally. Unprecedented political commitment to address TB has been summoned, from the Central Government through States and Districts. Domestic investment in TB has nearly quadrupled since the last JMM in 2015. This response is commensurate with the nation's severe and disproportionate burden of TB. Further, acceleration of global progress against TB and MDR-TB is being led by India, as recognized in the WHO's [Global TB Report 2019](#).

Tangible achievements include an additional 700,000 people with TB disease detected in the past two years and notified through the upgraded NIKSHAY national digital information system. RNTCP leveraged near-universal mobile network access and India's digital payments infrastructure to deploy social support via accountable electronic direct benefits transfer (DBT), which has been expanded for all TB patients. RNTCP also learned how to effectively engage private providers, who account for most healthcare delivery services, and is scaling up these and other innovative

approaches, remarkably reaching 1 million in the private sector over the past two years. In addition, RNTCP has responded to the dangerous problem of drug-resistant TB, and is making progress towards offering universal drug susceptibility testing for people diagnosed with TB, employing 1530 rapid molecular diagnostic devices (NAAT), testing 1 million people with TB, and ultimately detecting and treating 58,347 TB patients with multidrug or rifampicin resistant forms of TB in 2018. Enabling these expansions reflects a new commitment to patient-centered services and care, emphasizing community engagement and mobilizing the general health system in the national effort against TB.

Despite these accomplishments, the challenges ahead remain daunting and are accompanied by a risk of failure to achieve the national goals unless concrete and deliberate actions are promptly undertaken. Nearly 0.5 million people with TB disease remain missing to TB surveillance/notification and services, and are likely in private health delivery systems or the community. Those who are found experience attrition through the cascade of care; hundreds of thousands are lost along their journey through diagnosis and treatment, particularly among those reported by private providers. Furthermore, many patients reported by private providers could not be confirmed to have completed treatment. Many are not routinely screened or treated for drug resistance and key comorbidities such as HIV, diabetes, or malnutrition – all critical measures to maximize successful treatment outcomes and survival.

Scale-up of services has been slowed by limited supplies of drugs and diagnostics to meet the rapidly expanding demand. JMM visitors received anecdotal reports of drug stock-outs; these were

¹The End TB Strategy targets, in line with the SDG target for ending TB are by 2030 (relative to 2015), to achieve an 80% reduction in TB incidence, a 90 reduction in TB mortality, and eliminating catastrophic costs for patients and affected households.

not independently verified. Existing vacancies in allocated RNTCP staff positions in many states also limit progress. The power of India's general health system has not been harnessed for the national campaign against TB, particularly in settings with the highest burden of disease. Tools available to RNTCP, such as advanced molecular diagnostics, enhanced patient and adherence support systems, or newer drug regimens, still remain incompletely implemented.

Underdiagnosis of paediatric TB remains a challenge. The most pressing challenges include limited capacity for case detection, lack of sensitive diagnostics and inconsistent availability of child friendly anti-TB drug formulations for prevention and cure.

To overcome these identified challenges, the "mission mode" envisioned in the NSP must be enacted. A national movement to address TB, encompassing patients, civil society, communities and TB survivors, has yet to become fully implemented. The current trajectory, while markedly improved over findings of past JMMs, will fall far short of achieving the Prime Minister's commitment to end the TB epidemic by 2025.

The members of this 2019 JMM clearly and unequivocally support India's ambitions, and acknowledge that success will require a redoubling of effort and investment, marshalling the entire health system, investing in terms of both people and money, and deploying new approaches to rapidly interrupt person-to-person transmission of TB and save countless lives.

To approach the Prime Minister's commitment to reach the NSP targets by 2025, the Mission recommends the following ten actions:

1. **Mount the TB elimination campaign envisaged in India's NSP with clear accountability and multisectoral engagement** – inspired by lessons gained from Polio eradication in India. This TB elimination campaign must incorporate aggressive forecasting, and direct

procurement or innovative contracting for drugs and diagnostics to meet rapidly expanding demand. And consider renaming the RNTCP as the National TB Elimination Program (NTEP) to explicitly reflect this ambitious campaign. Translating these and other recommendations into action will require adequate financing for TB. An ambitious budget for the next 5 years is required, and the Government of India should **increase the level of financing for TB** based on robust estimates and work plans for the 2020-25 period, making sure that the most innovative aspects of the NSP are adequately funded based on proper budget forecasts. These plans must drive multi-sectoral action and accountability, based on the Right to Health, under the stewardship of a National TB Elimination Board, with State counterparts backed by legislation. And rapidly develop, implement, monitor and rigorously review TB Elimination plans for every State, and consider convening the eight mega-cities for a focused effort specific to these areas and commensurate with their high burden. Also act so that vulnerable and marginalized populations are served with urgency. India can only succeed if local government, communities, and civil society are mobilized to detect and support every person suffering from TB and every affected family.

2. **Provide urgent reinforcements to the existing workforce** of dedicated and skilled workers with additional trained persons to tackle the increased workload. Immediately hire pending vacancies at all levels of local, state and national level. Deploy human resources and outsource selected functions to properly address the unprecedented expansion of early TB case finding, up-to-date and quality-assured diagnostic laboratory services, expansion of newer approved treatment regimens, new prevention activities, management of private sector models, DBT schemes. Also, develop and execute a multi-year national and state human resource plan

that informs the targeted addition of trained and dedicated staff “fit for purpose” by relying on in-person and digital training platforms, using principles of quality improvement to strengthen cascades of care, and outsourcing support for capacity development.

3. **Rapidly scale-up private provider engagement**, by collaborating with qualified allopathic providers and AYUSH providers to find and successfully treat 2 million patients in 2020-2021. Leverage the newly released Guidance for Partnerships and technical support units for output-based contracting of the workforce and services required to reach and provide quality services to double the number of TB patients being treated today. Make use of conscious change management as the government undertakes the new ways of working inherent to output-based contracting, and consider using public funds to purchase privately supplied quality-assured drugs and diagnostics. Embed and implement reimbursement packages for outpatient TB services and for secondary and tertiary care provided under Pradhan Mantri Jan Arogya Yojana (PMJAY).
4. **Move from passive community engagement to full community participation and ownership**, with reliance on TB champions and TB Survivors working alongside programme staff in advocacy, planning, implementation and monitoring of the local, state, and national TB response. Invest in local TB forums which are effective change agents able to work at reducing/eliminating stigma and a human rights response framework.
5. **Invest in TB surveillance staff and systems for accurate, complete, and timely information** that ensures the collection and analysis of high-quality, effective service delivery, performance monitoring, and understands the drivers of TB transmission. A network of national-, state-, and district-level TB Surveillance Units should be established by 2020. Augment the surveillance network with technical assistance to help address emerging priorities, build communities of practice, use local data for local action, and rapidly respond to outbreaks.
6. **Deploy new precision diagnostic tools and ensure access to prompt, quality-assured testing for accelerated progress**, and scale-up advanced diagnostics services and TB surveillance capacity. Displace insensitive sputum smear microscopy with molecular TB diagnosis fully decentralized nationwide, alongside outsourcing to India's enormous private laboratory capacity, for 20 million advanced molecular diagnostic tests annually. Provide rapid drug susceptibility testing to all eligible persons diagnosed with TB disease -- adult and pediatric, public and private.
7. **Support patients comprehensively throughout treatment, using a people-centered approach**. Enable people identified with TB disease to initiate, and sustain themselves on patient-friendly treatment regimens, including via budgeted support for patient peer groups, and eliminate the social and economic impacts of disease. Supplement staff, and community support and use of digital tools. Strengthen the DBT system and nutritional/ social support implementation for differentiated care according to need and context, to reach all TB patients and secure nutritional gains and end catastrophic costs. Provide access to the latest evidence-based and recommended drug regimens for improved treatment and outcomes of people with drug-resistant forms of TB.
8. **Re-design and pursue targeted active case finding efforts**, learning from experiences to better screen epidemiologically-defined key affected populations and close contacts of people with TB disease. Emphasize the proven roles of digital chest x-ray screening and rapid molecular diagnostic tests.
9. **Deploy and evaluate ambitious plans to**

implement TB preventive treatment of household and other close contacts, children, PLHIV and other locally-defined high-risk groups, using new, shorter regimens (reaching an expected 6 million eligible persons annually by 2021).

10. **Invest in research to develop additional new tools required to end TB** and in the rapid uptake of available new tools, products – such as simple triage/screening, use of non-sputum clinical specimens for accurate bacteriologic diagnosis of extrapulmonary and paediatric TB, and simpler/safer/shorter universal curative TB treatment regimens. Immediately scale-up available tools, such as

novel specific skin tests (e.g. C-TB) for diagnosing latent TB, automated digital chest x-ray interpretation, and new drugs/regimens, and based on the latest evidence-based global guidance. Expand research investments with urgency against these national and global needs.

The members of the 2019 JMM agree that the recommendations above represent the minimum required to fulfill the Prime Minister's national and global commitment and reach End TB in India by 2025. These recommendations are largely in line with India's NSP, and a new expanded budget is required commensurate with the historically unprecedented national ambition.



1. Introduction

The previous World Health Organization (WHO) - Government of India (GoI) Joint Monitoring Mission (JMM) was conducted in 2015; much has changed in India's tuberculosis (TB) landscape since then. Several recommendations provided by that 2015 JMM and follow-up work during National Consultative Meetings in Delhi (October 2016 and March, April 2017) supported the development of India's National Strategic Plan for Tuberculosis 2017-25: Elimination by 2025 (NSP). This NSP was launched in 2017 with the full endorsement by India's Prime Minister Narendra Modi, who subsequently reinforced the country's commitment to ending TB in India by 2025 (five years ahead of the Sustainable Development Goals of 2030) during the first ever United Nations High-Level Meeting (UNHLM) on ending TB, held in New York September 2018. This ambitious declaration and unprecedented political support served as the background context for the 2019 WHO-GoI JMM. In order to conduct a successful JMM with clear, actionable recommendations for the GoI, specific objectives and a sound methodology were required. The WHO-GoI JMM is one of the largest JMMs in the world with a diverse set of multidisciplinary expert participants.

This final report, including the format in which it is presented, is a direct result of discussions among members of the JMM. Participants were provided with terms of reference to review twelve distinct thematic areas. During thematic discussions, it was agreed that the report's thematic findings and recommendations should be grouped under the four pillars of India's NSP (Build, Prevent, Detect, Treat). As such, this report is structured to present the objectives and methodology used for this JMM, followed by observations, findings, and recommendations for each thematic area clustered into the aforementioned pillars. In addition, this JMM was preceded by an abridged Epidemiological Review of TB in India. A separate report of that Epidemiological review is

forthcoming, but some relevant information collected during that review has been incorporated into this report. Lastly, the report contains annexes with other relevant information, such as the six state reports and participant list.

1.1 Objectives

The main goal of this JMM is to review the progress, challenges, and plans for India's TB control efforts in the setting of the NSP 2017-2025, and to advise GoI, WHO, and partners on the pathway towards achieving Universal Access to TB care. To achieve this, the JMM participants were asked to focus on the following key objectives and terms of reference, and to assess:

1. Mid-term progress of the NSP and recommendations for course corrections.
2. Current performance and sustainability of the Programme and development of recommendations for future activities
3. The TB surveillance system, monitoring & evaluation strategy and analysis of the epidemiological data including digital initiatives
4. Diagnostics of TB and multidrug resistant TB (MDR-TB) in the country and the operation of the laboratory network.
5. Implementation of basic TB services and programmatic management of drug resistant TB (PDMT).
6. Partnership strategies and progress within and outside of the health sector for ending TB in India.
7. Assessment of research priorities and its progress.
8. The collaborative framework for TB comorbidities, its implementation, gaps analysis and recommendations thereof.
9. Childhood TB, including drug resistant TB (DR-TB) diagnosis and management.

10. The diagnostics and anti-TB drug procurement and supply chain management.
11. Current engagement with civil society organizations (CSOs) and patient groups, and the extent to which their potential contribution to the detection, treatment and care of individuals with TB has been maximized.
12. Progress on implementation of multisectoral accountability framework (MAF-TB) and addressing determinants of health.
13. Social protection and nutritional support.
14. Strategies and progress for management of latent TB infection among people living with HIV/AIDS (PLHIV) and children in India.
15. Human resources (HR) and development, health system strengthening (HSS) and programme financing.
16. Technical assistance (TA) requirements for the programme to facilitate ending TB in India.
17. Identify and present specific recommendations regarding the actions and priorities for ending TB in the country as per the set target of 2025.

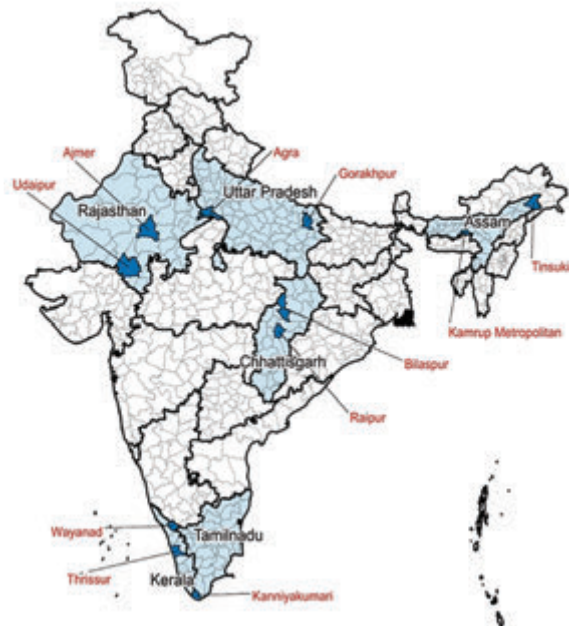
1.2 Methodology

The WHO-GoI JMM conducted a two-week intensive review of the TB program in India during November 11th to 22nd, 2019. As one of the largest JMMs in the world, this JMM welcomed 165 multidisciplinary professionals (32 international and 133 national experts), including representatives from WHO, technical agencies, development agencies, national institutes, medical colleges, and civil society. These distinguished participants were carefully divided into teams to ensure, as much as possible, distribution of different areas of technical expertise among each of the field groups. Six state teams (Assam, Chhattisgarh, Kerala, Rajasthan, Tamil Nadu, and Uttar Pradesh) were created, and further subdivided into eleven district teams (Figure 1). The sites to be visited were jointly pre-selected by WHO Country Office (WCO) and RNTCP/MoHFW, taking into consideration different criteria, such as diversity in burden of disease, urban and rural settings, geographic dispersion, and range of perceived

programmatic performance.

WHO and GoI organizers of this 2019 JMM identified and designated specific leaders for Thematic, State, and District Teams. Following an introductory first-day orientation and review of the terms of reference, all JMM participants traveled to spend the first week of the review observing TB program activities by conducting field visits and meetings with relevant stakeholders in the 11 designated districts from six states. During the second week, JMM participants reconvened in New Delhi to develop and articulate observations, findings, and recommendations across the various teams. Full review participants were engaged in the JMM for the entirety of the two-week review, while additional participants joined later to participate in thematic discussions and report writing.

Figure 1: In the map above, the states and districts highlighted in light and dark blue, respectively, were visited by the JMM team.



During scheduled site visits and meetings with relevant district and state level stakeholders, teams were directed to focus their observations on twelve specific thematic areas: (1) Epidemiology, Surveillance, Supervision, Monitoring & Evaluation; (2) Preventative Services; (3) Case Finding, Diagnostics & Laboratory Services; (4) Treatment

Services for Drug Sensitive TB; (5) Programmatic Management of Drug Resistant Tuberculosis; (6) Comorbidities & Childhood TB; (7) Multi-sectoral Engagement & Patient Support Systems; (8) Partnerships and Urban TB; (9) Community Engagement, Advocacy and Communication; (10) Health Systems Strengthening; (11) Technical Assistance to End TB in India; (12) Research & Innovation.

When the JMM participants reconvened in New Delhi, the state teams consolidated their findings and presented these to all JMM participants to elicit feedback and incorporate additional comments (see Appendix 1 for State Reports). Next, the participants split into teams across the twelve thematic areas; these thematic teams worked to develop consensus on the main observations, findings, and technical recommendations. During thematic team discussions, it was decided to further group the twelve themes under the four pillars of the NSP (Detect, Treat, Prevent, Build); thematic groups met in the four pillar groups to further combine and later present findings and recommendations for added feedback from all JMM participants. Finally, an executive summary was created from the state, thematic, and pillar presentations. This summary of key findings and recommendations was presented on the final day of the JMM to high-level representatives from the Ministry of Health and Family Welfare (MoHFW) and WHO.

Following the summary of key recommendations, the designated leads for Thematic, State, and District Teams submitted draft written reports to cover each of these designated areas. These reports were consolidated and edited by JMM participant (M Monsicat), then further reviewed and edited by JMM Lead (KG Castro), and submitted to WHO Leads (M Parmar, R Ramachandran, and K Rade) and RNTCP Deputy Director General-TB (KS Sachdeva).

1.3 Background: Epidemiology, Surveillance, Supervision, Monitoring and Evaluation

After decades of successful program implementation, India has accomplished numerous impressive achievements in tuberculosis prevention, care and control. Since its inception, the RNTCP has contributed to screening more than 80 million people for tuberculosis, successfully treated 15 million patients and saved millions of lives.² However, India continues to bear the largest number of TB patients, and TB-related deaths in the world.³ The epidemiology of tuberculosis in India is heterogeneous, both from an epidemiological perspective and in terms of programmatic performance.⁴ Results from subnational TB prevalence surveys^{5,6,7,8,9,10,11} annual rate of tuberculosis infection (ARTI) surveys¹² and analysis of routinely collected programme

² Mandal S, Chadha VK, Laxminarayan R, et al. Counting the lives saved by DOTS in India: a model-based approach. *BMC Med* 2017;15:47.

³ World Health Organization. Global tuberculosis report, 2019. WHO: Geneva, 2019. (WHO/CDS/TB/2019.15).

⁴ Chadha VK. Tuberculosis epidemiology in India: a review. *Int J Tuberc Lung Dis*. 2005;9:1072–82.

⁵ Aggarwal AN, Gupta D, Agarwal R, et al. Prevalence of pulmonary tuberculosis among adults in a north Indian district. *PLoS One*. 2015 Feb 19; 10(2):e0117363.

⁶ Chadha VK, Kumar P, Anjinappa SM, et al. Prevalence of pulmonary tuberculosis among adults in a rural sub-district of South India. *PLoS One* 2012;7:e42625.

⁷ Katoch K, Chauhan DS, Yadav VK, et al. Prevalence survey of bacillary pulmonary tuberculosis in Western Uttar Pradesh, India. *J Infect Pulm Dis*. 2015;1:1–7.

⁸ Kolappan C, Subramani R, Radhakrishna S, et al. Trends in the prevalence of pulmonary tuberculosis over a Period of seven and half years in a rural community in South India with DOTS. *Indian J Tuberc* 2013; 60:168–176.

⁹ Narang P, Mendiratta DK, Tyagi NK, et al. Prevalence of pulmonary tuberculosis in Wardha district of Maharashtra, Central India. *J Epidemiol Glob Health*. 2015;S2210-6006(15)00035-0.

¹⁰ Rao VG, Bhat J, Yadav R, et al. Prevalence of pulmonary tuberculosis – a baseline survey in central India. *PLoS One* 2012;7:e43225.

¹¹ Sharma SK, Goel A, Gupta SK, Mohan K, Sreenivas V, Rai SK, et al. Prevalence of tuberculosis in Faridabad district, Haryana State, India. *Indian J Med Res*. 2015;141(2): 228–235.

¹² Chadha VK, Sarin R, Narang P, et al. Trends in the annual risk of tuberculous infection in India. *Int J Tuberc Lung Dis*. 2013;17:312–9.



surveillance data^{13,14} reveal substantial local variation in prevalence, rates of HIV coinfection, drug-resistant forms of TB, and utilization of TB services in the private sector.

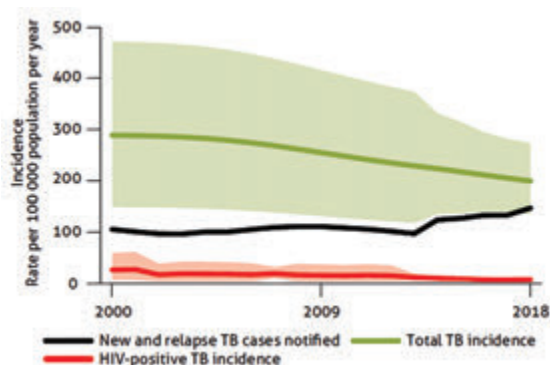
As mentioned in the Methods section, an abridged epidemiological review of TB in India was conducted in the weeks before the JMM. The information that follows is a summary of the full report and is meant to set the context for the observations, findings, and recommendations that follow.

TB Burden

TB Incidence

In 2018, India notified 2,155,894 patients,¹⁵ representing a 23.9 percent increase in total notifications as compared to 2015.¹⁶ The total estimated TB incidence in 2018 was 199 patients per

Figure 2: Trends in annual number of notified TB patients, estimated TB incidence among new, previously treated (relapse) and HIV positive – India: 2000–2018.



Source: WHO Global TB Report, 2019.

100,000 persons (95% Confidence Limits [95%CL]: 136–273).¹⁷ TB incidence appears to be on the decline; with a 8.3 percent rate decrease since 2015 (2015: 217; 95%CL: 112–355).¹⁸ These trends appear to be consistent among new, previously treated and HIV positive patients (Figure 2).

It should be noted that current estimates of incidence rely on the extent of under-reporting (assumed at 40 percent based on expert opinion). However, recent analysis of private drug sales data suggested that an enormous number of TB patients are seeking treatment in the private sector (1.2–5.3 million patients per year).¹⁹ While it is unknown how many of the patients studied were over-diagnosed, there are concerns that the true incidence may be much higher than has been estimated, despite consistent and stable trends in drug sales.²⁰ The pending results of the national prevalence survey holds promise to recalibrate our assumptions and calculate more accurate burden estimates.

TB Prevalence

Direct estimates of TB prevalence have not been obtained since the first nationwide prevalence survey in 1955–1958.²¹ Current estimates for national TB prevalence are mathematically derived from previously conducted state-based surveys.²² In 2009, national TB prevalence was estimated at 301 per 100,000 population based on annualized adjusted data from sub-national surveys among about 715,989 participants across 10 geographies (Table 1).²³ National TB incidence estimates are derived from the prevalence data of the Gujarat survey alone by dividing the prevalence estimate by

¹³ Joint Monitoring Mission India. Report of the Joint Monitoring Mission India, 2015. Available from: <http://www.tbonline.info/media/uploads/documents/jmmdraft2015.pdf>.

¹⁴ Government of India, Ministry of Health and Family Welfare, Central TB Division. TB India 2017: Revised National Tuberculosis Control Programme Annual Status Report. New Delhi: Government of India, 2018.

¹⁵ World Health Organization. Global tuberculosis report, 2019. WHO: Geneva, 2019. (WHO/CDS/TB/2019.15).

¹⁶ World Health Organization. Global tuberculosis report, 2016. WHO: Geneva, 2016. (WHO/HTM/TB/2016.13).

¹⁷ World Health Organization. Global tuberculosis report, 2019. WHO: Geneva, 2019. (WHO/CDS/TB/2019.15).

¹⁸ World Health Organization. Global tuberculosis report, 2016. WHO: Geneva, 2016. (WHO/HTM/TB/2016.13).

¹⁹ Arinaminpathy N, Batra D, Khaparde S, et al. The number of privately treated tuberculosis cases in India: an estimation from drug sales data. *Lancet Infect Dis*. 2016 Nov;16(11):1255-1260.

²⁰ Arinaminpathy N, Batra D, Maheshwari N, et al. Tuberculosis treatment in the private healthcare sector in India: an analysis of recent trends and volumes using drug sales data. *BMC Infect Dis*. 2019;19(1):539.

²¹ Indian Council of Medical Research. Tuberculosis in India: A National Sample Survey; ICMR Special Report Series No.34, 1955–1958. ICMR: New Delhi, 1959.

²² Chadha VK, Anjinappa SM, Dave P, et al. Sub-national TB prevalence surveys in India, 2006–2012: Results of uniformly conducted data analysis. *PLoS One*. 2019 Feb 22;14(2):e0212264.

²³ Chadha VK, Anjinappa SM, Dave P, et al. Sub-national TB prevalence surveys in India, 2006–2012: Results of uniformly conducted data analysis. *PLoS One*. 2019 Feb 22;14(2):e0212264.

the estimated duration disease and applying the rate of decline in annual ARTI. Thus, in 2018, the estimated TB incidence was 2.7 million (1.8–3.7 million) patients. This estimate has declined at a steady pace of 2 percent per year since 2015. Applying the observed decline of 4.5 percent per year in annual risk of TB infection, (as the trends in ARTI have been observed to be directly related to trends in prevalence), the estimated incidence in 2019 would be about 200 per 100,000 population.

While a nationwide national prevalence survey has begun (September 2019), results from the 500,000 persons, 625 survey sites will take longer to complete and finalize. In the interim, a recent publication summarized sub-national surveys and revealed wide geographic variation and discordance with the corresponding annual notification rates (Table 1).²⁴

Table 1: Subnational prevalence survey estimates, and prevalence to notification ratio.

Location (year)	Estimated prevalence* among bacteriologically-positive patients (95% CI)	RNTCP notification rate* for bacteriologically-positive patients corresponding to the mid-year of the survey	Prevalence to notification ratio
Banda, Uttar Pradesh (2009)	528 (434, 623)	76	6.9:1
Chennai, Tamil Nadu (2011)	357 (295, 419)	70	5.1:1
Faridabad, Haryana (2008)	171 (124, 218)	74	2.3:1
Gujarat (2011)**	439 (371, 507)	95	4.6:1
Jabalpur, Madhya Pradesh (2009)	337 (258, 416)	69	4.9:1
Kanpur, Uttar Pradesh (2009)	481 (277, 686)	59	8.2:1
Wardha, Maharashtra (2008)	189 (140, 237)	62	3.0:1
Pooled Estimate	350 (261, 439)	72	4.9:1

*per 100,000 persons

**state-wide survey

Adapted from: Chadha VK, Anjinappa SM, Dave P, et al. 2019

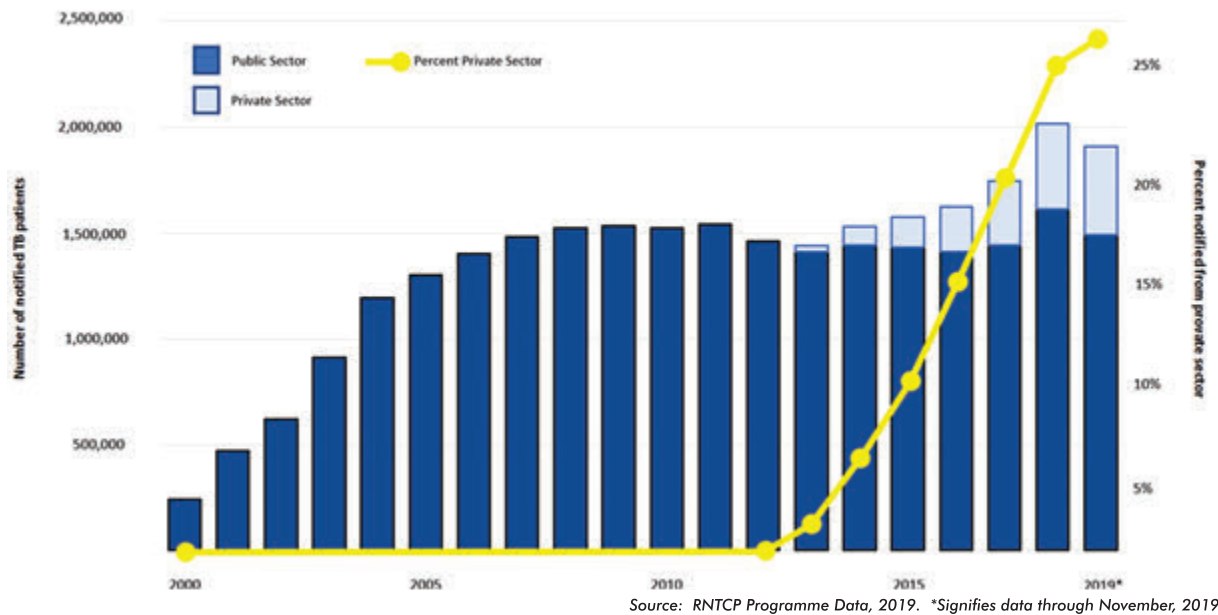
The observed ratio of TB prevalence to TB notification rates reported in this study was 4.9:1 (range: 2.3–8.2 to 1).²⁵ These findings suggested – in addition to the Arinamipathy et al. estimates noted above – a substantial proportion of patients remain outside the programme or remain undiagnosed and untreated in the community. Noteworthy targeted and nationwide efforts have attempted to address this gap. In 2012, the GoI declared TB as a notifiable disease. All public and private health providers are now required to notify all diagnosed and/or treated TB patients to their respective District TB officers. Mandatory

notification not only improved epidemiological surveillance but also extended the range of services available to patients from the RNTCP. All registered patients may now access accurate diagnosis, effective no-cost treatment, including treatment for drug-resistant forms of TB, contact tracing (screening, testing, treatment as appropriate), and social support systems. Indeed, the proportion of patients notified from the private sector has substantially increased. In 2013, only 2 percent of all notified patients were from the private sector; this proportion has increased to 28 percent in 2019 (Figure 3).

²⁴Chadha VK, Anjinappa SM, Dave P, et al. Sub-national TB prevalence surveys in India, 2006–2012: Results of uniformly conducted data analysis. PLoS One. 2019 Feb 22;14(2):e0212264.

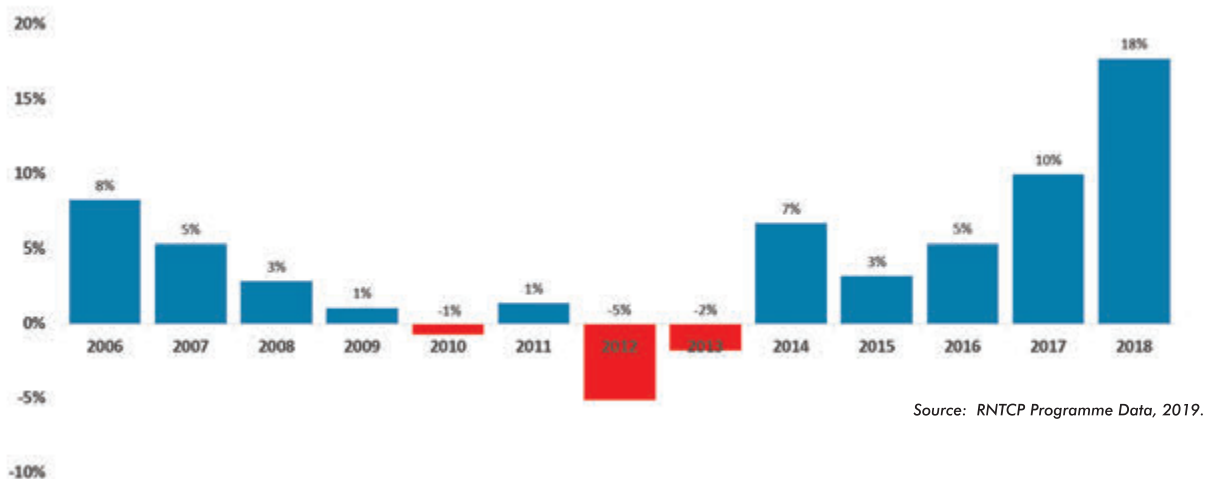
²⁵Chadha VK, Anjinappa SM, Dave P, et al. Sub-national TB prevalence surveys in India, 2006–2012: Results of uniformly conducted data analysis. PLoS One. 2019 Feb 22;14(2):e0212264.

Figure 3: Number of notified TB patients from public and private sectors, 2000–2019.



Overall case notification has also improved since the last JMM. A significant year-after-year case notification increase has been observed since 2015 (Figure 4), including an 18 percent increase in overall notifications from 2017 to 2018.

Figure 4: Percent annual notification difference from the preceding reporting year - India 2006-2018



It remains unclear if the positive trend for increases in case notifications resulted in more TB contact investigations, more opportunities to prevent transmission, or reduced the progression from infection to disease with impacting overall

incidence. Recent models suggest that focus on TB disease alone has a limited impact on the reduction in future incidence without the additive effect of TB preventive treatment for people with latent TB infection (LTBI).²⁶ Current estimates for the number

²⁶Houben R, Menzies NA, Sumner T, et al. Feasibility of achieving the 2025 WHO global tuberculosis targets in South Africa, China, and India: a combined analysis of 11 mathematical models. *Lancet Glob Health*. 2016;4:e806–e815.

of persons with LTBI in India is substantial.²⁷ Assuming a conservative average of four household contacts per notified patient and 50 percent tuberculosis infection rate among them, an estimated 4 million new tuberculosis household

infections occur in India every year.^{28,29,30} Without further action and investment, 24 million new tuberculosis household infections will occur by 2025 (Table 2).³¹

Table 2: Potential burden of latent tuberculosis infection among household members by antituberculosis drug resistance profile, India—2016.

Drug susceptibility testing results	Proportion with result n (95% CL)	Estimated number of TB index patients n (95%CL)	Estimated number of household TB infections n (95%CL)
Drug susceptible	72.0 (70.7, 73.2)	1 263 569 (1 240 755 to 1 284 629)	3 032 566 (2 977 812 to 3 083 110)
Any resistance to isoniazid	11.1 (10.3, 12.4)	194 800 (180 761 to 217 615)	194 800 (180 761 to 217 615)
Any resistance to rifampicin	6.2 (5.5, 6.9)	108 807 (96 526 to 121 092)	108 807 (96 526 to 121 092)
Any resistance to fluoroquinolone	5.1 (4.5, 5.8)	89 503 (78 973 to 101 788)	89 503 (78 973 to 101 788)
Pooled Estimate	--	--	3 976 030 (3 862 310 to 4 140 291)

Adapted from: Moonan PK, Nair SA, Chadha VK, et al. 2011

TB Mortality

As observed in the 2015 JMM report,³² there remains no complete reporting of the accurate causes of death in India. Mortality estimates were derived jointly under the aegis of Indian Council of Medical Research (ICMR) and Institute for Health Metrics and Evaluation (IHME) using the vital registration data. The mortality age-stratified rates were rescaled to sum all-cause mortality using a modelling approach that converges with trends with TB incidence and TB prevalence. Various co-variables were used to inform the model. In 2018, this analysis estimated 450,000 (including TB attributable deaths in PLHIV) persons died of TB. TB and HIV together account for 5.4 percent of all deaths in 2018, the percentage contribution being highest in the productive age groups of 15–39 years and 40–69 years at 11.5 percent and 6.9 percent respectively.

At the global level, India follows the routine surveillance and reporting guidelines recommended by the WHO and considers any death that occurs during TB treatment as a TB-related death. Attributing all-cause mortality can overestimate TB case-fatality rates. Thus, mortality estimates in India rely on a subset of data from mostly urban (but weak) vital registration systems. The risk of bias towards underestimation of TB deaths remains high as medical certification is less likely in rural areas, and amongst the poor – two populations at greatest risk of TB mortality. In 2018, less than 15 percent of all deaths in India had a medically certified cause of death registered with civil registration; a substantial proportion of certified deaths were attributed to cardiac or respiratory arrest. Nevertheless, WHO estimated that 440,000 (95%CL: 408,000–472,000) HIV-negative persons died of TB in 2018.³³ This

²⁷Cohen A, Mathiasen VD, Schön T, Wejse C. The global prevalence of latent tuberculosis: a systematic review and meta-analysis. *Eur Respir J*. 2019;54(3):1900655.

²⁸Narasimhan P, MacIntyre CR, Mathai D, et al. High rates of latent TB infection in contacts and the wider community in South India. *Trans R Soc Trop Med Hyg*. 2017;111:55–61.

²⁹Office of the Registrar General and Census Commissioner, India, 2018. HH-01. Normal households by household size. Available from: <http://www.censusindia.gov.in/2011census/hh-series/hh01.html>.

³⁰Khaparde K, Jethani P, Dewan PK, et al. Evaluation of TB Case Finding through Systematic Contact Investigation, Chhattisgarh, India. *Tuberc Res Treat*. 2015; 670167.

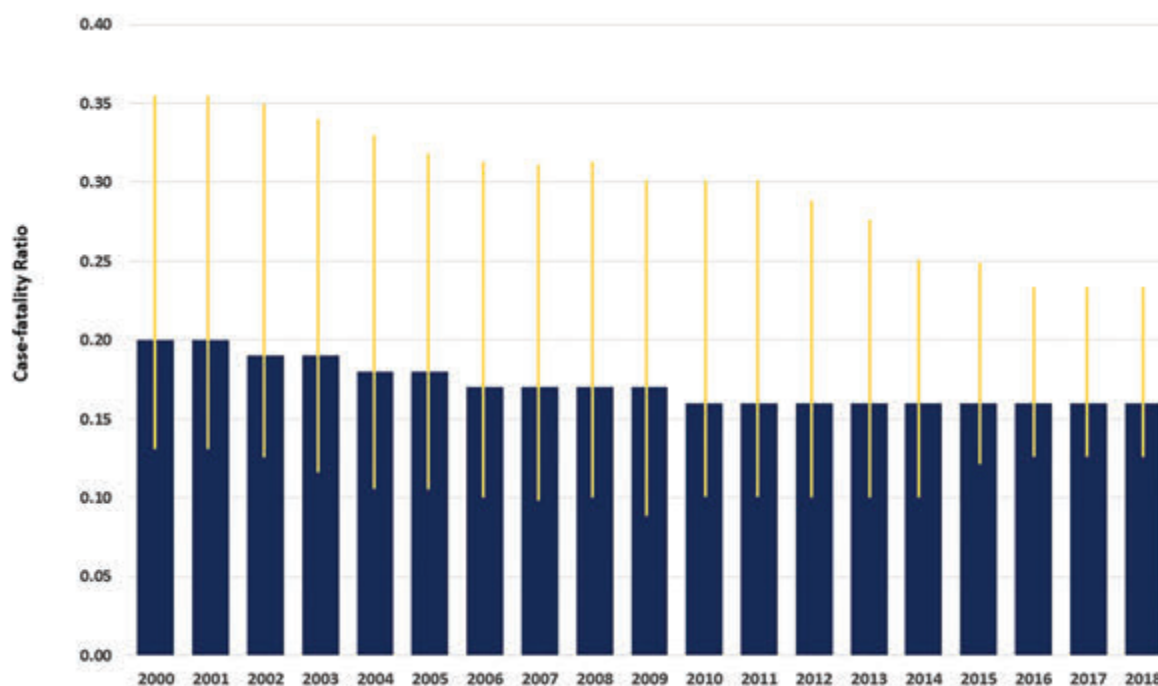
³¹Moonan PK, Nair SA, Chadha VK, et al. Tuberculosis preventive treatment: the next chapter of tuberculosis elimination in India. *BMJ Glob Health*. 2018; 3(5):e001135.

³²Joint Monitoring Mission India. Report of the Joint Monitoring Mission India, 2015. Available from: <http://www.tbonline.info/media/uploads/documents/jmmdraft2015.pdf>.

translates into an estimated TB mortality rate of 32 deaths per 100,000 (95%CL: 30,000– 35,000).³⁴ Using the best available data from the Global Disease Burden Studies conducted in 2013, and 2016, an estimated 545,516 (95%CL: 450,129–650,735) HIV-negative persons die of TB annually in India;^{35,36} including an estimated TB mortality rate of 40 deaths per 100,000 (95%CL: 33–48), 14,000,000 years of life lost (YLL) per year.³⁷ YLL is an estimate of the average years a person would have lived if he or she had not died

prematurely. As an alternative measure of mortality rates, this method gives more weight to deaths that occur among younger persons. Thus, the interpretation of 14 million YLL relative to 40 deaths per 100,000, suggests more younger persons are dying of TB than older persons in India. The annualized case-fatality ratio (i.e. estimated mortality / estimated incidence) is presented in Figure 5. The case-fatality ratio has remained stable over time.

Figure 5: Annualized case-fatality ratio – India, 2000–2018.



95% confidence limits are represented by yellow lines.

Source: RNTCP Programme Data, 2019.

³³World Health Organization. Global tuberculosis report, 2019. WHO: Geneva, 2019. (WHO/CDS/TB/2019.15).

³⁴World Health Organization. Global tuberculosis report, 2019. WHO: Geneva, 2019. (WHO/CDS/TB/2019.15).

³⁵Murray CJ, Ortblad KF, Guinovart C, et al. Global, regional, and national incidence and mortality for HIV, tuberculosis, and malaria during 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2014;384(9947):1005-70.

³⁶Menon GR, Singh L, Sharma P, et al. National Burden Estimates of healthy life lost in India, 2017: an analysis using direct mortality data and indirect disability data. *Lancet Glob Health*. 2019;7(12):e1675-e1684.

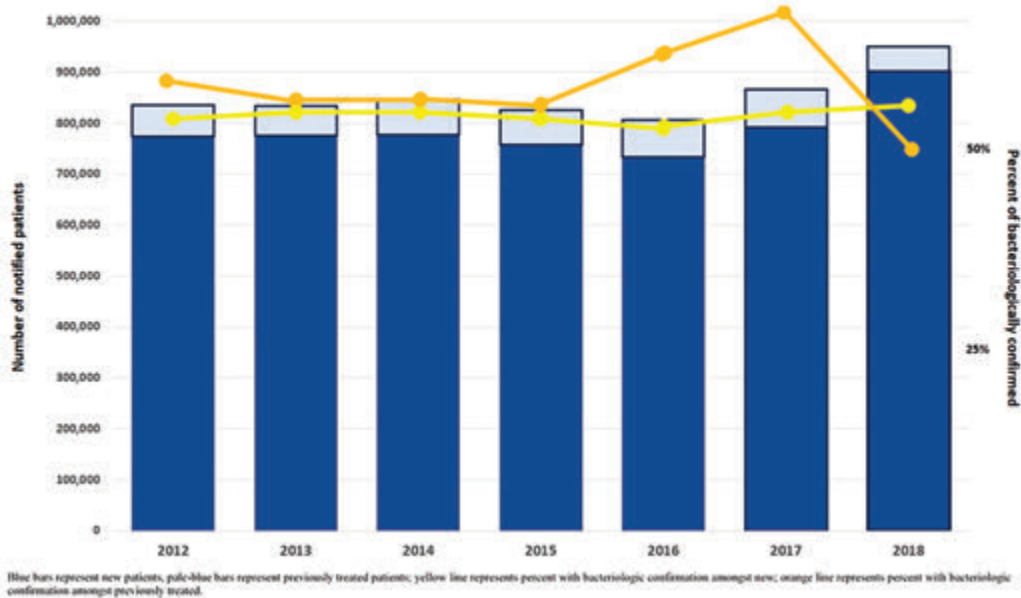
³⁷Menon GR, Singh L, Sharma P, et al. National Burden Estimates of healthy life lost in India, 2017: an analysis using direct mortality data and indirect disability data. *Lancet Glob Health*. 2019;7(12):e1675-e1684.

Presumptive examinations, bacteriologic confirmation, and HIV testing

Accurate diagnosis is the leading prognostic factor for curing TB. Bacteriologic confirmation of TB disease is essential for starting the most effective treatment course and to monitor clinical outcomes. Recent models suggest that improving access to accurate diagnosis by simply replacing sputum-smear microscopy with rapid molecular test such as

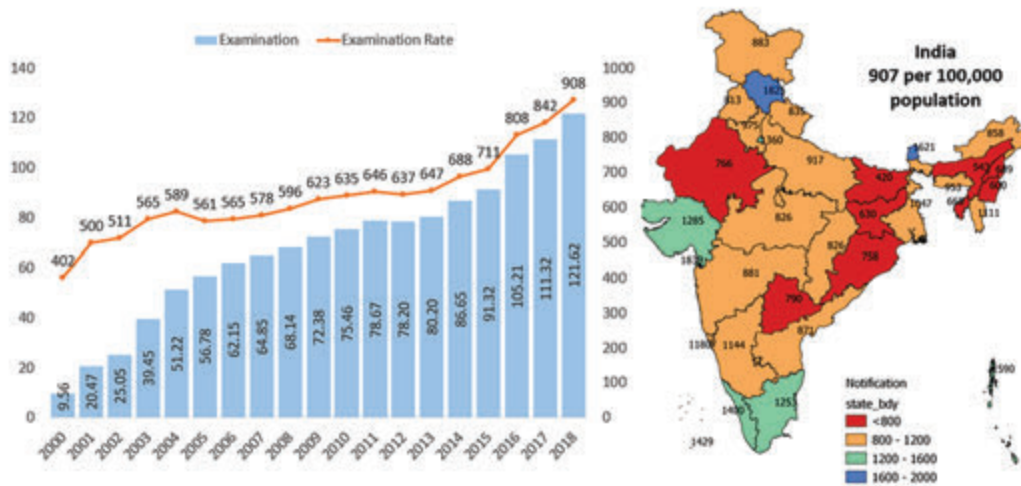
CB-NAAT with GeneXpert (Xpert MTB/RIF) can result in a 7 percent annual reduction in TB incidence, and 12 percent annual reduction in TB mortality.³⁸ Since 2012, bacteriologic confirmation amongst new and previously treated patients in the public sector has remained relatively stable (Figure 6). This is despite the number of presumptive examinations increasing over time with wide geographic variation (Figure 7).

Figure 6: Bacteriologically confirmed notifications amongst new and previously treated patients – India, 2012–2018.



Source: RNTCP Programme Data, 2019.

Figure 7: Number of and rate examinations amongst presumptive TB patients – India, 2000–2018.

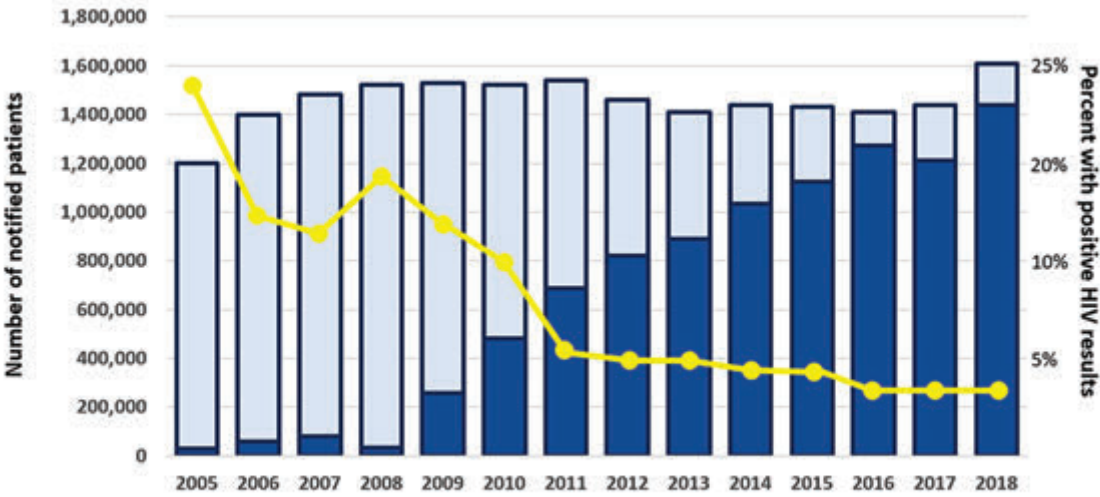


Source: RNTCP Programme Data, 2019.

It is expected that the number and proportion of examinations and bacteriologically confirmed patients will increase overtime with the proposed installation and utilization of CB-NAAT, especially in regions previously underperforming. The proportion of drug-resistant patients diagnosed and treated is also expected to increase with CB-NAAT utilization with approved rapid diagnostic tests, such as Xpert MTB/RIF and/or TrueNat MTB and TrueNat MTB-RIF Dx.

Since 2005, 9,421,533 patients received HIV testing during TB treatment, among these 453,713 (4.8 percent) had positive results. HIV testing has substantially increased overtime; from less than 2 percent tested in 2005 to more than 89 percent tested in 2018. During this time, the percent with positive results has significantly declined (Figure 8). In 2018, 49,047 TB patients tested positive for HIV, 44,142 (90 percent) received ART.

Figure 8: Number of TB patients tested for HIV and percent with positive results – India, 2000–2018.



The pale-blue bars represent notified TB patients, the blue bars represent number of TB patients tested for HIV and the yellow line represents percentage with positive HIV results.

Source: RNTCP Programme Data, 2019.

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Drug resistant tuberculosis

Substantial investments to scale up quality-assured laboratory services throughout the country have been made since the 2015 JMM. Drug-susceptibility testing (DST) is now available to detect resistance against the most commonly used anti-TB drugs, paving the way for appropriate treatment



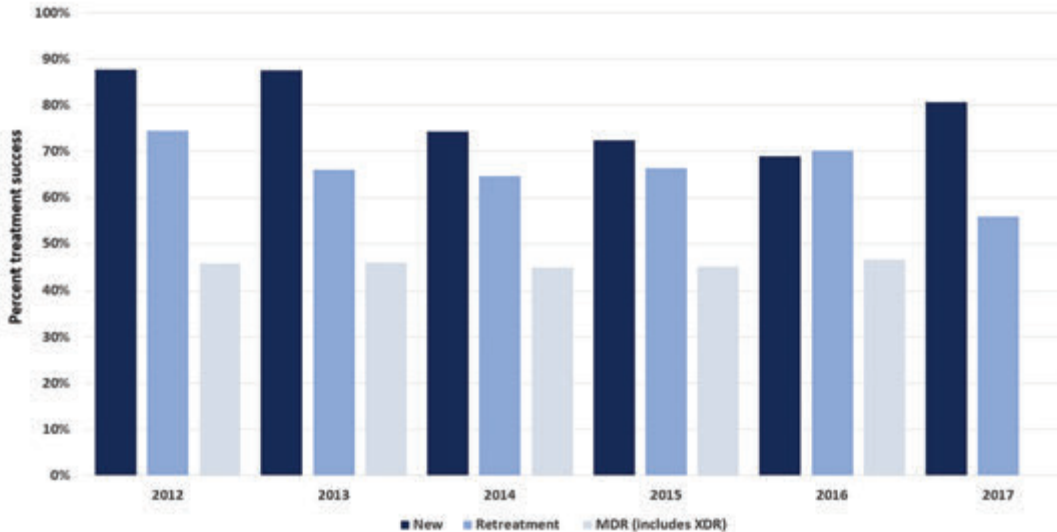
selection of people with drug-resistant TB through individualized, DST-guided regimens. During 2007–2018, India tested 2,798,599 patients using CB-NAAT and line-probe assays (LPAs). These tests — which remarkably reduce the time to MDR identification from months to days — detected 236,725 drug-resistant TB patients. Among those tested, 166,472 (70%) were started on MDR-TB treatment, including 11,948 patients with a more severe form of extensively drug resistant TB (XDR-TB). In 2018, 797,263 patients were tested, 58,347 were diagnosed as drug-resistant (7%), and 46,569 (80%) were started on PMDT. Provisional information for 2019 estimate that 67,241 RR-/MDR-TB patients will be notified (85 percent of NSP target), and 59,945 (89%) placed on PMDT. The RNTCP is hereby commended for an impressive scale up and performance in a relatively short period of time. However, despite a commitment to implement universal DST for people diagnosed with TB, a substantial proportion of TB patients (approximately 64%) remain without an effective DST-guided treatment in 2018. In 2018, WHO

reported an estimated 130,000 (95% CL: 77,000, 198,000) patients with RR-TB, and an estimated 9 RR-TB patients per 100,000 population.³⁹

Treatment outcomes

At a national-level, TB treatment success (i.e., completing treatment or sputum-smear conversion) has been relatively stable amongst new sputum-smear positive TB patients with drug susceptible disease (Figure 9.) However, amongst patients with drug-resistant TB treatment success remains poor (below 50 percent) and there has been no meaningful change for several years. Also, there is a worrisome trend for decline in treatment success amongst previously treated TB patients (Figure 9). Death during DR-TB treatment remains relatively high, at 20 percent, and a substantial proportion of drug-resistant patients are lost to follow-up (18 percent). A recent study suggested a significant proportion of deaths during MDR-TB treatment may be attributed to TB-related causes.⁴⁰

Figure 9: Annual proportions of successful treatment outcome among new sputum-smear positives, previously treated, and drug-resistant TB patient cohorts– India, 2012–2018*



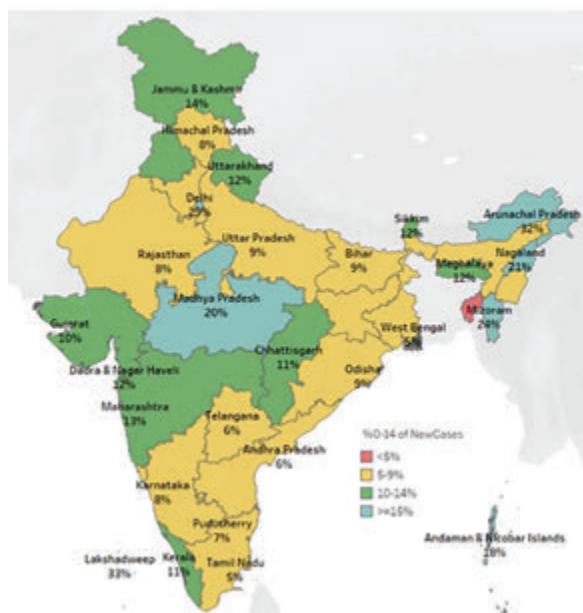
Source: RNTCP Programme Data, 2019.
*MDR cohort for 2017 not available.

³⁹World Health Organization. Global tuberculosis report, 2019. WHO: Geneva, 2019. (WHO/CDS/TB/2019.15).
⁴⁰Naik PR, Moonan PK, Nirgude AS, et al. Use of verbal autopsy to determine underlying cause of death during treatment of multidrug-resistant tuberculosis, India. Emerg Infect Dis. 2018;24(3):478–484.

Vulnerable populations: children, elderly, women, and social determinants for TB.

India also contributes to about one quarter of all pediatric cases in the world and about 10 percent of all notified cases were estimated to be in children aged 0 – 14 years⁴¹. Therefore, an estimated 267,000 incident TB patients aged 0–14 occurred in 2018. However, 129,510 children have been notified in 2018 representing less than 6 percent of all notifications. Children continue to be relatively underrepresented in the national TB surveillance system. While the number of notifications amongst 0–14-year-old patients substantially increased over the past five years (n=95,709 in 2014 to n=129,510 in 2018), children are only a minor fraction of total notifications each year (less than six percent annually). There also appears to be substantial geographic variation in pediatric notification (Figure 10).

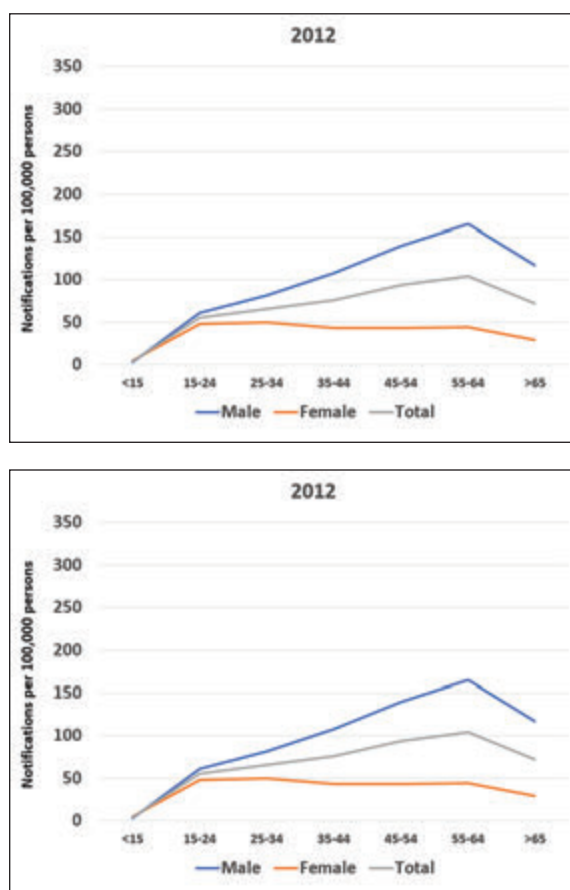
Figure 10: Proportion of pediatric notifications (0–14 year old) amongst all notifications by geography – India, 2018.



Source: RNTCP Programme Data, 2019.

As seen with global TB notifications, the proportion of women with TB appears lower than men. Women-specific TB notifications have increased across all age strata since 2012, but TB notifications are substantially higher for men (Figure 11). The graphs in Figure 11 of TB notification rates for 2012 and 2018 by sex and age-groups, suggest that age-specific TB notification rates (per 100,000) have been steadily higher with increasing age, except for a lower rate in age group above 65. This may reflect missing patients in this older age group. In contrast, TB rates are consistently lower in women than men in all age-groups.

Figure 11: Age- and sex-specific notification per 100,000 person – India, 2012 and 2018.



Source: RNTCP Programme Data, 2019.

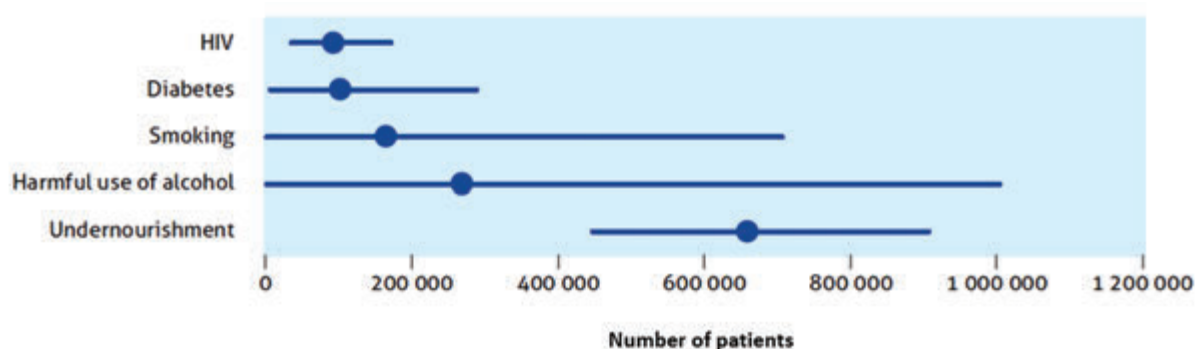
⁴¹Dodd PJ, Gardiner E, Coghlan R, Seddon JA. Burden of childhood tuberculosis in 22 high-burden countries: a mathematical modelling study. *Lancet Glob Health*. 2014;2(8):e453-9.

Socio-economic determinants of health associated with TB include the behavioral, economic, political, social and conditions that influence how and where people are born, develop, live, work, and age.⁴² Apart from accessing medical care, there is increasing evidence of the role of these factors in health and TB epidemiology.⁴³ These determinants influence all stages of TB pathogenesis: risk of exposure, susceptibility for progression to disease, time to diagnosis, time to treatment, treatment compliance, development of drug resistance, relapse, recurrent disease, post-treatment disability, and ultimately cure.⁴⁴

India is simultaneously burdened by multiple health conditions that have been associated with TB, including undernutrition, diabetes, excessive alcohol use, and tobacco smoking. These syndemics (term developed by Merrill Singer in 1990s to describe the aggregation of two or more concurrent or sequential epidemics or disease clusters in a population with biological interactions, which exacerbate the prognosis and burden of disease) are further fueled by poverty, indoor (e.g. solid cooking fuels) and outdoor air pollution, and overcrowding. To date, there has been no

systematic assessment of the burden of socio-economic determinants of TB in India. The only quantification of the true magnitude and contribution of these factors toward the burden of TB in India can be extrapolated from the Global Burden of Disease study.⁴⁵ This analysis quantified the contribution of tobacco, alcohol and raised fasting plasma glucose (including effects of diabetes and pre-diabetes) to the TB burden in India: 4 percent, 11 percent and 11 percent respectively for the year 2010. There is no direct estimate of the contribution of the national prevalence of poverty, undernutrition, overcrowding, and air quality on measures of TB disease burden. Nevertheless, WHO published estimates of the number of TB patients attributable to the five main risk factors (HIV, diabetes, smoking, harmful use of alcohol, and undernourishment) based on mathematical modeling and assumes from the Global Burden of Disease study⁴⁶ and other sources (Figure 12).⁴⁷ Based on this analysis, undernutrition contributed the largest fraction of TB patients in 2018, followed by harmful alcohol use, smoking, diabetes, and HIV, respectively.

Figure 12: Estimated number of TB patients attributable to social determinants of disease – India, 2018.



Source. *Global tuberculosis report, 2019.*

⁴²Lönnroth K, Castro KG, Chakaya JM, et al. Tuberculosis control and elimination 2010–50: cure, care, and social development. *Lancet*. 2010; 375(9728):1814–1829.

⁴³Duarte R, Lönnroth K, Carvalho C, et al. Tuberculosis, social determinants and co-morbidities (including HIV). *Pulmonology*. 2018;24(2):115-119.

⁴⁴Hargreaves JR, Boccia D, Evans CA, et al. The social determinants of tuberculosis: from evidence to action. *Am J Public Health*. 2011;101(4):654-62.

⁴⁵Murray CJ, Ortblad KF, Guinovart C, et al. Global, regional, and national incidence and mortality for HIV, tuberculosis, and malaria during 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2014;384(9947):1005-70.

⁴⁶Murray CJ, Ortblad KF, Guinovart C, et al. Global, regional, and national incidence and mortality for HIV, tuberculosis, and malaria during 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2014;384(9947):1005-70.

⁴⁷World Health Organization. *Global tuberculosis report, 2019*. WHO: Geneva, 2019. (WHO/CDS/TB/2019.15).

To date, there has been no nationally representative study of catastrophic costs for TB in India. Smaller, local studies (with varying methodologies, populations and settings) suggest that 7 to 32 percent of TB patients in India experience catastrophic costs during the diagnosis and treatment of TB.^{48,49,50,51}

Surveillance, Monitoring and Evaluation

The enhancement of the national surveillance system, based on NIKSHAY, since the 2015 JMM was commendable and unprecedented. NIKSHAY was readily available and used by all RNTCP staff, and witnessed at all field visits during this JMM. Most staff used the NIKSHAY mobile phone application, or using RNTCP-supplied e-tablets. NIKSHAY was used for real-time reporting and recording of key variable (e.g., name, age, sex, address, treatment start date, laboratory results, HIV status). The use of NIKSHAY for real-time treatment adherence documentation was lagging and, in most instances, delayed by up to one month.

We observed gaps in a few key surveillance areas. First, data verification, particularly for accuracy, is not consistent nor regular throughout the country. There is no plan in place to check for data verification, or timeliness of entry. Second, we observed duplicative systems of recording information (e.g. laboratory and treatment hard-copy registries), and nearly all field visits reported back the maintenance of both paper-based and electronic records. This often doubles recording and reporting burdens, and opens the surveillance system to potential errors and/or duplications. Third, there is an expanding and evolving

information ecosystem within the health system, yet there is limited interoperability between diverse applications. Fourth, patients with microbiological test results available after notification cannot be changed in NIKSHAY. Hence, there is a strong potential for misclassification of notified cases as clinically diagnosed (vs. bacteriologically-confirmed) within the national TB surveillance system. Fifth, there are unrealistic outcome-based targets, not consistently grounded by field reality. Finally, there is limited capacity for epidemiologic analysis and using data for action throughout the various levels of the national TB programme.

Recommendations

1. Build and mentor a strong surveillance, epidemiology, and monitoring and evaluation workforce. Further investments in TB surveillance staff and systems for accurate, complete, and timely information that ensures high-quality, effective service delivery, monitors performance, and detects and responds to community transmission. A network of national-, state-, and district-level TB Surveillance Units should be established by 2020. Augment the surveillance network with technical assistance to help address emerging priorities, building communities of practice, using local data for local action, and rapidly responding to outbreaks.
2. Use local data for local action; create process indicators that are vital for larger outcomes. A network of National-, state-, and district-level TB Surveillance Units (noted above) should develop processes for ensuring and maintaining accurate, complete, and timely

⁴⁸Prasanna T, Jeyashree K, Chinnakali P, et al. Catastrophic costs of tuberculosis care: a mixed methods study from Puducherry, India. *Glob Health Action*. 2018;11(1):1477493.

⁴⁹Sarin R, Vohra V, Singla N, et al. Identifying costs contributing to catastrophic expenditure among TB patients registered under RNTCP in Delhi metro city in India. *Indian J Tuberc*. 2019;66(1):150-157.

⁵⁰Shewade HD, Gupta V, Satyanarayana S, et al. Active case finding among marginalised and vulnerable populations reduces catastrophic costs due to tuberculosis diagnosis. *Glob Health Action*. 2018;11(1):1494897.

⁵¹Veesa KS, John KR, Moonan PK, et al. Diagnostic pathways and direct medical costs incurred by new adult pulmonary tuberculosis patients prior to anti-tuberculosis treatment - Tamil Nadu, India. *PLoS One*. 2018;13(2):e0191591.

information in NIKSHAY. This team should assess local data for trends in epidemiology, service delivery, monitors performance, and detects and responds to community transmission (e.g., outbreaks). Formal surveillance data integrity plans and processes at the national, state and district levels should be established by 2020. These plans should include processes for data validation and verification.

3. Develop user-friendly, virtual “workspaces” and data visualizations to prompt local public health action. NIKSHAY should include modules that prioritize contact investigation information, TPT surveillance, and post-treatment surveillance.
4. Accelerate alignment and streamline all health information systems and applications. (Prioritize TB LIMS)
5. Phase out paper-based recording systems to eliminate duplication of effort.

2. Findings and Recommendations

The following findings, observations, and subsequent recommendations are the product of the two-week intensive 2019 WHO-Gol JMM. These observations and recommendations are framed around the four pillars of the NSP, 2017-2025 (Build, Detect, Treat, Prevent), and provided for each of twelve thematic areas.

2.1 Build

2.1.1 Partnerships and Private Provider Engagement

It has been estimated that up to 70 percent of TB patients in India seek care from private providers. The NSP targets indicate the

ambition of the RNTCP and Gol in addressing this issue – a full 97 percent of additional notifications for 2015 to 2020 are projected to come from private sector providers (Table 3). Therefore, NSP success requires private provider engagement success - across the entire diagnostic and treatment cascade. This requires a doubling of the national TB response – converting a partial program (mostly covering the public sector) to a full program (covering both public and private sectors), and include all the necessary expansions in capacity for fund flows, human resources, logistics, patient support systems, and monitoring of outcomes.

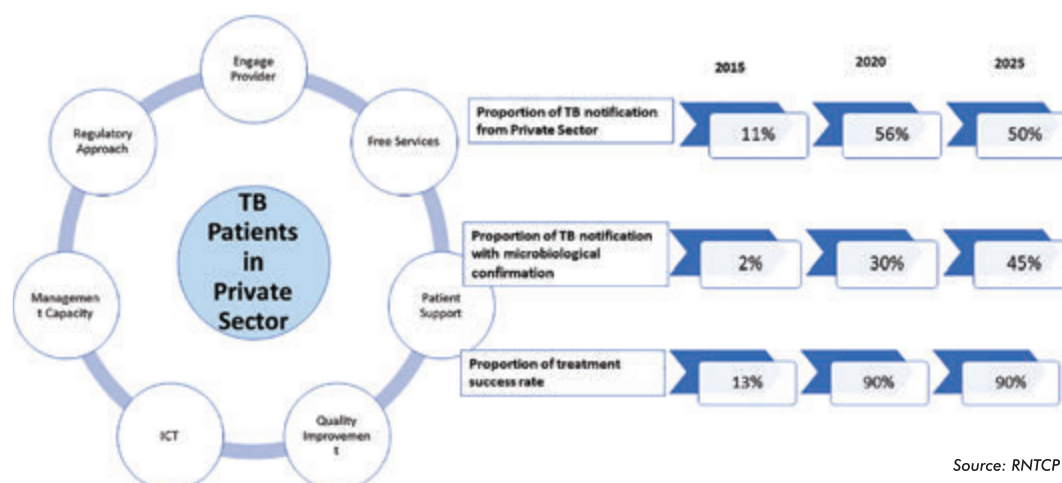
Table 3: NSP’s Baseline and Targets for Total TB Patient Notification and Total TB Patient Notification from Private Providers

OUTCOME INDICATORS	Baseline	Target		
	2015	2020	2023	2025
1. Total TB patient notification (in millions)	1.74	3.6	2.7	2
2. Total patient Private providers notification (in millions)	0.19	2	1.5	1.2

Source: National Strategic Plan for Tuberculosis 2017-25: Elimination by 2025

The NSP also outlines the various approaches necessary, and the associated sub-targets in this effort, which can be seen in Figure 13 below.

Figure 13: Reaching TB Patients in the Private Sector



Source: RNTCP

Private provider engagement (PPE) in India was historically a combination of two efforts: (1) engagement of private medical colleges, which was generally successful and continues to date; and (2) pilot engagement of other private providers prior to 2018, which produced some good results and lessons but relied heavily on donor funding, and did not persist (or expand) after projects ended. Domestic investments in PIPs and PPSAs have facilitated private sector engagement but have not been expanded to scale.

The main models for PPE more recently and their characteristics are:

1. Universal Access to TB Care (UATBC)
 - a. Three major sites (Mumbai, Patna, Mehsana) starting in 2014
 - b. Vouchers for program drugs and diagnostics allowed tracking of patients through the cascade
 - c. Use of call center for notification and adherence support
 - d. Full patient cascade
 2. Private Provider Support Agency (PPSA)
 - a. Evolved from the UATBC approach
 - b. Main model being pursued now and in the near-future plans
 - c. Like UATBC, significant HR for provider engagement, linkages, and patient support. In the JMM team's judgement, it is essential to have such intensive support when there is a high density of private providers (e.g., urban) and/or low ratio of public staff: TB patients
 - d. Like UATBC, the concept is outsourced management, and the intention was to improve diagnostic processes and use program diagnostics and drugs
 - e. In reality, current PPSAs rely primarily on physicians' own diagnostic processes (only 25% of PPSA notifications are bacteriologically confirmed (BK+)) and on patients buying market drugs (only 7% of PPSA notifications use program FDCs)
 - f. Guidance for contracting these and other services was launched during the second week of the 2019 JMM
 - g. Plan is in place to contract for ~350/750 districts within the coming financial year
3. RNTCP direct engagement
 - a. Primarily using existing RNTCP staff (Public-Private Mix (PPM) coordinator to direct and motivate, TBHVs to track patients)
 - b. So far has yielded ~2/3 of private notifications
 - c. In the JMM team's assessment, this is currently a weak model that needs strengthening
 - d. Can be supported by Schedule H1 drug (i.e., drugs that are only sold by prescription of medical practitioners) notification: where operational, the H1 system can identify patients who can then be assigned to an HV
 - e. Supported by NIKSHAY – and some hospital record systems may become interoperable with NIKSHAY
 - f. Overall, the remaining tasks beyond notification (Universal Drug Susceptibility Testing (UDST), HIV, and Diabetes (/DM) screening, outcomes, etc.) still have notable gaps in performance

Achievements

The RNTCP has made notable progress in private provider engagement. Achievements to date are listed below:

- Interface agency approach (PPSA)
- Gazette Notification for Mandatory TB Notification
- Improved NIKSHAY
- Establishment and Use of the Call Centre
- Incentives for TB Notification
- NIKSHAY Poshan Yojana (NPY)

Additionally, private sector notifications have increased drastically (Figure 14) to reach over half a million nationally. This major achievement has greatly improved surveillance and awareness of the true TB burden, and made important inroads on bridging the cultural and programmatic divide between public and private sectors. To help drive this effort, 48 patient provider support agencies (PPSAs; described further below) have been operating using input-based financing and

producing both results and lessons for the future, and 145,000 and 35,000 private sector patients have benefited from the use of public sector CB-NAATs and fixed-dose combination (FDC) drug programs, respectively. More recently, 48 new PPSAs have been contracted on an output-based financing arrangement through domestic budget – since this is a recent effort, these PPSAs are not yet producing results.

Figure 14: TB Patients Notified from the Private Sector, 2012-18

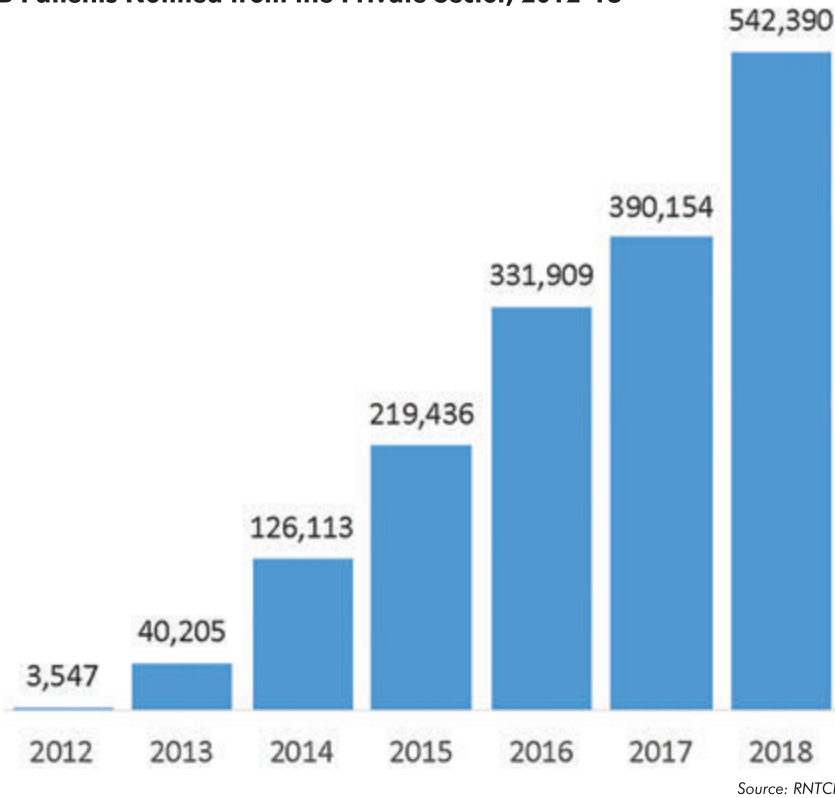
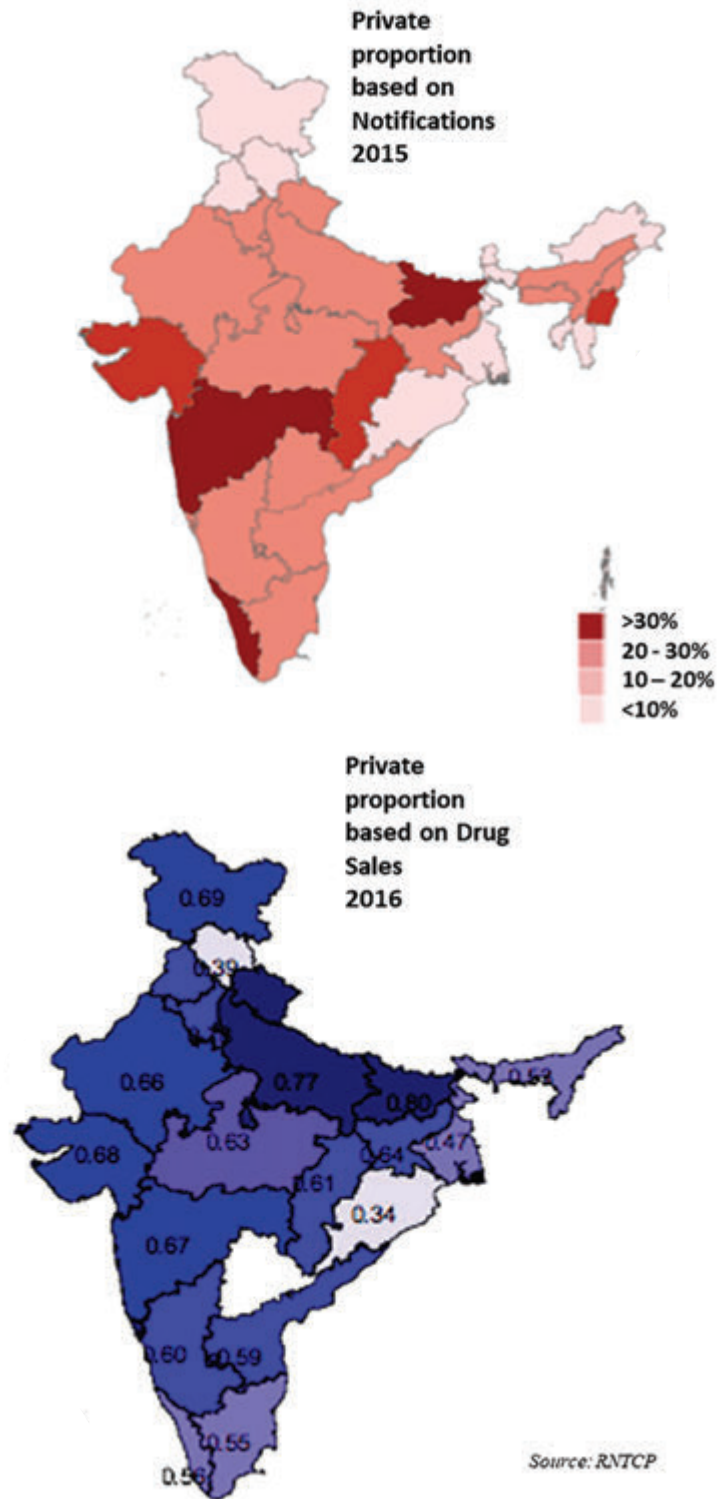


Table 4: TB Patient Notification from the Private Sector and Other TB Continuity of Care Indicators

Indicators	2017	2018	2019*
Proportion of TB notification from Private (state range: <10-56%)	19%	25%	28%
Proportion of microbiologically confirmed TB patients out of those notified by private sector	14%	16%	20%
Treatment success rate of TB Patients in the private sector	38%	60%	NA



Figure 15: Heat Maps Depicting the Variation by State of Private Provider TB Case Notifications and Private Provider TB Drug Sales



Challenges and Opportunities

Challenges:

- Less than 80% of privately notified patients (even in PPSA) currently don't benefit from programme services⁵²
- Weak government capacity for contract management
- Especially, unreliability of Govt payment (noted during JMM site visits, but not yet quantitated comprehensively)
- Limited experience of potential implementers in performing PPSA functions
- Data challenges: outcomes, transfers, duplicates, etc.

Opportunities:

- Excellent NSP and high-level commitment to ambitious PPE
- Introduction of digital data and adherence technologies
- New Partnership Guidance and pending Technical Support Units (TSUs)
- Existing engagement models
- Increased enforcement of mandatory notification / Schedule H-1 in some areas
- Emerging private business models: consolidation, chains, e-pharmacies, etc.
- Expansion of Pradhan Mantri Jan Arogya Yojana (PMJAY)
- Emerging Artificial Intelligence (AI) tools for X-ray reading and predictive analysis
- CTD's collaboration with AI partners

Main Recommendations

The JMM team applauds India's level of ambition and effort in this area, but also recognizes the vast amount of work still remaining to achieve quality PPE at scale. To analyze this in more depth, we now examine two big shifts that the JMM team believes are necessary to move this overall effort forwards:

1. Moving to output-based contracting
2. Improved models to get beyond notification

Shift #1: Output-based contracting

Output-based contracting means that service providers are paid for the results (e.g., notifications, volume of testing, achievement of quality of care measures, and successful treatment outcomes) rather than for inputs (e.g., staffing costs, computers, transportation, training, or other commodities). It is commonly used in health systems globally in both public and private systems – and its increased use is also an important part of the evolution of health systems as countries grow economically. Examples in India include PMJAY, which pays hospitals for each package of care provided. And many low- and middle-income countries adopt output-based contracting and results-based financing to contract Nongovernmental Organizations (NGOs) to deliver public health programs (screening, maternal care, etc.).

The rationale, or expected advantages of output-based contracting, include:

- More accountability of the implementer for the outcome
- More flexibility to the implementer on having innovative ways to implement
- Reduced micro-management by public program and less time spent on rules on inputs, approaches, and processes related to implementation

The first step to implementing output-based contracting is identifying services appropriate for output-based contracting (e.g. the quantity of services must be easy to measure). For TB, these and other issues are addressed in the newly issued [Guidance Document on Partnerships](#), which is a flexible but critical guide to the way forward on contracting both PPSAs and other subsets of TB services.

Output-based contracting raises a number of risks – examples of these potential risks are outlined in the Table 5 below, along with mitigation steps that have been put in place or need to be pursued.

⁵²BK+, UDST, FDC, NPY, PP incentive, public health actions, treatment support, patient information etc.

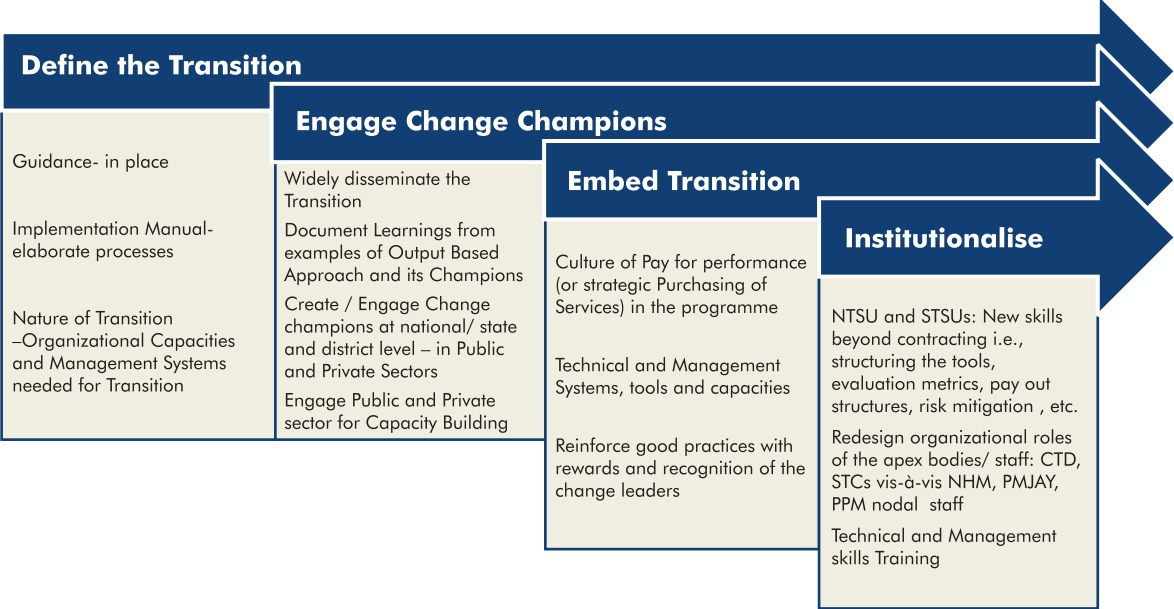
Table 5: Examples of potential risks and corresponding mitigative steps for transitioning to output-based contracting.

Risk(s)	Mitigation
Insufficient budget under PPM, PPSA contracting line at both state and national level.	Ongoing advocacy for fund availability.
Limited government capacity to: <ul style="list-style-type: none"> - Scope specifications and assess market, to negotiate a reasonable contract; - Stick with output-based design and avoid micromanagement; - Avoid procurement and contracting delays that could lead to gaps in services or delay payment to financially fragile Implementing Partners (IPs) (historically National Health Mission (NHM) mechanisms to move files have been slow). 	Build government capacity.
	Provide contract templates in guidance and create additional tools as needed.
	Increased contracting, financial management and monitoring and evaluation (M&E) staff via the planned rollout of the TSUs.
	Consider centralized contracting for some settings.
Limited capacity of IPs to estimate, plan, and deliver required services.	Build capacity on the guidelines, different contracting models, and how to design and submit proposals under these new models.
	Consider national purchasing of private lab and drug services, especially for use in areas without experienced implementers.
	Add a project management system to NIKSHAY so that every implementer doesn't need to create their own such system.
You get what you pay for: a forgotten indicator = a neglected area.	The guidance document(s) include(s) all the relevant and proposed indicators.
Danger that payment targets could motivate the submission of bad data	Implement regular and spontaneous audits, and monitoring processes (household visits, drug refills, etc.) that can be triangulated against the main reported outcome.

Since transitioning from input-based contracting to output-based contracting is such a significant shift in mindset, a deliberate approach to change management is crucial. A suggested framework for such a process is below (Figure 16).



Figure 16: Example framework for shifting from input- to output-based contracting.



Shift #2: Improved models to get beyond notification

In PPE, there has been an invaluable shift from donor-funded projects to nationally owned efforts, but some elements of quality have been lost or require strengthening, as seen by the low performance on indicators beyond notification. Access to donor or publicly funded diagnostics and drugs was a critical component of UATBC not only to reduce the financial burden on patients, but also to improve the quality of diagnosis and care and to track patients through the treatment cascade – if a program is paying for the commodities, it can “see” into the operation of the program. This public supply of commodities was somewhat lost in many of the subsequent PPSAs, but the JMM team recommends a strong effort to re-establish a focus in this area. A number of options for this are outlined below, and the JMM team supports the continued flexibility, as expressed in the Guidance Document on Partnerships, on encouraging local decision-making that aligns such choices to the local situation. Indeed, the use of output-based financing puts more of this decision-making in the hands of the implementing organizations.

For both the PPSA and RNTCP direct engagement models, improving the models requires:

1. More complete notification:
 - a. Schedule H1 drug monitoring can identify non-notified TB patients. The caveat: H1 is only truly operational in 7-10 states, and there is a need for simpler tools to link the H1 and NIKSHAY systems;
 - b. “Soft” engagement: Indian Medical Association (IMA) to disseminate messages to its members, advocacy, and monitoring of outcomes.
2. Tracking patients until treatment outcome:
 - a. Schedule H1 (above) and/or vouchers (see below) can indicate progression of treatment;
 - b. Auditing system are needed to verify outcomes;
 - c. To track TB patients after transfer out, the use of Aadhaar unique identity numbers will be critical, and/or TB Health Visitor (TBHV) or PPSA staff can find out directly from patients
3. Diagnostics and drugs: For PPSAs, RNTCP can

also consider national purchasing of private lab and drug services, especially for use in areas without experienced implementing partners who may struggle to put together the many requisite elements for a strong PPSA. (See below)

Drug Access Options:

The JMM team notes the heavy emphasis in the Guidance Document on Partnerships on programme-supplied FDCs. This will be appropriate in some settings but does run the risk of interruption in supply or stockouts leading to mistrust of the public sector by private providers and risks to private patients, poor contract performance (since the public sector did not hold up its end of the contract), and survival and funding of the overall scheme. The JMM team therefore recommends research, in at least some locations, of the last three options listed below, which make use of the private sector supply chain either partially or completely.

1. Private patient collects program drugs from primary health centre (PHC) (only viable if private patients are willing to shift into relying on drugs provided by public services).
2. Program (or PPSA) places a full course of drugs with the provider; regular calls by TBHVs (or PPSA staff) to check progress (a challenging option for supply chain management since India does not use patient-wise boxes).
3. Place program drugs in local private pharmacies, or Jan-Aushadhi (initiative to make quality drugs readily available in dedicated stores). The program then pays the pharmacy 100 rupees per month per patient for their dispensing services. This scheme is already operational in Mumbai and Mehsana.
4. Place program drugs in the regional stores of pharmacy chains, and pay the chain both for the operation of the local supply chain and for dispensing.
5. Use online pharmacies, especially in sites most chemists have stopped stocking anti-tubercular treatment (ATT).
6. Vouchers for drugs that flow through the private supply chain. If there are concerns

about private sector stock-outs, the avoidance of such stock-outs can be one of the payment metrics in the contract. Establishing such a scheme requires the following:

- a. Negotiate a final sales price with pharmaceutical companies, including the cost of operating the supply chain, and distribution markups (note: these costs in the public sector supply chain are “hidden” under other budget line items);
- b. Use existing private pharma supply chain to get drugs to selected pharmacies;
- c. Distribute vouchers to physician providers;
- d. Pay pharmacies via voucher.

Diagnostic Access Options:

Similar themes emerge in the area of access to diagnostics (and in both areas, the suggested approaches can be strengthened via Direct Benefit Transfer (DBT) payments to patients and providers). For diagnostics, there are insufficient CB-NAAT machines, lab technicians and chest X-ray (CXR) capacity in the public sector, so the JMM team does not consider it viable to use only public diagnostic capacities.

1. Public purchasing of private lab services – with embedded cost of staff, machine, and cartridges. For cartridges, these can be purchased by the private sector under the Initiative for Promoting Affordable and Quality TB Tests (IPAQT) concessionary price (currently patients pay 1600-2200 rupees (\$USD23-30), but it should now be the public sector that picks up the ultimate cost (e.g., via vouchers).
2. Use of the national free diagnostic scheme: in private labs that are co-located with district hospitals, the public sector pays for services, including the cost of the private lab organizing sputum transport.

RNTCP Direct Engagement:

There are a number of recommendations that are specific to RNTCP direct engagement, since this model has limited staff:



1. Additional staff recruitment: States and districts require budgeting guidance on asking for more staff to manage both public and private patients.
2. Document and disseminate existing models for linking patients identified via Schedule H1 drug notification to TBHVs.
3. For tracking patients: Set the expectations that (a) all patients (public and private) in a TB Unit (TU) are the responsibility of the public TU staff, and (b) TBHVs call (check in) with notified private TB patients at least once a month. See also Schedule H1 drug and voucher discussion above to help track patient progress.
4. Leverage professional associations for advocacy, awareness and further education.
5. Limited contracting of the most challenging pieces.
6. Build capacity of PPM coordinators, Senior Treatment Supervisor (STS) and TBHVs.

Additional Recommendations:

The ambition and approaches outlined here are already present in the NSP, with the exception of the shift to output-based financing. Thus, the JMM recommendations focus on strengthening the existing programmatic directions rather than introducing a significant change in direction – but with the recognition that important NSP elements require considerable work. Thus, in addition to the suggestions above, the JMM recommends the following:

1. Clarify ambition level:
 - a. Aim for full coverage, using drug volumes as the denominator.
 - b. Aim for more intense coverage, reaching more providers to catch patients earlier. This prioritization of early detection should include extending rapid molecular diagnostics to the “bottom of the pyramid” primary care sector, including AYUSH and other registered medical practitioners (e.g., World Health Partners (WHP) experience)
2. PPSAs and other partnerships:
 - a. Contract TSUs as soon as possible; provide extensive training and handholding on application of new Guidance Document on Partnerships; adjust guidance frequently in light of experience.
 - b. CTD/National Technical Support Unit (NTSU) to monitor timeliness and completeness of payment to IPs, and resolve problems promptly as required.
 - c. External funding partners to consider co-funding, to de-risk the GoI payments to IPs.
 - d. Make maximum use of the Call Centres on notification, voucher validation, follow-up calls to patients⁵³.
3. CTD to provide guidance on strengthening the RNTCP direct engagement model.
4. Strengthen processes to verify reported outcomes (particularly on treatment success).
5. Ensure that all NIKSHAY improvement cycles consider functionalities for engaging private providers.
6. Public sector to reimburse the purchase of privately-supplied molecular diagnostics and FDCs, capitalizing on efficiencies in private supply chains.
7. Empanelment of selected private hospitals as PMDT providers, and inclusion of these facilities in supply chain for Second Line Drugs (SLDs) programs.
8. Use and expand Schedule H-1 drug reporting to identify TB patients, and improve systems to link from Schedule H1 to NIKSHAY so that programme services are extended to such clients.

⁵³E.g., the use of the call center in Patna enabled them to use a staff to patient ratio of 1:32 versus the 1:15 seen in other efforts.

9. Medium to long term: Work with PMJAY to test mechanisms for including outpatient TB services in social health insurance. Consider using fee for service payments for TB under PMJAY, since this aligns with the current use of DBT for specific payments, and with both the positive and negative lessons in other Asian countries.⁵⁴
10. Conduct regular assessments: prescription audits on quality of prescribing; standardized patients on quality of diagnosis and treatment practices; time and number of providers to reach care; proportion of private diagnoses who are truly TB.
11. NTSU to ensure cross-learning visits to promote a learning agenda on PPSAs.
12. Scale up bundled models of chest X-ray AI, NAAT, Integrated Digital Adherence Technology (IDAT) and electronic pharmacies.

Key Messages

Notifying TB patients is an important gateway, but does not produce the desired public health impact – and risks encouraging complacency. We must also extend the full range of programme services⁵⁵ in a verifiable way. Effective notification needs to be defined as notification linked to care (complete and successful treatment).

1. Both major models need extensive support and adaptation:
 - a. Performance-based contracting is bold and needed. It requires urgent contracting of TSUs by March 2020, and rollout of the [Guidance Document on Partnerships](#), tools, capacity building, digital systems, and efficient payment and contract management measures.
 - b. RNTCP direct engagement model requires documentation, guidance, and tools.
2. Strongly consider using public funds to purchase privately supplied drugs and

diagnostics.

2.1.2 Multisectoral Engagement and Accountability

The NSP (2017-2025) presented well-defined key strategies for multisectoral engagement, though they were spread across a number of sections of the strategy. These included:

- Working across ministries/stakeholders in “Mission mode”;
- Proposing TB impact modelling on social determinants;
- Addressing social determinants through multi-sectoral approach;
- Mapping of key populations and strategies for some populations;
- Prioritized locally-defined groups for active case finding (ACF) within urban, rural and tribal areas

The NSP also included suggested actions for corporate sector involvement and urban TB control, and which are addressed in another section of this report (see sections on Urban Tuberculosis and Health Systems Strengthening, respectively).

During the 2019 JMM, the teams looked at progress made on multisectoral engagement, related to the points above and commitments made at the UNHLM on TB in September 2018, related to multisectoral accountability, and major points regarding multisectoral collaboration and high-level review recommended in the [Multisectoral Accountability Framework for TB \(2019\)](#). This Framework was produced at the request of the World Health Assembly and the United Nations General Assembly. Given the time constraints, members of the JMM were not able to meet with counterparts in other Ministries during its two-week review. Therefore, this brief assessment relied on briefings provided by CTD leadership and staff, and relevant written documents, as well as impressions gained during some field visits.

⁵⁴Wells WA, Stallworthy G, Balsara Z. How tuberculosis programs can navigate the world of social health insurance. *Int J Tuberc Lung Dis*. 2019 Jan 1;23(1):26-37. doi: 10.5588/ijtld.18.0289.

⁵⁵BK+, UDST, FDC, NPY, PP incentive, public health actions, treatment support, patient information etc.

Further, the NSP calls for “mission-mode” actions. By definition, a “mission mode” high-level national TB elimination effort would require clearly defined objectives, scopes, implementation timelines and milestones, measurable outcomes, and service levels. This is yet to be fully realized within and beyond the health sector to enable accountability and fulfillment of vision and goals towards ending TB by 2025. The Prime Minister has made bold commitments and the MoHFW has set forth approaches to aim to meet those commitments through the NSP and additional measures.

Achievements

- The MoHFW has established an Inter-Ministerial Committee for TB with 25 ministries participating so far. It has set its TORs, held two meetings and has the intention to create a joint operational working group.
- With help from partners, the RNTCP has already developed and published a [National Multisectoral Action Framework on a TB-Free India](#). This document outlines key efforts planned, particularly with regard to health workplaces and corporate contribution and engagement. An operational plan for this document is the next step in fully operationalizing the key activities.
- Memorandums of Understanding (MOUs) have been signed with the Ministries of Defence (MoD); Railways; and Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy (AYUSH) for TB activities.
 - Special initiatives have already been launched with the Department of Post (DoP), Ministry of Labour & Employment, Ministry of Panchayati Raj, and Ministry of Women and Child Development (MWCD) for TB-free workplaces.
- There is a wide array of state- and district-level good practice examples of

multisectoral actions, including the groundbreaking TB elimination plan for Kerala and for Himachal Pradesh as well TB-free city examples.

- A [National Multisectoral Action Framework on a TB-Free India](#) provides an excellent annex on other potential state-level schemes for further providing TB patient support including social benefits available beyond TB and outside of the health sector.
- Some state teams saw outstanding efforts in place working with tribal development authorities in reaching some tribal populations by using human resources and budgets available through these authorities and coordinating activities through RNTCP and general health staff.
- Work with Railways appears well developed, as well as with some industries.
- The existence of major new Government-wide initiatives with ample resources, high-level support and momentum, including Ayushman Bharat, Public Distribution System (PDS), supplementary nutrition programs, Smart Cities, Ujjwala Yojana, Swachh Bharat all provide major opportunities for integration of, and collaborations on, objectives for ending TB.

Challenges and Opportunities

As these are relatively early days for many elements of multisectoral engagement, significant challenges were also noted under each of the areas noted above.

- Important progress has been made in the TB response because of highest-level engagement and commitments made through increased budgets. Yet some of the structures needed to enable a mission-mode effort with actions and accountability still need to be established and activated.
- Lack of information and clarity of the

accountability of the Inter-Ministerial Committee.

- With 25 ministries engaged, the focus of the collaboration now appears diffuse.
- While the first round of MOUs is an important step, there appears to be an exclusion of some of the top priority ministries.
- Contributions to ACF efforts in some areas have relatively low yield, suggesting a need to shift strategies to better identify and target populations for ACF activities.
- While it is commendable that a [National Multisectoral Action Framework on a TB-Free India](#) exists, there may be some missed opportunities.
 - It was difficult to assess whether the NSP elements on modelling on the social determinants of TB were taken forward, and whether actions had been advanced on mapping key populations and interventions.
 - This is a significant element of baseline work that can contribute to robust planning for multisectoral action.

Recommendations

1. Enter full “mission-mode” within and beyond the health sector. As suggested and clearly articulated in the NSP, “mission-mode” actions are needed to enable accountability and fulfilment of vision and goals towards ending TB by 2025.
 - a. Using the support of the Prime Minister’s bold commitments, the MoHFW now needs to take action on activities already set forth in the NSP and additional measures to meet those commitments.
2. Establish a functional TB Elimination Board. As envisioned in the NSP, a whole-of-government approach, including multisectoral engagement, is needed to overcome the critical and persisting bottlenecks in implementation.
 - a. This Board should include the highest-level participation from central and state levels, and from all major stakeholders including civil society representation.
 - b. An operational body should accompany this high-level board to help manage regular interactions. Lessons learned from the successful eradication of Polio in India, and other successful elimination efforts, indicate that regular government divisions cannot pursue these efforts through existing management structures alone.
 - c. This TB Elimination Board could also serve a critical need for a periodic review body. This would help India fulfil its commitment to have a high-level accountability mechanism as set out in the political declaration of the UNHLM.
3. Functionalize and strengthen existing Civil Society Forums. These Forums seem to exist at national and state/district levels but they need to be activated and robustly operated to drive scaled-up action and as another key level of multisectoral accountability.
4. Consider formalizing a TB multisectoral accountability framework within the MoHFW. The core of the framework could be the TB Elimination Board.
 - a. This would further help strengthen measures already taken for enhanced multisectoral engagement.
5. Provide more information and clarity are needed on accountability of the Inter-Ministerial Committee, including who the Committee is accountable to and how it will be made robust in its actions.
 - a. It could report to the overall high-level TB Elimination Board (see more below).
 - b. Roles and responsibilities need further clarification, including how this Committee relates to actions to be taken at state- and district-level. Further, budgetary responsibilities also need clarification.

⁵⁶The last 2015 JMM included TORs for addressing key populations while the 2019 JMM did not.

- c. Its operational plan will need to clearly state immediate and medium-term deliverables and define performance indicators.
 - d. There needs to be a clear secretariat/focal point within the MoHFW.
6. Given the limited capacity to support the multisectoral engagement so far, a focused intensive effort with a few ministries that drive budgetary commitments and accountable actions may produce results that can, as first examples, drive much greater commitments from more ministries thereafter.
 7. For ACF activities, focused high-priority multisectoral engagement with relevant ministries, specifically with the Ministries of Home Affairs (MHA), Mines, and Labour & Employment, will likely increase systematic screening efforts, reporting on results, and action taken for diagnosis and care based on the results.
 - a. Key populations (e.g. miners/people working in dust-generating industries and associated communities; prisoners and detainees; etc.) should produce higher yields.
 - b. Consider publishing special reports on actions taken among focused populations and tribal populations nationally.
 8. To successfully enter mission-mode across all sectors, an increase in human resources (HR) and financial support from key ministries beyond health will be needed. These resources should be carefully measured and monitored on a periodic basis (at least yearly).
 9. Revisit the National Multisectoral Action Framework on a TB-Free India through a national consultation to assess whether its major focus on the workplace can be expanded to further address other multisectoral challenges. This consultation should include key non-governmental stakeholders working on health across sectors and affected people and communities.
 10. Take action to explicitly state how major national initiatives/programmes are and can

contribute to ending TB given their scope and potential: including, Ayushman Bharat, PDS, supplementary nutrition programs, *Smart Cities, Ujjwala Yojana, Swachh Bharat.*

Key Messages

1. Drive multisectoral action, based on the right to health, via a TB Elimination Board and state/local counterparts, and inter-sectoral Committees, operational plans (with ambitious and achievable deliverables for priority sectors, with indicators and accountability, and stakeholder engagement. This should be done in early 2020.
2. Engagement of stakeholders within and beyond health, and within and beyond government, especially civil society and independent voices are essential.
3. India can and should be a global pathfinder for multisectoral accountability.

2.1.3 Health System Strengthening

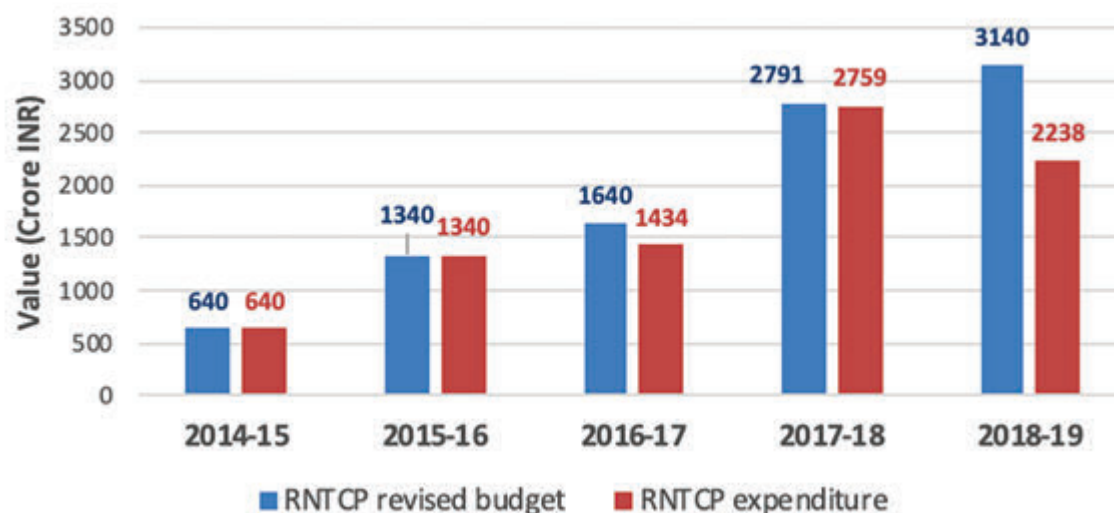
The NSP (2017-2025) explains a number of key strategies for health system strengthening (HSS). The JMM chose to group strategies to focus on five main areas: health financing, governance, procurement, financial flows, and HR. Each section below is organized under these main themes.

Achievements

Health Financing:

- There is strong political commitment at the highest levels that is matched by financial commitment.
- A rapid budget increase from 2015 to 2019 was quickly implemented to support the ambitious goals of the NSP (2017-2025). The RNTCP budget more than doubled since the launch of the NSP (Figure 17).
- *Innovative and results-based financing for high impact NSP interventions have been identified (i.e. private sector scale-up and DBT).*

Figure 17: RNTCP Budgets and Expenditures, 2014 to 2019



Source: RNTCP Programme Data, 2019.

Governance:

- The NSP clearly outlines key governance interventions and structures that need to be in place to end TB by 2025.
- Multiple expert groups are in place to assist in the restructuring and expansion of the CTD.
- Emphasis has been placed on increasing engagement with the private health sector and civil society organizations (CSOs).

Procurement:

- Seven of the ten positions for Procurement and Supply Management (PSM) experts at the national level have been filled.
- The NIKSHAY Aushadhi programme has been developed and deployed at all levels.
- A government order was issued to mitigate acute local drug shortages by facilitating emergency drug procurement for up to 25 percent of the states' total annual drug requirement for all drugs.
- Efforts have been made to begin expanding access to quality TB drugs supply for the private sector.
- Successfully using domestic budget streams for procurement of molecular diagnostics, including reagents, for the first time.

Financial Flow:

- In 2018-19, 71 percent of the annual budget (Rs. 3140 crores) was spent as per the data made available during the JMM. This includes 83 percent of grant-in-aid provided to and spent by the states (Rs. 1017.19 crores expended against the release of Rs. 1224.64 crores to states).
- The electronic Public Financial Management System (PFMS) was rolled out to all the districts to improve the efficiency of district-level accounting.

Human Resources (HR):

- HR levels better aligned to the need and to block level TB units
- In 2014, there was one Senior Treatment Supervisor (STS) per 4.13 lakh population; in 2019, there is one STS per 2.74 lakh population.
- Workload Assessment for undertaking the new initiatives outlined in the NSP is in process and nearing completion.
- Training contents, methodology, and tools have been updated with new modules and contents.
- A performance-based incentive system has been designed and approved to help address the implementation gaps in performance of frontline workers.

Challenges and Opportunities

Health Financing:

- Lack of assessment of NSP cost and budgetary needs past 2021.
- No system in place to monitor out-of-pocket and catastrophic health expenditures for TB.
- Continued gaps in coordination with the National Health Authority (NHA) to better implement AB-PMJAY schemes for TB patients.

Governance:

- While interventions are clearly articulated in the NSP, there is a lack of implementation at all required levels.

Procurement:

- Continued issues regarding tender failures and long lead times for procurement. The lead time for the Central Medical Services Society (CMSS) can be anywhere from 13 to 15 months, while the Global Drug Facility (GDF) is typically six to eight months.
- Ongoing challenges with low stock or shortages of necessary lab and drug supplies (e.g. unavailability of adequate buffer stocks, shortages of SLDs (cycloserine) and other anti-TB drugs (rifabutin, pyridoxine).
- While NIKSHAY Aushadi is able to generate a myriad of useful reports to support drug quantification and inventory management, there is a lack of capacity at all levels to use, interpret and act on available data.
- Absence of a central level agency for post-dispatch quality assurance for more than 12 months
- Persisting lack of or insufficient infrastructure of drug stores in some states (Figure 18).
- Central, state and district level warehouses continue to house expired medicines in their already limited space.
- In some states, there continues to be a lack of formalized, reliable transportation mechanisms for state to district/sub-district level transfer.

Figure 18: NIKSHAY Aushadi report on the percentage of state drug stores (SDS), district drug stores (DDS), tuberculosis unit (TU) drug stores, and peripheral health institution (PHI) drug stores active. There is a noticeable decrease in stores from the national to peripheral level



Financial Flow:

- Insufficient, incomplete and untimely fund flow from RNTCP budgets to states.
- Burn rate and budget release varies by states (Figures 19 and 20).
- Marked delays (range of 52-262 days) in release of the first installment of the budget.

19: This graph shows the wide Figure range in the burn rate of 2018-2019 by region.

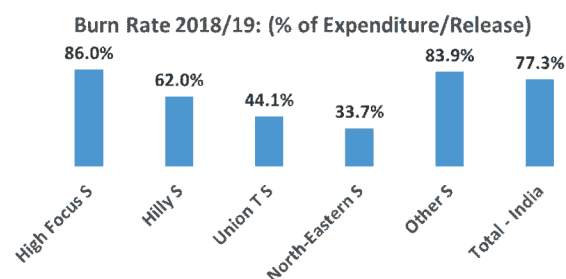
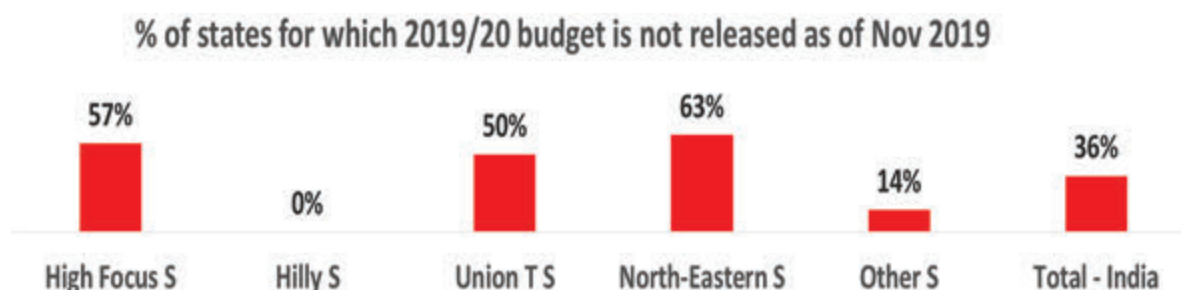


Figure 20: This graph shows the range in the percentage of the 2018-2019 budget released by region.



- Inefficiencies in monitoring budget and expenditures. At the state level, excel sheets separate and independent from the PFMS are used to track financials.
- Lack of capacity for implementing and monitoring important financial systems. For example, technical staff (i.e. STS, state tuberculosis laboratory supervisor (STLS), etc.) are responsible for accounting entries and DBT transactions.
- Delays in effective auditing processes. For example, untimely submission of audit reports by state and delayed appointment of auditor firms by NHM persists.

Human Resources:

- High vacancy rates of key positions at all levels, including the general health system and RNTCP (Figures 21, 22, 23, and 24).
 - Some project implementation plans (PIPs) included proposals to recruit contractual staff but this was not approved.

Figure 21: The graph above represents the vacancy rate (%) for state-level positions.

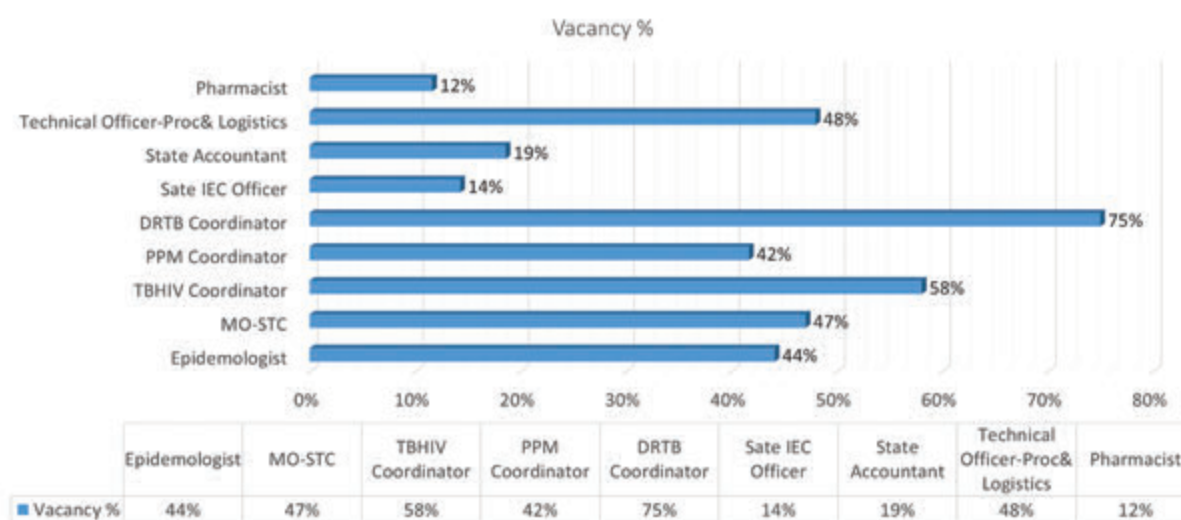


Figure 22: The graph above represents the vacancy rate (%) for district-level positions.

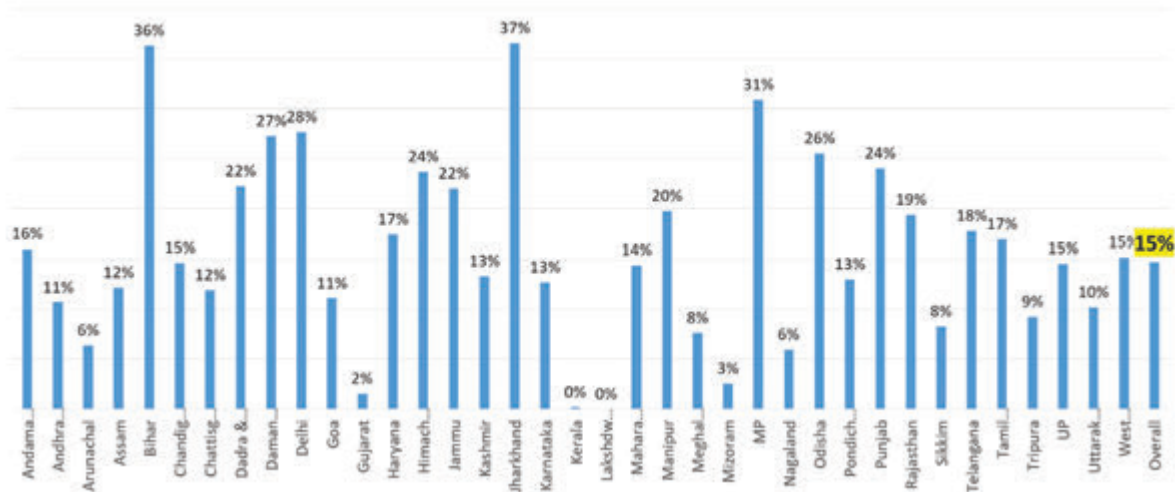


Figure 23: The graph above shows the number of approved positions for the culture and drug sensitivity testing (CDST) labs and the number of actual filled positions at the CDST labs.

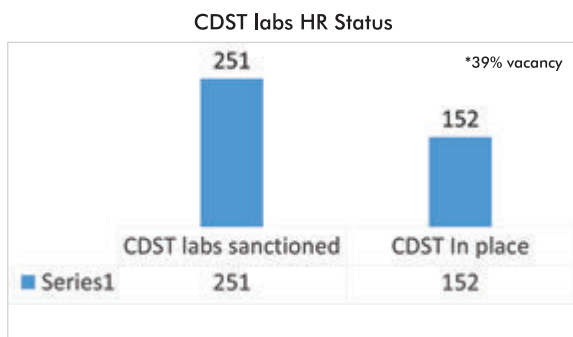
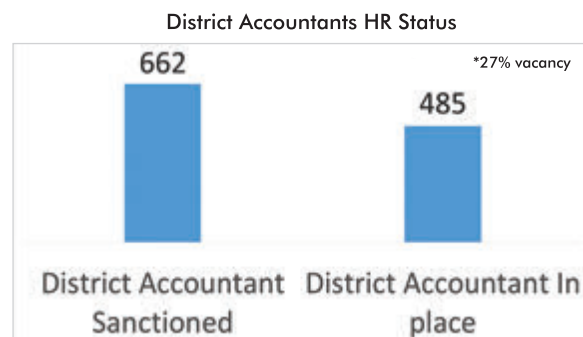


Figure 24: The graph above shows the number of approved positions for district-level accountants and the number of actual district-level accountant positions filled.



- The Terms of Reference (TOR) for staff at the state, district and sub-district level are not representative of the expanded, ambitious scope of the NSP.
- State level decision on salary scales leads to inequity among states. Further, these scales are often ill-aligned with market rates leading to lack of interested, qualified applicants
- While some strides have been made in ensuring that adequate training of

- personnel, gaps persist. For example, a needs assessment has not been completed at all levels and e-training modules are not yet operational.
- A marked lack of capacity at the State Tuberculosis Training and Demonstration Center (STDC) perpetuates weak state and district/sub-district level capacity to support the increasing programmatic demands of the RNTCP to provide quality assurance, supervision, and monitoring.

Recommendations

Health Financing:

1. Complete a costing exercise through 2025 for the NSP 2017-25 as soon as possible.
 - a. In order to end TB by 2025, this exercise will need to take into account all activities including scale-up of relevant activities required to reach this ambitious goal.
 - b. Additionally, consider the commensurate financial resources that may be required with increased PPE.
2. Obtain and regularly review TB expenditure estimates from public health expenditures and national health accounts.
3. Periodically measure and monitor the out-of-pocket and catastrophic health expenditures for TB.
4. Further strengthen coordination with NHA to be able to address financing issues particularly on AB-PMJAY in-patient and potentially outpatient packages for TB patients.
5. Build capacity at national and state level for transition from input- to output-based strategic purchasing using TA from other partners, donors, and/or stakeholders as necessary.

Governance:

1. Expedite the implementation of the governance structures described in the NSP at all levels. This should include the introduction and use of TB elimination board(s) (see more under the Multisectoral Accountability and Engagement section).
 - a. This should include effective monitoring and accountability frameworks.
2. Rapidly employ methods of further strengthening governance for efficient private sector engagement (see more under the Partnerships and Private Provider Engagement section).

Procurement:

1. Consider creating an alternative or back-up

mechanism, in addition to the CMSS, to expedite procurement of drugs and diagnostics and reduce the excessively long lead times.

2. Further integrate the NIKSHAY Aushadhi and NIKSHAY softwares to minimize duplication of efforts and inefficiencies at the service delivery level.
 - a. Engage specific TA and technical partners to guide and support enhancements and integration of NIKSHAY Aushadi.
3. Prioritize conducting a needs assessment on, and upgrading of, the supply chain infrastructure focusing on drug stores at all levels.
4. CTD should immediately (as soon as possible but no later than June 30, 2020) establish and disseminate guidelines with specific instructions on disposing and writing off of anti-TB drugs to drug stores at all levels.
5. Research and implement a formalized transportation mechanism that optimizes the supply chain management at the state level of drugs and other supplies to the district/subdistrict level.

Financial Flow:

1. Disseminate a formal communication from MoHFW and RNTCP leadership mandating the use of ePFMS at the state level and beyond in order to systematize financial reporting as soon as possible.
2. Mandate states to provide up-to-date information on financial contributions for the next fiscal year (FY) by the end of the financial year (April).
3. NHM to appoint auditors in a timely fashion. Following which, there should be regular submission of auditor's reports and audited Ucs.

Human Resources:

1. Prioritize filling of existing vacant key positions (e.g. DR-TB, Lab, Accountant, Logistics & Procurement, and PPM Coordinators) at all levels with qualified candidates.

2. Create and hire the additional required positions at all levels – national, state, district, and field – to implement the expanded and ambitious scope of the NSP.
3. MoHFW leadership should engage state level authorities to update salary and staffing structures of RNTCP staff to accommodate the implementation of activities.
4. Strengthen staff capacity at all levels by:
 - a. Performing training needs assessment at all levels (i.e., CTD and states).
 - b. Monitoring and reporting of CTD and state level implementation of approved CTD and STDCs training plans.
 - c. Outsourcing of training as needed to ensure national coverage of quality training, to include the development and implementation of in-person and distance-based training modalities.
 - d. Including specific training on patient centered care. This should consist of building the capacity of staff at all levels to provide counseling and responsive, supportive care that is sensitive to the principles of human rights and the persisting prevalence of gender, ethnic, and socioeconomic discrimination and stigma (see more in the Advocacy, Communication, and Community Engagement and Ownership section).
5. Prioritize capacity building of the STDCs to execute their key functions.
 - a. Ensure that continued monitoring and evaluation of the STDCs is implemented in order to quickly course correct existing and add new activities as needed.
 - b. Employ the use of TA as necessary to ensure that STDCs are functioning effectively and efficiently.

Key Messages

1. The absence of a well-prepared HR workforce continues to be a major bottleneck in achieving the goal of a TB free India by 2025.

As a matter of utmost urgency, the JMM urges the Gol to address HR shortcomings by updating RNTCP staffing requirements at all levels – national, state, district, and field – (to include, but not limited to, quantity, skills mix, salary scale, quality of in-service training of staff at all levels) by April 2020 and prioritizing recruitments of positions at all levels by December 2020.

2. There are unacceptable lag time delays in procurements. An alternative procurement mechanism must be developed while also supporting the full deployment and utilization of NIKSHAY Aushadi to realize efficiency gains by June 30, 2020.
3. The continued increase in TB allocations by the Ministry of Finance are commended. In order to meet the SDG target by 2025, it is important to sustain, and in some cases continue to increase, funding levels for TB, as supported by accurate, robust costing exercise(s) of the NSP from 2020 to 2025. It will be particularly important to ensure that the most innovative aspects of the NSP are adequately funded.
4. The full transition of states to using PFMS (by April 2020) to expedite timely expenditure and auditing reporting to help improve budget execution and consecutively NSP implementation. Explore TA options offered by various partners in improving PFMS utilization.

2.1.4 Tuberculosis in Urban Populations

The NSP recognizes urbanization in India as a driver of the persisting TB epidemic noting that epidemiologically, urban areas in the country are typically characterized by higher prevalence of TB with higher Annual Risk of TB infection (ARTI), and rural areas are characterized conversely. The NSP acknowledges that ‘weak public health infrastructure and the crowding out effect’ in urban areas coupled with weak referral and outreach severely limits access of the poor to urban health services in general and TB services in particular. The NSP confirms that synergy of TB services with existing health service delivery in urban areas

through the Urban Health Mission will ensure optimal use of scarce resources and allow for integration. Several strategic interventions are identified within the NSP that include governance structure, planning, private sector engagement, social mobilization, TB within urban primary care services, strengthening of referral services, active case finding in urban slums, involvement of medical colleges, community-based surveillance and collaboration and partnerships with other stakeholders, especially convergence with other ministries and departments.

Achievements

The RNTCP has made remarkable progress in integrating TB control within health departments in urban populations in the country.

- The urban PHCs and Community Health Center (CHCs) now include 'treatment centres' that provide a dedicated space and staff for TB service delivery.
- The programme leverages the ongoing slum and vulnerability mapping (this is one of ten thrust areas of the NHM across the country) for active case-finding.
- The PPSA model for engaging the private sector has been prioritized and rolled out in 48 cities.
- For urban settings, the programme provides dedicated HR to support patients and their treatment as well as to improve community awareness of TB – one TBHV is provided for every 100,000 population and this adds to the general health staff already provided through the National Urban Health Mission (NUHM) to support service delivery in the urban PHCs and CHCs.
- TB is also a part of the health and wellness centres within NHM providing greater visibility and access to TB services for patients, communities and health providers.
- The Mumbai model – a mega-city with wide access to TB service delivery –

provides an example for service delivery in complex and very large urban settings. This model should be customized for and implemented in other similar contexts across India.

Challenges and Opportunities

While many great strides have been made in addressing the unique challenges of TB in urban settings, some areas of challenge persist.

- **Governance and Accountability:** Health departments within urban local bodies (cities with a population greater than 50,000 people, including all state- and district-level headquarters) do not directly report to the state health department. These departments are accountable to their local bodies and the municipal commissioner of the corporation, who is also the chief executive supporting administration of that local body. Coordination should happen through the state-level NHM leadership but this is not happening across all states.
- **Migration:** [Economic Survey, 2017](#) revealed that inter-state migration is increasing. Economic circumstances and job seeking behaviors account for this rise in state-to-state mobility. [National Sample Survey, 2007 -2008](#) (NSS, 2007-08) data suggests that there were about 18.5 million inter-state migrants in 2011, of which 11 million were estimated to be in the 20 to 29-year age group. There is also evidence of rural to urban migration, with these migrants staying for longer periods in their new location. The JMM teams reported that migrant populations were an area of challenge and concern to the RNTCP across states, with a need for focused technical assistance and guidance on how to manage these groups.

The upsurge in migration and the absence of affordable housing has resulted in an expansion of

slums in urban areas. It is estimated that 31 percent of India's population now lives in urban areas and about 21 percent of the urban population lives in slums. This translates to about 62 million people across India living in urban slums. Migrant labourers living in urban slums are a vulnerable and key sub-population that need education on, and access to, TB services.

Opportunities:

- Capitalizing on multi-sectoral engagement. Within the NUHM, the Ministries of Housing and Urban Affairs (MHUA) and Women & Child Development (MWCD) are working together to implement programs relating to wider determinants of health like drinking water, sanitation, school education, etc. NHM leadership also provides oversight and coordination of the two sub-missions National Rural Health Mission (NRHM) and NUHM. Prioritizing TB and using the existing platform of inter-ministerial collaboration would increase awareness of TB and promote access to TB services. Additionally, there needs to be a concerted effort to further expand the inter-ministerial network to facilitate cross-sectoral learning. Examples include: (1) working with the Ministry of Finance to coordinate and potentially assume responsibility for DBT to alleviate the programme's bottlenecks and workload, and (2) coordinating with the MHUA to assist in ensuring that the full continuum of TB services are available to migrant populations throughout the spectrum of their mobility.
- Identifying opportunities for, and making use of, Corporate Social Responsibility (CSR). Particularly in urban settings, there may be more possibilities for CSR. Following an amendment passed April 2014 to the Companies Act, 2013, India is the world's first country to legislate mandatory CSR contributions. As part of their CSR compliance, companies are

encouraged to invest in areas such as education, poverty, health, gender equality, and hunger. An additional amendment in 2019 requires companies that do not fully spend their CSR funds to disclose the reason(s) for non-spending and to carry forward any unused CSR funds to the following year. In 2018, companies spent an estimated 47 percent more on CSR as compared to 2014-2015; companies contributed about 7,536 crores INR (1 billion USD) to CSR initiatives with the healthcare sector receiving about 25 percent.

Recommendations

Governance:

1. Continue to leverage NHM leadership at state level to engage the RNTCP within urban local bodies at the national, state, and district level.
2. High-level advocacy to prioritize TB Free India within mega-city corporations at the commissioner and additional/joint commissioner level offices. Examples of activities include: sensitization meetings; creation of platforms at different levels that include the corporation leadership; working with the Ministry of Housing and Urban Affairs to help monitor progress of TB control, followed by regular quarterly reviews as appropriate.
3. Intensify the frequency of convening of partners and scale of the implementation response in the mega-cities with a special focus on ensuring sufficient HR and financial allocations in proportion to the burden of disease, and on strengthening epidemiological surveillance (including geo-mapping) especially for high-burden drug-resistant TB (DR-TB) mega-cities.

Operational:

1. Consider expanding use of Aadhaar unique identity numbers, perhaps integrating these as a unique patient identifier within the NIKSHAY system. This will allow for easier monitoring



and tracking of urban and migrant patients seen by various health providers.

2. Targeted interventions in slums and other areas with vulnerable populations (mobile populations, homeless, etc.) to ensure access to TB services, notification of TB patients, and treatment support for TB patients with special focus on transient or migratory patients.
3. Expand guidelines on programmatic management of DR-TB (PMDT) to include guidelines on addressing migrant populations, and coordinate with the relevant ministries (including the MoUD), securing additional resources from interested donors as needed, to support the integration of TB services for migrant populations in urban settings.
4. Extend contact management to workplaces and non-relatives in shared housing to account for the particularly crowded nature of workplaces and prevalence of shared housing in urban areas.
5. Further promote and ensure adherence to airborne infection control (AIC) practices across the board but especially in urban settings (e.g. in public transport).
6. Promote policy change for mandatory/voluntary leave for those patients who are smear or culture positive in workplaces, schools and colleges. Explore ways to mitigate risks associated with discrimination, stigma, patient rights, etc.

Key Messages

Urban populations are large, complex, and require targeted interventions and multisectoral coordination in order to successfully end the TB epidemic. With the rise of inter- and intra-state mobility and movement, particular attention must be placed to address the specific needs and challenges posed by migrant and vulnerable populations; these will often require unique, and innovative interventions.

2.1.5 Patient Support Systems

Integrated patient-centered care and prevention is

one of the pillars of WHO's [End TB Strategy](#), and is particularly pertinent for India, where millions of new cases occur annually and more than 400,000 TB deaths occurred last year. Studies suggest that a significant proportion of patients incur high out-of-pocket costs and even catastrophic expenditures when seeking services, even where TB care is available free of charge. Enabling patient/people-centered prevention and care continues to be an enormous challenge for India as it seeks to end the TB epidemic by 2025. This is an area that offers tremendous opportunities to improve outcomes for patients, their families and communities. Patient support systems are fundamental to integrated patient-centered care.

TB continues to disproportionately affect key, vulnerable populations. For example, poverty-stricken and poor communities are more vulnerable to the disease because of greater exposure to TB infection in their communities, malnutrition, overcrowding, indoor air pollution. Further, these communities also face geographic, economic, educational, and/or cultural barriers to not only accessing but also seeking and complying with care. Additionally, among these communities you find marginalized populations like migrant workers, who often develop the disease working in locations distant from home and require special attention, and tribal people, who often live in remote and inaccessible locations.

The key strategies outlined in the NSP on patient support systems are:

- Implementation of TB treatment services in health facilities and communities.
 - Develop a patient-centered plan that includes: i) initial and frequent follow up counseling of patient and family members ii) supervision of treatment through treatment supporters iii) locally managed nutrition support iv) screening for adverse reactions, treatment interruptions, co morbidity management v) linkages to social support schemes
 - Decentralization of treatment services



through information and communication technologies (ICT) support.

- Extend patient support services for patients in private sector which are the same as for patients in the public sector mentioned
- Regular and long term follow up and rehabilitation of all treated TB patients

The strategies above refer to the educational needs of the patients and the need for supportive supervision. Since the last JMM in 2015, the issue of nutritional support in India's patients has gained traction. In 2017, the RNTCP released a [Guidance Document for Nutritional Care and Support](#) for patients with active tuberculosis in India, which recommends that a nutritious diet, adequate in calories and proteins, is required as an adjunct to the therapy of TB patients in India. In 2018, the GoI launched a DBT scheme – the NIKSHAY Poshan Yojana, and provided a monthly benefit of Rs. 500 to enable both private and public sector TB patients to afford a nutritious diet. The RNTCP also has implemented ICT based adherence monitoring (99 Directly Observed Treatment, Short-course (99DOTS)) in selected states and locations, and made a call center operational. These are positive steps. Further, in 2018, the RNTCP released the results of a study on [State Initiatives on Patient Support Systems for TB elimination in India](#), which documents the various initiatives of cash assistance, nutritional support, and livelihood assistance being implemented in different states in India. This is also part of the Multisectoral Engagement Framework of the RNTCP.

For the purposes of this section, the JMM chose to focus on DBTs and adherence support systems. As background, DBTs for patients were first initiated in April 2018 via NIKSHAY version 1. Due to early challenges, DBT payments were incorporated into a NIKSHAY version 2 launched in September 2018. This is the first time that direct payments to patient bank accounts were initiated, and there has been an initial learning phase. Initially built as an

accommodative system to ensure payments to maximum number of people, NIKSHAY was adapted to address rising challenges which included some instances of misappropriation (estimated at less than one percent). Some of these updates included tagging each beneficiary to a unique bank account number, and moving from facility to individual identifiers for program staff.

Achievements

DBT:

- The launch of DBTs is ground breaking because it enables direct payments to TB patients, irrespective of any identity or other requirements. The consecutive extension to tribal populations, treatment supporters and private providers is commendable.
- In the first year, more than 2 million patients received at least one instalment of incentives, equating to about 55 million USD being dispersed.
- A basic deduplication module, all four NPY payments modules, tribal scheme, treatment supporter, and payment to private providers were developed and deployed in NIKSHAY. These have since been verified by the Independent Verification Agency (IVA) as a part of the World Bank credit to the TB program.

Adherence Support Systems:

- Adherence support system have been integrated into NIKSHAY with a single unified interface for refill monitoring and different digital adherence technologies (ICT), including 99DOTS, Medication Event Reminder Monitors (MERMs), Operation ASHA (OpASHA) and virtual/video directly observed treatment (VDOT).
- Integrated Digital Adherence Technologies (IDAT) tools have been deployed in key sites across the country to understand acceptability and implementation needs.

Challenges and Opportunities

DBT:

- Timeliness and coverage: There are

differences in initial and subsequent payments across public and private sectors (Table 6). Delays in payment from the time the patient is notified is also a challenge.

Table 6: Shows the DBT cascade (Patients notified from January through June 2019).

Drug Sensitive TB	Public	Private
Bank details available of those notified	83%	43%
Bank details validated of those notified	68%	34%
1st Incentive paid of those notified	52%	22%
Drug Resistant TB	Public	Private
Bank details available of those notified	82%	80%
Bank details validated of those notified	58%	58%
1st Incentive paid of those notified	50%	49%

- Equity: Access to benefits in remote and tribal areas remains a challenge (no bank accounts, cooperative banks etc.).
- Adequacy: It is not clear if the amount offered for nutritional and financial support via NPY is adequate.
- Impact on core function of patient supervision in RNTCP: The STS is unable to spend adequate time focusing on core patient supervision functions due to competing responsibilities on supporting enrolment for DBT.

Adherence Support Systems:

- Lack of adequate counseling for patients with drug-susceptible tuberculosis needs strengthening.
 - Currently, per RNTCP mandate, only MDR-TB receive the information on the disease treatment and prevention by a counselor.
 - Patients with drug-susceptible tuberculosis do not have access to an assured system of patient education supplemented by patient information material on disease treatment and prevention during the course of treatment.
- Current counseling practices are not

comprehensive and do not include information on gender, ethnic, and socioeconomic discrimination and stigma.

- Nutritional assessment, counseling and support:
 - Persisting high prevalence of severe undernutrition and related comorbidities in TB patients, particularly drug-sensitive TB (DS- TB), requires immediate further attention and action - such as use of body mass index (BMI) to identify those at high risk for drug-induced hepatotoxicity and death, and in need of specific support for nutritional recovery.
- Patient supervision for adherence: NIKSHAY is currently not used for entering refill monitoring and dosing implementation data. The data is currently entered on treatment cards by health care workers, resulting in the need for paper documents and treatment cards. Additionally, limited information on patient adherence for patients notified by private sector providers.
- Deployment of digital adherence technologies: With the exception of the deployment of 99DOTS in Gujarat, there has been limited deployment of ICT and

IDAT tools. A dashboard showing treatment adherence digital options has also been available in other states, and should enable comparative adherence on multiple technologies for a number of TB patients linked. Early data suggest that patients can greatly benefit from innovative adherence support options and switching protocols and support to take medicines.

- Lack of disability assessments at the end of TB treatment and linkage to social welfare schemes. Many patients with extensive pulmonary tuberculosis are unable to return to their previous occupations because of extensive lung damage. Some types of extrapulmonary TB can also be disabling.

Recommendations

The JMM team has proposed recommendations based on the challenges faced during the initial roll out period of the past 18 months.

DBT (via NPY):

1. Patient (Equity and Access): Ensure timeliness of first and subsequent payments to ensure availability of monies to patients who need it the most (vulnerable populations); when they need it the most (timeliness). Do not delay initiation of treatment for the purpose of DBT requirements.
2. Recommended NIKSHAY improvements:
 - a. Consider integrating the use of Aadhaar authentication, but do not exclude in its absence.
 - b. Initiate centralized DBT payments at the national level concomitant with measures for real-time entries.
 - c. Implement practices to provide transparency and communication to patients around payments.
3. Deploy patient cost study to assess and address out-of-pocket expenses. Continuously monitor and review patient and nutritional outcomes following DBT payments

to inform revisions in payment.

4. Evaluate the use of program staff involvement in DBT (e.g., STS) by:
 - a. Reviewing findings of the recently initiated time motion studies for different program personnel (STS);
 - b. Explore alternative or outsourced agencies options to address the observed gaps.

Adherence Support systems:

1. Enabling treatment adherence:
 - a. Provide TB patient counselling support to all patients and families (in their local languages) at the point of diagnosis and in the continuum of care. Counselling should be human rights-based and include information on disease prevention, treatment and adherence, and social benefits (including DBT) as well as information on gender, ethnic, and socioeconomic discrimination and stigma associated with TB.
 - i. Capacity of staff at all levels must be built to accomplish this level of patient support.
 - b. Strengthen community-based patient support by the health system (ASHA, MPW and STS) supplemented with ICT and IDAT. Establish and link these with other community patient groups and blended ICT adherence support systems. Convene a national meeting on deploying appropriate adherence support that are based on patient choices/preferences and in-line with local needs.
 - c. Optimize the use of NIKSHAY to monitor refill and follow-up review adherence information.
 - d. Patient nutritional assessments should be conducted and dietary counseling modules (e.g. mobile apps⁵⁸) consistent with WHO Guidelines on [Nutritional care and support for patients with tuberculosis](#) should be made available to healthcare workers so that they are educated on the link between nutrition and TB, and can

inform patients on best practices for nutrition recovery.

2. Social Benefits:
 - a. States should be encouraged to provide social benefits and nutritional support beyond NPY (Hybrid model) in keeping with the current best practice document on State Initiatives on Patient Support Systems for TB in India.
 - i. Explore other options for nutritional support delivery including PDS.
 - b. The MoHFW should provide access to comprehensive inpatient care without cost for all TB patients under Ayushman Bharat, and continue its work towards outpatient packages.
 - c. Implement formal patient disability assessments at the end of TB treatment and link patients to social welfare schemes as necessary.
3. Patient Screening:
 - a. With a view to reducing mortality, implement a triage tool for severity assessment to identify severely ill patients and support their access to care which is currently limited because of paucity of beds for TB at the district.
 - i. A triage tool based on nutritional status, vital signs and presence of anemia has been suggested in the RNTCP document on nutritional care and support.
 - b. Implement a differentiated care approach for patients with comorbidities and complications to improve treatment outcomes (see sections on Comorbidities and Childhood Tuberculosis).
 - c. Implement simple systematic relapse surveillance via phone calls made to patient cohorts at regular intervals to ascertain if relapse has taken place over a two-year period.
4. NIKSHAY Improvements:
 - a. Develop a patient transfer module to ensure initiation and tracking of patients

that move within the health system. The RNTCP should consider a patient transfer module which will provide seamless access to treatment initiation.

- i. This is particularly important in the case of migrant workers who require to be transferred quickly (see section on Tuberculosis in Urban Populations).
- b. Develop task lists in NIKSHAY for linking, tracking pediatric contacts with pop-up messages (see section on Childhood Tuberculosis).
- c. Consider post-treatment follow-up.

Key Messages

1. In order to end TB by 2025, there needs to be a comprehensive patient-centered care and support that prioritizes patient literacy, risk assessment, community-based adherence support tools, and nutrition (DBT + direct nutritional support).
2. DBT is an important initiative with potential to reduce catastrophic costs and improve patient outcomes, but its implementation should be redesigned and realigned to enable programme staff to carry out their core function in core patient support and care activities.
3. Patients need disability assessment and rehabilitative services at the end of treatment, to enable positive long-term outcomes for patients and their families.

2.1.6 Community Engagement, Advocacy, Communication, and Social Mobilization

The designated JMM group reviewed the progress in implementation of the strategic interventions listed under the chapter on Advocacy, Communication, and Social Mobilization in the NSP, 2017-2025. It is apparent that a massive social movement is urgently required to achieve Prime Minister Modi's bold, unprecedented, and ambitious target of ending TB by 2025. An important first step towards this will be the effective

integration of this thematic area within all the four pillars of the NSP: Detect, Treat, Prevent, and Build.

Below are the key messages and findings, including achievements and persisting challenges, and actionable recommendations, from this mission's field observations, and inclusive team discussions.

Achievements:

- Political Commitment – At the highest level, the Prime Minister's Office is actively leading and monitoring the fight to end TB in India.
 - The domestic budget for the RNTCP has more than tripled with this commitment.
- State initiatives – The commitments by several States for TB Free status, combined with national efforts to end TB, have been widely publicized by the leadership in some states. The creation of state and district elimination boards in a few states establishes an accountability system for this goal (e.g., in Kerala).
- TB forums – The structure of TB Forums is defined for national, state, and district levels.
 - TB forums need to be supported to ensure that they are functional and effective.
- Communications – There is improvement in the content of communication material on TB with campaigns bearing high-profile public faces (e.g., Bollywood celebrity Amitabh Bachchan).
- TB Champions – TB survivors and champions are playing increasingly important roles in the TB response.
 - Building the capacity of TB survivors to become champions, and of TB affected communities to play a larger role in decision making and patient support, is the next step in actualizing the leadership potential of these crucial actors.
- Community engagement – The importance of engaging the community is being

recognized, and there is better community engagement in TB prevention and care.

- A differentiated approach in engaging communities and key population groups will need to be implemented, including in active case finding campaigns.
- Community engagement needs to move to the next level of community ownership.

Challenges and Opportunities

- Political Commitment – The full potential of all elected representatives, including MPs, MLAs, and Gram Panchayat members, is yet to be realized to capitalize on Prime Minister Modi's leadership and commitment (see Multisectoral Engagement and Accountability section).
- State initiatives – Most states have not been able to set up accountability mechanisms for ending TB (see Multisectoral Engagement and Accountability section).
- TB Forums – Forums have not been made functional at all intended levels.
- Communications – Continued engagement with media and ongoing campaigning measures.
 - Implementation of communication campaigns needs to be ongoing, rather than in short, infrequent, bursts, and effective monitoring and impact evaluation needs to influence new communication strategies and content.
 - Engagement of media has been reactive or patchy, and needs to become proactive.
 - High impact campaigns are largely operated from Central level and often not adequately tickled and adapted at State and peripheral level.
- Community engagement – Challenges in effective community engagement continue to persist; specifically, there is a lack of rights-based approaches and legal interventions, and untapped potential in community monitoring of service quality.



- Gender and stigma continue to be huge issues.
- Human Resources – There continues to be limited capacity at district, state, and national levels to effectively implement community engagement, advocacy and communication activities.

Recommendations:

1. Implement TB Forums at the national, state and district levels, and ensure their effectiveness by:
 - a. Conducting regular meetings (e.g., quarterly) aimed at identifying problems in need of solutions and providing updates on progress made;
 - b. Ensuring community ownership by designating civil society co-chairs along with the government officials;
 - c. Ensuring diversity in the TB forums in terms of gender and key populations;
 - d. Empowering forums to contribute to program quality improvement and assurance through ongoing capacity building of their members;
 - e. Monitoring governance, actions, and outcomes;
 - f. Ensuring adequate funding; and
 - g. Learning from, and adapting, initiatives of proactive states/districts across India making progress towards TB elimination (e.g., Kerala).
2. Engage in high-level advocacy with the National Parliament and State Assemblies (e.g., Telangana) by:
 - a. Introducing TB laws based on the principles of human rights;
 - b. Establishing, where not yet implemented, a TB Committee/Sub-committee under the Health Committee;
 - c. Encouraging Members of Parliament (MP) to review TB as a priority in their constituencies, and to consider the use of MP funds and available resources to address local needs (e.g., District Mineral Development Fund in tribal areas); and
- d. Ensuring participation of the Panchayati Raj Institutions (PRI) in district and sub-district level TB Forums.
3. Implement, monitor and evaluate the impact of communication campaigns by:
 - a. Following the principles of rights-based, multilingual, culturally appropriate, age-appropriate, and gender sensitive communication; and
 - b. Outsourcing the design, implementation, and evaluation of communication campaigns to dedicated and professional creative agencies.
4. Address the persisting gender gap by:
 - a. Ensuring equitable participation of women in RNTCP TB responses and decision making, including in TB Forums; and
 - b. Rapidly reviewing and implementing the gender response framework.
5. Eliminate stigma and discrimination related to TB by:
 - a. Developing a comprehensive strategy to understand, mitigate, and eliminate stigma and discrimination; and
 - b. Ensuring continued measuring and monitoring of stigma reduction.
6. Strengthen community mobilization and ownership of TB responses by:
 - a. Empowering communities through participatory trainings on treatment literacy, rights, counselling, peer support, and funding;
 - b. Providing communities with tools for monitoring services (e.g., Apps);
 - c. Addressing specific needs of key populations (e.g., migrants, tribal populations, children) using vulnerability mapping techniques;
 - d. Linking community engagement to all four pillars of the NSP (Detect, Treat, Prevent & Build) and by monitoring the outcomes;
 - e. Preparing communities for active or enhanced case finding;

- f. Learning and scaling up best practices from other programs (e.g., Polio, HIV, others); and
 - g. Developing and including an indicator on community engagement in State and District Score Cards.
7. Address human resource gaps and develop the capacity of RNTCP staff:
- a. Speed up recruitment of planned social scientists and community mobilizers at national, state and district levels;
 - b. Build capacity of staff to effectively engage with communities and key population groups on issues of stigma, rights, age and gender;
 - c. Build capacity of staff to collect and respond to feedback from community monitoring of services;
 - d. Outsource activities to NGOs under partnership guidelines as needed;
 - e. Obtain technical assistance to augment and compliment the technical capacity available at the national, state, and district levels; and.
 - f. Publish all RNTCP guidelines and frameworks through an open web consultation to allow for input from all stakeholders.
- 2. Invest in establishing TB Forums at all levels, including sub-districts, making them effective agents for quality improvement and assurance along the care continuum;
 - 3. Conduct round-the-year communication campaigns that are strategically designed by outsourced expert agencies to influence positive behaviors and improved awareness;
 - 4. Systematically align towards promotion and protection of human rights, gender equity, and provision of differentiated care for key populations;
 - 5. Eliminate stigma and discrimination towards persons with or affected by TB, and towards their families; and
 - 6. Advocate for a rights-based TB Law to be passed by Parliament, and for the establishment of a Parliamentary Sub-committee on TB.

2.1.7 Research and Innovation

From review of the NSP 2017-25, the importance of re-invigorating TB research in India particularly for optimizing services, informing policy, and developing new tools is clearly evident. For many years, TB research was largely confined to major studies by national institutes, research supported by national and state networks, and research funded by external donors. Over the past 3 years, the landscape of TB research has substantially shifted; Indian TB researchers have more funding opportunities than ever before (see Table 7⁵⁹ for an illustrative list of sources for funding research).

Key Messages:

Create and foster a nation-wide social movement, similar or bigger to the 'Swachh Bharat' campaign in India with the same level of resources and details in place, to end TB by doing the following:

1. Empower communities, especially key

Table 7: An illustrative list of potential sources of funding for TB research in India grouped nationally and internationally.

National Sources (e.g. national and state governments, local organizations, etc.)
RNTCP (CTD, State TB Cell, OR committees, NTI)
ICMR—India TB Research Consortium
ICMR— Task Force studies, Intra-mural funds

⁵⁹This table was authored by the writers of this section and is meant to be illustrative and not exhaustive in nature.

Dept of Biotechnology/ BIRAC
Dept of Science and Technology- CSIR
State Health Budgets
Intra-mural Funds of National Institutes (AIIMS, PGIMER etc.,)
Indian Institute of Technology (Internal Funds)
Ministry of Tribal Affairs (MoTA)

International Sources	
WHO	The Union
Global Fund	FIND-India
USAID	UNITAID
Bill and Melinda Gates Foundation	India Health Fund (Tata Foundation)
NIH	Pharmaceutical Companies (J&J, Eli Lilly)
US-CDC	Wellcome Trust
TB- REACH (Stop TB Partnership)	

One of the most noteworthy changes in the Indian TB research landscape is the establishment of the India TB Research Consortium (ITRC) as an extramural program of the ICMR. This domestically-funded, extramural program was originally envisioned as an independent entity, but ultimately remained within the Department of Health Research in order to capitalize on

institutional strengths. With a budget of more than Rs 120 Crore and multiple studies currently underway, the ITRC has been increasingly active since its inception.

- The NSP details some very specific research activities of which many have been completed or are currently underway (Table 8).

Table 8: Status of Research Activities Proposed in the NSP, 2017-2025

Source: Multiple

Proposed Activity	Status (as of Nov. 2019)
Implementation research for active case finding among key populations	Incomplete: massive ACF activities but little research being done, and what is done is not yet informing policy.
Implementation research for demonstration of resource optimization for implementation of newer diagnostic algorithms	Incomplete
Conduct operational research to determine the feasibility of chemoprophylaxis / preventive therapy in different risk groups (contacts of TB / DR-TB, etc.)	Planned: by ITRC, 3 studies pending to start
Initiate testing/evaluation of at least 3 new diagnostic/prognostic tests (preferably of Indian origin) for diagnosis of TB, DR-TB & latent TB	Started: ITRC - Truenat/AG, culture in bottle; C-Tb

Initiate pilot of at least 3 novel regimens for drug-sensitive and drug-resistant TB in through Implementation research for those already piloted elsewhere and through clinical trials for completely novel regimens	DSTB: 2HRZC/2HRE, High dose RIF, and adjunctive Tx. XDRTB: BEAT TB (9BDLzC) MDR: 9BCLzLv (regimen might change). Stream 2 under RCT. (Adaptive trial)
Initiate testing of at least 1 candidate vaccine in Indian population	Started: VPM0001/Aso1 vs Mw Placebo in contacts; VPM0001 in cases.
Initiate at least one large scale genetic susceptibility study, preferably from the same sample of that of TB prevalence survey	Not Started
Initiate a TB elimination project through implementation research in at least 3 districts in the country	Started: Kerala, Ernakulam, Idduki, Chennai
Perform. feasibility studies for uptake of new tools including replacement of smear microscopy with molecular diagnostic methods at the Microscopy level	Started: TrueNat, Xpert
Strengthen Operational Research through an institutional mechanism at NTI	Not started but proposed: National OR committee and TOR; National Research Center.
Perform Operations Research for feasibility of introduction and scale up of IGRA	Not Started
Perform operational research on TB/DM to determine best treatment strategies, regimens and durations.	Not Started
Build capacity for tuberculin production/identify new tuberculin or sub-unit Antigen for TST	Started: C-Tb

In order to effectively reach the diverse populations across the country, continued innovation and adaptation are key. This means moving beyond available NSP and technical guidelines. In other words, the program itself must remain fluid and dynamic at all levels. Flexibility and innovation have been encouraged at the national level, but appear to be lacking at the local-, grassroot-level. While there have been some incredible micro-level innovations as local programmes struggle to implement new policies and reach isolated and

remote populations, these innovations have remained largely compartmentalized and hidden with very limited scale-up or uptake into broader policy and practice.

In the following sections, the JMM authors grouped program challenges and opportunities, and recommendations under five broad research and innovation categories: institutional structure and capacity; operational research (OR); case finding and detection; treatment; and prevention.



Achievements

Institutional Structure and Capacity:

- Positive shift in TB Research landscape with an increase in potential funding sources.
- NSP outlines specific research activities, and many of these activities have been initiated and are ongoing.
- Some States (e.g. Gujarat and Karnataka) have been able to articulate state-level needs and target OR activities against them.

Operational Research:

- National-level priorities have been identified and updated in 2017 by the ITRC for OR.

Case Finding and Detection:

- CB-NAAT has been scaled-up to district-level facilities.
- In 2018-2019, nationwide ACF campaigns were conducted. For the most part, these efforts were community-led screenings of geographical areas that public healthcare workers perceived as containing the largest number of high-risk individuals.
- A dramatic increase in the number of TB notifications from the private sector.
- After a decades long gap in surveillance knowledge, the First the [First National Anti-Tuberculosis Drug Resistance Survey](#) (NDRS) finally clarified the nature of anti-TB drug resistance in India, for first- and second-line drugs.

Treatment:

- The RNTCP programme has finally shifted to daily dosing for the basic TB regimen no longer insisting on universal use of labor-intensive DOT.

Prevention:

- Some states (e.g., Kerala, Chennai) have

completed vulnerability mapping as a baseline analysis for potential activities.

- Interesting and promising studies on vaccines and prevention are currently underway.
 - RATION study: a randomized control trial (RCT) that is using food as vaccine among household contacts; and
 - Two multisite vaccine RCTs.

Challenges and Opportunities

Institutional Structure and Capacity:

- Persisting administrative barriers stifle research and scale-up of innovations.
- With the launch of new activities and initiatives (e.g., PPE, DBT, ACF, contact tracing, NIKSHAY), the capacity and management ability of the RNTCP appears strained. Integration of new tools requires a degree of RNTCP-led implementation science and this is not happening.
- Innovations at the national level are difficult to recognize, capture and integrate into the program. At the local level innovations are not adequately scaled-up or included into broader policy and practice.
- While collaborations have been proposed with Brazil, Russia, India, China and South Africa (BRICS) and six meetings have been held in the last two years, no clear plan forward has been proposed or publicized as a result of these efforts.
- The inception of a National Research Cell within the National Technical Institute was initially proposed ten years ago but it has yet to be approved and launched. This Cell is intended as a solution to the perpetual challenge of securing operational research (OR) funding, lack of capacity for OR and dissemination and use of findings to inform updated evidence-based policies.
- There have been expressions of interest in the creation of an open data system to



encourage researchers to mine and utilize the wealth of existing data generated by RNTCP and Partner agencies.

Operational Research:

- Lack of state-level OR focal points with the capacity for OR planning, training, and funds to implement programmatically-relevant OR. In many cases, field visit teams observed that this responsibility was left to a designated officer, the State or Zonal OR chairmen, and consultant, and there were limited capacity building efforts.
- From the materials reviewed and observations made by the team, limited investments and progress made on the national-level OR priorities particularly in: RNTCP management, addressing the socioeconomic impact and catastrophic costs of TB and integration into universal health coverage schemes (e.g., State insurance programs).
- While there are national-level OR priorities, it is important that priorities are identified at the state-level. Field visit teams observed that, in many cases, states sporadically, if at all, attempted to clearly articulate needs and match OR priorities respectively.
- The incredible potential of the electronic data system, NIKSHAY, remains largely untapped. For example, OR could help address the continued widespread gaps in data and its quality and lack of participation by general health staff.
 - Secondary analysis of program data is limited to annual reporting.
 - While vast data streams are converging into NIKSHAY, this wealth of information is largely inaccessible to researchers.

Case Finding and Detection:

- The extremely wide gap between early case

detection and the need to aggressively reduce transmission dwarfs the case finding and detection accomplishments thus far.

- Inadequate tools and strategies in place to efficiently and effectively screen high-risk populations at scale. The diagnostics currently being developed and/or evaluated in India are not likely to meet the country's needs.
- Lessons learned and best practices from the nationwide, large-scale ACF activities have not yet been synthesized, reviewed, or ultimately feedbacked into policy recommendations.
- Even with the availability of new and innovative case-finding tools (molecular diagnostics, CDR, AI algorithms, C-Tb), insensitive smear microscopy continues to serve as the primary diagnostic test for most cases of presumptive TB.
- Lack of capacity in detection of Isoniazid (H) resistance at the point-of-care level persists. As a result, only a small proportion of the total estimated H-resistant TB has been detected and treated.
 - Similarly, only a small portion of children and extrapulmonary TB patients have been successfully screened for drug resistance.
- While private sector notification has increased, the program has not yet internalized those notifications or reached those patients with comprehensive public health actions. This results in the lack of equitable access to care and services for private sector TB patients.

Treatment:

- Ongoing clinical trials offer promising pathways to incrementally improved treatment for extensively drug-resistant TB (XDR-TB) and rifampicin-resistant TB (RR-TB), but those trials will not yield a single transformative regimen for all patients



detected with RR-TB. The NDRS articulated a denominator for different forms of anti-TB drug resistance.

- Persisting challenges in treatment monitoring and adherence, especially for TB patients notified by private sector providers. There is an inability to reach the privately treated TB patients with program-procured drugs, and effective management of RR-TB and other drug resistance.
 - While many options both physical and digital (e.g., 99DOTS, call center support, ICT, IDAT, MERM) were provided by the programme, these have not been made available to staff and patients for use.
- There is a gap in implementation research on the programmatic deployment of new regimens.
- Uptake of new regimens at the field-level is lower than expected. This issue remains to be systematically evaluated because it has not yet been adequately addressed by reflexive training and advocacy alone.
- Ongoing challenges in both the design and adequacy of the subsidy (for nutritional support) are present in the DBT program (see the sections on Health Systems Strengthening and Patient Support Systems). Implementation deficiency in private sector TB patients is also an issue.

Prevention:

- TB prevention as a recognized and intentional programmatic activity has yet to launch at scale. Intrinsic challenges in the detection of incipient disease limit the value of "targeted testing and treatment of latent TB infection," as immunoreactivity (via the TB skin test (TST), interferon gamma release assay (IGRA)) remains a poor predictor of risk of disease progression.
- Low uptake of chemoprophylaxis, even among the groups who are recommended for empiric treatment of latent TB infection

(LTBI) (i.e., household contacts under 6 years of age and PLHIV).

- Continued uncertainty on the strategy to use for any expansion (e.g., test and treat vs. just treat), and new globally approved regimens (e.g., 3HP) are pending additional clinical research in India which may further delay introduction.
- AIC remains an issue in health care facilities despite the completion of several pilots and the roll out of national guidelines. Part of the challenge is that intrinsic managerial nature of AIC interventions but another other issue is the lack of suitable tools (e.g., the low cost and maintenance of LED ultraviolet air germicidal irradiation (UGVI) fixture made in India) for scale-up mostly.
- Lack of linkage between vulnerability studies and surveys to prevention efforts.

Recommendations

Instructional Structure and Capacity:

1. Improve ITRC-RNTCP linkage:
 - a. Articulate India's TB elimination needs with specific TPP to ITRC.
 - b. Refresh the ITRC pipeline with RNTCP-driven needs, including cessation of things that are not considered a critical path to TB elimination.
 - c. Consider creating a dedicated technical cell and/or set of program officers to support researchers through administrative processes, along with terms of reference to encourage and facilitate translation of findings into evidence-informed policies.
2. Leverage the Model Rural Health Research unit (MRHRU) for intensified TB surveillance. There are 18 such units across the country under the Department of Health Research. These units have dedicated staff who are engaged in research based on local needs. These MRHRUs can serve as surveillance centers for TB at no additional cost.

Operational Research:

3. Update RNTCP OR agenda with genuine priorities, and issue calls for proposals against top needs. Clarify ownership on driving operational research and implementation science, as there is overlap between ITRC and the RNTCP OR mechanisms. Perhaps ITRC is best for complex studies/managing prospective surveillance sites where interventions can be embedded and quickly tested. RNTCP ownership may be advantageous for state/local OR to identify limitations in the cascade of diagnosis and care, and improve program management/efficiency.
4. Empower the NTI based National Research Cell to help manage the knowledge needs for TB elimination with an independent and fully-staffed secretariat equipped to:
 - a. Conduct innovation identification evaluations and feedback into policy;
 - b. Provide TA to States on OR needs and priorities and calls for proposals;
 - c. Build OR capacity development for researchers; and
 - d. Create an IT platform for transparent processes and funding flows.

Case Finding and Detection

5. Make a concerted national effort to develop and deploy a TB triage and screening test by investing in both research and evaluation of already available global candidates. This is considered the highest priority research need.
6. Conduct formative evaluation(s) of ACF campaigns, and develop differentiated guidelines. These guidelines should at minimum include information on when to conduct activities, whom to target, how to screen in different groups and/or settings, and when/where not to use ACF.
7. Optimize the diagnostic algorithm currently recommended by public sector providers across all sectors.

8. Develop approaches and rapidly scale-up digital CXR screening by leveraging AI tools.
9. Develop and deploy decentralized complete rapid DST (e.g., next-generation sequencing (NGS), etc.).

Treatment:

10. Urgently fast-track trials for simpler, safer, shorter regimens for all forms of TB. Consider the following starting with RR-TB as the model and employing an adaptive and pragmatic design that includes pediatrics, patients with comorbidities etc.
11. Develop and validate a non-sputum biologic marker of cure for use instead of time/dosing for clinical trials, and adapt for program use.
12. Evaluate the reasons for low uptake of newer drugs/regimens and identify measures to rectify them.
13. Identify and assess patient-centric approaches to improve treatment adherence by introducing new digital treatment support tools and by building on the experience of the first-generation products that failed to scale (see section on Patient Support System).

Prevention:

14. Improve the utility of vulnerability mapping by researching best methods and then scaling up intervention efforts
15. Establish an optimal ACF and preventive treatment strategy inclusive of efficacy/effectiveness of treatment, durability of protection and models on impact of intervention on TB disease and deaths at local level by developing surveillance sites in high transmission settings (large community cohorts) and then following them prospectively (without treatment) to identify profile(s) most predictive of disease. These cohorts may then also be used for intervention studies.
16. Evaluate the predictive value of incipient disease (C-TB, signatures of risk and progression/outcomes).
17. Evaluate relative efficacy of AIC options, and



develop better indigenous low cost UVGI fixtures.

18. Fast-track research on safe and effective vaccines and contribute to early adoption.

Key Messages

The JMM recommends urgently revising the ITRC pipeline to RNTCP's needs; evaluating the current TB elimination efforts at the state- and district/sub-district-level (e.g., Kerala, TB-free cities) to inform scale-up of best practices; directly supporting OR to address gaps and challenges in the private sector cascade of care (e.g. detection, adherence); improving the DBT and social support package(s) and their processes, and then monitoring economic impact, catastrophic costs, and cost-effectiveness to identify priority areas for investment and allocation of resources; and investing in identifying a scalable model for UHC integration and TB package in AB-PMJAY. Additionally, developing and rapidly deploying a TB triage or screening test(s) and a non-sputum point-of-care diagnostic test to be used in effective ACF and prevention strategies will be critical if India is to meet the Prime Minister's commitment to reach the 2030 SDG target by 2025.

2.1.8 Technical Assistance to End Tuberculosis in India

India is enriched with a large pool of technical TB experts as is evident by the fact that more than 60 percent of the countries globally have received TA from an Indian national for their TB programs at least once. A variety of technical committees on various thematic areas function at the national level provide the RNTCP with policy and operational guidance. The program is also receiving TA through a variety of mechanisms and sources (see illustrative list⁶⁰ below).

- National Institutions
- TB Association of India
- Medical Colleges
- WHO (e.g. RNTCP TA project)
- USAID partners (including Karnataka Health Promotion Trust, WHP, REACH, SHOPS+, THALI, Challenge TB, FIND)

- The Union
- Bill and Melinda Gates Foundation (BMGF)
- Stop-TB-Partnership (including through the GDF and TBREACH)
- GF (e.g. JEET project implemented with CHRI, CHAI, and FIND)
- World Bank
- Parliamentarian Forum - GCAT
- Community Empowerment organizations (e.g. GCTB SATB, GHS, etc.)
- Support for Research through Niti Aayog, CDC, Wadhvani AI, TISS, IIPH etc.

Achievements

- An expansive network of technical experts supported by domestic and donor resources with a vision to continue expansion
- To date, all of the recommendations from the WHO technical support network (TSN) assessment report have been implemented. These changes include the expansion of the consultants network, an increase from 80 to 148 technical consultants are in place, including 26 at CTD and 8 regional consultants, and transition to domestic funding of the TSN.
- There is also an appetite for focusing support to priority technical areas (e.g., PPE, DR-TB, TB surveillance) by using the new regional consultants in conjunction with the continued TA from WHO and other development partners.

Challenges and Opportunities

- Continued space challenges and constraints at the CTD.
- There are additional areas in need of technical-managerial assistance beyond what the network has offered.

Recommendations

1. Considering the magnitude of the growing operations and needs, technical assistance

⁶⁰This is meant to be an illustrative list that may not be exhaustive of all current, past, and future TA sources.



- needs to continue to be expanded and scaled-up geographically and in technical areas with additional continued resources to increase coverage in order to end TB by 2025.
2. Provide infrastructural support (e.g., office space) to accommodate the present and future expansion of the network.
 - a. With the proposed expansion, space will likely continue to be a challenge in national and sub-national units. This issue needs to be addressed proactively.
 3. Ensure that existing and expanded TA remains focused on relevant thematic areas and has the capacity to address new themes as they emerge.
 - a. The JMM team recognizes that WHO contributes value in TA based on their core competencies, role, and experiences. A list of emerging or additional thematic areas has been identified by JMM that will need technical-managerial assistance and should leverage expertise from WHO and other development partners to facilitate smooth implementation. This list includes: (more information on each area listed below may be found in other sections of the report).
 - i. Epidemiological intelligence units (at all levels)
 - ii. Prevention
 - iii. DBT, finance, project implementation plan (PIP) preparation (state- and district-levels)
 - iv. Community mobilization
 - v. Addressing Social determinants, e.g. nutrition/housing etc.
 - vi. Operational/Implementation Research
 - vii. Quality of care for TB patients including adherence monitoring, post treatment monitoring and care, social support, etc.
 - viii. Stigma and discrimination
 - ix. TB in urban populations (particularly in slums and migrant workers)
 - x. Tribal TB
 - xi. Procurement and SCM
 - xii. Laboratory network services
 4. Consider providing TA beyond the RNTCP/CTD to strengthen PPM, universal health coverage, output-based contracting, and include other Ministries (e.g., Ministries of Information Technology, Planning, Urban Development, etc.) to help them support TB elimination by 2025.
 5. Development and deployment of an information system that compiles all available technical assistance experts (ensuring to include areas of particular expertise). This mechanism could serve as a pool of short- and long-term national and international consultants that would allow the TB program to quickly respond to TA requests. Partners providing TA support could facilitate this activity.

Key Messages

The JMM team applauds the efforts made by the Gol in ensuring the availability and use of TA. By implementing suggested recommendations (i.e. expansion and domestic funding) for strengthening the TSN, an important step has been made in advancing effort to a TB free India. The next step is to ensure that TA is focused on the emerging needs and technical areas of the program (see list above for list of emerging needs). To sum up, in order to end TB by 2025, the JMM recommends the expansion, both geographically and technically, of technical assistance that is supported by sustained additional resources.

2.2 Prevent

2.2.1 Preventive Services

The NSP 2017-25 has dedicated an entire section on TB preventive services and clearly outlines strategies for its expansion including:

- scale-up of TB preventive therapy (TPT) among contacts of TB patients;
- addressing social determinants of TB through multisectoral collaboration; and
- scale up of AIC through activities and innovations.

- Some potential interventions include: certification of health facilities for AIC compliance; facility risk assessment; cough corners; personal protective equipment for staff and periodic screening for TB signs and symptoms; separate infection prevention facilities for infectious drug sensitive (DS) and DR TB patients; ongoing monitoring dashboards or checklists for AIC practices etc.

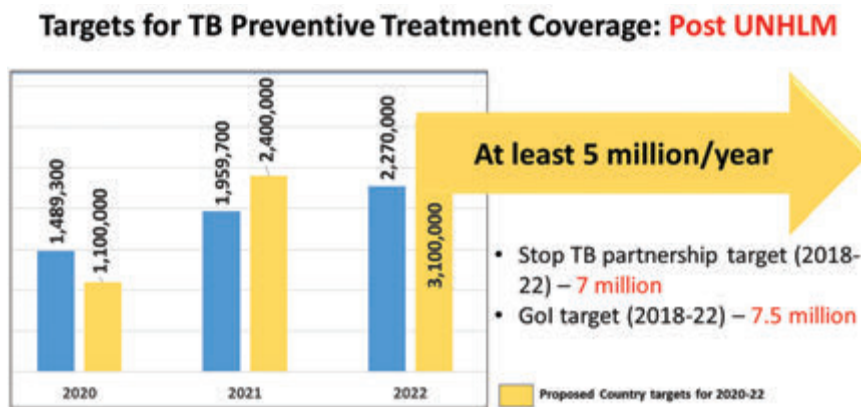
the RNTCP revised their targets for TB preventive treatment. The new targets are to provide TPT to 7.5 million eligible individuals by 2022 and continue the rapid scale-up by providing TPT to at least 5 million eligible individuals in expanded target populations in 2022 and beyond (Figure 25).

Achievements

- Since 2017, and particularly in 2019, there has been a marked increase in coverage of TB preventive services among child household contacts of TB patients (Figure 26).

Following the UNHLM on TB in September 2018,

Figure 25: Shows the new TPT coverage targets.



- Some progress has also been noted in household contact investigation to reach child contacts of TB patients for TPT provision. In 2019, close to 40 percent of

households of notified TB patients were visited with 378,000 child contacts identified and 247,000 (65 percent) child contacts received TPT (Figure 27).

Figure 26: Shows the progress made in TPT coverage among child household contacts.

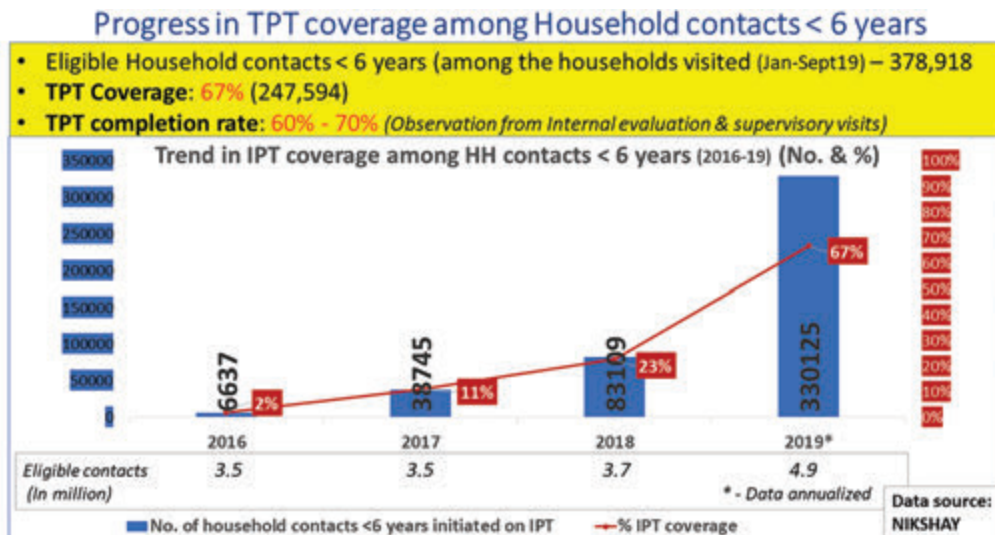


Figure 27: Shows the progress made in household contact investigation among child household contacts.

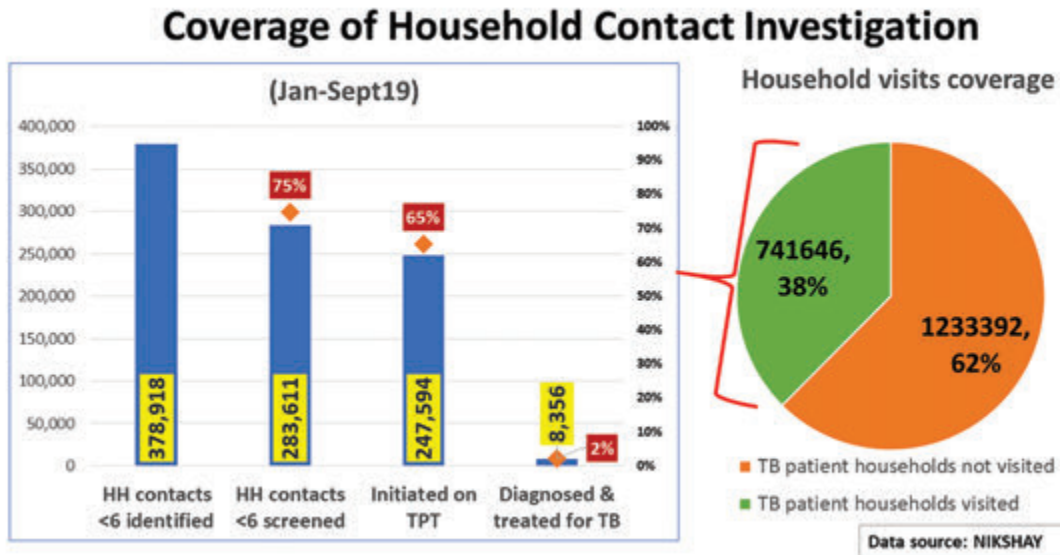
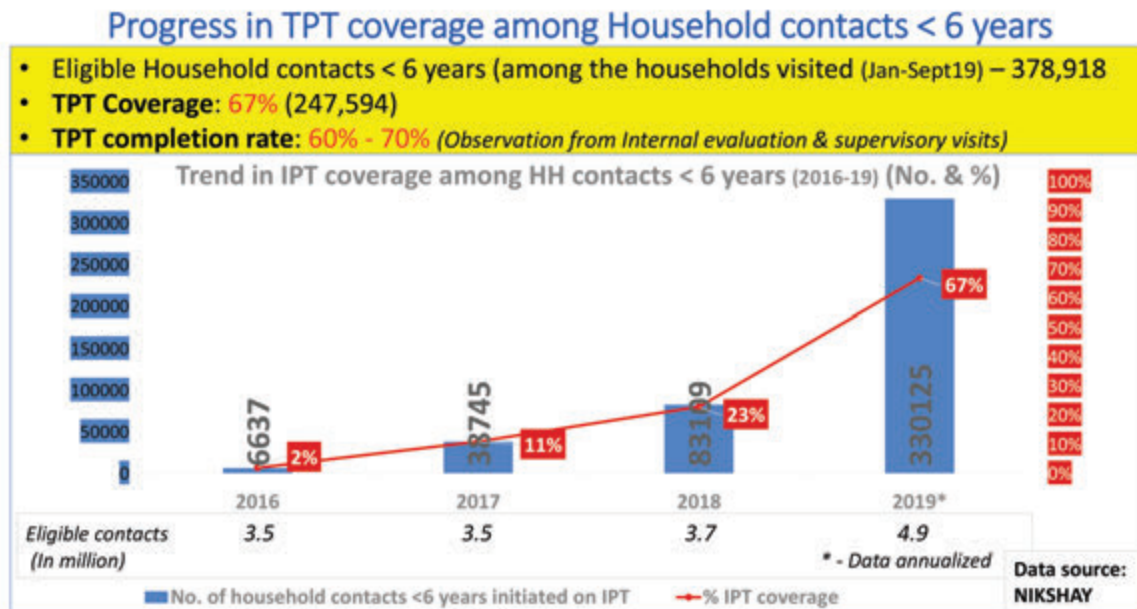


Figure 28: Illustrates the progress made in TPT coverage among PLHIV.



- Since 2017, national TB and HIV programmes have also demonstrated momentum in improving the coverage of TPT for PLHIV (Figure 28). Close to 52 percent of PLHIV on treatment have received TPT by 2019.

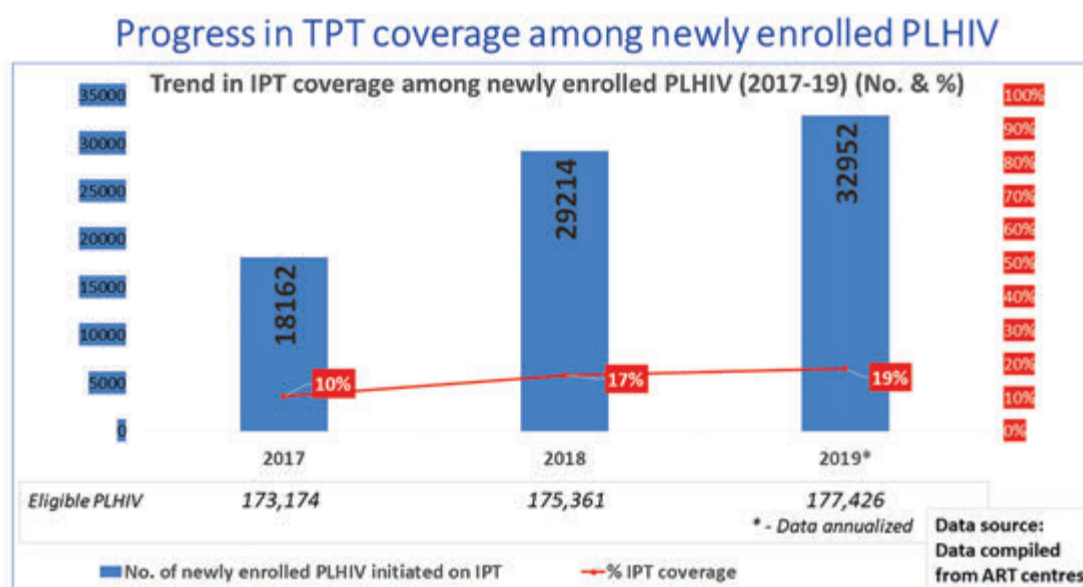
- RNTCP is also currently testing operational feasibility of the WHO mobile application in Chhattisgarh to strengthen recording and reporting of cascade of care for TB preventive treatment.
- Some sporadic examples of good practices of AIC were also observed. For example, TB screening among healthcare workers using CB-NAAT in Chhattisgarh, vulnerability mapping, cough corners, AIC awareness campaigns and distribution of home AIC kits in Kerala.

Challenges and Opportunities

- While important first steps were taken by the program to start TPT interventions, some gaps remain:
 - Low priority given to TPT by the national

- TB and HIV programs;
- Low coverage of TPT among PLHIV newly enrolled in care (Figure 29);
- Low coverage of household contact investigations;
- Restricted eligibility criteria for TB preventive treatment;
- Shorter regimen of TB preventive treatment has yet to be implemented;
- Lack of policy to fast-track “coughers” in waiting areas in secondary and tertiary care hospitals;
- Non-existent contact investigations for TB patients detected and notified from private sector; and
- Missing information due to gaps in cascade data (in NIKSHAY and/or patient records).

Figure 29: Illustrates the low coverage of TPT among PLHIV newly enrolled in care.



- Similar to TPT, crucial first steps were made in AIC, but there are persisting gaps:
 - Low priority given to AIC by national TB and HIV programmes and the general health system;
 - Lack of implementation of AIC interventions at health facilities;
- Triage and fast tracking of symptomatic persons limited to HIV care sites;
- Absence of consistent supply and use of personal protective equipment (e.g., N95 particulate respirator masks) (only seen in MDR-TB centres); and
- Inadequacy of health care workers

(HCWs) screening practice and data on TB among HCWs

Recommendations

1. Secure the funding and resources to support the planned rapid scale-up of expanded evaluations to benefit from TB preventive services by reaching 5 million per year and cover all eligible individuals by 2022 (and beyond) with TPT by RNTCP. The MoHFW and NHM should make available and approve the increased budget necessary to support: expansion of contact investigation to ALL household and other contacts; mapping of target populations; roll-out of shorter preventive treatment regimen; increased LTBI testing; the increase in human resources needed to support TPT efforts; demand generation for interventions; implementation of AIC; consistent availability of IC precautions and personal protective equipment.
2. Establish a TB prevention cell at national- and state-level to coordinate implementation and monitoring of TB preventive services. This includes providing additional dedicated staff at the TB unit level to coordinate, supervise and monitor expansion of TB preventive treatment services and systematic implementation and monitoring of AIC measures.
3. Integrate TB preventive services in all ACF efforts at health facilities, in communities and among vulnerable populations.
4. Integrate TB preventive services into all efforts for public-private initiatives (e.g., JEET, PPSA) to ensure systematic contact investigation and linkage to TB preventive treatment for all eligible individuals.
5. Strengthen household contact screening and evaluation by:
 - a. Developing and providing a package of financial incentives for service providers (public and private) to ensure access to public transportation and to necessary laboratory tests, complete coverage of household contact investigation, initiation of TB preventive treatment and follow-up to complete the course of preventive treatment.
 - b. Aggressively promoting engagement of peripheral health institute (PHI) staff, community structures/initiatives, etc.
 - c. Providing additional human resources at district- and state-level to support, supervise and monitor implementation.
6. Expand the scope and coverage TB preventive treatment services so that it is in line with the milestones of UNHLM (2022) and India's target to End TB 2025 by:
 - a. Start a nationwide catch-up campaign to achieve universal TPT coverage for all PLHIV in care and child (under five-years of age) household contacts of notified TB patients. The ultimate goal is to achieve this universal coverage (including those notified by the private sector) among these two eligible groups by 2021.
 - b. Consider immediate expansion of the target population for TB preventive treatment in line with the latest WHO guidelines with the goal of achieving nation-wide TPT coverage among all eligible contacts by 2022.
 - i. Start implementation of TPT for household contacts five-years of age and younger in select demonstration districts and/or union territories to generate country experiences by first and second quarter of 2020. Within a subset of the target population in demonstration sites, conduct systematic LTBI testing and X-ray to generate local data on the burden of LTBI and determine the need for a systematic LTBI testing policy for further scale-up. In these demonstration districts national programme should consider outsourcing of collection of blood specimen, transportation and testing while skin-test-based technology becomes available for programmatic use.

- c. Establish mechanisms for TPT adherence support and adverse events monitoring to ensure prompt action and management of the rare adverse events.
 - d. Build staff capacity for counselling to address the specific needs of healthy adult contacts and other target populations by providing training, job aids, and other supportive tools.
 - e. Expand the coverage and monitoring of TB preventive services to other WHO recommended clinical risk groups (e.g., patients on dialysis, anti-TNF treatment).
7. Rapidly adopt and expand implementation of shorter rifamycin-based TPT regimens (e.g., 3HP, 1HP, 3HR, 4R)
 - a. Considering the rapid scale-up of molecular diagnostics, the National programme should explore TPT for contacts of DR-TB patients based on drug susceptibility patterns of index cases.
 - b. The National programme should also consider procurement of technology-based tools for adherence support to support the shorter regimen treatment (e.g., ICT, IDAT). Lack of availability of Pyridoxine (vitamin B6) should be promptly resolved to prevent common adverse events associated with H use, but should not be considered a bottleneck in starting TPT.
 8. Strengthen monitoring and evaluation by ensuring that data is systematically captured on cascade of care for TPT in the NIKSHAY platform and scaling up digital tools like LTBI mobile application and contact register. These efforts should also include mechanisms to assess TPT completion and monitor TB among HCW.
 9. Employ the help of TB survivors and champions to generate TPT demand. Operationalize and leverage the newly released [Guidance Document on Partnerships](#) for advocacy and implementation of TPT activities.
 10. Strengthen AIC through effective implementation of administrative and environmental measures such as:
 - a. Leveraging ongoing initiatives (e.g., scale-up of health and wellness centres under the Ayushman Bharat scheme and initiatives by the NHM such as Kayakalp) and promote inclusion of AIC as a criterion for awards.
 - b. Consider launching a sustained national campaign for cough hygiene (e.g., implement mass media, awareness programmes in education institutions).
 - c. Developing and rolling out an updated implementation guide and supportive standard operating procedures on AIC (to include information on patient flow, engineering measures at health facilities, etc.).
 - d. Promoting innovations (e.g., AIC helpdesks to help identify and fast-track presumptive TB patients).
 - e. Ensuring compliance with national AIC guidelines at the RNTCP supported facilities (e.g., laboratories, MDR-TB wards, others) by leveraging infection control committee meetings.
 - f. Taking a leadership role in coordinating and monitoring AIC compliance in all health care facilities.
 - g. Develop and disseminate information, education, and communication (IEC) specific for AIC and TPT (e.g., promoting routine cough hygiene, fast-tracking presumptive cases).
 11. Strengthening measures to protect HCWs by implementing:
 - a. Mandatory, systematic screening HCW for TB as a part of overall health checkups at recruitment, annually and as needed.
 - b. Large coverage of free access to CXR, CB-NAAT, and additional tests for TB infection (TST, IGRA).
 - c. A referral and follow-up process to ensure for HCWs who are screened positive for latent TB are provided at least one course of

shorter TPT regimen followed by ongoing surveillance for emergence of TB symptoms.

12. Continue research and fast-track adoption of new products and innovations:
 - a. Engaging the ITRC in designing and validating new vaccine candidates (including the two candidates (VPM1002 and MIP) that are currently in Phase III trials.
 - b. Continuing to support vaccine research and fast-track clinical trials and necessary regulatory approval procedures so that the products could progress through all stages of validation.
 - c. Fast-tracking validation and roll out of LTBI diagnostic tests (e.g., C-TB, NGS, IGRA).
 - d. Approving rifapentine for programmatic use.
 - e. Addressing concerns around the high background rate of H resistance. The National programme should consider using shorter rifamycin based regimen (e.g., 4R), enhancing coverage of drug sensitivity testing of index cases (including patients notified by private sector) and generating evidence around use of index case DST-guided preventive treatment regimen among eligible contacts. Data collected from implementation may inform global guidance for the management of contacts of drug resistant TB cases.

Key Messages

The JMM team recognizes that the program has taken significant strides in ramping up TB prevention services, including aligning its targets with UNHLM goals and rolling out of TPT to PLHIV and child household contacts. In order to reach a TB free India by 2025, the JMM team recommends an increase in funding and resources with specific attention to support the scale-up required of both TPT and AIC activities to meet these ambitious targets.

2.3 Detect

2.3.1 Case Finding, Diagnostics and Laboratory Services

Within this thematic area, we discussed the implementation of the NSP 2017-25 strategy for 1) the early and complete detection of all TB patients including intensified case finding strategies and addressing high risk populations, and 2) the provision of diagnostic services with a focus on revised laboratory expansion plan, planning for scale-up of new diagnostics within the revised [Technical and Operational Guidelines for TB Control in India](#)(all forms) in both adults and children and public-private partnerships for laboratory testing and specimen transport.

Achievements

- All diagnostic tests for all forms of TB are available free of direct cost in the health system at all levels.
- TB patient notifications have steadily improved over the past three years – from both public and private sector health facilities.
- Many states are meeting or exceeding targets for patient notification in the public sector.
- The presumptive TB case rate has been steadily increasing over the past three years.
- In 2018, approximately 189 million persons were screened for TB during active case finding investigations and 47,307 TB patients found.
- Microscopy services appear to be adequate. Microscopy services have been expanded and further decentralized from 1 per 100,000 to 1 per ~65,000 population. External quality assessment consists of blinded rechecking and on-site evaluations (OSEs).
- There has been a dramatic expansion of molecular testing from 620 sites in 2015 to 1530 sites in 2018. The Truenat MTB and

MTB Plus test have been evaluated and are being deployed to increase further molecular testing capacity.

- All diagnostic tests for pre-treatment evaluation are available free of direct cost at the nodal and district DR-TB Center.

Challenges and Opportunities

The completeness of contact investigation as a tool for active case finding and identifying candidates for preventive therapy coverage are variable. While contact investigations for patients diagnosed in the public sector were usually done, contact investigations for patients diagnosed in the private sector were often lacking. Household contacts younger than six years of age were not consistently placed on TPT (as detailed in the Prevent section above).

- Documentation of contact investigations, their laboratory evaluations, and outcomes were often incomplete.
- Universal DST
 - The definition of universal drug susceptibility testing (U-DST) used by RNTCP should be reviewed as well as the method for calculating the percentage of patients receiving a DST. The current RNTCP definition of U-DST is actually a measure for universal rapid molecular testing for detection of TB among all notified patients (not bacteriologically confirmed patients) which makes India's success less impressive. That is, a CB-NAAT result of *Mycobacterium tuberculosis* (MTB) not detected is not logically different from a culture result of no growth – neither is a drug-susceptibility test and those patients should not be included in the calculation for U-DST.
 - ♦ Note that the WHO definition of universal DST is that all bacteriologically confirmed patients should undergo DST for at least rifampicin ®. Among those detected

with RR-TB additional DST should be done for at least fluoroquinolones.

- In many states, 60 to 70 percent of eligible notified patients diagnosed in the public sector received a CB-NAAT, but only 15 to 25 percent of eligible notified patients in the private sector received a CB-NAAT.
- Patients are required to do three or four visits to get a diagnosis (smear) and eventually submit a sample for CB-NAAT.
 - ♦ Patient-important turnaround times (TAT) (from diagnosis to receipt of laboratory test results) can be greater than two weeks for a test that takes two hours.
- Many newly diagnosed smear-positive patients are not monitored to ensure they submit a specimen for CB-NAAT. Patients are simply referred to another DMC for sample collection with no follow-up to determine if they actually received the test. A process is needed to track patients.
- Adequacy of laboratory infrastructure to address the diagnostic demand
 - ♦ Human resources – lack of qualified staff, training, retention, salaries, competencies.
 - ♦ The FIND support for many laboratory technicians (LTs) in intermediate reference laboratories (IRLs) and DST laboratories ends on March 31, 2020; there is no clear transition to state support of these lab positions. In the Ajmer IRL for example, FIND supports 10 positions.
 - ♦ Vacancies in laboratory positions are common. For example, only seven of nine sanctioned LT positions in the Ajmer IRL are filled.
 - ♦ Senior TB Laboratory Supervisors (STLS) are responsible for supervising up to 20 microscopy centers and several do not

have vehicles and reimbursement of travel costs is often quite delayed.

- Salary structure is not adequate to address the required competencies of the sanctioned positions and attract suitable qualified personnel. Salaries for TB laboratory workers are not competitive in the marketplace.
- Budget – although funds are allocated, funds are not available to purchase supplies and reagents. There are issues with disbursement and underutilization of approved funds.
 - Procurement of laboratory consumables and reagents is not taking place regularly and in a timely manner.
 - In some sites visited, the State had been unable to purchase reagents for ~4 years which has led to the use of expired reagents. It is noteworthy that MGIT, CB-NAAT and LPA kits are provided centrally by other sources (FIND, GoI) and procurement and distribution has not been an issue.
 - Maintenance and calibration of CB-NAAT, MGIT, and HAIN instruments and BSCs were being conducted and documented through a central annual maintenance contract (AMC). Other than instruments on the central AMC (e.g., UPS), funding for maintenance and calibration was inadequate in some states. Additionally, AMCs were lacking in some states.
 - Inadequate laboratory capacity contributes to missed opportunities for early diagnosis and places a burden on an already overburdened nodal TB lab, on patients, and on community workers needing to reach diagnostic services (CB-NAAT, microscopy, underutilization of chest X-rays). In general, TB diagnostic capacity and easy access needs strengthening.
- Ensuring sustainability of laboratory

operations, constantly testing and adopting newer transformative ways of facilitating diagnosis and maintaining TAT is a challenge for the program. Effective implementation of a new diagnostic algorithm across public and private sectors will require augmentation of laboratory capacity.

- Precise role of PHI microscopy centres (MCs) is unclear – some PHI MCs have insufficient number of samples to maintain proficiency. The number of PHI MCs to supervise also places a large burden on STLSs.
- Rapid molecular diagnostic services: NAAT, FL-LPA/ SL-LPA, Gene Sequencing (NGS/Pyro sequencer)
- Inadequate molecular testing capacity: CB-NAAT instruments are overburdened in some sites, but some sites do less than 150 tests a month.
- Not all CB-NAAT sites follow the national algorithm with respect to the priority of testing – 1) U-DST 2) key populations (e.g., PLHIV, children), 3) smear-negative, X-ray suggestive of TB, 4) other presumptive TB. Offering CB-NAAT indiscriminately (i.e., without a rigorous risk assessment) to all persons suspected of having TB when they present to the CB-NAAT site is thought to be contributing to overutilization of CB-NAAT and interfering with priority testing.
- In some states, chest X-ray is underutilized. In other states, X-ray services are not available for hard-to-reach populations.
- A high proportion of clinically diagnosed patients are in the private sector – up to 80 percent of notified patients. This has implications for DST as well as assessing the quality, accuracy and completeness of TB diagnosis and patient notification.
- Sample transport mechanism
- In several states, less than 40 percent of specimens were received within the target time of 72 hours of collection.



- This contributes to a high rate of contamination of cultures (e.g., more than 20 percent for MGIT cultures) which in turn results in delays in receipt of test results because of the need to repeat culture and subsequently delays in initiation of appropriate therapy.
- Specimen transport occurs only once or twice a week in some sites. This contributes to the overly long patient-important TAT (from diagnosis to receipt of laboratory test result) (e.g. more than two weeks to get a result for a test that takes two hours).
- Poor specimen transport creates travel burden and expenses for patients.
- In some areas, patients are referred to a testing facility rather than referring specimens. Some patients are required to travel 50 to 60 kilometers.
- Lack of MOU at state level for specimen transport.
- Biosafety
- Direction airflow was inadequate or non-existent in several of the visited facilities, which resulted in inadequate protection for workers, the community and the environment.
- Biomedical Waste Management Guidelines (2018) were not implemented in all laboratories.
- AIC procedures were inadequate in the health care facilities visited, especially in-patient waiting areas.
- Laboratory Information Management System (LIMS) and integration with NIKSHAY
- LIMS is just being implemented and seamless integration into NIKSHAY is not yet realized.
- External Quality Assessment
- Blinded rechecking is being conducted. However, results are concerning in some states in that very few laboratories were found to have any errors (including quantitative errors).
- Key performance indicators (KPIs) from IRL also have inconsistencies, more than 10,000-line probe assays (LPAs) conducted with no invalid results of errors.
- OSEs are being conducted but monitoring of the implementation and effectiveness of the recommended corrective actions is not being done routinely.
- STLSs in some states have not been provided with vehicles per national guidelines; this greatly impacts ability to monitor laboratories.

Recommendations

Priority:

1. Ensure that laboratory support for contact investigations is readily accessible, contacts are comprehensively and promptly identified and tested/evaluated, and quality results are consistently documented to assess the yield of additional TB cases identified, as well as contacts with latent TB infection in need of TPT.
2. Urgently seek financing opportunities to fill key staffing gaps and update salary and staffing structure.
3. Take advantage of the considerable testing capacity available in the private sector and engage private sector laboratories for end-to-end operations (turnkey model) including specimen collection, transport, reflex testing, pre-treatment evaluation and providing reports within stipulated TAT for patient management.
4. Focus ACF and intensified case finding (ICF) efforts on vulnerable and high-yield populations, institutions and individuals, and use sensitive screening and detection tools.
5. Design and implement an efficient specimen referral and results reporting system that is responsive to local epidemiology and geography and minimizes patient-important TAT.
6. Accelerate implementation of U-DST by

expanding rapid molecular testing capability through efficient utilization and localization of existing and new NAAT instruments and engaging private sector laboratories for the provision of molecular testing.

Specifically Actionable:

7. Contact Investigation is an excellent opportunity to detect additional TB patients.
 - a. Contact tracing must be done promptly and systematically.
 - b. Programs must monitor and supervise quality and completeness of contact tracing.
 - c. Hold the program accountable for completeness and quality of contact tracing, perhaps by including an in-state scoring system.
 - d. Ensure that contact investigation of pediatric TB patients to identify the source case is done for all pediatric TB cases.
 - e. Repeat contact tracing at the end of treatment and during follow-up to detect newly developed cases and document treatment outcome.
 - f. Ensure availability of testing (e.g., IGRA) and follow-up (TPT) for contacts.
8. The yield of ACF and ICF is low and the screening is resource intensive.
 - a. Focus ACF and ICF efforts on vulnerable and high yield populations, institutions and individuals by:
 - i. Identifying and mapping vulnerable populations, institutions and individuals
 - ii. Ensuring that vulnerable individuals in high-yield settings be screened (e.g., health care facilities, shelters, old age homes, refugee camps, correctional facilities and other high-risk locations, such as specific workplaces)
 - iii. Including follow up of treated patients as a high yield population to be actively screened (i.e. identify relapse and reactivated TB)
- iv. Using sensitive tests (digital chest X-ray, CB-NAAT) to detect patients during ACF/ICF screenings – do not rely on smear only.
- v. Providing guidelines and training to ensure that screening and follow-up are completed correctly. Monitor the quality of screening.
- vi. Evaluating cost efficiency and cost benefit of ACF/ICF and early case detection.
 1. Note the benefits of ACF are more than case detection (e.g., raise community awareness).
- vii. Including screening for TB in multi-disease screening efforts in the community and vulnerable populations.
9. Efficient specimen transport can improve TB detection.
 - a. Be patient centric – refer specimens not patients.
 - b. Monitor and document KPIs for specimen referral and results reporting, especially TAT. Initiate corrective actions to minimize TATs for referral for NAAT, LPA, culture, and DST.
 - c. Perform a network optimization study of the specimen referral and results reporting system.
 - i. Use network planning, simulation or optimization tools for design and planning with an emphasis on access to services and patient flow through the diagnostics cascade.
 - ii. The optimal specimen referral pathway may vary by geography and local epidemiology and infrastructure.
 - d. Explore the use of the PPSA model to facilitate specimen collection and transport for NAAT and other testing (e.g., LPA, culture, DST)
 - e. Streamline the specimen collection process by:

- i. Minimizing the number of visits needed to get a diagnosis and NAAT
 - ii. Considering 1) collecting specimens for smear microscopy; 2) storing all specimens while smear testing is done, and 3) for any newly diagnosed smear-positive patient, sending the stored specimen to the CB-NAAT site
 - iii. Conducting training to ensure capacity and competency for collection of quality sputum specimens and specimens from children and presumptive extrapulmonary tuberculosis (EPTB) for intended use are available.
 - iv. Ensure the availability of adequate numbers of specimen collection containers suitable for the intended use (e.g., Falcon tube for CBNAAT specimens).
10. Laboratory Capacity must be increased to meet the demands of the new TB diagnostic algorithm and emphasis on rapid testing.
- a. Urgently seek financing opportunities to fill key staffing gaps and update salary and staffing structure.
 - i. Current staffing and salary structure (under NHM) are inadequate and do not match the skills and competencies needed to address the laboratory supported need for the ambitious plans of the NSP and to attract qualified personnel.
 - ii. Ensure existing experienced and trained laboratory staff at IRLs and National Reference Laboratories (NRLs) are absorbed with state programs as guided by Gol.
 - b. Engage private sector laboratories for end-to-end operations (turnkey model) including specimen collection, transport, reflex testing, pretreatment evaluation and providing reports within stipulated TAT for patient management.
 - i. Program can learn from the experience of the National AIDS Control Organization (NACO) who has successfully contracted a private laboratory network that is fully equipped to do high volume testing of viral loads among HIV infected patients across the country.
 - ii. Outsourcing may be particularly useful for specialized tests such as IGRAs.
 - iii. Build capacity for certification and monitoring and ensuring the quality of testing in private sector laboratories. Include IRLs in engaging laboratories and monitoring of quality. Consider institutionalizing the quality assurance mechanism of laboratory services for the private sector, irrespective of free service provision. The EQA system for ELISA test in the private sector conducted by the HIV laboratory network may be a model ad resource.
 - c. Ensure timely reporting of test results to patients and providers.
 - i. Deploy diagnostics connectivity to improve reporting and monitoring of TAT.
 - d. Emphasize quality, reliability and safety in the laboratory as well as the adequacy of facilities, infrastructure and utilities.
 - i. Conduct and document annual training or refresher training in biosafety for all laboratory staff.
 - ii. Ensure that national biosafety and waste management policies and procedures are implemented in all laboratories.
 - iii. Ensure that basic occupational health services and annual TB screening of HCWs are available in all facilities.
 - e. Ensure the availability of adequate numbers of well-trained competent laboratory staff in existing laboratories and planned new laboratories.
 - i. Take advantage of e-tools to ensure the uniformity of training. All training must be accompanied by competency testing

- and certification.
- f. Forecast diagnostics and laboratory requirements in-line with the new algorithm and ensure a regular supply of reagents and consumables. Improve efficiency and capacity for procurement within state-level teams.
 - g. Conduct a diagnostic network optimization exercise for existing instruments and testing capacity (NAAT, LPA, culture) to assess the need for additional laboratory capacity, and optimize access to diagnostic services.
 - h. Expand capacity of conducting extra-pulmonary tests like imaging, histopathology, cytology at least one in each district - either through public or private sector.
 - i. Evaluate the utility of noninvasive procedures and alternative biological specimens (e.g., stool) for diagnosis of TB in children).
11. CXR is an important entry point into the TB diagnostic algorithm. Especially with respect to triaging smear-negative presumptive TB patients and children for further testing (e.g., CB-NAAT) as well as screening during ACF/ICF.
 - a. Standardize CXR utilization through clear standard operating procedures for TB screening, diagnosis and treatment monitoring.
 - b. Define the role of and access to timely tele-radiology. Expand X-Ray reading capacity through tele-radiology, training of medical officers and use of artificial intelligence enabled tools.
 - c. Clearly define the role of CXR as a triage tool for NAAT in the national testing algorithm and implement.
 - d. Enforce and monitor adherence to CXR algorithms.
 - e. Develop systems to track CXR conducted, CXR abnormal, and referral for further testing and to track linkage of abnormal CXR with CB-NAAT testing.
 - f. Expand use of mobile digital CXR vans to improve access to X-ray services in hard-to-reach areas.
 12. Accelerate U-DST for all notified patients in both the public and private
 - a. Improve access to and capacity for NAAT by:
 - i. Expanding NAAT testing capacities - add instruments and optimize NAAT instrument placement and utilization
 - ii. Creating mechanisms for outsourcing molecular tests to private sector laboratories in areas where RNTCP capacity is over-utilized or not available
 - iii. Ensuring that NAAT sites follow the priorities in the national testing algorithm. Give priority to testing for U-DST and for key populations
 - iv. Conducting first line-LPA testing in accord with national diagnostic testing algorithm.
 - b. Sensitize private sector providers to the importance of submitting specimens for DST.
 - c. Consider providing incentives for submitting specimens for U-DST.
 - d. DST Algorithm and capacity must also address DST for the new drugs (e.g., BDQ).
 - e. IT enabled patient support systems could also be a choice for ensuring complete coverage of U-DST.

Key Messages:

1. Minimize patient-important TATs (time from diagnosis to taking action on a test result) to avoid delays in diagnosis and initiation of appropriate therapy as well as loss to follow.
2. Use a systems approach to develop a robust, patient-centric diagnostic system that emphasizes access to quality-assured rapid molecular tests and ensures the timely flow of specimens and information.
3. Prioritize conducting, documenting and

monitoring systematic contact tracing. Hold programs accountable for completeness and quality of contact tracing, perhaps, by including contact tracing in-state scoring system.

4. Focus ACF/ICF on vulnerable populations and individuals and use sensitive tests to improve yield. Make ACF more efficient and less resource consuming.

Additionally, the team would like to highlight the new ideas or strategies presented in this section that are beyond the current NSP:

- To increase TB case detection, implement a phased replacement of smear microscopy with NAAT as the initial diagnostic test for all persons with presumptive TB.
 - This is mentioned in the NSP and would require 8,000 NAAT instruments.
 - Cost estimate: about 50 million USD to test 20,000,000 presumptive TB patients - 15 million USD for instruments and 32 million USD annually for cartridges.
 - Acid-Fast Bacillus (AFB) smear microscopy will still have an important role in treatment monitoring, screening for NTM, and as triage test in some settings.
 - The role of chest X-ray as a triage tool for NAAT should be clearly defined and implemented in the national testing algorithm.
- Rapid and reliable laboratory testing is a patient right
 - Increase community awareness of the TB diagnostic pathway and opportunities to seek care – promote care seeking behaviors and reduce patient drop out.
 - Create demand from private sector clinicians for access to rapid testing.
- Emphasize prevention of infectious TB – stop TB before transmission occurs

- Expand contact investigations and use of TPT.
- Develop epidemiological strategies to identify transmission of infection in critical populations and geographical zones.
- As tools become available, consider methods and strategies to identify and treat subclinical, or incipient, TB.
- Implement or expand a surveillance system for DR-TB in order to better understand and address trends in the epidemiology of DR-TB in the various regions of the country.

2.4 Treat

2.4.1 Treatment Services for Drug Sensitive Tuberculosis

In this section the team examined the current implementation and gaps of treatment of drug sensitive TB (DS-TB) strategies as presented in the NSP. The subsections below specifically focus on six of the nine proposed activities in Chapter 7 of the NSP: Treatment Services. These focus areas are: adherence and monitoring, care cascade monitoring, private providers, patient empowerment, clinical support, and pharmacovigilance.

Achievements

- The RNTCP programme has adopted global recommendations on treatment of DS-TB. In 2018, the country eliminated the 'Category II' regimen for Previously Treated TB patients. With this move, the programme is now providing an all-oral regimen for all DS-TB patients, and has been able to address the issue of adverse events arising due to injectable use.
- The Programme has also worked towards empowering TB survivors by conducting mentorship training for them and developing their capacity as "TB Champions". These Champions have been playing an increasing role in

treatment support for TB patients. They are strong, credible, and vocal advocates who not only support but also own the cause of ending TB. States and Districts have also enacted TB forums in which TB patients, or their families are represented, and administrators directly interact for feedback about diagnostic and therapeutic services.

- Furthermore, engagement with the private sector has increased which has enabled better adoption of RNTCP policies and better provision of public health action by the programme for patients seeking care in the private sector. This has also led to a significant increase in the notification from the private sector.

Challenges and Opportunities

While great strides have been made, there are persisting programmatic challenges. Based on the field visits and inputs from various experts, the group has identified the following challenges in the implementation of NSP 2017-25 focus areas.

Adherence and Monitoring:

- Lack of sufficient monitoring and supervision by programme managers and supervisory staff continues to be an ongoing challenge in implementation of policies.
 - Certain aspects of the treatment of DS-TB patients such as the need for ensuring that patients actually consume their medicines, is highly dependent on the supervision of treatment supporters in the community and institutions. Supervisory staff must ensure that the support being offered by treatment supporters to the patients is sufficient and as per patient needs.
 - There is a dearth in monitoring the availability of medicines, timely and complete filling up of records, NIKSHAY entry.

- It has been noted that most supervisory staff, including the most crucial position of STS, are finding it difficult to devote time to monitoring and supervision of programme activities due to being burdened with tasks related to DBT.

- While long-term follow-up of patients at 6-, 12-, 18- and 24-months post successful completion of treatment is already a part of the National Policy, it is not being implemented.
- A need to also conduct long-term contact investigations was observed as it is known that TB occurs in both adult and children family members and contacts of infective TB patients, with the maximum probability of disease in the first two years following exposure.
- Insufficient prioritization and implementation of adherence technology.
 - Lack of clarity among field staff on DOT procedures, including frequency of DOT. After the introduction of a daily regimen for DS-TB, daily DOT is required but this is not happening at the field-level.
 - In addition, multiple options for adherence are now available and the choice is expected to be made by the peripheral staff in concurrence with the patient.
 - Insufficient or slow uptake of IDAT in the states the JMM team visited. ICT based adherence technologies have also been introduced, but their adoption is dependent on the states.

Diagnosis and Care Cascade Monitoring:

- Quality and frequency of staff training is highly variable.
 - The team observed that many practices did not comply with RNTCP prescribed guidelines (e.g., non-adherence to the

diagnostic algorithm, difficulty in identification and management of adverse events).

- Additionally, it was noted that the quality of training was not being measured. Many quality issues such as delay in obtaining laboratory results and consequent delay in initiation of treatment were also noticed by the group. These system issues in the care cascade of a TB patient (e.g. detection, treatment, prevention of TB care) need to be addressed through regular good-quality training.

Private Providers:

- No system is in place to track treatment adherence, compliance and outcomes of patients in the private sector. In India, most patients in both rural and urban areas tend to seek care from a private provider, which signifies a need for better strategies for private sector provider engagement in ensuring universal access to quality TB care for all.

Patient Empowerment:

- The programme has supported the establishment of a TB Champions network but continued scale-up and induction of effective TB forums at all levels is not yet realized.

Clinical Support:

- Lack of implementation of the diagnostic algorithms across all facilities. The JMM team observed this at many of the facilities visited.
- Absence of proper progression of patients, whose weight increased by more than five kilograms, through weight bands
- An observed need for decision making support systems for healthcare providers at all levels was noted.

Pharmacovigilance:

- Limited capacity for proper identification, management and reporting of adverse events (Aes), especially for FDCs.

Recommendations

Adherence and Monitoring:

1. Outsource or provide TA to address the burden of DBT at the state- and district-level. In order to enable better supervision and monitoring of activities, technical and supervisory staff of RNTCP to be freed from DBT related tasks.
2. Implementation of a monthly review of STS, STLS, and or medical officer TB control (MOTC) by DTOs using a checklist should also be made mandatory.
3. Generate a geo-map to illustrate location and availability of supervisory staff. Consider providing tools (e.g., tablets) for this exercise from the national-level.
4. Ensure that long-term follow-up (for up to two years) post-treatment is being observed. Additionally, both children and adult contacts should also be followed up for two years to enable early detection and treatment of TB disease.
 - a. Using the Kerala model for contact investigations as an example, consider employing the use of a patient-based register for recording the prescribed long-term follow-up of patients and contact for two years.
5. Prioritize the implementation of adherence technologies by:
 - a. Ensuring the availability of DAT at the state-level.
 - b. Tailoring adherence technologies to individual patient needs by using a combination of DAT and traditional adherence support mechanisms as needed.
 - i. Consider employing a checklist to enable staff at the treatment centres to work with the patients to find the right



combination. The JMM team suggested that mechanisms should be prioritized into three categories/mix of interventions:

1. **First priority:** Digital adherence technology (99DOTS for DSTB/ MERM for DRTB & Pediatric TB) in addition to family members as treatment supporters (followed by once a week supervisory visit to patient's home by supervisory staff of the PHI).
 2. **Second Priority:** Community based (involving ASHA or other community member) institutional treatment supporter depending on the distance a patient has to travel. This option may be applicable for patients who are not eligible or not willing to use DAT.
 3. **Third Priority:** In cases like sick and bed-ridden patients or children, a family member could be assigned with the responsibility to be the treatment supporter for the patient. In these cases, too, supervisory visits by PHI staff would be required to build the capacity of the family to offer DOT.
- c. Ensuring that a joint informed decision (between the patient and provider) is made

taking into consideration the patient's medical and practical needs, personal choices, and agency.

- d. Building capacity of all treatment supporters, especially community and family-based treatment supporters, through the PHI. This could include informational brochures in local language(s) on basic TB knowledge, transmission, treatment, and role of DOT to highlight the importance of adherence, and integrated into the general health system based on PHI.

Care Cascade Monitoring:

6. Implementing quality training both at time of onboarding and regular intervals thereafter at all levels.
 - a. Consider structuring onboard training as modules to cover the various key topics.
 - b. Realize the potential and optimize utilization of e-platforms (e.g., ECHO, Swasthya e-Gurukul) for training.
7. Employ the quality improvement (QI) model to help staff identify problems, build a team, conduct root cause analyses, and begin the plan, do, study, act (PDSA) cycle on a biannual basis (Figure 30).
 - a. Performance should be measured on a run chart with course correction every three to

Figure 30: A visual representation of the PDSA cycle.



Figure 30: A visual representation of the PDSA cycle.



six months if no significant progress is recorded.

Private Providers:

8. Explore the feasibility and consecutively support the establishment of System for TB Elimination in Private Sector (STEPS) Centres in all private healthcare facilities (i.e., Kerala), along with a formal evaluation to inform its expansion to other states.
9. Optimize the role of JEET staff for PPE including empowering staff to suggest potential PPSA mechanisms for PIPs.
10. Better utilization of JEET staff for engagement with private practitioners and proposing other PPSA mechanisms through the PIP.
11. PPSA mechanisms will need to support private providers mapping, referral for diagnostics/treatment/public health action to the public sector, training of private providers on RNTCP protocols, and NIKSHAY reporting, and ready access to free FDC for privately treated TB patients.

Empower patients:

12. Support the scale up of the network of TB Champions using NGOs and other partners.
 - a. Important to ensure the neutrality and independence of the network of Champions.
 - b. Consider strengthening the role of TB Champions as peer-supporters for TB patients cared for in private and other sectors.
13. Leverage the reach of TB Champions to interact with high-risk populations and patients that have a history of adherence issues.
14. Harness the experience of TB Champions to inform policy makers about how to better mold service delivery for specific patient groups.

Clinical Support:

15. Beyond training(s), build capacity of staff with resources and materials (e.g., ready reckoners, pamphlets, job-aids) for easy

reference.

16. Develop a 'clinical decision support' (CDS) tool and integrate into the NIKSHAY system. This tool can help address the lack of standard diagnostic algorithms and assist staff in prescribing the correct regimen. An additional indicator of clinical decision support can also be considered for data entry into NIKSHAY.

Pharmacovigilance:

17. Build and further strengthen the capacity of field workers and treatment supporters to identify symptoms of possible AEs.
18. Implement regular trainings, sharing of case studies and e-training sessions (e.g., through ECHO/Swasthya e-Gurukul), to enable medical officers to better identify and manage AEs due to FDCs.
19. Establish clear pathways of referral for AEs for the treatment supporter. A model referral pathway may be recommended by the programme which should then be adapted to local settings by the district/sub-district-level, keeping in mind the practical feasibility.
20. Develop and disseminate clear information to the states, districts and PHIs on the availability of loose drugs for first-line-treatment that may be used in the event of AEs due to FDCs.

Key Messages

1. Ensure treatment adherence and strengthen its supervision and monitoring using new digital adherence technologies.
2. Strengthen and sustain high-quality training for staff at all levels.
3. Effective PPE in the management of DS-TB management along the care cascade from case finding to treatment outcome.

2.4.2 Programmatic Management of Drug-resistant Tuberculosis

India is one of the twenty countries listed by WHO with the highest estimated numbers of incident MDR-TB cases. The [First National Drug Resistance](#)

[Survey](#) (NDRS) (2014 – 2016) has been completed. Any drug resistance among new patients was found to be 22.5 percent, among previously treated patients 36.8 percent, and among all patients 28 percent. MDR-TB among new patients was 2.8 percent, among previously treated patients 11.6

percent, and among all patients 6.2 percent (Table 9). This translates into an estimated 130,000 (77,000-198,000) individuals suffering with MDR-TB/RR-TB emerging each year in the country.

Table 9: Results of 1st National DRS survey, 2014-2016

	New TB patients (95% CI)	Previously treated patients (95% CI)	DST results
DST results	3065	1893	4958
Susceptible	2374 (77.46%) (75.93 – 78.92%)	1196 (63.18%) (60.96 – 65.36%)	3570 (72.01%) (70.73 – 73.25%)
Any drug resistance	691 (22.54%) (21.10 – 24.10%)	697 (36.82%) (34.64 – 39.04%)	1388 (28.02%) (26.77 – 29.29%)
Any drug resistance	691 (22.54%) (21.10 – 24.10%)	697 (36.82%) (34.64 – 39.04%)	1388 (28.02%) (26.77 – 29.29%)
MDR	87 (2.84%) (2.28 – 3.49%)	220 (11.62%) (10.21 – 13.15%)	307 (6.19%) (5.54 – 6.90%)
MDR + any second line injectable agent (SLI)	6 (6.90%) (2.57 – 14.41%)	5 (2.27%) (0.74 – 5.22%)	11 (3.58%) (1.80 – 6.32%)
M D R + a n y fluoroquinolone (FQ)	21 (24.14%) (2.57 – 14.41%)	46 (20.91%) (15.73 – 28.89%)	67 (21.82%) (17.33 – 26.87%)
Extensively drug resistant TB (XDR-TB)	2 (2.30%) (0.28 – 8.06%)	2 (0.91%) (0.11 – 3.25%)	4 (1.30%) (0.36 – 3.30%)

Source: <https://www.tbcindia.gov.in/showfile.php?lid=3315>

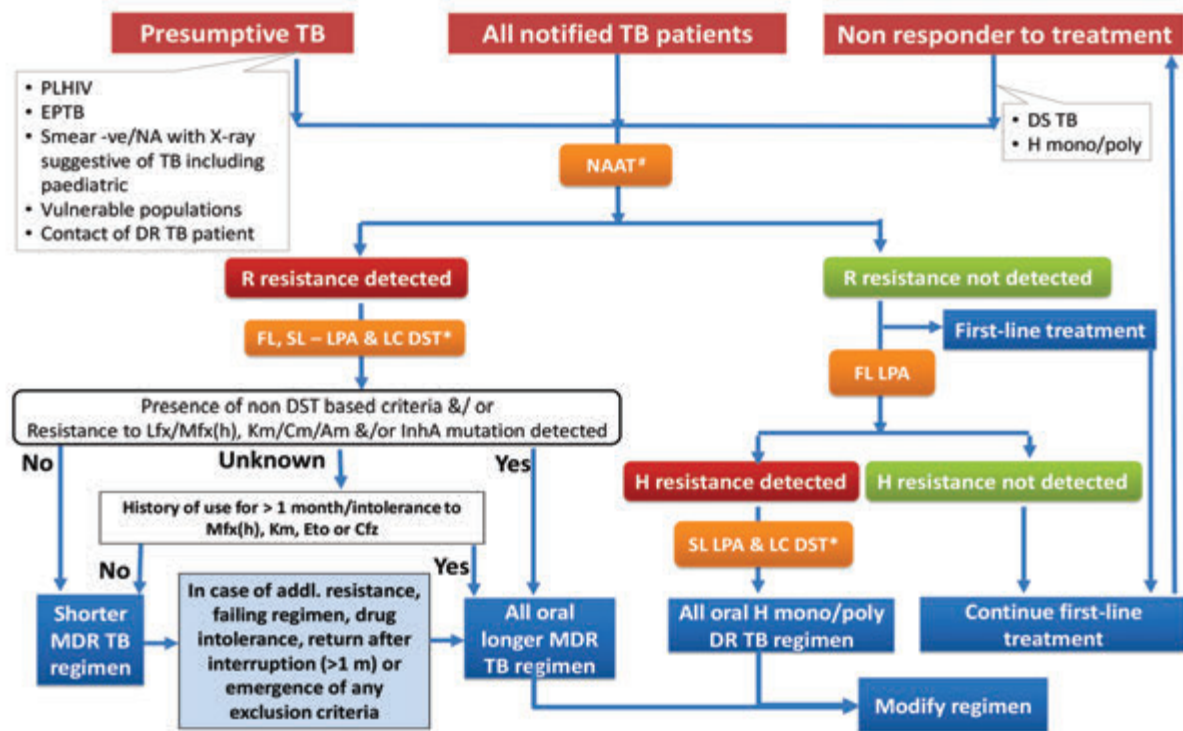
Achievements

The RNTCP initiated services for DR-TB patients in 2007, and has in recent years made great strides since that start. Many new initiatives have been introduced to improve DR-TB care.

- The updated 2019 RNTCP PMDT guidelines are aligned with current global recommendations. “Universal” DST (i.e., testing of all TB patients for R resistance) was initiated in September 2017 and scaled-up to the entire country from January 2018.

- Laboratory capacity has continued to be scaled up, with 1,530 CB-NATT (i.e., 1,180 GeneXpert, 350 TrueNAAT) units available across the country (vis a vis NSP 2019 target of 1835), 64 laboratories conduct LPA testing (vis a vis NSP 2019 target of 54), and second-line drug susceptibility testing (SL-DST) is available in all States. The revised integrated DR-TB diagnostic algorithm recommends testing of all notified TB patients for R and H resistance, and all RR-TB patients for fluoroquinolone (FQ) and second line injectable (SLI) (Figure 31).

Figure 31: Revised integrated DR-TB diagnostic algorithm.



NAAT include CBNAAT & TruNAAT

*LC DST will be done as per the diagnostic algorithm

** Refer table of exclusion criteria for shorter MDR-TB regimen

- There is country-wide access to treatment regimens with new and repurposed drugs (FQ, linezolid [LZD], clofazimine [CFZ]). Namely:
 - Bedaquiline (BDQ) containing regimen - a cumulative total of 7,965 patients have been enrolled up to September 2019;
 - Shorter treatment regimen (STR) for DR-TB patients - a cumulative total of 46,129 patients have been enrolled up to September 2019;
 - Regimen for H-resistant cases a cumulative total of 18,904 patients have been enrolled up to September 2019; and
 - Delamanid (DLM) containing regimen is available in 7 states (Chandigarh, Kerala, Karnataka, Lakshadweep, Orissa, Punjab and Rajasthan) for adults and in all states for children aged

between 6 to 17 years - a cumulative total of 321 patients have been enrolled up to September 2019.

- The 2019 guidelines recommend that the number of standard regimens for the various DR-TB patients be reduced from the current 11 to 3 (6-9 months regimen for H mono-/poly-resistant patients; 9 to 11 months STR regimen; a 18 to 20 months fully oral longer regimen containing new drugs for those RR-/MDR-TB patients ineligible for the STR – currently available in 7 states [Delhi, Gujarat, Kerala, Karnataka, Puducherry, Tamil Nadu and West Bengal]) (Table 10). Once all the necessary capacity building has been completed, the regimen will be rolled out to the remaining states. The choice and design of treatment regimens for children is as for adults.

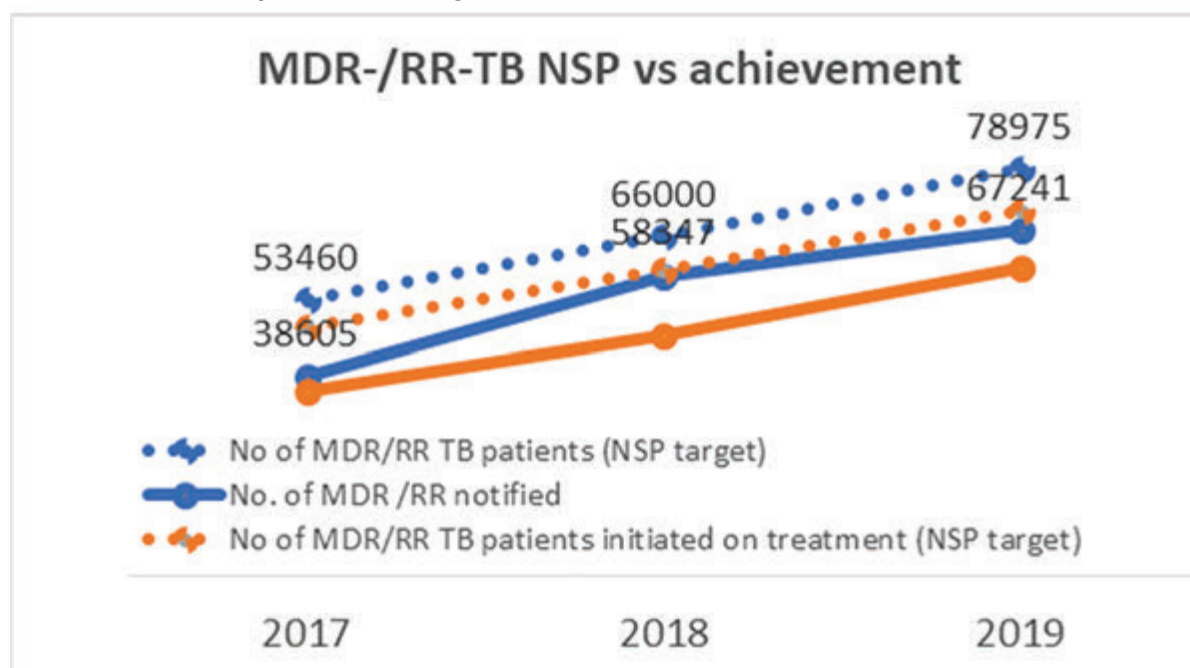
Table 10: Standard regimen for initiating treatment of RR-/MDR-TB or H mono- or poly DR-TB

Regimen class	Intensive phase	Continuation phase
H mono/poly DR TB (R resistance not detected and H resistance)		
All oral H mono-poly DR-TB Regimen	6 Lfx R E Z	
RR-/MDR-TB		
Shorter RR-/MDR-TB regimen	4-6 Mfxhd Km/Am Eto Cfz Z Hh E	5 Mfxhd Cfz Z E
All oral longer RR-/MDR-TB regimen	18-20 Bdq(6) Lfx Lzd Cfz Cs	

Source: 2019 RNTCP PMDT Guidelines

- In 2019, an estimated 67,241 RR-/MDR-TB patients will be notified (85 percent of NSP target). However, this equates to just 52 percent of the estimated overall MDR-/RR-TB burden as per WHO. 89 percent (59,945) of the notified patients were placed on treatment (Figure 32).

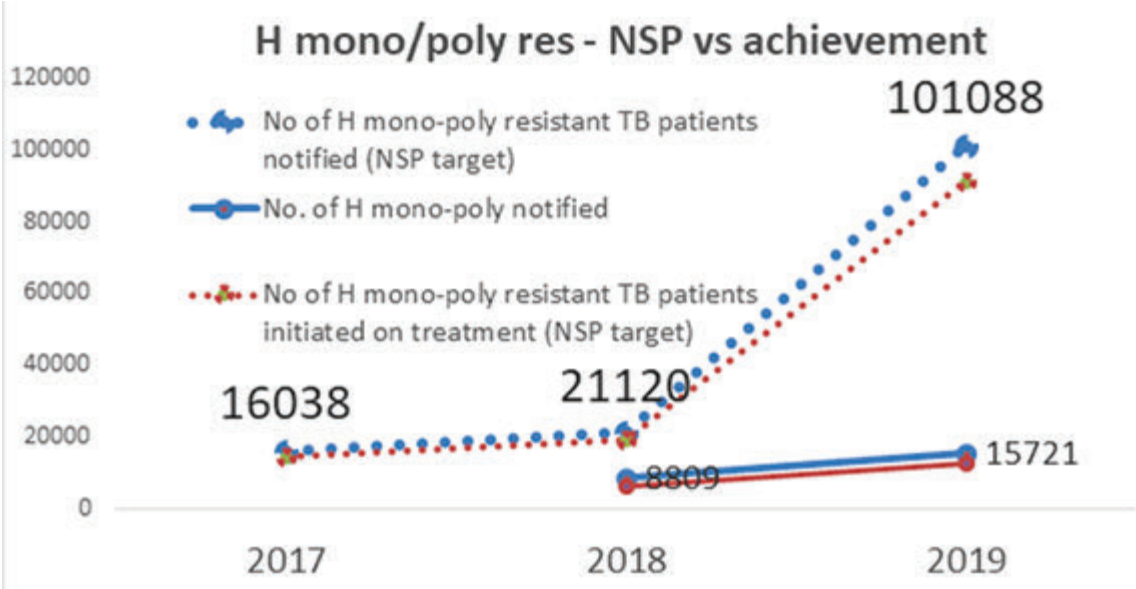
Figure 32: An illustration of the MDR-/RR-TB patients notified and initiated on treatment as compared to the targets.



- In 2019, 15,721 Hr-TB patients were notified (just 16 percent of NSP 2019 target, Figure 33)⁶¹

⁶¹Note that the presented totals for 2019 are annualized estimates based on data available up to September 2019.

Figure 33: This graph illustrates the number of Hr-TB patients were notified and initiated on treatment as compared to the NSP targets.

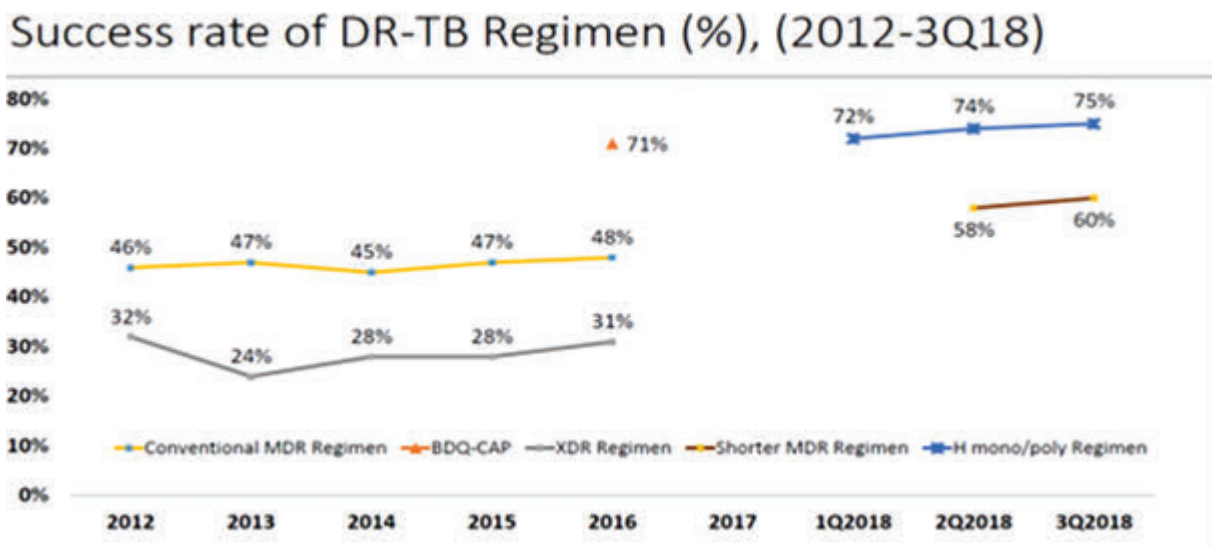


- Treatment is largely ambulatory, with the management and care of DR-TB having been decentralized to the district level predominantly. To date, there are 151 nodal DR-TB centres and 526 district DR-TB centres. The nodal DR-TB centres are primarily responsible for the initiation of DR-TB who are ineligible for the STR, and managing patients who either have complicated disease and/or serious adverse events during their treatment.
- Support structures for patients have been put in place. There is counseling provided to the patient and family via professional counseling services through nodal DR-TB centres, for cough etiquette and other aspects of AIC, information on the disease and treatment, and linkages to social protection schemes, along with travel support for travel for sample collection, pre-treatment evaluation and adverse event management. Financial support via NYP of Rs. 500 per month is provided until completion of treatment.
- The private sector has been engaged in various aspects of the diagnosis and treatment of DR-TB patients, ranging from the provision of U-DST to patients notified from the private sector, free diagnostics and drugs, availability of patient support mechanisms, and access to new drugs in coordination with the N/DDRTBCs.
- States and districts have been provided with the local purchase of SLDs in the event of any drug supply chain issue in order to ensure uninterrupted availability of SLDs for the DR-TB patients. Active drug safety monitoring and management (aDSM) mechanisms have been introduced in partnership with the Pharmacovigilance Programme of India (PVPI). Initially a cohort event mechanism was implemented at the BDQ Conditional Access Programme (BCAP) sites for the first 600 patients treated with BDQ containing regimens. Subsequently, the intermediate package for active TB drug safety monitoring and management (defined by WHO as reporting of all serious adverse events and AEs of special interest) was endorsed by RNTCP for roll-out to all sites treating DR-TB patients.
- Despite the many achievements of RNTCP in regard to the provision of PMDT, the reported

treatment outcomes overall to date remain poor. The reported treatment success rates in the 2016 patient cohort were 48 percent for MDR-/RR-TB patients enrolled on the conventional MDR-TB regimen, and 31 percent for the treated XDR-TB patients (Figure 34). However, patients treated under the BDQ-CAP initiative, who had more extensive

resistant patterns, reported 71 percent success. Patients enrolled in later years on the STR and on the Hr-TB regimens had better-reported success rates, although 58 to 60 percent for the STR is lower than expected and the program intends to analyze reasons for the same.

Figure 34: This graph shows the trend in the treatment success rate for DR-TB from 2012 to 2018.



- Of the PMDT related recommendations from the JMM 2015, two have been completely achieved, 12 have been partially achieved and/or are ongoing⁶² Those recommendations related to

proposed research topics were “partially achieved” overall (see section on Research and Innovation).

⁶²Completely achieved (2): Consider revisiting treatment duration as per the WHO 2011 PMDT guidelines; The RNTCP should continue to procure SLDs at the Central level for the entire country. Partially achieved (12): The JMM recommends that the RNTCP carry out a study to understand the drivers of the DR-TB epidemic; The RNTCP should strengthen the e-health management information system between diagnostic facilities, programmatic units and treatment centres; The RNTCP should address the factors associated with unfavourable treatment outcomes and should - i. continue building capacity to offer DST at diagnosis in all TB patients, with prompt initiation of appropriate treatment, ii. promote and monitor STCI in the private sector, iii. modify treatment according to DST results, iv. ensure timely payments of enablers and incentives as per existing policy and offer nutritional interventions to patients and their families where appropriate, v. strengthen adherence monitoring and support via counselling, pharmacovigilance and community engagement, vi. explore and implement alternative patient adherence support systems, vii. implement scale up linked to local capacity for earlier detection and move towards universal DST as per the NSP 2012-2017; viii. introduce new drugs as per WHO recommendations (BDQ and DLM); The MoHFW should strengthen the mechanisms for engagement of all uninvolved medical colleges in RNTCP’s PMDT activities, and enable private providers to have access to RNTCP’s network of rapid diagnostic laboratories; The MoHFW should support better linkages for MDR-TB patients and families to social support schemes such as the RSBY, etc.

Challenges

- Whilst the recent national DRS survey quantified the level of DR-TB burden in the country, the drivers of the DR-TB epidemic remain little understood. The targets laid out in the ambitious NSP are challenging in themselves. However, they need to be even more ambitious if the actual DR-TB epidemic in India is to be tackled.
- Many of the challenges faced by RNTCP in implementing PMDT are cross-cutting, being impacted by many different areas of the health systems and partnerships. Human resources and their development remain a major cross-cutting issue for both the public and private sectors. This relates not just to adequate numbers of staff, but also their job responsibilities, and capacity. With the adoption of the updated 2019 PMDT guidelines, there will be a huge challenge related to their dissemination, training and implementation.
- The terminology and implementation of “Universal DST” as practiced today is somewhat misleading, being conducted on notified cases and a select group of presumptive cases rather than on all the presumptives (see Figure 31).
- Also, although at a national level, it was reported that over 50 percent of notified TB cases had been tested for resistance to at least R, this varied across locations and sectors. For example, in Gorakhpur district, the overall figure was given as 45 percent (Q1 to Q3 2019). However, the levels amongst those patients notified from the public and private sector were significantly different with that of private sector patients much lower (64 versus 17 percent) – this finding was seen more widely than just in the Gorakhpur district.
- Although improving, only 70 percent (29,217 / 41,611) of the notified RR-/MDR-TB patients during the Q1 to Q3 2019 had a SL LPA test conducted. Challenges were observed in sample collection, transportation, and TAT of results versus implementation of the current (2017) diagnostic algorithm. TATs were reported in weeks or even months for rapid molecular based tests (with test times of 90 minutes [CB-NAAT] and 36 hours [LPA]). The implementation of the 2019 diagnostic algorithm will require a significant increase in laboratory capacity, especially of the rapid molecular tests (CB-NAAT and LPA), and DST for the new and repurposed drugs. It will also need to be revisited based on the recommendations of the NTEG - Diagnostics group, the new guidelines of CDC/ATS/IDSA and the upcoming WHO recommendations / guidelines.
- Delays in pre-treatment evaluation and initiation of treatment were observed during the field visits. There was variable availability of the SLDs across the states, with uniform unavailability of pediatric friendly SLD formulations.
- The percentage of patients enrolled on Bdq-containing treatment regimens out of those who were eligible, was low and the reason for this was overall unclear although resistance by clinicians to initiate patients on the new drugs was observed by some field teams.
- Quality assurance (QA) systems under the local drug procurement mechanisms were unclear, and the agent tasked with such activities is not appointed. Drug stock management and storage at state and district level were observed to be sub-optimal.
- It was observed in certain sites that the management and care of the DR-TB patients had not been completely

decentralized. The respective teams were however unable to explore this issue further to gain a better understanding of the reasons for this. But at other sites, issues were observed with infrastructure at the district hospitals, training and linkages for pre-treatment evaluation.

- There were consistent concerns from the observations of the JMM from the field visits, related to supervision activities and the monitoring of the quality of patient care. The supervisory staff were observed to be heavily engaged in more administrative processes (e.g., DBT distribution) to the detriment of field supervisory activities.
- The quality of patient care, taking in various aspects such as counselling, laboratory investigations, treatment adherence, adverse events monitoring and management, follow-up examinations and patient support, was observed to be of concern. As yet, the integrated DR-TB module is not available in NIKSHAY. Also, the nodal DR-TB centers do not have access to the patient related information and district level data, which creates challenges to monitoring the progress of patients.
- A final challenge is linked to the reality of the rapidly evolving global landscape in regards to DR-TB diagnosis and treatment. The country needs to keep pace with such global developments and the changes rapidly fed into the country's national policy, medical education and health systems, with timely dissemination to all relevant providers.

Recommendations

1. The RNTCP to conduct a study to better understand the drivers of the DR-TB epidemic in India. Whole genome sequencing should be applied appropriately to support said study and surveillance activities.
2. A better understanding of the burden of DR-TB in the private sector is also required and RNTCP needs to explore how this can be assessed.
3. Institutional strengthening of DR-TB spaces: national-, state- and district-level with capacity building, ensured staffing, mentoring, monitoring and reporting linkages. Specialized tertiary level institutions to be introduced at the top of the proposed tiered network of DR-TB care institutions.
4. Use of modern technologies and methods (e.g., use of e-platforms, blended learning, etc.) for capacity building (both via pre- and in-service training), mentoring and monitoring of said activities.
5. Align and streamline health information systems between diagnostic facilities, programmatic units and treatment centres to ensure timely transmission of all relevant information/data, with complete linkage and integration to NIKSHAY and NIKSHAY Aushadhi.
6. Fast-track U-DST for all notified TB patients, while ensuring availability of diagnostics and scale-up of laboratory capacity, including the required LPA capacity, for implementation of the 2019 integrated algorithm in line with the envisaged scale-up of DR-TB diagnosis and treatment.
7. To fill access gaps, engage with the private sector network of laboratories for end-to-end operations (turn-key model) including specimen collection, transportation, reflex sequential testing as per national algorithm, testing for pre-treatment evaluation and providing reports with timely TAT for patient management, in line with the STCI. RNTCP can learn from the experience of NACO on the outsourcing of viral load testing to private sector laboratories.
8. Ensure uninterrupted availability of quality assured SLD, including pediatric formulations, "new" drugs and regimens, and repurposed drugs, in the public and private sector, using

- domestic funding. Perform frequent forecasting and quantification exercises at least for six monthly procurement planning which needs to be supported by frequent assessment (once in two months) of drug consumption trend and SLD stocks in pipeline.
9. Ensure quality of local drug procurement mechanisms, including urgent hiring of in-country agent.
 10. Initiate in-country discussions regarding licensing under the Patents Act of the “new” drugs (e.g., BDQ and DLM), allowing for generic manufacture and supply, and for reducing prices and improving access.
 11. Ensure strict adherence and monitoring of Schedule H1 drugs. Consider prescription audits from the private sector.
 12. Introduce quality improvement tools to monitor and ensure quality of care, to include:
 - a. Conducting urgent situational assessment of the decentralization of DR-TB care, and taking appropriate actions as identified to complete this process and subsequently monitor activities.
 - b. Clearly outlining the work functions of each level of DR-TB care management, ranging from peripheral centres to nodal DR-TB centres.
 - c. Tracking, monitoring and supporting patients, both in the public and private sectors, from timely diagnosis (including provision of required DST), prompt initiation of the optimal treatment regimens, to completion of treatment with appropriate follow-up during and after treatment.
 - d. Introducing quality improvement tools to monitor and ensure quality of care for patients. This should include an assessment of the quality of supervision by the RNTCP supervisory staff.
 - e. Considering additional nutritional support through the public distribution system.
 - f. Assessing implementation of aDSM activities and revising guidance on aDSM as required. Use of modern technology to strengthen peer-led learning and decision-making mechanisms of the management of adverse events in DR-TB patients during treatment.
 - g. Strengthening the linkages between the routine service facilities and the network of specialized referral centres for surgical intervention, management of DR-TB in EPTB DR-TB with co-morbidities, Pediatric TB, etc.
 - h. Widen coverage under Ayushman Bharat to include TB patients requiring hospitalization for longer than 24 hours.
 - i. Two-year post-treatment follow-up of successfully treated DR-TB patients to detect relapse at an early stage.
 - j. Expedite DR-TB module integration into NIKSHAY, grant access to NIKSHAY to nodal DR-TB centres, ensure optimum use of NIKSHAY for monitoring of patient management.
13. Prioritize introduction of new drugs and/or regimens for DR-TB treatment via feasibility and/or implementation assessment under programmatic conditions (i.e., “Deploy, Evaluate, Adapt and Scale-up”), with the priority on building the evidence base for an all oral shorter treatment regimen for DR-TB patients.
 14. Pilot/conduct operational research for LTBI treatment among contacts of confirmed DR-TB patients.
 15. Use the in-country opportunities to learn from the best practices from the different states and districts:
 - a. Provision of free diagnostic services via the NHM “Free Diagnostics Initiative” – it should be expanded to cover the tests required for pre-treatment evaluation and follow up of DR-TB patients
 - b. First Referral Units through NHM – could

- support pre-treatment evaluation
 - c. Community engagement
 - d. Best practices from BDQ-CAP project
 - i. Engagement of PVPI for aDSM
 - ii. Monitoring and follow-up
 - iii. Dissemination of drug safety finding among physicians
 - e. Availability of e-platforms such as the ECHO platform and peer-led learning and decision-making mechanisms.
16. Convene regular national level deliberations on evidence-based recommendations by WHO and other international bodies for inclusion in the national PMDT guidelines – create recommendations as a “living document” to enable the timely review and updates of selected sections as new evidence becomes available, and make these available to the country’s health and education systems, to be disseminated widely, implemented, and monitored.
 17. Document and disseminate the RNTCP’s PMDT related experiences by publishing information that can be referenced and shared with the broader global community.
 18. Consider the establishment of an additional monitoring cell at National level to monitor the

implementation of new regulations, legislations, gazette notifications, and policy recommendations being released from time to time by the programme.

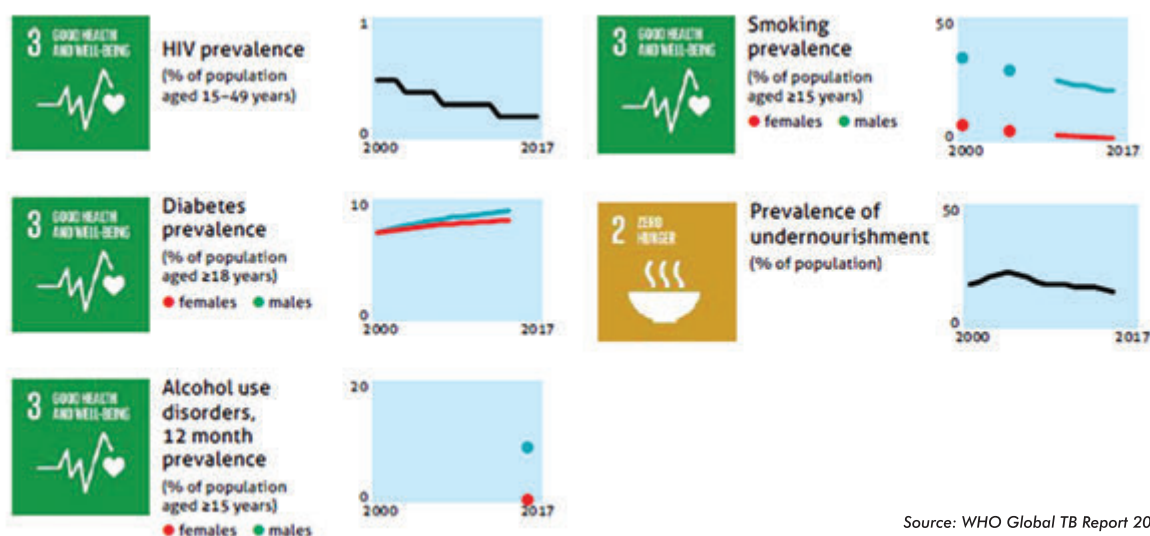
Key Messages

1. Significant achievement at the policy level but challenges remain at the implementation level, especially regarding quality of care for the DR-TB patients.
2. Human resource shortages and development are cross cutting issues.
3. The DR-TB landscape is rapidly evolving - the country needs to keep pace uniformly with global developments and the changes fed timely into the country’s medical education and health systems

2.4.3 Comorbidities and Childhood Tuberculosis

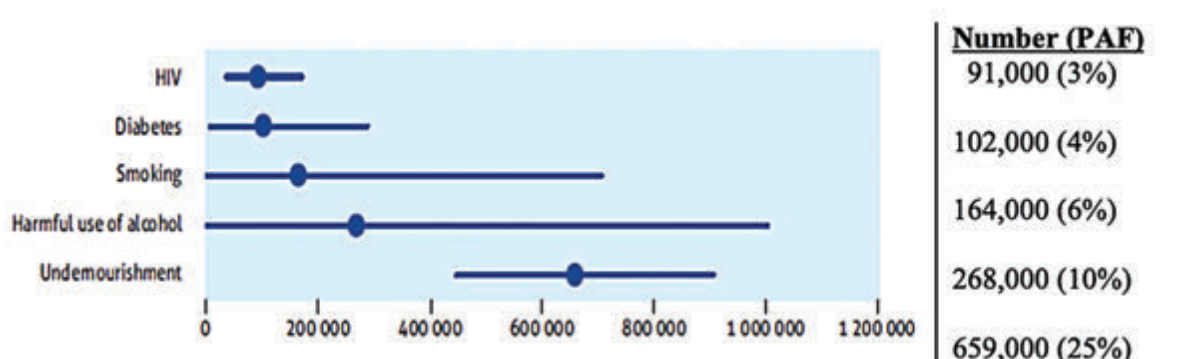
In the WHO’s [Global TB Report 2019](#), the figure below is used to illustrate the TB co-morbidities as related to SDG indicators. The report also goes on to breakdown the number of TB cases attributable to the top five risk factors: HIV, Diabetes, Smoking, Harmful Alcohol Use, and Undernourishment (Figure 35 and 36).

Figure 35: Indicators in the SDGs associated with TB incidence



Source: WHO Global TB Report 2019

Figure 36: Number and percentage of TB cases Attributable to Five Risk Factors, India 2018



The NSP 2017-25 lists a number of key strategies on addressing TB co-morbidities (see text box below).

Key strategies for co-morbidities in NSP (2017-25).

Implementation frameworks

National framework for collaborative TB-HIV activities-2013, updated for upfront CB-NAAT- 2015

Four-pronged strategy on TB/HIV focusing on prevention, early diagnosis & treatment, Supervision & monitoring & implementation in special situations

- Colocation of diagnostic & treatment centres
- Upfront use of CB-NAAT for PLHIV
- Daily FDC for Anti-TB treatment
- H prophylaxis therapy
- Single window delivery of TB and HIV services

National Framework for joint TB- Diabetes collaborative activities-2017

National Framework for joint TB-Tobacco collaborative activities-2017

Guidance document: Nutritional care & support for patients with TB in India- 2017

Guidance document on TB-HIV Linkages for Targeted Intervention (TI) & Link Worker Scheme- 2018

Guidance document on HIV & TB intervention in Prisons and other Closed Settings-2018

Framework for collaboration with Ministry of Social Justice and National Drug Deaddiction Programme under MoHFW (planned)

Achievements

The program has made significant strides in implementing activities (Table 11).

Table 11: This is a list of indicators that shows the percentage achieved against the targets set in the NSP.

Achievements so far	Target 2018	Achieved 2018
% of TB cases with known HIV status (NTP NSP)	80%	67%
Proportion of notified TB/HIV cases initiated on CPT (NTP NSP)	100%	93%
Proportion of notified TB/HIV cases initiated on ART (NTP NSP)	100%	90%
% of presumptive TB cases with known HIV status (as per RNTCP Policy)		45%
% PLHIV screened for TB at last visit (NACP)	90%	94%
Colocation of DMC and HIV testing facilities (as per RNTCP Policy)		87%
Colocation of ART centre and CBNAAT facility (as per RNTCP Policy)		90%
TB patients tested for Diabetes (National Framework but targets not yet set)	-	39%
Co-location of DMC and DM screening facilities (not target set)		73%
TB patients screened for tobacco use (National Framework but targets not yet set)	-	30%
TB patients screened for alcohol use (National Framework not yet developed/targets not set)	-	28%
TB patients screened for nutrition (National Framework but targets not yet set)	-	?

- Collaborative frameworks for TB and priority comorbidities (TB/HIV, TB/DM, TB/tobacco, TB/nutrition) are in place, with the framework on alcohol and drug addiction outstanding.
- There has been a steady increase in uptake of collaborative activities – with particularly impressive gains on HIV-associated TB resulting in an 84 percent reduction in mortality since 2010.
- Single window services for TB/HIV have been rolled out within ART centres, CB-NAAT rolled out as the first TB diagnostic test for PLHIV and 99DOTS ICT adherence rolled out for TB/HIV patients.
- 73 percent of DMCs are co-located with diabetes screening facilities.
- Nutritional support through financial incentives for all patients in all States and in-kind schemes provided in 16 states (mainly for DR-TB patients and patients from poor areas).
- Efforts are underway to reach key populations through targeted interventions.

Challenges and Opportunities

TB/HIV:

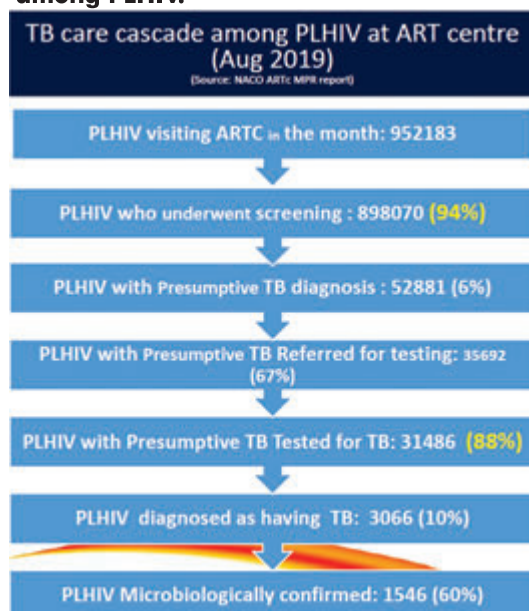
- Persisting high TB/HIV mortality rate (12 percent compared with 3 percent of all new and relapse TB patients from the 2017 cohort) and late presentation of PLHIV to care (average 150 CD4 cell count on enrollment, Agra) (Figure 37).
- Plans to adopt WHO recommendations on lateral flow urine lipoarabinomannan assay (LF-LAM) is an opportunity to incorporate latest 2019 WHO recommendations on LF-LAM and scale-up nationwide.
- Ongoing HIV mortality audits should provide further information on TB/HIV deaths including reasons for mortality.

Figure 37: Trends in the treatment outcome of TB/HIV patients from 2010 to 2017.

Year	All TB-HIV Total Case Registered/ Notified	Treatment Success	Died	Failure	Lost to follow up	Transfer red out	Treatment regimen changed
2010	43093	77%	13%	1%	6%	2%	0%
2011	47097	78%	11%	5%	4%	1%	0%
2012	34134	77%	13%	1%	7%	1%	0%
2013	45911	77%	13%	1%	7%	1%	0%
2014	44257	76%	13%	1%	6%	2%	1%
2015	38894	77%	14%	1%	6%	2%	1%
2016	39702	77%	14%	1%	6%	1%	1%
2017	33366	70%	12%	1%	5%	-	0.2%

- Continued gaps in cascade from TB screen to diagnosis among people attending HIV care (Figure 38).
- Inconsistent knowledge of the “4S” TB symptom screen among staff and patients interviewed in ART clinics.

Figure 38: The TB cascade of care among PLHIV.



- Limited CB-NAAT access (in particular for PLHIV attending the 39 ART centres that are linked to CB-NAAT sites in other

facilities/districts) and long turnaround time from sample collection to treatment start reported (two weeks). Just over three quarters (22042/28544) of new and relapse cases diagnosed in 2018 were with GeneXpert.

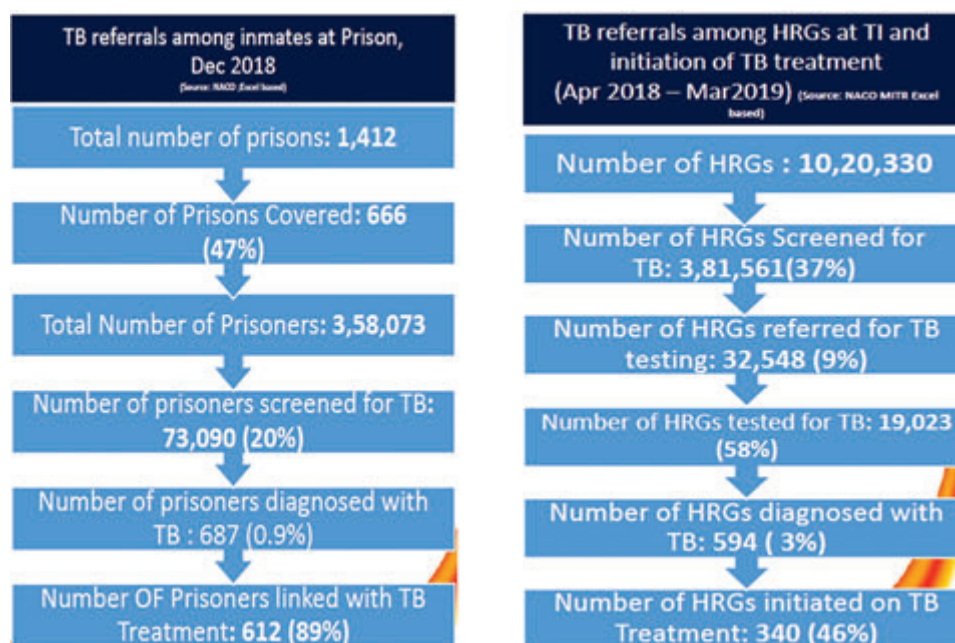
- Plans to strengthen QI by RNTCP and National AIDS Control Program (NACP).
- Multi-disease platform facility of CB-NAAT supporting strategic placement in all ART centres/PPTCT clinics for early infant diagnosis of HIV, HIV viral load monitoring and viral hepatitis. In this context, it is crucial to continue to assess the need for new modules to meet these diverse laboratory diagnostic demands.
- Limited coverage and/or reporting of HIV testing and ART services among TB patients in private sector (UP: 14 percent known HIV status and 8 percent of ART coverage in 2018)
- Partnership guidelines/MOUs with NACP could be more conducive to encourage HIV testing by private practitioners and diagnostic facilities.
- Area for strengthening data linkage between ART services, NIKSHAY and private sector.
- ART services are still centralized, including

drug distribution, particularly in states that do not have a high burden of HIV.

- 36 percent coverage of ART among TB patients reported through NIKSHAY in the public sector at district and state levels (UP), although high coverage reported by NACP – reconciliation of ART data at district or state level, limited.
- Plans for further decentralization of ART services and for differentiated service delivery - opportunity to promote further decentralization of ART to CHCs at sub-district level in states not deemed high HIV burden.

- Health and Wellness Centres under Ayushman Bharat provide an opportunity for ART decentralization.
- Plans for integration of data systems of both programmes
- Room to expand coverage of TB/HIV interventions among high risk groups and key populations (Figure 39).

Figure 39: TB cascade of care among prison inmates and HRGs.



- HIV testing among people with presumptive TB in the public and private sector is only implemented in two thirds of districts and coverage in these districts is limited.
- Studies in India show as high a yield of HIV testing among people with presumptive TB as among people with confirmed TB.

- The policy on HIV testing among presumptive TB patients is in place and the RNTCP and NACP plan to scale up across the country.
- Unavailability reported for certain key drugs, such as cotrimoxazole, pyridoxine and rifabutin for PLHIV on second-line ARVs.

- Linkage of procurement, supply and management (PSM) systems.
- Lack of systematic joint planning and limited capacity to conduct regular joint TB/HIV supervision.
- Parallel data systems for TB and HIV, whilst transitioning from paper-based to electronic, requires staff to complete multiple formats, including for comorbidities – resulting in short-cuts, poor quality and data on comorbidities not always captured in both systems.
- Plans for integration of data systems
- Plans for unique patient identifiers

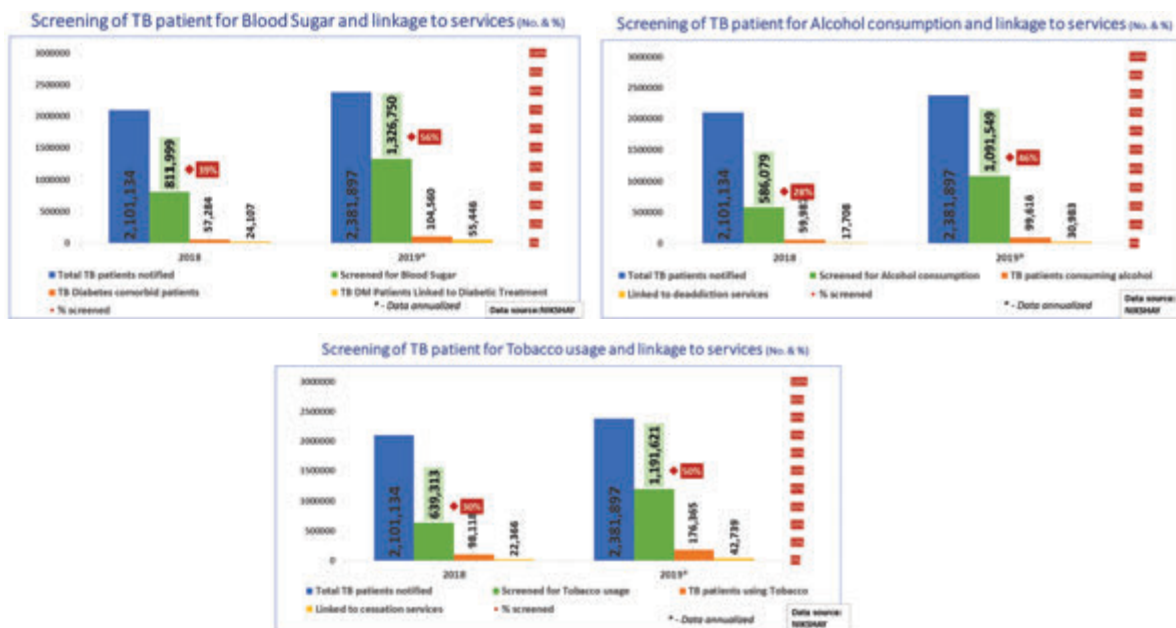
Other comorbidities:

- Gaps in the cascade of TB/ noncommunicable disease (NCD) co-morbidity screening and co-management.
- Low coverage and/or reporting of screening with high drop-off rates for referral or co-management of the

comorbidities for diabetes (including blood sugar values), tobacco cessation, baseline nutritional status in TB patients (Figure 40). This was evident from NIKSHAY in public and even more so in the private sector. Opportunities:

- Building on the TB/HIV scale-up experience, consider targeted approach informed by mapping of joint/multiple burden to scale up activities.
- Plans for cross-ministerial collaboration to enhance food security and scale up community-based nutrition interventions.
- Plans for incorporation of nutritional screening and counselling as part of NIKSHAY mobile application
- Plans to establish linkages between call centres and tobacco and TB programmes to enable counselling support, and for TB and DM management services.

Figure 40: Screening of TB patients for potential co-morbidities (i.e. blood sugar, tobacco usage, alcohol consumption).



- Suboptimal implementation/documentation/monitoring of TB screening in diabetes services (6 percent), Tobacco cessation centres (outside of the 16 districts where there are focused interventions and screening rates are reported to be 100 percent), and nutrition rehabilitation centres).
 - Ongoing plans to strengthen QI by RNTCP
 - Coordination mechanisms and joint supervision mechanisms need to be established or strengthened for diabetes, tobacco, alcohol across all States and Districts.
 - Plans to strengthen collaboration through setting up TB-comorbidity committees at national, state and district levels.
 - Screening for depression/anxiety among MDR-TB patients not routinely conducted.
 - While counsellors are in place for MDR-TB patients, capacity to screen for depression, anxiety and mental health conditions was limited.
 - Planned scale-up of the Framework for collaboration with the Ministry of Social Justice and National Drug Deaddiction programme under MoHFW provides an opportunity to scale up screening for mental illness also.
 - Parallel data systems for TB and NCDs - no linkage between the data systems for TB and NCDs, resulting in difficulties in reconciliation of data and in understanding the true joint burden.
- placement of CB-NAAT for multi-disease testing in all clinics providing ART and prevention of parent to child transmission services.
4. NACP and RNTCP to continue roll-out of co-located, integrated TB and HIV testing and treatment services, through select PHC/CHC and Health and Wellness Centres under Ayushman Bharat at sub-district level, while ensuring access to at least one district "Single Window Service" in districts not qualified as high HIV burden districts. Both NAP and RNTCP must strive to strengthen universal screening services for people with HIV and people with TB.
 5. RNTCP, NACP and National Programme for Prevention and Control of Cancers, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) to conduct joint surveillance of the joint/multiple burden of TB, NCDs, and HIV and, building on experience of scale-up of TB/HIV activities, identify most at-risk populations (age, sex, geography and special populations) and set targets to drive scale-up of collaborative action.
 6. RNTCP, NACP, NPCDCS and National Tobacco Control Programme (NTCP) to put in place mechanisms that facilitate the implementation and recording and reporting of screening and co-management of HIV, diabetes, tobacco and alcohol use and malnutrition in TB patients, notified by private providers.
 7. RNTCP, NACP, NPCDCS and NTCP to increase capacity to conduct joint monitoring and supervision, and introduce quality improvement measures for TB and comorbidities across the cascade of screening, diagnosis, care and prevention services in both public and private sectors.
 8. RNTCP, NACP, NPCDCS and NTCP to collaborate to link information management systems with the same unique identifiers to ensure integrated case-based management and pharmaco-vigilance, integrated procurement and supply management of

Recommendations

1. RNTCP and NACP to urgently address shortages of cotrimoxazole, rifabutin, and pyridoxine and put in place measures in 2020 to improve forecasting and procurements to avoid drug shortages.
2. RNTCP and NACP to adopt and scale up LF-LAM guidelines (WHO 2019) as part of the advanced disease package of care for PLHIV.
3. RNTCP and NACP to consider strategic

commodities, and systematically phase out paper-based systems. In the interim phase, parties to strengthen recording and reporting of collaborative activities, including data reconciliation at clinic, district and state levels in both public and private sectors.

9. RNTCP and NACP to continue efforts to scale up collaborative TB/HIV activities within targeted interventions and to this end, systematically engage and build the capacity of networks of PLHIV to assist in collaborative action.
10. RNTCP, National Viral Hepatitis Control Program (NVHCP) and NACP to consider assessment of joint burden of TB and viral hepatitis and leverage the collaborative TB/HIV platform to incorporate targeted integration and referral of services for screening and management for viral hepatitis among TB patients as and where deemed necessary.
11. RNTCP and NACP to conduct operational research to a) identify root cause of high TB/HIV mortality during TB treatment, b) to conduct patient pathway analysis for TB and comorbidities and c) include comorbidities within a catastrophic patient cost survey.
12. As part of plans for scale-up of the Framework

for collaboration with the Ministry of Social Justice and National Drug Deaddiction programme under MoHFW, strengthen the capacity of counsellors and personnel selected to deliver drug and alcohol screening activities to deliver screening and counselling for mental illness also.

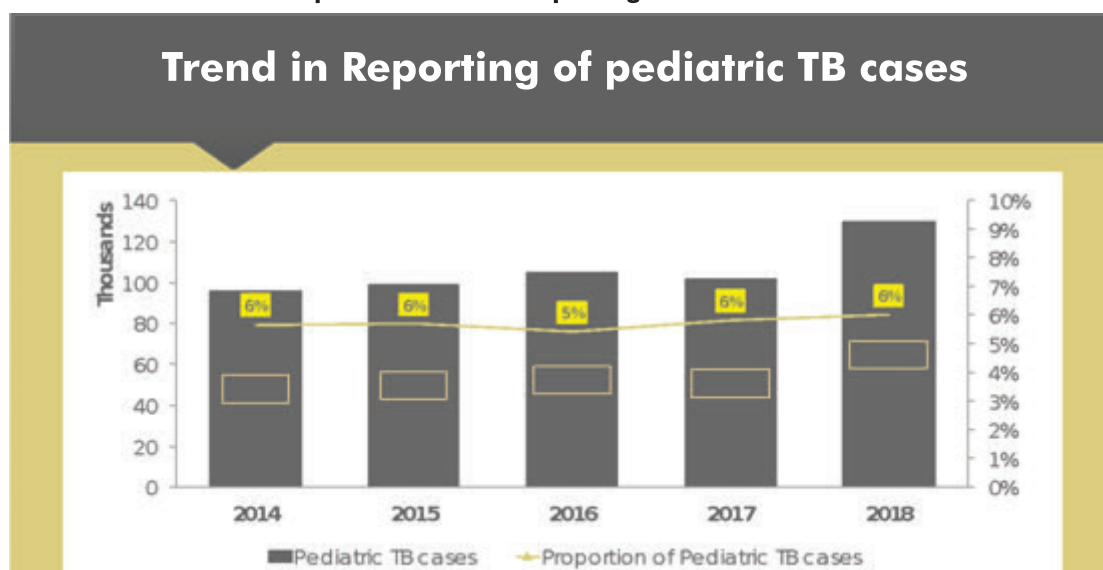
Key Messages

1. Understand the burden of TB and co-/multi-morbidities, set targets and take integrated action to scale.
2. Understand the cascade and linkage gaps, and barriers in accessing care, and work across the health system and with communities to improve quality of delivery and recording and reporting of integrated services in both public and private sectors.
3. Continue the momentum of decentralization of ART services and colocation of TB and HIV treatment to sub-district level to allow more patient-centred care for patients with HIV-associated TB.

2.4.3a Childhood TB

India is among one of the countries with the highest burden of TB where about 342,000 incident cases of pediatric TB are estimated to occur every year

Figure 41: National trends in pediatric TB case reporting.



accounting for 31 percent of the global burden. The case detection rate in India for children is 39 percent. The country has wide geographical variation in the TB epidemic with the magnitude several local epidemics remaining hidden due to inadequate data and surveillance systems. This indicates the potential for missed cases particularly from most privately-treated patients.

Achievements

The following section describes summaries of observations as per the 4 pillars of the RNTCP

Build:

Recognizing the need to address the burden of childhood and adolescent TB, India has instituted a series of strategies in the TB NSP (2017-25) including:

- Establishment of a focal point and a national Childhood TB working group with terms of reference and representation from academics, practitioners, and other stakeholders.
- Development of [Pediatric TB guidelines](#) for use by public and private practitioners with a plan for evaluation of implementation in 2021.
- Roll out of the national digital information system (NIKSHAY) for recording, reporting and monitoring of TB related information for prevention and care as well as monitoring drug supply chain management.
- Increased engagement of the private sector providers. The RNTCP works with the Indian Academy for Pediatrics for the development and updating of pediatric TB guidelines and building capacity for pediatricians and medical officers. Private pediatricians and other care providers treating TB in children are also engaged and able to contribute to the TB notification system.
- Engagement of community health workers is widely practiced through structures such as Rashtriya Bal Swasthya Karyakarm (RBSK) for contact screening, referral of samples for CB-NAAT, referral of symptomatic cases, and treatment support. To advance the

implementation of DOT, family members are being trained and empowered to serve as treatment providers for children with TB.

- Launching a scheme of providing monthly nutritional support as part of the NPY in 2018 with the aim of addressing the high proportion of malnutrition among TB Patients. A digital payments infrastructure via accountable electronic benefits transfer is being expanded for all TB patients.
- Updating the current RNTCP [Pediatric TB Guidelines](#) (2019) that recommends Bacillus Calmette-Guerin (BCG) vaccination for all newborns under the universal immunization programme; rapid molecular testing for TB diagnosis of childhood and adolescent TB; cost-free child friendly daily drug formulation; and extensive TB preventive therapy for at-risk children.
- Notification of TB among children varies across states with a range of five to eight percent (expected is more than 10% of total TB) indicating underreporting and underdiagnosis (Figure 42).

Figure 42: Progress in the number and percent)among total TB) of pediatric TB Patients



Prevent:

The JMM team identified the following in reviewing the current implementation of prevention methodologies:

- Contact investigations - mainly implemented through engagement of community volunteers (incentivized) but also carried out at health facilities. The community volunteers apply the

symptomatic screening criteria to refer suspected cases to the referral network while keeping registers. They also provide support for treatment - providing TPT for eligible children.

- BCG vaccination is carried out by a universal immunization programme with a national coverage of 92 percent.
- No AIC interventions practiced in public or private facilities. There is also indication of low awareness of infection control practices (e.g., routine use of cough etiquette), inadequate protection of children and family members or close contacts in households or community settings where open TB cases including MDR cases cohabit (see text box).

Stories from the Field

A community health worker who spoke with the JMM team members relayed the story of a family who had multiple cases of childhood TB. Patient 1 was an 18-year-old diagnosed with TB. One year later, Patient 2, the younger (16 years old) sibling of Patient 1 was diagnosed with TB. Then three years later, Patient 3, the mother of Patients 1 and 2, was diagnosed with TB. The community health worker noted that she had provided care for all three family members through treatment support. Though there is a chance for new infection from multiple sources which could have caused the subsequent infection in the other family members, this case may also highlight the potential gaps in AIC which allows the transmission to continue for years within the same family, or missed opportunities for early case detection, treatment, and prevention.

Detect:

The JMM team identified the following in reviewing the detection methods in childhood TB:

- In order to enhance case finding, novel methods of sample collection such as gastric lavage and induced sputum have

been included in the programme. However, due to limited capacity of health care providers and lack of point-of-care non-sputum based sensitive diagnostic tests for children, TB is often missed or diagnosed very late.

- CB-NAAT is being offered free of charge for diagnosis among children with symptoms suggestive of TB. Over 1.6 lakhs presumptive TB cases were tested in 2018 under the programme. However, use of testing is limited due to inadequate capacity of HCWs to identify presumptive TB in children and to collect samples using gastric lavage.
- CXR is available at hospitals but is underutilized for diagnosis at health facilities. Children suspected of TB are often not referred for CXR.
- Weak integration with other programmes (e.g., MCH, HIV, nutrition, others) limits the potential for early detection of TB cases though the potential for comorbidities is very likely.

Treat:

The JMM team observed the following in the implementation of childhood treatment regimens:

- The national childhood TB working group works closely with the TB programmes with defined TORs and has developed pediatric TB guidelines to be used at both public and private facilities.
- Though training sessions on childhood TB are conducted at regular intervals, the reach and scope of the training is outpaced by the demand and need.
- There is limited capacity of child health care providers, especially at the peripheral levels of the health delivery system. Given the challenge in early detection and quality of care, studies show that children with TB present late in the course of TB disease resulting with high mortality (see text box).
- New child friendly flavored dispersible



formulations of daily FDCs have been implemented across the country since January 2018. However, the supply of these drugs is not consistent and stockouts have been reported in some states. In addition, Cotrimoxazole Preventive Therapy (CPT) and pediatric formulations for MDR-TB are not routinely available. Reasons include delay in procurement and regulatory issues in the process of approval of use of drugs for pediatrics.

Stories from the Field

During a field visit, the JMM team that visited Chhattisgarh met with a 19-year-old who was treated for TB two years ago and completed treatment. When discussing his educational status, he reported that he had dropped out of school two years ago when he was first diagnosed with TB. When asked why he did not return to school upon completion of his treatment, he noted that he did not feel comfortable when people spoke about his illness and he felt that his friends do not want to spend time with him anymore. The conversation highlights the need to address issues of stigma and discrimination in children and adolescents with TB through age-appropriate psychosocial support to ensure school enrollment and better TB treatment outcome.

Challenges and Opportunities

Build:

- There is a paucity of targets and indicators for child and adolescent TB. Previous surveillance activities excluded children thus no comprehensive data to inform planning and programming targeting specific needs of children and adolescents with TB.
- Lack of comprehensive data on contacts investigations/reverse (or source) contact investigations, prevention, and treatment follow-up. There is a poor linkage of records (child & family index case) to facilitate decision cascade for screening/and care.

Survival and predictors of mortality in childhood TB cases in a tertiary referral TB hospital

In a retrospective study on mortality in childhood TB in a tertiary referral hospital, researchers found that out of a total of 2163 admissions, 1380 patients were childhood TB cases (under 15 years of age) requiring admission. A total of 74 of those childhood TB admissions resulted in death with a mortality rate of 5.36%. Of the 74 deaths 43 (58.1%) occurred in the first week of admission out of which 7 (9.4%) deaths occurred on day 1, 9 (12.16%) deaths occurred on day 2 while 28 (37.84%) deaths occurred from day 3 to 7 of admission to hospital. The study highlights the importance of early diagnosis and timely treatment to reduce mortality.

Source: Prof (Dr) Sangeeta Sharma, Head of Pediatrics, National Institute of Tuberculosis and Respiratory Diseases, Sri Aurobindo Marg, New Delhi, India

- Inadequate number of trained healthcare workers for quality pediatric TB care.
- Suboptimal involvement of private sector in addressing pediatric TB burden.
- Lack of childhood TB specific advocacy, communication and social mobilization (ACSM) activities
- Inadequate representation of children and adolescents in operations research

Prevent:

- Contact investigations not routinely implemented.
- Inadequate integration or linkages with other programmes (MCH service platforms, HIV, nutrition, others) leading to missed opportunities for screening.
- Inadequate infection control measures at health facilities and within households.
- Sub-optimal completion rates of TPT- H chemoprophylaxis (six months).

Detect:

- Inadequate HCWs capacity to suspect, investigate and diagnose child TB cases.
- Difficulty in obtaining samples from younger children leading to under-diagnosis.
- Lack of sensitive diagnostic tools for children; often TB is missed or diagnosed very late.
- Limited access and use of diagnostic services (e.g., chest x-ray available only in hospitals) suboptimal use of Xpert diagnostic tests for extra-pulmonary TB.

Treat:

- Lack of holistic and age-appropriate quality care of the child and adolescent with TB
- Inconsistent supply and unavailability of child-friendly formulation for TB (MDR drug for pediatric treatment not available, CPT availability is inconsistent)

Recommendations

Build:

1. Prioritize activities to meet the specific needs of childhood TB in planning, programming, and funding.
 - a. Consider developing a national roadmap for childhood and adolescent TB.
2. National inventory studies to assess the extent of under-reporting.
3. Case-based surveillance disaggregated by age (ideally 0–4; 5–9; 10–14; and 15–19 years).
4. Set national child and adolescent TB targets.
5. Strengthen advocacy and awareness through developing and dissemination of childhood TB specific ACSM materials.
6. Ensure psychosocial support including education for school age children and adolescents with TB.
7. Promote and support priority research areas:

- a. Sensitive point of care diagnostics (non-sputum based).
- b. Validation of newer drugs/regimens and vaccines.
- c. Paediatric TB care models.
- d. Effect of TB-related stigma and discrimination on children and adolescents with TB.

Prevent

8. Strengthen contact tracing and reverse contact tracing with decision cascade for recording, TPT and follow-up and tracking.
9. Urgently operationalize the guidelines for LTBI treatment to all eligible beneficiaries.
10. Training and provision of supplies for implementation of AIC measures at household, community, and health facilities.

Detect

11. Expand screening at entry points (e.g., NRC, MCH programmes, IPD/OPD, school).
12. Link records of family for contact/reverse contact tracing and decision cascade for early identification for treatment/prevention and tracking.
13. Increase access and use of CXR for pulmonary TB and leverage Xpert tests for EPTB (e.g., for clinical specimens to diagnose TB lymph node disease). Consider options for outsourcing supporting services (e.g. Hand holding by COE Tele radiology, AI).
14. Build the capacity of staff by holding preservice and in-service training using different systems (e.g., e-platform, ECHO). Consider using selected institutions as centres of excellence for paediatric TB to build core capacity for trainers and cascading of targeted training to all levels.

Treat

15. Ensure quality of care for TB in children and adolescents. Consider a differentiated service model in line with quality improvement to meet the specific needs of children and adolescents with TB.

16. Implement guidance for escalation of care to a specialist.
17. Ensure the availability of isolation beds for seriously ill and MDR-TB.
18. Employ the use of treatment support mechanisms (e.g., education, psycho-social, training of the treatment supporter).
19. Fast track child friendly TB formulations for MDR-TB and TPT.

Key Messages

There is remarkable commitment and notable progress in TB elimination efforts with important policy and strategic directions for addressing childhood TB. The most pressing challenges

include weak contact tracing, limited capacity for case detection, lack of sensitive point of care diagnostics and inconsistent availability of child friendly anti-TB drug formulations. In addition, the gap in surveillance data to inform the national burden of TB hinders the ability to target and measure outcomes of age appropriate interventions for childhood and adolescent TB. It is therefore critical to ensure that the NSP includes targets and indicators informed by local data including inventory TB surveillance for children and adolescents. As 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.



3. Annexes

3.1 State Level Reports

3.1.1 Assam

State Visit

The Assam State team visited two districts: Kamrup Metropolitan and Tinsukia. Below are key findings from the various sites visited.

Key Observations:

- Assam ranks second in State TB Index Scoring amongst medium size states; State demonstrated initiative to adapt the same index for scoring their districts.
- Assam has targeted three districts (Dima Hasao, Goalpara, and Majuli) for Ending TB.
- Community, primary health system, and private sector engagement for TB outreach and collaborative projects.
- TB Champions, schools and media engaged in social mobilization and community awareness.
- Best practices – JEET, teleradiology, outsourcing of key services by NHM (clinical, laboratory, pharmacy) observed; but RNTCP needs coordination with the NHM initiatives, and systematic scaling up.

Recommendations:

1. *Acknowledge the Prime Minister's call to End TB by 2025, by formally declaring "Assam TB Free Mission" through a well-articulated, costed TB Elimination plan (e.g., Bihar, Chhattisgarh, Himachal Pradesh, Kerala, Sikkim, Tamil Nadu).*
2. *Develop and implement a State TB Elimination Plan under the patronage of the Chief Minister to coordinate, implement, and monitor the plan. Include a comprehensive, evidence-based, and well-funded plan to accelerate activities to End TB.*

3. *Ensure sufficient human resources to commensurate with current, and expanded TB Elimination activities; enhance workforce (both technical and administrative), build capacity, supportive supervision to produce a safe, skilled and motivated workforce.*
4. *Build and utilize technical support mechanisms at State- and National-level partnerships, including the private sector.*
5. *Scale-up innovations for success, leverage teleradiology, integrate community engagement via TB Champions, TB forums; strengthen partnerships with private laboratories, corporate hospitals, industry (e.g., tea estates, coal and oil companies).*
6. *Improve private practitioner's engagement to find, prevent, treat and care for all persons suffering from TB through increased financial support and coordination.*
7. *Leverage the general health system and Panchayati Raj Institutions – challenge them to achieve TB Free Villages, Blocks and Districts.*
8. *Accelerate administrative processes for approving and disbursing expenditures; benefits and enablers need to be passed on to treatment supporters and patients in a timely manner; leverage key stakeholders to improve access to direct benefit transfer (e.g. banking sector, Indian Postal Service).*
9. *Engage multiple sectors and leverage existing systems for nutritional, social protection, community support and counselling services; (i.e., focus on ACSM activities that promote proper cough etiquette, adequate ventilation, and the discontinued use of solid fuels for indoor cooking).*
10. *Upgrade and maintain high-quality infrastructure for TB services at the State and District TB Centres, renovation of the State Warehouse, expand the diagnostic network to include private laboratories and facilities; strengthen processes in Medical Colleges.*

Utilize the facilities already available at the Department of Microbiology at Assam Medical College (i.e., culture and drug susceptibility testing; first- and second-line LPA); expand the laboratory network for culture and drug susceptibility testing to include the Department of Microbiology at Silchar Medical College.

11. *Engage medical colleges and corporate hospitals* to enhance notification, expand services to vulnerable populations, children, extrapulmonary TB, MDR TB, non-communicable diseases (e.g., malnourished, diabetics, psychiatric illnesses, and persons who abuses substances and alcohol), and environments that exacerbate TB (e.g., indoor pollution).

Kamrup Metropolitan District

TEAM MEMBERS

Dr. Mukta Sharma (District Lead), Dr. Umesh Alavadi, Dr. Reshu Agarwal, Dr. Avi Kumar Bansal, Ms. Deepthi Chavan, Dr. D Deka, Mr. James Malar, Ms. Miruna Mosincat, Dr. Bhavesh Modi, Mr. Andualem Oumer, Dr. Anil Jacob Purty, and Dr. Sangeeta Sharma.

BACKGROUND

Kamrup Metropolitan District (KMD) is one of 33 districts in Assam. The district is largely composed of the city of Guwahati and has an estimated population of 1,393,612 (1,528 km²) – the largest urban population in Assam, and northeast India. Guwahati is considered the “gateway to the northeast” as a major transportation hub for commerce and tourism. KMD is one of the fastest growing locations in India; with nearly 19 percent population growth rate over the past 10 years. The literacy rate of the district is high (88 percent). KMD is prone to seasonal flooding (April through October), especially low-lying areas adjacent to the Brahmaputra River, due to poor drainage systems in the city.

NOTIFICATION, REPORTING AND RECORDING

During the first ten months of 2019, 3878 TB patients were notified (n=3007, 88 percent public sector; n=871, 22 percent private sector). A trend for increased notifications has occurred since 2015. In 2018, public sector notifications doubled, and private sector notifications tripled from the previous year (2017). Treatment success rate has a stable trend amongst new (87percent, 2019) and previously treated (81percent, 2019) patients in the public sector; and 49 percent amongst new patients in the private sector. A minority (33 percent) of notified patients in the public sector have documented HIV status; however, testing is readily available. Few patients in the private sector have documented HIV status, and testing is not routinely conducted in the private sector. The vast majority of notified patients with known HIV status were tested in the public sector. Since October 2018, 58 percent of the eligible patients (n=3640) and 1 (0.14 percent) of the registered private providers (n=68) have received cash transfers. However, 69 percent of the eligible treatment supporters (n=20) received DBT during the same period. NIKSHAY was readily available and used by all RNTCP staff. Most staff used the mobile phone application or the RNTCP supplied tablets. NIKSHAY was utilized for real-time reporting and recording of key variables (e.g. name, age, sex, address, treatment start date, laboratory results). The use of NIKSHAY for real-time treatment adherence documentation was lagging and, in most instances, delayed by up to one month.

PREVENTION

TPT initiation among PLHIV was approximately 60 percent, with 85 percent completion rate. TPT for household children under 6 was observed and available; however, due to lack of systematic contact investigations (25 percent of eligible index patients investigated) the proportion of eligible children receiving TPT is low. We found no evidence of TPT (implemented or otherwise planned) in other high-risk groups or among adult household contacts. AIC awareness and

implementation in the general health system was lacking, and there is no routine TB screening of healthcare workers. There was a worrying number of healthcare workers (more than 5 five), and TB treatment supporters who became ill with TB in the recent past, suggesting potential nosocomial transmission. Fast tracking of symptomatic patients (i.e. four symptom screening) was observed in the community ART Centre, though the ART staff were not aware of the TPT recommendations for all PLHIV. Generalized AIC at community health centers was not observed in outpatient departments, radiologic departments, and laboratory/diagnostic departments. These areas were characterized by patients crowding in congested areas. We observed no triaging or systematic processing for patients with potential respiratory symptoms consistent with TB.

CASE FINDING, DIAGNOSIS AND LABORATORY SERVICES

The district has 13 DMCs and additional non-DMC health facilities are being converted into diagnostic centers for CB-NATT. The district has three digital radiology facilities, and one mobile radiology unit. Rapid rifampin-resistance detection (e.g. surrogate marker for MDR-TB) is available through CB-NAAT. The integrated DR-TB diagnostic algorithm with a cascade of sequential testing (i.e. smear-microscopy, CB-NAAT, LPA and culture) was being followed; and testing is free of direct cost to all patients. In total, 1948 TB patients had valid CB-NAAT testing for DR-TB; this represents approximately 64 percent of all notified TB patients. However, the yield may be improved by more focused case finding measures, and improving the efficiency of sample collection and transport. In spite of the specimen transportation system being in place, substantial loss and delays in appropriate treatment initiation occurred during repeat sample collection and transportation. Currently, sputa are batched, presumably to reduce transportation cost. This practice was found to negatively impact the time to diagnosis, and sequential testing required for second-line tests. Leaks in the treatment cascade were observed; specifically, during sequential testing (e.g.

CBNAAT, first- and second-line LPA). Moreover, the IRL is experiencing multiple resource constraints (i.e. aging equipment requiring maintenance, limited supplies and reagents, fuel and most notably, inadequate human resources) that are adversely affecting the quality of service delivery. No agency was available for routine maintenance of microscopes. An intensified focus on turn-around times was also noted, including the need to explore options for private sector outsourcing. ACF campaigns in the urban slums using a mobile CB-NAAT machine occurred, but with a lower than expected yield. During October 2018 to October 2019, 6793 people were screened in the slum resulting in only nine diagnosed patients among 244 sputa collected. Routine systematic household contact screening is minimal.

DRUG-RESISTANT TB (DR-TB)

In 2019, 24 DR-TB patients were diagnosed; 14 (58 percent) were initiated on BDQ-based treatment. In the public sector, 62 percent of notified patients received CB-NAAT testing. CB-NAAT utilization has increased in 2019 (i.e. averaging 400–500 tests per month); a 20 percent difference from 2018. DR-TB patients were offered pre-treatment investigations free of direct costs under the Chief Minister's free diagnostic scheme. This program has made significant efforts to keep up with frequently changing national PMDT guidelines. DR-TB care is decentralized and available at district DR-TB centers, but this was not observed in practice. DR-TB patients in outer districts often travel to the nodal state-based DR-TB center for the necessary investigations and initiation of PMDT. No formal meeting of the DR-TB Committee has taken place for some time. Faculty of Guwahati Medical College and Hospital are not involved in treatment decisions of DR-TB patients receiving care at the nodal DR TB Centre. Real-time, DST-guided treatment is not fully implemented in neither the public nor private sectors. Follow-up supervision and monitoring of patients was also sub-optimal. There was no mechanism for AE monitoring. There were human resource constraints and NIKSHAY portal constraints for aDSM.

CO-MORBID CONDITIONS AND CHILDHOOD TB

We observed underdiagnosis and underreporting of pediatric TB; two percent in KMD (four percent in Assam). Routine sample collection (e.g. gastric lavage, fine-needle aspirate collection) and testing from pediatric presumptive TB was not observed in neither public or private sectors. High rates of TPT in children were reported within households evaluated — noting that contact investigation implementation was suboptimal. The team noted good community awareness practices in private health facilities, NGOs, and schools (e.g. awareness was high in the school visited). Single window services for HIV and TB were observed; high visibility of TB in ART centers was noted. ART treatment rates in co-infected patients were over 85 percent. However, HIV testing among TB patients is low. High mortality rates amongst PLHIV, and advanced HIV clinical presentations were also noted, suggestive of delays in TB diagnosis and treatment. Gaps in NIKSHAY entry for TB-HIV co-infected patients led to non-disbursement of NPY. The proportion of TB patients screened for diabetes was 42 percent; however, screening of TB among diabetics was not seen.

COMMUNITY ENGAGEMENT AND PARTNERSHIPS

Partnerships were visible across all sectors, and this was seen as an area of strength. The s maintains multisector partnerships with a wide range of stakeholders; including AYUSH providers, tribal populations, the Indian Military Branches, the India Railway, various NGOs, and private health institutions. TB Champions are trained, engaged, and confident. Public awareness campaigns appeared accurate, visible and high profile (i.e. community meetings and campaigns). There is engagement of media actors (i.e. print, radio, TV, online). However, these successes were relationship-dependent, more can be done to systematize them at an institutional level; this requires high-level negotiation at state and national levels. Limited access to comprehensive counselling including on mental health, nutrition,

treatment literacy, confidentiality and stigma were seen as potential threats. High out-of-pocket expenses for tests, accommodation and travel for people needing TB treatment (and family members) and incentive payments being rejected were observed. Engagement of local traditional healers, industry (i.e. tea plantations, brickworks), political leaders, and the media was lacking.

PUBLIC-PRIVATE MIX (PPM)

In 2019, 22 percent of the total notifications were by the private sector; the majority by the Joint Effort for the Elimination of TB (Project JEET). We observed strong coordination between DTC and JEET; including initial mapping of all health care providers. Private sector treatment support is available through JEET. A letter issued by the Deputy Commissioner has helped the district improve TB notification from private providers; supplemented by sensitization meetings for private practitioners. Laboratories and pharmacists were less involved in the PPM work, however.

HEALTH SYSTEM

Policies, guidelines, regulations, program implementation plans, organizational structures are available. Integration of TB services in urban health facilities was observed within a well-defined and rational hierarchy of RNTCP services delivery systems. National and donor funding is available; including district-level increases in procurement and infrastructure investment (e.g. LGB Chest Hospital, Guwahati). FDCs, and SLDs are provided free of direct cost. Available information management systems included NIKSHAY, NIKSHAY Aushadhi, and TB LIMS; however, there was limited interoperability of these systems. There are duplicative systems of recording information; maintaining both paper-based and electronic records. Connectivity to NIKSHAY is inconsistent; resulting in delays for entry of data. There is good storage conditions and adequate space at the district, IRL and health facility levels. Availability of drug quality-control mechanisms at state level; more than 100 drug seller's licenses were suspended due to non-compliance with

regulations. However, the team noted a lack of ownership by the general health system (i.e. non-RNTCP workforce). There is underutilization of NIKSHAY by the general health system. A major challenge is inadequate and de-motivated human resources (including contractual staff). Low salary, lack of health insurance, and inadequate training and supportive supervision. Nascent investments in community systems for health were also noted.

Overall, the JMM team members were of the view that Kamrup has made significant progress. However, opportunities for early diagnosis to interrupting the chain of TB transmission, and TPT are still being lost; this can be avoided. There is a need for a clear branding and visibility of the End TB Program, beyond the TB facility. This will create awareness, generate demand, and reduce stigma. Visible political commitment and monitoring at all levels of the administration will help to boost the morale of the program, support integration, and generate adequate investments in ending TB.

RECOMMENDATIONS

1. Sustain the political and financial support to the TB program, go beyond the health sector to increase multisectoral accountability.
2. Provide support/guidance to the TB program on systematic partnership and collaboration with relevant stakeholders (education/railways/ armed forces/ private sector etc.).
3. Negotiate visibility for the “End TB” campaign by supporting widespread awareness of TB outside the public sector health facility through branding, media engagement (including social media).
4. Support the uptake and utilization of GOI subsidies and entitlements for TB patients, treatment supporters and private sector by streamlining payments from the GOI to beneficiaries (patients, private sector providers etc.) and addressing the provision of payments to those who have no bank account (e.g. homeless/no address proof).
5. Strengthen coordination between the TB

Program and NCD through the State TB-Comorbidity Committee.

Tinsukia District

TEAM MEMBERS

Dr. Patrick Moonan (District, and State Lead), Dr. Vineet Chadha, Dr. Di Dong, Ms. Smirty Kumar, Dr. Shamim Mannan, Dr. Sreenivas Nair, Dr. Malik Parmar, Dr. Pirabu Ravanan, Dr. KS Sachdeva, Dr. S Somasekar, Dr. Sriram Selvaraju, and Dr. Palash Talukdar.

BACKGROUND

Tinsukia is a predominantly rural (91 percent of population) district in the eastern most part of the state of Assam, with an estimated population of 1.4 million (3790 km²). The Indian State of Arunachal Pradesh borders Tinsukia to the north and east; the most eastern end of the district is 80 kilometers away from the Myanmar international border. A substantial proportion of the population work and reside within tea plantations, and are at high risk of TB due to poor living conditions (e.g. overcrowding, inadequate or no ventilation) indoor use of fossil fuel for cooking, alcoholism, and poverty.

NOTIFICATION, REPORTING AND RECORDING

The total number of TB notifications in the district has decreased from 3255 patients in 2015, to 2192 patients through the first ten months of 2019. An increased proportion of notifications from the private sector (13 percent to 26 percent) occurred during the same time period. Treatment success rate of new and previously treated patients also decreased since 2015 (90 percent to 69 percent amongst new; 75 percent to 61 percent amongst previously treated); presumably due to the increases in non-evaluated treatment outcome status in the private sector. ACF is organized in collaboration with the various tea gardens, and also the district jail; however, the yield has been less than one percent of all notifications. Routine, systematic household contact screening is minimal. The majority of notified patients in the public sector

have documented HIV status, and testing is readily available. Few patients in the private sector have documented HIV status, and testing is not routinely conducted in the private sector. DBT was initiated and progressively increased with time. During April 2018 to August 2019, 30 percent of the eligible patients (n=4304) and 77 percent of the registered providers (n=35) have received cash transfers. However, none of the eligible treatment supporters (n=303) received DBT during the period. NIKSHAY was readily available and used by all RNTCP staff. Most staff used the mobile phone application, or RNTCP supplied tablets. NIKSHAY was utilized for real-time reporting and recording of key variable (e.g. name, age, sex, address, treatment start date, laboratory results, HIV status). The use of NIKSHAY for real-time treatment adherence documentation was lagging and, in most instances, delayed by up to one month.

PREVENTION

TPT initiation among PLHIV was 14 percent. TPT for household children under 6 was observed and available; however, due to lack of systematic contact investigations the proportion eligible children receiving TPT is low. There is no routine screening of healthcare workers for TB; at least two healthcare workers have been treated for TB in the recent past, suggesting nosocomial transmission. Fast tracking of symptomatic patients (i.e. four symptom screening) was observed in the community ART Centre, though the ART staff were not aware of the TPT recommendations for all PLHIV. Generalized AIC at community health centers was not observed in outpatient departments, radiologic departments, and laboratory, diagnostic departments. These areas were characterized by patients crowding in congested areas. We observed no triaging or systematic processing for patients with potential respiratory symptoms consistent with TB.

CASE FINDING, DIAGNOSIS AND LABORATORY SERVICES

The district has 15 DMCs and additional PHIs are being converted into non-DMC diagnostic centers.

The district has five digital radiology facilities, and one mobile radiology unit. All radiographs are interpreted by contractual remote radiologists via tele-radiology; with a turnaround time of less than 48 to 72 hours. At the district-level hospital (civil, secondary care), we scanned chest radiographs from patients who presented two days previously for potential images consistent with TB. Among 17 chest images, there were 4 (24 percent) potential presumptive TB patients based on radiologic presentation; among these patients, only one (25 percent) was referred to the DMC for further evaluation using smear-microscopy or CB-NAAT. This suggests that potential TB patients were missed or delayed in diagnosis. Rapid rifampin-resistance detection (e.g. surrogate marker for MDR-TB) is available through CB-NAAT. The integrated DR-TB diagnostic algorithm with a cascade of sequential testing was being followed; testing is free of direct cost to all patients. However, patients with CB-NAAT positive/rifampin-sensitive patients were not sent for first-line LPA; this results in missed diagnosis of H mono-resistant and poly-drug resistant patients. In total, 1948 TB patients had valid CB-NAAT testing for DR-TB; this represents approximately 64 percent of all notified TB patients. However, the yield may be improved by more focused case finding measures, and improving the efficiency of sample collection and transport. Currently, sputa are batched, presumably to reduce transportation cost. This practice was found to negatively impact the time to diagnosis, and sequential testing required for second-line tests. As a result, there are delays (in some cases up to 30 days) in initiating effective DR-TB treatment. Improper technique, measurement, and concentration was observed for producing disinfecting solutions, nor was the disposal process consistent with international standards. Thus, the handling and disposal of biomedical waste (e.g. CB-NAAT cartridges, Falcon tubes) were not safe and appropriate for practice.

DRUG-RESISTANT TB (DR-TB)

All DR-TB patients undergo free pre-treatment evaluation at the District PMDT Centre. This implies all DR-TB patients must travel to Assam Medical



College, Dibrugarh to start MDR-TB treatment, and manage adverse drug events with subsequent follow-up at the district DR-TB facility. The district DR-TB facility has professional counselling services, and ECG available. There is only one public physician (Medicine)-specialist for TB in the entire district, he is nearing retirement, and not trained in current policies for DR-TB management. The DR-TB coordinator is well-trained, motivated, committed, and demonstrated a good understanding of national PMDT policies and practice. The DR-TB ward (one "isolation room") at the district-level, tertiary care center has not been utilized to date. We observed this isolation room with inadequate ventilation and inappropriate AIC measures in place. To date, the district has started two patients on a BDQ-based regimen. However, there is a need to strengthen local expertise for local (decentralized) DR-TB management, improvement in civil works of DR-TB ward, and increased services from private specialist consultants (e.g. pulmonologist, medical specialists) who are available in the district.

CO-MORBID CONDITIONS AND CHILDHOOD TB

We observed underdiagnosis and underreporting of pediatric TB; 3.8% of all notified patients in Tinsukia are pediatric TB (four percent in Assam). Routine sample collection (e.g. gastric lavage, fine-needle aspirate collection) and testing from pediatric presumptive TB was not observed in neither the public or private sectors. Nearly all children with TB were diagnosed using clinical presentation; in rare instances with radiologic evidence. The majority (11 of 15; 73 percent) of the DMC are co-located with Integrated Counseling and Testing Centers (ICTC); CB-NAAT laboratories are co-located with link ART centers. Among all notified TB patients in 2018, 66 percent had a documented HIV status; albeit this is almost exclusively from the public sector. CB-NAAT is available free of direct cost to all PLHIV, and cotrimoxazole prophylactic treatment is also available for opportunistic infection management. All TB patients managed for TB were screened for

diabetes; we found no evidence that diabetic patients were screened for TB. Excessive alcohol consumption was noted as a major public health problem in the community; as many as 85 percent of the adult population consumes alcohol daily, and approximately 20 percent are considered "alcoholics". Professional psychological counselling is available at the primary public health center, and is used for TB treatment adherence, treatment for substance use (e.g. tobacco), excessive alcohol use, and other psychiatric illness (e.g. anxiety, depression, schizophrenia). Some cross referrals were observed between the recently established tobacco cessation program and RNTCP; however, this area needs further promotion and strengthening with enhanced training, documentation and more regular coordination and supervision.

COMMUNITY ENGAGEMENT AND PARTNERSHIPS

Collaborative partnerships were visible across all sectors; this was seen as an area of program strength. The District NTP has engaged many of the large tea estates, oil companies, coal mining companies, non-government organizations and private sector health institutions in TB outreach, care and treatment. DBT benefits were available in all the tea gardens visited and for all the patients interviewed. Thirty-four (94 percent) of the private providers have received DBT. Out-of-pocket expenses, especially for drug refill was observed, and most DOT was facility based. It is common practice for patients to present weekly at the health facility to collect their drug refill. Private industries (i.e. tea estates, oil and coal companies) have resources devoted to health and are willing to invest in TB elimination; this needs further formal exploration. Traditional healers were observed to be the first point of contact in most rural settings; these healers should be formally engaged in the elimination strategy.

HEALTH SYSTEM

Despite recent downward trends, treatment success and overall notifications, the District TB team is



committed to delivering high-quality TB services. Tea Estates' medical services have committed "TB Free Garden" campaigns that fund TB screening and services to employees and their families; including free transportation of patients to a higher level of treatment facility elsewhere (i.e. PMDT). These are "Models of Excellence" which have been recognized at the State level (Ledo PHC). The district has out-sourced some laboratory and tele-radiology services. Counselling provided by professional counsellors to TB patients. However, the team noted a lack of ownership by the general health system (i.e. non-RNTCP workforce). There is underutilization of NIKSHAY by the general health system. Available information management systems included NIKSHAY, NIKSHAY Aushadhi, and TB LIMS; however, there was limited interoperability of these systems. There are duplicative systems of recording information; maintaining both paper-based and electronic records. Connectivity to NIKSHAY is inconsistent; resulting delays for entry of data. There are various health system-level integration programs (e.g. PMJAY, psychological counselling, smoking session and non-communicable diseases). Some of the hospitals involved in TB treatment and care are integrated with PMJAY; however, these facilities have not sent TB-related claims to PMJAY. TB program remains vertical and key positions remain vacant. For example, the lack of finance staff has led to delays in payment approvals and processing contracts and DBT. Moreover, there is an immediate need to address low salary, lack of health insurance, and inadequate training and supportive supervision. We observed deficient training of staff in all categories.

KEY ACHIEVEMENTS

- Commitments from District TB Officer and her team in implementing TB services.
- Enthusiasm of the District Collectorate in making Tinsukia TB free.
- Existing "Models of Excellence" (Ledo PHC), which may be reciprocated in other health facilities. (Appreciation to Ledo PHC MO).
- Chapakhowa (TB Unit Sadiya) –

Teleradiology and outsourced lab services, professional psychological counselling available.

- Existing coordination between RNTCP and NTCP.

RECOMMENDATIONS

1. Ratify the "Intensified Action Plan to END TB by 2025" in Tinsukia; increase budgetary justification in the 2020–2021 PIP; engage all stakeholders and community in the "TB Free Tinsukia" Plan.
2. Expedite the recruitment and staffing of all vacant posts in the district (especially, STS and district accountant to accelerate payment processing and approvals to ensure timely contract payments and DBT payments).
3. Expedite training (and refresher training) to all staff in all categories: including RNTCP staff (DTO, PMDT Coordinator, TB-HIV Coordinator, STS, STLS); Medical College faculty and staff; DR TB physician-specialist, and other civil hospital physicians (pediatricians, medical officers) general health staff; PHI medical officers, ANMs, MPWs, CMEs for PPs.
4. Harness financial and material support from Coal India and private Tea Gardens for TB diagnostic services implementation (CSR funds may be tapped); formalize a partnership mechanism.
5. Conduct *systematic* contact investigations for all patients and their families. This includes: a) home visits for all index patients within 2 weeks of treatment initiation (to enumerate all household contacts), b) symptom screening of all contacts (to find concurrent patients), c) sputa collection for all presumptive TB patients (when appropriate), and d) follow-up home visits at the start of continuation phase (repeating steps a – c). For all contacts with no evidence of active TB (using chest radiography when available and appropriate), TPT should be offered.
6. Operationalize the District DR-TB Center;

consider outsourcing physicians services and specialists; and refurbish the DR-TB ward (isolation unit) to make it AIC compliant by installing open windows in the exterior wall above the toilet, installing open windows facing the atrium, installing a simple exhaust fan (outflowing) in the wall above the toilet.

7. Optimize ACF activities to high-risk neighborhoods and villages by mapping vulnerable populations (e.g. individual Tea Gardens, slum, coal miners), targeting mobile screening drives to locations with the highest expected prevalence (i.e. cases per 1000 person population), and avoiding case finding activities in low-risk, low-yield populations which divert scarce resources from core TB elimination tasks.
8. Amplify the involvement of the general health system staff; include NHM.
9. Review current biomedical waste management policies and update these policies to ensure practice for safe handling and disposal of biomedical waste according to international standards (see [WHO's Safe management of wastes from health-care activities, 2017](#)).

3.1.2 Chhattisgarh

State Visit

The team visited two districts: Bilaspur and Raipur. Sites visited included (among others) district TB centers, CHCs, PHCs, sub centres, prison hospital, JSS hospital and AYUSH hospital. In addition, the team interviewed various stakeholders including state, district policy makers, health staff, DOT providers and patients. Below are key findings from the various sites visited.

The state of Chhattisgarh has a population of 29.5 million, with 32 percent living in tribal areas. There are 5206 sub centers, 837 primary health centers, 170 community health centers and 27 district hospitals providing TB services in the state. The state has 789 DMCs, 155 functional TUs, 21 DRTB centres and four Nodal D-TB wards.

NOTIFICATION, REPORTING AND RECORDING

Achievements

- From January to October 2019, Chhattisgarh has been able to achieve 77 percent of its notification target (public sector 87 percent and private sector 59 percent), set by the CTD.
- Schedule H1 surveillance contributed to approximately 10 percent of case notification in 2018 (2700 cases notified). Drug inspectors have also strongly enforced the maintenance and compliance of H1 schedule register among the chemists in the state.

Challenges and Opportunities

- The state has not fully operationalized the policy of notification at diagnosis. Records are entered in NIKSHAY only after treatment initiation and those with presumptive TB or those diagnosed with TB are not entered in the system.
- There is a lack of systematic data verification attempts by staff; the staff appear to be unaware of standard operating procedures. As a result, there is:
 - Incomplete data related to most of the TB/HIV, DR-TB, and a subset of private patients;
 - Data discrepancies between hard copies (i.e. lab register, patient treatment cards) and NIKSHAY at DTC Kalibadi, Tatibandh, and pharmacy; and
 - Lack of linkage of records of contact screening for children and families, leading to unclear patient pathways for decision for TPT or treatment.
- There is limited data analysis and use of data for program improvement and decision making.



Recommendations

1. All presumptive TB cases, as well as those diagnosed, need to be entered into NIKSHAY. Consider utilizing existing NHM infrastructure at the HWC level and above to facilitate this.
2. Strengthen supervision and monitoring using the existing SOPs for triangulation incorporating NIKSHAY records in the process.
3. Undertake convergence with the general health system for screening and case reporting.
4. Institute regular internal program reviews as a routine program monitoring mechanism.
5. Data quality assurance during supervision needs to be systematic.
6. Build capacity of state and district staff for routine surveillance, data management and data use for decision making and program improvement

PREVENTION

Achievements

- TPT coverage of 49 percent among PLHIV (92 percent in Raipur).
- Operational feasibility of LTBI screening and treatment along application facilitating data recording and monitoring is being piloted in Rajnandgaon.
- Healthcare worker screening for TB conducted in 2017 using CB-NAAT (23,895 screened, 1,497 presumptive TB, 7 TB cases diagnosed).

Challenges and Opportunities

- Provision of H therapy among child contacts has improved but exact coverage is unknown, potentially due to gaps in NIKSHAY data collection.
- No AIC interventions implemented in neither public or private facilities; symptomatic cases are also not fast tracked.
- Lack of regular TB surveillance among

health care workers.

Recommendations

7. Engage MPWs/Mitanins (ASHA) to help provide TPT to child and adult contacts.
8. Incorporate AIC interventions in the State PIP interventions to complement existing infection control measures.
9. Implement regular, periodic healthcare worker screening as a TB surveillance tool (similar to the 2017 campaign mentioned above).

CASE FINDING, DIAGNOSIS AND LABORATORY SERVICES

Achievements

- Steady increase in private sector contribution to TB case notification (4,981 TB cases in 2015 to 10,855 TB cases in 2018).
- Microscopy services have been Decentralized to all PHIs with laboratory technicians.

Challenges and Opportunities

- Loss of TB cases along the diagnostic pathway: low presumptive TB case examination rate, capacity for molecular diagnostics does not match demand (U-DST coverage is 54 percent) and underutilization of radiology in the diagnostic algorithm.
- Suboptimal specimen transportation system (only eight percent of samples are received at IRL within 72 hours) and substantial delays in notifying patients of results.
- Unacceptably low yield of ACF efforts suggesting a need to change approach and improve quality of these efforts.
- Existing IRL capacity not enough to meet the optimal testing demand of the State.
- Administrative processes for the sustainability of quality IRL services are



unclear. In March 2020, there is a possibility of complete staff turn-over without adequate handover; this will lead to a loss of trained and skilled staff that could result in the collapse of the State's IRL services.

Recommendations

10. Design a detailed plan to improve case finding. Consider including a systematic screening of vulnerable populations including children, training and immediate implementation of new diagnostic algorithms, match CB-NAAT need to demand and explore the utilization of digital x-rays with AI to facilitate ACF efforts.
11. Implement a more robust specimen transportation mechanism with standardized processes to ensure better patient turnaround times.
12. Engage with the private sector to offer free molecular diagnostics and other DST to privately managed cases.
13. Expedite the establishment of two planned IRLs. Retain the existing skilled and trained IRL staff to ensure the continued functioning of quality diagnostics.

DRUG-SENSITIVE TB (DS-TB)

Achievements

- The national DSTB treatment strategy including regimen, duration, and dosages were implemented (95 percent of all diagnosed cases are on treatment).
- High treatment success rate for DS-TB (public sector 87 percent, private sector 57 percent - verified by phone and entered in NIKSHAY).

Challenges and Opportunities

- High proportion (88 percent) of treatment initiation in the private sector is based on only clinical diagnosis.
- Gap in data on treatment regimens for 95 percent of patients in the private sector.

- No use of digital adherence technology for treatment monitoring.

Recommendations

14. Increase private sector engagement by rapidly deploying the modified PPSA model to improve TB case notification, ensure quality of care, treatment and treatment completion.
15. Continuously evaluate the program through standardized patients and prescription audit(s).
16. Employ the use of digital adherence technology as appropriate.
17. For TB/HIV patients, ensure timely TB treatment initiation and completion.

DRUG-RESISTANT TB (DR-TB)

Achievements

- DR-TB Treatment has been decentralized (OPD based) in 22 of 27 (81 percent) districts.
- Eligible patients are on new treatment regimens as appropriate.

Challenges and Opportunities

- Healthcare providers are not knowledgeable on the proper DR-TB management practices.
- No systems of pharmacovigilance and death audits in place.
- No center of excellence for DR-TB.

Recommendations

18. Employ the use of e-platforms (like ECHO) to develop capacity and improve DR-TB patient management.
19. Integrate clinical decision support mechanisms into NIKSHAY to assist with difficult cases.
20. Integrate NIKSHAY with vital registration system and pharmacovigilance
21. Establish a center of excellence for DR-TB diagnosis and treatment (perhaps through AIIMS hospital).



CO-MORBID CONDITIONS AND CHILDHOOD TB

Achievements

- 82 percent of TB patients know their HIV status (59 percent among children).
- Systematic TB screening among PLHIV conducted.

Challenges and Opportunities

- Underdiagnosis of TB among children; only 6 percent of all TB cases are among patients under 14 years of age compared to the estimate of 10-12 percent incidence rate.
- Assessment of HIV status of presumptive TB patients underway but needs much attention.
- No system in place for fast tracking symptomatic cases for sputum testing and smear for PLHIV. In addition, turnaround times for CB-NAAT are too long.
- Treatment success is low (65 percent) among TB/HIV patients (21 percent are not evaluated, 10 percent death rate).
- Cotrimoxazole not provided to PLHIV.

Recommendations

22. Intensify case detection of pediatric TB by using all point of care entries (e.g. MCH, NRC, Immunization).
23. Update, disseminate, and implement new pediatric TB diagnosis algorithms and guidelines.
24. Ensure availability of preventive treatment (Cotrimoxazole and H) for all PLHIV.
25. Enact systems that will improve the clinical management and follow-up of TB/HIV patients.

MULTI-SECTORAL ENGAGEMENT, PATIENT SUPPORT SYSTEMS, PARTNERSHIPS, AND URBAN TB

Achievements

- RNTCP is engaged with 13 corporations to

also provide TB services.

- In 2016 and 2018, a systematic TB screening was done in prisons.
- Food baskets provided to patients as DBT.
- PPSA light model of engaging private providers is being used.
- TB champions are being engaged through the TB call to action project.
- All UPHCs are DMCs (45/45).

Challenges and Opportunities

- Program staff are managing the NPY benefits and it is a time-consuming endeavor.
- State has not scaled up the use of ICT adherence technologies such as 99DOTS. Procurement of printed drug blister pack sleeves are pending.
- There is no reconciliation of in-kind benefit disbursement to patients NPY in NIKSHAY because of an unclear process of reporting and monitoring.
- Challenges in the procurement process of benefits have led to substantial differences in initial and subsequent benefits across public and private sector patients.
- High out-of-pocket expenditures for seeking TB care.
- Private sector primarily providing only clinical diagnosis.
- RNTCP and NUHM prepare action plans in silos.

Recommendations

26. Re-visit the rationalization of using program staff for managing the DBT system (STS); review findings of the recently initiated time/motion studies for different program personnel (STS) and explore alternative options to addressing the issues.
27. Ensure the procurement of necessary consumables for ICT based adherence technologies by including this activity in the PIP and expediting their procurement.
28. Expand engagement of TB champions to address



the gaps in and ensure practice of patient-centric care.

29. Expand comprehensive TB care under UHC.
30. Expedite the roll-out of PPSA to improve TB care in the private sector.
31. Work together to coordinate PIP across the State health system.

COMMUNITY ENGAGEMENT AND ACSM

Achievements

- Strong, motivated and a well engaged system of 'Mitanins'. The team met a group of 30 such workers (UHC-Raipur) who were knowledgeable on TB, were involved in TB household screening during their routine visits for other health programs, and provided treatment support to patients.
- Successful use of social media platforms (e.g. Facebook, YouTube and twitter etc.) for raising awareness.
- District TB forums have been formed and 54 TB Champions trained.

Challenges and Opportunities

- Mass awareness campaign (TBHDJ) has not yet been initiated in the state; limited MID media campaign throughout the state.
- Sub-optimal functionality of TB Forums and no patient literacy support is available in the state.

Recommendations

32. Expedite appointment of ACSM officer position to facilitate state ACSM activities.
33. Ensure that every district has at least one TB champion to help raise awareness and reduce stigma and discrimination by mentoring more TB champions. Consider incentivizing champions.
34. Mandate that Kayakalp project is implemented in all government health facilities.
35. Ensure the effective use of TB Forums at all levels to drive ambitious END TB vision.

HEALTH SYSTEM

Challenges and Opportunities

- For the last four years, eight positions at the state TB cell and 17 positions at STDC have remained vacant; this compromises the capacity and ability of the state cell to effectively implement and monitor RNTCP programming.
- High vacancy rate for many key positions at state- and district-level (90 percent specialist and 44 percent medical officer positions are vacant).
- Lack of engagement of general health system staff (e.g. MOs, RHOs, ANMs, Pharmacists) in the provision of TB services.
- Unequal salary compensation for RNTCP staff as compared to other program staff with similar workloads/responsibilities.
- Underreporting in PFMS with expenditure at approximately 50 percent in 2018.
- Procurement delays and low supply levels at the state-level.
- Centralized usage of NIKSHAY/NIKSHAY Aushadi at the district and TU level with a lack of its utilization at facility- or district-level.

Recommendations

36. Prioritize and expedite the filling of vacant positions at the state TB cell to improve coordination and monitoring of program implementation.
37. Ensure a functional STDC by fast tracking recruitment of vacant positions to strengthen training, monitoring, surveillance and training
38. Retain well-trained, experienced existing staff at IRL to ensure its continued smooth functioning.
39. Provide 'at par' salaries for TB program staff to ensure parity and equity across all the programs.
40. Increase the accountability of block medical officers, PHC MO and RHO to ensure all

cases complete the TB care cascade through dedicated programs reviewed at state-, district-, and block-levels.

41. Increase engagement of general health system staff (e.g. MOs, pharmacists ANMs, MPWS) to improve TB case management and ensure successful treatment.
42. Conduct routine review of TB program performance at the highest district- and state-levels to ensure accountability and to drive performance.
43. Train staff in and ensure use of PFMS across all financial transaction systems.
44. Prioritize TB procurement and supply at the state-level to avoid stockouts of drugs and other commodities.
45. Transition to real-time electronic recording from PHC level into NIKSHAY and NIKSHAY Aushadhi.
46. Improve the infrastructure at district- and facility-level as per SOPs.

TECHNICAL ASSISTANCE TO END TB AND RESEARCH AND INNOVATIONS

Achievements

- Currently TA is provided by WHO consultants.
- Provision of food baskets as nutritional support for TB patients and engagement of Mitanins for comprehensive TB care is a best practice example for the country.

Challenges and Opportunities

- Ongoing procurement delays for drugs, food baskets and laboratory consumables.
- Lack of operational research (OR) agenda that is properly informed by local data and needs.

Recommendations

47. Seek TA for procurement to ensure a consistent and reliable supply chain.
48. Develop State OR agenda and engage

medical colleges and other academic institutions for OR.

Bilaspur District

TEAM MEMBERS

Mr. Richard Cunliffe (District Lead), Dr. Sudarsan Mandal, Mr. Bruce Thomas, Ms. Marion Grossmann, Dr. Pankaj D. Nimavat, Dr. Tarak Shah, Dr. Manu E. Mathew, Dr. Kshitij Khaparde

BACKGROUND

Bilaspur is one of the progressive districts and it ranks in the first seven districts of the state. Overall, the infrastructure of the TB program aligns with the plans of the RNTCP with nine TUs, 57 DMCs, three GeneXpert labs and one DR-TB ward. The annual case notification rate is 167 cases per lac per year and the TSR for DS-TB cases is 87 percent and for DR-TB is 54 percent.

ACHIEVEMENTS

The district has taken a number of progressive measures for TB Control such as:

- Mitanins (ASHA workers) are at the grassroots of the district program. The workers are knowledgeable on proper symptom screening methods, testing and referral for patients from their community to the nearest DMCs and health centres.
- Jan Swasthya Sahyog (JSS) is an NGO providing advanced clinical support for TB care in the district. The group provides: patient-centric care including differentiating services provided on the basis of disease severity; follow-up (on phone) until treatment outcome; offer psychosocial support; comorbidity assessment and treatment; in-patient care for severely diseased patients; and nutrition support for undernourished patients. Approximately 28 percent of patients treated in a year are extra pulmonary cases as they provide facilities for testing and diagnosing extrapulmonary cases. They also conduct



outreach to sub-centres to provide additional outreach and public health functions.

- DMC is established in the prison hospital and there is systematic (verbal) screening of inmates at the time of entry into the prison and by health coordinators among the inmates.
- No shortage of drugs was observed by the team or reported recently to the district and sub-district level.
- Active engagement with many chemists in the urban area. All were maintaining schedule H1 Registers and communicating the necessary information to the DTO through the District Drug Inspectors. Once the information is received at the DTO, then the DTC staff reconcile it to remove duplicates and identify which doctor is prescribing private care and address any systematic issues.
- There is active engagement with some private practitioners including Apollo hospital and Life Care Hospital where diagnosed TB patients are put on TB treatment provided by RNTCP and work with the public sector (e.g. TBHV, STS, and Mitanins) for patient follow-up.

RECOMMENDATIONS

The State has committed to End TB by 2023, and the Bilaspur region including the Bilaspur District has been prioritized for the development of a micro- strategic plan which they intend to finalize by end of November 2019. As the State and District work to finalize strategic and implementation plans, the team recommended the following points to for consideration and inclusion:

1. Identify all cases in the district: Suspect examination rate is about 500 presumptive TB cases examined per lac per year (national average is closer to 1000). Considering the urgency for TB elimination, it should be ensured that all presumptive TB cases are identified and referred promptly for testing. A

few ways of improving case identification are:

- a. Ensure that no presumptive TB cases are missed once they enter the healthcare system at PHIs that are non-DMC by either referring patients to appropriate facility or collecting for transport to nearby testing facility.
- b. Identify areas where adding a DMC would improve access to patient testing and initiate DMCs in those PHIs. Consider expanding DMCs to the PHCs without a center; 16 in the district.
- c. ACF campaigns in high-risk, vulnerable populations and geographic hotspots. These efforts should make use of mobile X-ray van at ACF sites and prisons so that the presumptive TB cases can be screened with a high sensitivity tool.
- d. Strengthen referrals from health facilities and monitor existing capacities during supervision using exit interviews, referral trends and positivity rate of referred cases.
- e. Strengthen ACSM activities (e.g. print media, wall paintings, awareness drives, district TB forums, school awareness campaigns/ competitions, etc.)
- f. Increase engagement of private practitioners including traditional health care providers for TB referral services and case notification by using:
 - i. Continuing medical education (CME) opportunities, one-on-one meetings, following-up on referred cases, etc. CME events should include active participation by physicians, updates on programmatic processes and guidelines, stories of TB Champions, adverse effects management etc.
 - ii. Awareness drives and creating effective linkages between private sector, traditional health care providers and public systems to promote presumptive TB case referrals for diagnosis confirmation.
 - iii. Review and further strengthen local



mapping to link private providers with existing RNTCP workforce to ensure referral of presumptive TB cases, effective transport of patient samples, short turnaround times, availability of medicines for treatment initiation, and patient follow-up.

2. Improve quality of care to completion (Treatment success is currently 87 percent however, patients not evaluated is about 11 percent)
 - a. Strengthen monitoring of cases on treatment using treatment supporters, monthly home visits or health center visits, and follow-up testing and DST.
 - b. Implement ICT based adherence technology such as 99DOTS and MERM so that self-reporting of adherence is possible and staff can prioritize monitoring of cases that interrupt treatment.
 - c. Ensure availability of TPT products (e.g. Pyridoxine tablets) to improve TPT coverage of under-five contacts and PLHIV. These are available in local store supply and may be procured or patients may be reimbursed.
3. Strengthen training, monitoring and supervision and HR capacity
 - a. DTO needs to be full time for TB (currently splitting time with other disease areas like Leprosy, HIV, RSKS as well as a range of various administrative activities in the district).
 - b. Recruit for 2 STS and 1 DEO positions vacancies.
 - c. Fill Specialist Doctor positions (90 percent vacant), Medical Officers (26 percent vacant). Consider amending the State's policy on the definition of 'Specialist Doctors' to include diploma holders with experience.
 - d. Strengthen NIKSHAY data entry. Entry into NIKSHAY currently happens only after the treatment initiation. Current guidelines state that entry take place from the PHI at the time of presumptive TB by the PHI referring the case. Labs providing diagnostic test details need to enter results against the cases referred to them. This would allow a heightened degree of surveillance as the entire TB cascade from referral for testing to treatment would be tracked.
- e. Requests for testing from CDST labs need to be initiated in NIKSHAY by the health facility referring the case/sample to be tested. This would ensure complete reason for testing, patient details etc. to be available to the lab at the time of testing and it will significantly reduce the much-duplicated effort in transcribing the process and test result in paper forms and registers.
- f. Monitor and scale-up U-DST coverage, aim to increase coverage from the existing 42 percent to approximately 70 percent of all notified cases.
- g. Conduct refresher trainings for staff and MOs whenever lapses in program performance is observed.
- h. Prioritize TB Elimination specific review at the highest level in the District by District Collector.
4. Integration of TB program with general health system
 - a. TB care should be owned by the general health system comprising the block medical officers, PHI medical officers and RHOs. This ownership should increase general health system accountability from referral to diagnosis to treatment initiation to regular follow-up until successful treatment completion.
 - b. Role of RNTCP staff should be elevated to monitoring and supervision to be able to fill in the gaps when identified.
5. Address issues in quality of services
 - a. DR-TB Ward CIMS: Common ward for both male and female patients, with a toilet under construction, and poor



cleanliness. AIC measures are insufficient. The JMM team was informed that COPD patients were accommodated in the same ward (which potentially will lead to further spread of infection).

- b. Utilization of GeneXpert/ CBNAAT site: There are two sites (CIMS with 330+ tests per month and DH with 180+ tests per month). Pendency of testing at CIMS is 400 test samples which signifies a need to coordinate and utilize both sites optimally to provide rapid diagnostics.
- c. District drug store: Limited space leading to challenges in the organization of the drugs and expired drugs not being quarantined separately. There is an apparent need for more space and temperature monitoring.

Raipur District

TEAM MEMBERS

Dr. Anand Date, Dr. Senait Kebede, Dr. Manoj Jain, Mr. Ambrish Shahi, Dr. Amar Shah, Dr. Neeraj Agarwal, Dr. Neeta Singla, Dr. B Ramesh Babu, Ms. Sheffali Sharma, Dr. Shanta Achanta, Dr. Nishchit KR

BACKGROUND

Raipur, the capital city of Chhattisgarh has a population of 28.35 lakh with a district geographical area of 2,891.98 square kilometres and a population density of 941.36 with an urban population of 15.33 lakh and slum population of 5.26 lakh. Overall, the infrastructure of the TB program is as per RNTCP norms with 8 TB Units, 54 DMCs, 2 GeneXpert labs and 1 DR TB ward. In the last five years, the district has noted an increase in presumptive TB case examination rate from 771 cases to 1,055 cases per lakh population and an increase in notification rate from 103 to 188 per lakh population.

ACHIEVEMENTS

The district has taken several progressive measures in TB Control:

- Decentralization of microscopy services to all the PHIs.
- High treatment success rate; 90 percent for newly diagnosed and 74 percent for previously treated cases.
- High TPT coverage among PLHIV (97 percent).
- Engagement of Mitaniin (ASHA workers) with RNTCP at the grassroot level including involvement in symptom screening, patient referrals from community to the nearest DMCs or health centres and serving as a DOT provider.
- Decentralization of DR-TB care to district level with roll out of shorter DR-TB regimen on outpatient department basis
- Comorbidity monitoring and testing in place; 82 percent of TB patients know their HIV status, systematic TB screening among PLHIV is being done, and 58 percent of TB patients are screened for diabetes.
- A DMC has been established in the prison hospital and systematic (verbal) screening of inmates has been carried out at the time of entry into the prison and by health coordinators among the inmates.
- The team observed no shortage of drugs onsite or recently reported at the district or sub-district level. However, a shortage of drugs for treating MDR-TB in pediatrics as well as cotrimoxazole preventive therapy (CPT) for TB/HIV patients was observed.
- There is an active engagement with many chemists in the urban area. All of them are maintaining schedule H1 Registers and convey the necessary details to the DTO through the district drug inspectors. Once the information is received at the DTO, then the DTC staff reconcile it to remove duplicates and to identify which doctor is prescribing private care and address any systematic reason.

CHALLENGES AND OPPORTUNITIES

- Weak coordination between general health systems and TB service delivery. The



general health system (including the block medical officers) is not involved in TB program activities resulting in contractual staff or lab technicians bearing most of the burden for all TB activities. NIKSHAY entries are also not entered at PHI-level.

- Long-term vacancies of key positions including medical officer, DR-TB coordinator and 2 TB health visitor posts.
- Most of the medical officers and staff lacked up-to-date knowledge on the current (both technical and operational) guidelines and recent updates/changes in the programme.
- Although TB case notification has improved significantly over the past five years (from 104 to 189 cases notified per lakh population), there has been no significant improvement in 2019 as compared to 2018. Pediatric TB cases are also underreported (6 percent compared to the estimated proportion of 10 to 12 percent).
- The supply of CB-NAAT machines available does not meet the demand for molecular testing. Out of an estimated 18,000 presumptive TB cases in 2018 only around 6,000 were tested using rapid molecular diagnostics.
- ACF campaigns have very poor yields; the strategy needs to be revisited to focus on targeted areas/populations.
- The TB care cascade is weak resulting in leakage of patients across the TB care continuum. Community efforts to refer cases are strong but the institutional framework to establish referral linkages, receive patients/samples, run proper diagnostics, provide test results and initiate treatment in a timely fashion is weak.
- Lack of a robust sputum transportation plan. Currently used vaccine carriers are being re-used and cleaned manually with 5 percent phenol; proper disinfection practices are not being followed.

Sometimes samples are transported two or more days after collection.

- In 2019, the incidence of DR-TB is less than 2 percent of total notified cases.
- Missed opportunities to diagnose DR-TB cases due to suboptimal LPA testing—of the 1,811-sputum smear positive cases on treatment, LPA was completed for only 536 cases.
- Only patients put on treatment are being entered in the notification register. This creates a gap in information on symptomatic persons and patients diagnosed but not on treatment.
- Turnaround time of CB-NAAT test results is unacceptably high; the average turnaround is from 15 to 60 days.
- NIKSHAY Aushadhi is not being used at district or sub-district levels resulting in sub-optimal recording and reporting. Stock register not being maintained for SLD, discrepancies observed between drug stocks available in NIKSHAY Aushadhi, stock register and what is physically available in the store.

RECOMMENDATIONS

1. Develop a budgeted operational plan at the district level with a clearly articulated mission, vision, goals, objectives, and activity plan that includes specific timelines using local data to support and achieve the END TB targets.
2. Prioritize and expedite the recruitment and hiring process of contractual staff vacancies (PMDT coordinator, TBHVs) as well as general health system staff vacancies.
3. Build knowledge and capacity of DTO and other staff in basic epidemiology and data management to facilitate data driven decision making.
4. Implement systematic contact tracing and targeted intensified ACF by mapping key and vulnerable populations.
5. Optimize the TB diagnostic network to meet the goals and targets of the NSP algorithms



including adopting the new algorithms and enhancing the use of CB-NAAT, FL/SL LPA as well as radiology.

6. Ensure that no presumptive TB cases are missed or lost to follow-up once they seek healthcare from PHIs that are non-DMCs. Either the patient needs to be referred or samples need to be collected and transported to a nearby testing facility.
7. Scale-up effective PPE approaches; including increasing access to CB-NAAT testing for the private sector to increase the likelihood of proper and accurate diagnosis and strengthening mechanisms to ensure patient treatment outcomes are reported.
8. Increase the accountability of block medical officers, PHC MO and RHO for ensuring all cases complete the TB care cascade through dedicated program reviews at state-, district- and block-level. Increase the engagement of general health system staff (MOs, Pharmacist, ANMs, MPWS) to improve TB case management and successful treatment.
9. Ensure that samples of all DS-TB patients and RR-TB patients are transported to IRL for FL-LPA and SL-LPA respectively.
10. Ensure NIKSHAY entries for all persons with presumptive TB take place at the PHI level by the general health system staff. This will improve surveillance by tracking the care cascade from symptoms to diagnosis to treatment initiation to treatment outcome. Utilize NIKSHAY Aushadhi for tracking TB drug utilization.
11. Engage NCD clinics to screen diabetics for symptoms of TB and strengthen reporting of any TB coinfection cases.
12. Monitor budget head wise expenditure for optimal utilization of funds and implementation of activities.
13. Strengthen ACSM activities (wall paintings, awareness drives, district TB forums, school awareness campaigns/ competitions etc.) to address persisting challenges with discrimination and stigma.

3.1.3 Kerala

State Visit

The JMM Kerala State team consisted of 21 members. Apart from visiting facilities and patients in two separate districts (Thrissur and Wayanad), the team visited the state TB cell, KSACS, STDC, IRL at Thiruvananthapuram, CDST laboratory at Kozhikode, State Drug store, Nodal DR TB centers [Thiruvananthapuram & Kozhikode], Medical College STF Chairman, Corporate hospitals and had interactions with State Professional Medical Association leaders & State Drugs Controller.

Kerala's multi-layered sustained model of TB care and control is reflected in the reduced incidence rate of disease which was measured at 44 cases per 100,000 people, against the national average of 199 cases per 100,000 people. The annual decline rate of TB incidence in the state is three percent, which, again, is much higher than the national average. Kerala is also equipped to offer universal DST to all the diagnosed TB cases in the private and public sector. It has achieved 69 percent universal DST for R with CB-NAAT. Additionally, five districts offer universal DST for H also through line probe assay. Prevalence of R resistance in TB infected people in Kerala is one percent and H resistance is less than two percent

Achievements

- *TB elimination mission plan:* Kerala needs to be congratulated as one of the few states in India that have committed to be "TB Free" and eliminate TB by 2025. The Government of Kerala launched the "Kerala TB elimination mission" aligning with the SDGs, with objectives to achieve: TB Elimination by 2025; zero deaths due to TB; zero catastrophic expenditure. The TB Elimination mission document, which is a customized version of India's NSP for Kerala is being released as a Government Order.
- *Integration with primary health care:* TB services and elimination activities are well



integrated into the primary health care system in Kerala. TB control and services are the responsibility of the entire health system, at all levels, both public and private. Two MPHWs (Health worker-Male & Health Worker- Female) are available for every 5000 population and are made accountable for RNTCP activities.

- *Local self-government (LSG) stewardship for decentralized Planning & Implementation:* The LSG – at district, block and village levels – are interested, engaged and committed to eliminating TB. LSGs are involved in planning, monitoring and implementation of TB elimination activities and vulnerability reduction for TB. The district panchayat or the LSG also provide social, housing, nutritional, travel and rehabilitation support to patients and their families. State political leadership has called for action by local government leadership.
- *Private sector engagement through the system for TB elimination in private sector (STEPS):* TB Elimination in Kerala has engaged private sectors for many years through systematic engagement of private providers to diagnose, notify and treat TB patients. There is strong implementation of STEPS centers at private hospitals, and there is support and collaboration with private hospital consortiums and professional medical associations. These act as a link between the public and private sector. They provide a single window for TB case notification, linkage to treatment support, and also ensures that all public health and social welfare schemes offered to RNTCP patients are available to patients in the private sector. Kerala has successfully customized Project JEET for establishing self-sustainable STEPS centers in private hospitals for patient-centered and provider-friendly TB care.
- *TB elimination board and task forces:* TB

elimination boards were formed at district levels chaired by the district collector used for policy decisions and program monitoring. District TB Elimination Task Force, Panchayat and Municipality TB Elimination Task Forces formed at LSG levels for LSG stewardship and field activities helped in mobilizing additional support for the general health system and foster multi sectoral engagement.

- *Empowering community:* There has been a strong movement to involve community as stakeholders and empowering people with knowledge and information about TB.
- *Epidemiological evidence & compilation:* The state has completed epidemiological identification of vulnerabilities common to TB patients and mapping of those vulnerabilities. Epidemiological evidence of a declining TB notification rate despite increased cases finding efforts, declining drug sales in the private sector, right skewed age shifting further shifting to right, declining pediatric TB notification, low prevalence of RR-TB and good standards of TB care in the private sector was documented and observed.
- *Surveillance:* Timely TB reporting to NIKSHAY from hospital, periphery and private sector is happening. Drugs sales data is being used for surveillance. Schedule H1 surveillance initiated to identify missing cases by identifying providers.
- *Vulnerability mapping:* State has taken the innovative step to identify and map the entire population according to the vulnerabilities most responsible for TB disease. It is a significant and outstanding achievement that Kerala has mapped 27m (81 percent) of the population for vulnerabilities. The State has clear plans to link the vulnerabilities to ACF and vulnerability reduction and link to programmatic management of latent TB infection once rolled out. Currently the state has moved into phase two and is



actively screening those identified vulnerable people to find disease.

- *Periodic contact tracing*: The State maintains a contact register to track and document all contacts including those under six years old every three months.
- *Airborne infection control (AIC)*: AIC systems in place with an emphasis on the establishment of cough corners (system to screen, educate, provide masks and fast track respiratory symptomatic) at hospitals, awareness raising through the 'handkerchief revolution', and home AIC kits (which include 5 washable reusable clothed face mask, spittoon and disinfectant solution).
- Strengthening diagnostic services
- *Microscopy*: In the last year, 63 new DMCs have been enacted; 12 urban PHCs were upgraded to DMCs; 58 newly upgraded family health centers have DMCs. Currently 586 DMCs (Kerala has one DMC per 58,000 population, norm is 1 per lakh) are in place, of which 104 are in private hospitals.
 - *CB-NAAT*: In the public sector, there are 21 CB-NAAT machines being used efficiently at fixed facilities. In addition, two vehicles mounted CB-NAAT machines are serving in hard to reach areas (in collaboration with NUHM). An additional 13 CB-NAAT machines are with the private sector where arrangements have been made for running tests at subsidized rates through the IPAQT (Initiative for Promoting Affordable and Quality TB tests) scheme. Additional Lab technicians are being provided for the 14 CB-NAAT sites through NGO PP scheme with Indian Medical Association.
 - *CDST & LPA*: A new laboratory facility has been developed and certified for performing first line LPA at Government Medical College Kozhikode in addition to the IRL at

Thiruvananthapuram. The State has been able to ensure a successful transition of FIND supported staff to NHM ensuring uninterrupted provision of diagnostic services. The State is in process of utilizing Private lab (Amrita institute) for augmenting diagnostic capacity of DR-TB.

- *Specimen collection & transportation*: Efficient specimen transport systems are in place to transport samples from peripheral and private facilities to hub for CB-NAAT; extended hours to improve access to CB-NAAT.
- *Intensified case finding*: ACF is happening in NCD and ART clinics.
- *Patient centric TB services*: TB services are truly patient-centered with routine and systematic interventions including treatment support groups, holistic care of patients and control or prevention of social determinants using support packages that include monthly pensions, above the national DBT systems, and nutrition. The treatment support triad is a three-way transaction among the patient, treatment supporter and a representative of the health system at PHC for every 5,000 population and treatment support groups have helped to reduce the lost to follow-up rates including initial lost to follow-up rates.
- *Comorbidity management*: A system for periodic monitoring of ADRs and NCDs status is in place by medical officers through fortnightly clinical review of all persons affected with TB. Ensuring bi-directional screening for TB and NCDs through NCD clinics, free insulin scheme for TB patients, control of COPD through SWAAS clinics and tobacco cessation clinics.
- *Local solutions*: Kerala has created state- and district-specific solutions and implementation models for their challenges in TB control including:



- Unique schemes to address social determinants including a non-health department scheme addressing malnutrition among elderly.
- Unite for Healthy Ernakulam (U4HE) by the National Health Mission District Unit has successfully engaged private hospitals with a comprehensive public health package that has shown improvements in ensuring standards of TB care in India, vaccination coverage, better reporting of communicable diseases and averting outbreaks. It is a low-cost private sector engagement model and an example of good convergence of programs. U4HE is also working on capitalizing on the already existing resources and ensuring commitment of medical colleges for capacity building of private hospitals.
- Tribal department in Wayanad is providing nutrition, transportation and health support through tribal promoters, including TB screening among malnourished preschool children.

Challenges and Opportunities

- *Poor infrastructure and deficient HR at IRL:* The team observed that the IRL is neglected and ill-maintained. Lack of adequate HR results in long delays in laboratory processes and reporting results. Due to these, LPAs cannot be offered at baseline to all patients except in four districts. Infrastructure for IRL BSL3 lab is in need of upgrades to make it a center of excellence, this is a prerequisite for elimination. Lab needs better infection control facilities. Currently it is fully run by NHM contractual staff with low salaries and no career prospects despite performing highly skilled work and working long hours. Posts for Lab technicians remained vacant for a majority of the year with high staff turnover that resulted in shut down of the lab many times. This has affected patient services and management in terms of unacceptable delays, universal DST and follow-up reports, and has led to drop in treatment success rates of DR-TB patients.
- *Limited capacity of X-ray, CB-NAAT, LPA:* The diagnostic algorithm is not always followed to completion (CB-NAAT & X-rays) because of limited access to X-rays, saturation status of CB-NAAT machine and training issues. All CB-NAAT machines are working to their maximum capacity. The state needs to use CB-NAAT for TB diagnosis as cases are mobilized early through ICF and ACF and the intention is to cut down delays. Currently districts where first line LPA is carried out; samples of diagnosed TB patients are tested with first line LPA rather than CBNAAT in order to save the capacity of CBNAAT which is utilized to test presumptive TB. This has resulted in a decrease in LPA capacity: only 4 of 14 districts are undertaking first line LPA at baseline.
- *Lack of dedicated public health experts at STDC:* STDC has serious limitations in training capacity. Currently it is managed by three pulmonologists. As the state is moving towards TB elimination, there is not enough HR capacity at STDC to address the changing training needs especially as related to epidemiology, public health and managerial skills. Currently all epidemiological analyses and training at state and district level are dependent on external TA. The statistical wing of STDC is redundant.
- *Lack of documentation to properly evaluate cascade of care:* Presumptive TB are not referred through NIKSHAY and so the loss in cascade of care could not be captured.
- *Gaps in vulnerability mapping:* TB vulnerability mapping activities need

monitoring for validation and refinement. The activity has also not been carried out in urban areas.

- *Need for integration plan at local level:* MPH/ASHA have to make multiple visits to households for different programs leading to overburdening.
- *Inconsistencies in documentation:* Contact tracing and documentation is inconsistent.
- *Gaps in facility AIC:* The team observed gaps in formal AIC training and existing infrastructure.
- *Low uptake of TPT among PLHIV:* There is a low uptake of TPT among PLHIV due to ADR concerns.
- *High rate of random blinded re-checking (RBRC):* High percentage of slides checked for RBRC; in some districts 60 percent of slides are being rechecked by STLS. RBRC is consuming a disproportionately high amount of STLS staff time.
- *Delays in DBTs/other financial benefits:* Persisting delays in fund release from state treasury due to natural calamity and recurrent issues with PFMS observed.
- *Need standardize pediatric TB diagnosis:* Efforts to diagnose and treat pediatric TB are not uniform across districts. Pediatric TB management needs to be made standardized.
- *High proportion of clinical TB:* Proportion of extra pulmonary and clinical TB are exceptionally high (40 percent) in the state. There is a need to build capacity for microbiological confirmation of extra pulmonary specimens.
- *Lack of dedicated plans and policy for migrants:* No migration policy or plan to ensure universal access to migrants – in-migration (e.g. guest workers from other states) and out-migration (citizens of Kerala in the Middle East) – and maintain high standards of TB care currently in place.

Recommendations:

1. Diagnostics/laboratory services
 - a. IRL
 - i. Move the IRL to a better building to address the gaps in infection control practices.
 - ii. Invest in the IRL staff; this will ensure the provision of faster service to the patients and reduce the turn-around times for sample processing.
 - iii. Invest in permanent HR posts at IRL including in charge of IRL microbiologist, EQA microbiologist and senior lab technicians.
 - iv. Revisit salary structure of existing IRL staff.
 - v. Enhance the IRL to a center of excellence; this would require enhancements to more advanced technologies to support elimination such as genetic sequencing to track transmission dynamics.
 - b. LPA/culture/DST labs: Increase LPA capacity (add one additional LPA lab) and frequency of training at all levels to ensure implementation of the national diagnostic algorithm.
 - c. Enhance CB-NAAT capabilities. CB-NAAT must be the primary diagnostic tool for presumptive TB. Advocate for optimizing CB-NAAT use in the private sector. Approximately 160 additional modules are needed to cover the State for TB elimination.
 - d. Shortage and limited access of X-ray units: Advocate for and procure more Need to X-ray units including mobile X-ray units for hard to reach areas (e.g. Wayanad, Idukki).
2. Training/capacity building and restructuring of STDC – Implement training/retraining at all levels for new approaches and focused activities necessary for TB elimination. For example, training should be conducted to strengthen managerial and epidemiology



- skills. The State also needs more robust documentation and real time monitoring of epidemiological data to go for sub-regional certifications. To accomplish this, the STDC needs to be restructured with personnel that have the capacity to conduct training on a wide range of topics like public health, epidemiological and managerial skills.
3. Increase budget allocation: In order to successfully implement elimination activities, the corresponding budget will need to ramp up as TB cases go down. Develop a costed five-year plan for TB Elimination to use when advocating for more resources including increasing central and state shares, mobilizing CSR grants, crowdsourcing and external grants.
 4. Prepare for and expand LTBI management: Elimination should also include LTBI and preventive therapy. Begin building systems and processes to raise awareness and create demand for starting preventive therapy particularly to extend to vulnerable groups.
 5. State TB Elimination Board for multisectoral engagement: Translate District TB Elimination Boards to the State level for better intersectoral convergence for TB elimination. For example, LSGs, Tribal Welfare, Labor, Urban Affairs, Police, coordinating TB vulnerability reduction; Railways, ESI & other clinical management facilities for extending TB services.
 6. Build capacity of LSG: Invest in training the Panchayat leaders and officials to respond to the Health Minister's request for proposals around social determinants like diabetes control, malnutrition, smoking, COPD, alcohol, etc. This will improve reduction in these social problems in the community and will help end the TB epidemic.
 7. E-health/applications and AI: Prioritize electronic tracking of vulnerable individuals through e-health/separate applications and linking persons to NIKSHAY from presumptive TB status. Enhance vulnerability mapping with AI/geo-mapping to identify hot spots to add to vulnerability index.
 8. Strengthen facility-based AIC: Provide capacity building to engineers and hospital administrators for infrastructural modifications and after-systems for assessment and compliance at all health facilities. Include AIC in PIP to strengthen facility AIC implementation and put a formal assessment system in place.
 9. Operations research (OR): State needs more OR on TB elimination and evaluating/validating the new approaches like vulnerability mapping.
 10. TPT among TB/HIV: TPT among TB/HIV patients needs attention. Document ADRs and advocate for shorter and safer TPT regimens.
 11. DBT: The State needs to investigate the DBT delays and work together with other stakeholders to address the gaps.
 12. Integration: Devise a clear plan for integration at the grass root level; this will optimize resource management and improve efficiencies. Initiatives like 'Unite for Healthy Ernakulam' could be scaled up.
 13. Re-evaluate EQA: Re-evaluate EQA for microscopy and implement EQA for CB-NAAT.
 14. Strengthen health system to address vulnerabilities: Focus on strengthening diabetes prevention and control, chronic respiratory diseases (SWAAS), tobacco cessation clinics and the urban health system.
 15. Need systematic and committed TA: In order to build the program to the next level required for TB elimination, there is a need for regular, focused TA. Medical colleges should be a source of TA and will need to step-up to full this role. The requirements for more advanced technical assistance are in analytical epidemiology/big data analytics and AI.
 16. Migrant welfare policy: State needs to develop and implement a strong migrant welfare policy to handle in-migrants (e.g. guest workers) and out-migrants (e.g. especially citizens migrating to Middle East countries). The policy should include equitable to high-

quality care to all in-migrants as well as citizens of Kerala working in the Middle East.

17. Address cross-border issues: Create dialogues to address the cross-border issues and increase access for care at border sharing districts (e.g. Kasaragod, Palakkad).
18. Sub-regional certification: The State should prepare for sub-regional certification for TB elimination based on documentary evidence.

Thrissur District

TEAM MEMBERS

Ms. Amy Piatek, Dr. Son Nam Nguyen, Dr. Prahlad Kumar, Dr. Salil Bhargava, Dr. Himanshu Negandhi, Dr. Rahul Srivastava, Dr. Sandeep Bharaswadkar, Dr. Vaibhav Shah, Dr. Shibu Balakrishnan

EPIDEMIOLOGY

Achievements

- NIKSHAY use is nearly universal with staff confident in accessing and pulling out data for action; this includes use of the app.
- Excellent initiative in conducting vulnerability mapping to systematically identify high-risk. Over the span of six months, 6,950 survey volunteers (e.g. ASHA and others) visited 20 houses every Sunday reaching a total of more than 700,000 households. Approximately 89 percent of the population was categorized into vulnerabilities. Of the 25,000 “vulnerable” people screened in third quarter 2019, 6 were diagnosed with TB.

Challenges and Opportunities

- Although the vulnerability mapping identified people with presumptive TB, these presumptive cases have not been entered into NIKSHAY for routine monitoring. A separate excel database for the vulnerability mapping.

Recommendations

1. Validate the results of the vulnerability mapping exercise. Optimize use of mapping by incorporating geocodes and/or AI.
2. Ensure all relevant staff-level logins for NIKSHAY are being used.
3. Improve documentations and records of supervision at all levels.

PREVENTION

Achievements

- Strides have been made in implementing AIC initiatives in place including the use of biosafety hoods in microscopy labs, and the provision of infection control kits to patients for reducing transmission of infection.
- There is a contact register that tracks children <under six years old for TPT every three months.

Challenges and Opportunities

- Contact tracing was not observed in any of the facilities visited, and documentation was inconsistent.
- Although we saw cough corners in many facilities, AIC infrastructure was deficient.

Recommendations

4. Improve the efficacy of contact tracing districtwide.
5. Increase focus on LTBI diagnosis and treatment in order to take the next step in the Kerala Elimination Mission. Consider piloting LTBI diagnosis and treatment in a subset of patients.

CASE FINDING, DIAGNOSTICS AND LABORATORY SERVICES

Achievements

- There is a consistent, yearly upward trend in case notification from the private sector.



In 2019, one-third of CB-NAAT tests were private samples (130/403).

- There is an effective specimen collection and transport mechanism to CB-NAAT instruments in place for nearly all facilities; this is reducing the need for patients to travel to the CB-NAAT themselves.
- The district is utilizing the CB-NAAT capacity at its maximum, including extending hours to further increase capacity.
- There is ACF among “guest workers”; last year there were 7,073 screened in 1,252 camps with ten presumptive TB identified and no actual cases of TB diagnosed.

Challenges and Opportunities

- Turnaround time from specimen collection to CB-NAAT result is not routinely measured; however, health staff noted turnaround times from two to seven days.
- Currently, there are 39 DMCs across 94 PHIs; not every PHI without a DMC has a specimen transport mechanism to a DMC.
- Diagnostic algorithms are not always followed because of limited access to CB-NAAT and X-ray, and saturation of the single CB-NAAT instrument in the district.
- High percentage of slides checked for RBRC (35 percent in the district) leading to a significant increase in workload for lab technicians.

Recommendations

6. Prioritize the procurement of additional CB-NAAT instruments for the district; procure a 16-module instrument to replace the four-module instrument.
7. Improve access to X-ray especially for hard-to-reach populations (e.g. tribals).
8. Ensure specimen collection and transport from PHIs to DMCs.
9. Re-evaluate EQA for smear microscopy; implement EQA for CB-NAAT.

DRUG-SENSITIVE TB (DS-TB)

Achievements

- TB services are truly patient centric with a wide range of routine and systematic interventions including: treatment support groups; holistic care of patients and control or prevention of social determinants; post-TB management including SWAAS clinics; support packages including 1,000 rupees per month pension on top of the national DBT and nutrition packages.
- The team observed that there was a strong movement to involve community as stakeholders and to empower people with knowledge and information about TB.

Challenges and Opportunities

- Delays in DBTs were observed. The delays in the release of funds from the State’s treasury due to natural calamity and recurrent issues with PFMS.
- TB pensions (Rs 1,000 per month) only available for those TB patients below the poverty line.

Recommendations

10. Create a consolidated packet of information for patients and their families that includes information on treatment, compliance, side effects, infection control at home, and available support schemes (e.g. nutrition package, DBT).

DRUG-RESISTANT TB (DR-TB)

Achievements

- Thrissur has a very low number of MDR/RR-TB cases, this in part can be attributed to the high treatment success rate.
- The 2018 cohort of DR-TB patients had a 75 percent treatment success rate, which is higher than the national rate.



Challenges and Opportunities

- The team observed limited engagement of medical college for DR-TB treatment.

Recommendations

11. Create a DR-TB committee in government Medical College; provide inpatient facilities.

CO-MORBID CONDITIONS AND CHILDHOOD TB

Achievements

- Clear plan for scale-up and intensified ACF in NCD clinics to all institutions by November 2019.
- The district supports a number of patient support schemes that supplement other schemes to specifically address social determinants including a non-health department scheme which addresses malnutrition among the elderly.
- The team observed that there is a fortnightly clinical review of TB patients to manage comorbidities.
- The number of pediatric TB cases has been steadily decreasing in the district.

MULTI-SECTORAL ENGAGEMENT AND PATIENT SUPPORT SYSTEMS (see more under DS-TB Treatment)

Achievements

- The LSG at the district-, block- and village-level are interested, engaged and committed to the Kerala TB Elimination Mission in Thrissur. The LSG also actively participates in RNTCP activities and provides various types of support (social, travel, nutritional, etc.) to patients.
- There is a District TB Elimination Board and a District Elimination Task Force, along with Panchayat and Municipality TB Elimination Task Forces. All of these entities are multisectoral, including government and elected officials, citizens and affected communities.

Challenges and Opportunities

- Lack of a more robust representation from affected communities in the elimination task force groups.

Recommendations

12. Ensure that there is an increase in representation from TB survivors on all TB elimination task forces.

PARTNERSHIPS AND URBAN TB

Achievements

- With support of the JEET 'light' project, STEP centers for one-window TB services have been implemented in private hospitals.
- Support from, and coordination with, private hospital consortiums and professional medical associations including IMA.
- Successful initiation of H1 surveillance in private chemists/pharmacies; two new cases were identified through this surveillance in third quarter of 2019.

Challenges and Opportunities

- Medical colleges are not as engaged or used to their full potential in driving private sector participation in TB Elimination activities.

Recommendations

13. Draft and disseminate additional training for private doctors on policies and effective collaboration strategies with RNTCP.
14. Systematically increase the role of medical colleges specifically in vulnerability mapping and ACF activities and OR focused on elimination.

HEALTH SYSTEM

Achievements

- The RNTCP is well integrated into Thrissur's primary health care system.



- There is systemic use of junior health inspectors and junior public health nurses.

Challenges and Opportunities

- Some visited public sector medical officers were not aware of recent RNTCP policy changes.

Recommendations

15. Urgently fill critical vacant posts including the medical officer of medical college, district PPM coordinator and district program coordinator.
16. Provide continuous training opportunities to medical officers in the public sector, especially from specialty cadres, on evolving RNTCP policies and programs.

TECHNICAL ASSISTANCE TO END TB AND RESEARCH AND INNOVATIONS

Achievements

- The district supports very useful training/TA for NIKSHAY.
- A great trainer of trainers approach with subsequent cascade training is being implemented at district- and sub-district-level.
- The district greatly benefits from the TA provided by WHO consultants.

Challenges and Opportunities

- No systematic bottom-up mechanism to identify training priorities at the state- and district-level.
- Lack of training on management, leadership and soft skills.

Recommendations

17. Conduct a systematic TA and training needs assessment to identify training priorities at district-level.

Wayanad District

TEAM MEMBERS

Mr. Wilson Lo, Dr. Christine Ho, Dr. Rupak Singla,

Dr. Ashwani Khanna, Dr. Yatin Dholakia, Dr. Shobini Rajan, Dr. Jamie Tonsing, Dr. Manoj Toshniwal, Dr. Almas Shamim, Dr. Ravinder Kumar, Dr. Himanshu Jha, Dr. Rakesh PS

EPIDEMIOLOGY

Achievements

- The district has successfully conducted vulnerability mapping on all individuals using a weighted scoring system based on local epidemiology. Out of all individuals mapped, 41,000 (six percent) individuals were identified as highly vulnerable to develop TB. The district also conducts quarterly ACF among those vulnerable individuals: 50 percent of new TB cases have emerged from the six percent of vulnerable individuals identified.
- NIKSHAY entry is routinely completed by peripheral staff and private hospital nodal officers. Data on registers in most, but not all cases, matched with NIKSHAY entries.

Challenges and Opportunities

- One of the major challenges in the district is the systematic tracking of potential patients from vulnerable individual status to presumptive TB patient to TB positive case and treatment/post-treatment follow. The care cascade is also not routinely analysed.
- Outdated registers are commonly used.

Recommendations

1. Invest in the development of mobile- or web-based applications that could help systematically track all vulnerable individuals.
2. Implement a system to ensure that paper records and NIKSHAY entries match. Consider adding this responsibility into routine supervision responsibilities until recording and reporting is completely migrated to NIKSHAY.
3. Ensure the use of the key population column in records particularly for tracking the existing tribal population in the district

PREVENTION

Achievements

- Health facilities have a system in place for screening respiratory symptomatic patients; providing free masks, cough etiquette education, cough hygiene educational materials; and fast-tracking of presumptive TB cases in outpatient departments of health facilities by ASHAs.
- AIC kits are provided with washable and reusable masks, spittoon and disinfectant solutions to promote better patient education on cough hygiene and practice.
- A handkerchief revolution campaign for cough etiquette among school children.

Challenges and Opportunities

- AIC at facilities needs strengthening and optimization including better systems for cross ventilation and air exchanges in in-patient settings especially where TB patients are admitted.
- Further progressing on TB elimination will require expanding LTBI services.
- Contact tracing documentation evidence is missing for many patients.

Recommendations

4. Train hospital administrators in properly setting up systematic AIC for in-patient settings.
5. Prioritize LTBI management programming to further make progress on eliminating TB. Expand the target group for LTBI management based on vulnerabilities already mapped and treat LTBI with a shorter TPT.

CASE FINDING, DIAGNOSIS AND LABORATORY SERVICES

Achievements

- There have been ICF efforts in NCD clinics; a routine, complex four-symptom screening at all NCD clinics.
- The district has done a good job maintaining presumptive TB registers and

a system for sputum collection and transportation from PHIs to ensure minimal loss in patient care cascade.

- Systematic contact tracing is periodically conducted every three months with some documentation.

Challenges and Opportunities

- The diagnostic algorithm is not always properly followed (CB-NAAT, X-rays) because of the limited access to X-rays and saturation status of CBNAAT machines (approximately 400 samples per month).
- Specific challenges affecting tribal populations such as delays in diagnosis and lack of UDST to all tribal presumptive TB cases.
- Very few smear negative pulmonary cases seen. X-rays are not being offered to all patients.

Recommendations

6. Procure additional mobile vans with X-ray and additional CB-NAAT machines to meet the demand.
7. Devise and implement a well-planned and systematic ACF strategy using tribal promoters, hamlet ASHAs, etc.

DRUG-SENSITIVE TB (DS-TB)

Achievements

- There is a system of efficient service delivery to beneficiaries – all patients interviewed were satisfied with the services rendered and nutrition packs received (these were received as intended except for delays in DBT).
- All DS-TB patients are given FDCs. The drugs are issued by the drug stores and the JHI/JPHN carry it to the sub-center to which the patient belongs.
- Drugs are issued from the supply center to the patients for two weeks on average with verbal instructions on tablet consumption,



empty blisters are then collected.

Challenges and Opportunities

- For ARRs, some patients are travelling to tertiary care centers.

Recommendations

8. Invest in capacity building for ADR management and more patient education on where to seek care.

DRUG-RESISTANT TB (DR-TB)

Achievements

- UDST is offered to most eligible cases.

Challenges and Opportunities

- The team observed that old treatment cards were still in use, there are gaps in lab documentation, and persisting training issues on some of the components of PMDT especially as it pertains to patient follow-ups.
- The team observed that no aDSM forms were maintained on site.

Recommendations

9. Implement a continuous learning and training curriculum for staff, printing new records according to guidelines.

CO-MORBID CONDITIONS AND CHILDHOOD TB

Achievements

- Fortnightly clinical review for every TB patient for screening and management of co-morbidity and ADR; this is documented using a checklist.

Challenges and Opportunities

- Pediatric TB management needs to be strengthened; there is a lack of training on childhood TB management and a limited number of available pediatricians.
- UDST not offered to all children with signs

and symptoms of TB.

Recommendations

10. Devise and implement a comprehensive plan to address pediatric TB by training & retraining pediatricians. Consider including skill development for gastric aspirates for staff nurses.

MULTI-SECTORAL ENGAGEMENT AND PATIENT SUPPORT SYSTEMS

Achievements

- Multi-sectoral support and collaboration with aligned departments for TB elimination and patient support is commendable. Tribal Department is providing support, including nutrition and transportation services, as tribal promoters. The revenue department is providing Rs 1,000 as TB pension.
- Good patient support systems – Treatment Support Groups outside the health system under Local Self Government stewardship supporting the patient needs in terms of nutrition, vehicle and counselling helps to reduce lost to follow up.

Challenges and Opportunities

- Persisting delays in DBT and TB Pension; one possible explanation is that patients may not be aware of payments.

Recommendations

11. Specifically review multisectoral engagements activities in context of social benefits to find ways to address gaps.

PARTNERSHIPS AND URBAN TB

Achievements

- All 35 private hospitals are part of STEPS centers that have a trained nodal officer as a single window who notifies patients, gives RNTCP drugs, and ensures all public health actions. There is a private hospital consortium that provides policy support.

Professional doctors' associations under IMA advocate to follow STCI. District health administration utilises project JEET effectively and efficiently.

- The District has no PPM coordinator from RNTCP who can help with the general health system and private sector integration.
- The private pharmacy the team visited at Vinayak Hospital maintains an H1 register. The team also observed the last three months of entries, on an average six to seven pediatric formulations were sold per month.

COMMUNITY ENGAGEMENT AND ACSM

Achievements

- The Kerala TB Elimination Mission is being implemented as a people's movement against TB under the LSG stewardship. LSG task forces are planning, implementing and monitoring the TB Elimination Mission regularly.

Challenges and Opportunities

- The IEC displays in public places were not visible.

Recommendations

12. Increase the visibility of the TB Elimination Mission by investing and implementing a better communication strategy.

HEALTH SYSTEM

Achievements

- There is clear integration and ownership by the general health system. Service delivery has been well integrated from MPH/W to district chief medical officer level.
- Significant increases in allocations and expenditures, but the expenditure last year was still at only 71 percent.

Challenges and Opportunities

- Geographical access is a major challenge preventing tribal people from accessing diagnostic services like X-rays and CB-NAAT services.
- Improvement in capacity building of all cadre of staff needs considerable attention.

Recommendations

13. Procure more mobile X-ray units and portable NAATs to be used to solve the geographical access issues faced by individuals particularly tribal populations.
14. Continuous learning and training opportunities for staff at all levels with inclusion of private sector staff.

TECHNICAL ASSISTANCE TO END TB AND RESEARCH AND INNOVATIONS

Achievements

- The TA provided by WHO to TB Elimination Mission through RNTCP the TSN has been a valuable resource.
- The ICMR has done a study on prevalence of TB among tribal populations as a part of multi centric study.
- An ICMR study on smear negative TB is being completed in the district by STDC Kerala.

Challenges and Opportunities

- Best practices and results of the vulnerability mapping have yet to be scientifically disseminated.

Recommendations

15. Ensure the dissemination of all best practices and evidence of success.

3.1.4 Rajasthan

State Visit

The Rajasthan State team visited two districts: Ajmer



and Udaipur. Below are the key findings from the various sites visited.

KEY OBSERVATIONS

Achievements

- The JMM team observed that the State TB team under the guidance of the DMHS was very dedicated. The District TB teams were also dedicated and dynamic and are great examples of highly engaged primary health care staff.
- Over the past three years, TB case notifications have steadily improved— both in the public and private sector. Additionally, DR-TB notifications have also improved as has treatment initiation.
- All diagnostic tests are available, free of cost, at the Nodal and District DR-TB centers through various state schemes.
- DBT coverage is being scaled-up.
- There are examples of impressive initiatives with real impact; two examples are: the TAD SWACH programme in tribal areas and use of Rajasthan free diagnostic initiative to help and enable diagnosis of co-morbidities.

Challenges and Opportunities

- A large number of vacancies in key positions is crippling the State's ability to meet current demands as well as the ambitions of the NSP including diagnostic capacity.
- Substantial gaps were observed in the monitoring and supervision of the program activities – both at the state- and district-levels.
- Underutilization of budget and other bottlenecks are impacting timely payments for key activities (e.g. DBT, staff salaries, honoraria, expanded access to CB-NAAT etc.)
- Potential of the private sector is not yet fully tapped (incomplete mapping and

systematic engagement).

The team also noted more specific problem areas within the State outlined below.

HUMAN RESOURCES

Challenges and Opportunities

- Current staffing structure (under NHM) is inadequate and does not match the focus and ambition of the RNTCP's NSP Plan.
- Salary structure is not adequate to address the required competencies of the sanctioned positions and attract suitably qualified personnel.
- Inadequate training, especially on the newer RNTCP interventions and policies (e.g. UDST, PMDT, Tug, private sector) thereby impacting quality of implementation.

Recommendations

1. Urgently seek financing opportunities to fill key staffing gaps, and update the salary and staffing structure.
2. Prioritize recruitment of key positions, especially for the C-DST labs, district accountants, TU medical officers, ANMs and expand use of community health workers.
3. Expand the training agenda and adhere to the Training Calendar. This needs to be monitored at State level.

CASE FINDING, DIAGNOSIS AND LABORATORY SERVICES

Challenges and Opportunities

- Specimen transport: Delays in specimen transport contribute to high rate of culture contaminations, delays in test results and effective treatment initiation, and create travel burdens for patients.
- UDST: Only 64 percent of the eligible patients are receiving DST. CB-NAAT capacity and distribution are insufficient to provide complete and timely testing.



- Inconsistent and untimely procurement of lab consumables and reagents.
- Lack of a system to properly maintain and calibrate laboratory equipment.
- Biomedical Waste Management Guidelines (2018) are not implemented.

Recommendations

4. Identify appropriate agencies to carry out timely specimen transport from the PHC level.
5. Enhance CB-NAAT testing capacities (e.g. procure machines, cartridges, training etc.). Consider tapping into CSR and other sources.
6. Establish a dedicated state-level procurements committee to ensure effective and efficient procurement of special laboratory reagents and consumables.
7. Engage agencies for AMC and calibration.
8. Engage with the Rajasthan State Pollution Control Board to ensure adherence to bio safety policies, practices and norms.

PARTNERSHIPS: PSE AND PPM

Challenges and Opportunities

- State-wide private sector facility mapping is incomplete and potential for engaging with NGOs, private sector hospitals, other public health institutions (e.g. prisons, ESI, railways, military, etc.) are not fully realized.
- No systematic monitoring, reporting and accountability for outcomes of patients initiated on treatment in the private sector.
- Delayed payments to private providers which goes against best practices of a performance-based approach.

Recommendations

9. Map, engage and monitor all private providers as well as other PHIs.
10. Expand the PIP (using the newly developed Partnership Guidelines) to include additional Public-Private Support Agency (PPSA) from the

domestic budget (2020-21).

11. Request TA for output-based contracting of PPSA from partners through the CTD.
12. Expedite establishment of a TSU for strengthening PSE and DBT.
13. Recruit additional staff to cover PSE as per NSP recommendations.

DRUG-RESISTANT TB (DR-TB)

Challenges and Opportunities

- Many of the District DR-TB Centers are not yet fully functional.
- Poor record keeping and lack of coordination between the nodal DR-TB centres and the feeding districts.
- Vacancy of senior MOs at the Nodal DR-TB Centers (five out of seven positions are vacant); incomplete training of TU MOs and critical lack of support and supervision of primary care treatment support.
- Resistance among specialist doctors in the government to use highly effective newer drugs (e.g. Bedaquiline).

Recommendations

14. All the District DR-TB Centers need to be made fully functional with DR-TB wards and proper AIC in place.
15. Training and re-training to be conducted for all levels of staff for optimal monitoring and utilization of the best available treatment and safe and adequate treatment support.
16. Ensure that all eligible DR-TB patients receive the highly effective newer drugs as per national guidelines

COMMUNITY ENGAGEMENT, ACSM, AND PATIENT SUPPORT SYSTEMS

Challenges and Opportunities

- Poor disease awareness and persisting levels of stigma both within the community and among patients.
- Weak to no patient education; there is



limited counselling and family support.

- No clear engagement strategy for TB survivor/champion and community.
- TB forums are not activated in 22 districts. In districts that have activated the forums agendas are unclear and meeting scheduling is inconsistent.

Recommendations

17. Create and implement a focused survivor/champion and community engagement and awareness plan with monthly monitoring taking advantage of #TBHaregaDeshJeelega.
18. Use survivor networks, TB forums and community meetings for awareness and stigma reduction.
19. Build and improve capacity of health workers to provide comprehensive patient counselling and support.
20. Engage with key stakeholders to improve awareness and support patients' families and communities (e.g. rotary, local media, NGO's, colleges, schools) with monthly goals.

Ajmer District

TEAM MEMBERS

Dr. Lal Sadasivan S., Dr. Ronald Mutasa, Dr. Thomas M Shinnick, Ms. Tanya Gupta, Mr. Sreenivas Devarakonda, Dr. RS Gupta, Dr. Anuj Bhatnagar, Dr. Ameeta Joshi, Dr. V G Rao, Dr. Sarabjit Chadha, Mr. Chapal Mehra, Dr. Debadutta Parija, Dr. Jyoti Jaju, Dr. Sanjay K Sinha

KEY OBSERVATIONS

Achievements

- Extremely dedicated district team led by a dynamic DTO under the overall guidance of the Chief Medical and Health Officer.
- Over the past three years, TB case notifications have steadily improved – both in the public and private sector.

Challenges and Opportunities

- DTC is located 60 kilometers from Ajmer – leading to programmatic and administrative inefficiencies.
- In 2019, of the total TB cases notified, 6,517 cases, only 25 percent received DBT.

HUMAN RESOURCES

Challenges and Opportunities

- Persisting vacancy of critical positions; this is greatly affecting program implementation and performance. Details may be found in Table 1 below.
- Sr. TB lab supervisors are not provided with motorbikes, this impacts lab quality. Irregularities in TA payment further exacerbates the problem.
- Many staff and treatment supervisors especially the ASHA workers yet to be trained

COMMUNITY ENGAGEMENT, ACSM, AND PATIENT SUPPORT SYSTEMS

Achievements

- The district has an engaged team with a strong understanding of grassroots realities, but community awareness and patient support systems remain low.

Challenges and Opportunities

- Low awareness and understanding of disease in communities and patients. Limited or no patient education, counselling and family support. High level of stigma within communities. No clear local media and community engagement strategy.

Recommendations

1. Create and implement a comprehensive plan for community engagement and education; this should include participation from all relevant stakeholders (e.g. rotary, local media,



NGOs, colleges, schools, etc.) with monthly monitoring. This plan should also include details on the implementation of TB forums with a mechanism to monitor meetings and review outcomes of the forums.

2. Introduce ICT based adherence techniques. Engage with nursing schools to create patient and family education and support programs; this should also include capacity building for the health workers to administer said programs. Create a community-based program that is survivor and local leader-led to mitigate stigma. Develop and implement an engagement strategy with local media with the help of partners and other local agencies.

CASE FINDING, DIAGNOSIS AND LABORATORY SERVICES

Achievements

- Highly dedicated and hard-working staff who are following the national diagnostic algorithm and SOPs.

Challenges and Opportunities

- UDST: Only about 50 percent of patients are receiving CB-NAAT because machine capacity is insufficient to provide timely testing.
- Specimen transport: Less than 40 percent of specimens are received within 72 hours of collection; this contributes to high rate of contamination of cultures and delays in receipt of test results. Specimen transport occurs only once or twice a week. Time from diagnosis to receipt of laboratory test result can be greater than two weeks for a test that takes two hours
- Biosafety: Direction airflow was inadequate or non-existent in the visited facilities which resulted in inadequate protection for workers and AIC.

Recommendations

3. Streamline specimen collection for UDST. All PHIs should have a mechanism for sample collection and transport.

4. Procure more CB-NAAT units and ensure optimization of current machines.

PARTNERSHIPS: PSE AND PPM

Achievements

- The district employs a dynamic PPM Coordinator; however, he is responsible for two portfolios.
- From 2016 to 2018, notification from private providers has increased ten-fold (from 5 percent in 2016 to 28 percent in 2018).

Challenges and Opportunities

- PSE: Approximately 60 percent of private providers are mapped and registered in the NIKSHAY system this should be increased to at least 90 percent in the next two years.
- NGO hospital (largest private provider in Ajmer): Despite the huge potential, St. Francis Hospital's MOU with the DTO has not been renewed for two years. Timely payment of DP honorarium is a challenge.
- Outcomes monitoring and reporting: There is a major gap in monitoring and reporting on outcomes of patients managed in the private sector. Only 15 percent of patients in the private sector monitored for adherence. Documentation of treatment outcomes (i.e. treatment completion, treatment success) is completed by most private practitioners but the quality of the data is low.
- Delayed payments to providers: Payment delays range from two weeks to two months; this goes against the principle and practice of performance-based funding.

Recommendations

5. Staffing and resources: The PPM Coordinator's team needs to be expanded in order to ensure that the performance of the JEET TA is scaled-up to support the district. PPM Coordinator also needs to be supported with transport (motorbike/vehicle) to improve



the quality and comprehensiveness of the private sector work.

6. Improved monitoring and reporting on outcomes: DTO needs to undertake periodic reviews of the outcomes in the private sector in addition to the reviews on notification statistics.
7. Engagement with St. Francis: The district management team needs to renew engagement with St. Francis Hospital to tap into the huge potential of the hospital.

DRUG-RESISTANT TB (DR-TB)

The observations below were made from the team's visits to the District DR-TB Center (Beavar) and the Nodal DR-TB Center (Ajment).

Achievements

- DR-TB Center: All diagnostics are available at the nodal and district DR-TB centers.
- Initiation on BDQ containing regimen at nodal DR-TB center is only on an inpatient basis (two weeks).
- Separate space allocated for DR-TB

patients in the isolation ward in the District Hospital.

Challenges and Opportunities

- At the DR-TB Centre, the isolation ward is yet to be renovated and made functional despite the availability of funds.
- CB-NAAT site is housed in a run-down building which has been recommended for demolition.
- Coordination between the Nodal DR-TB Center and the three feeding districts is weak.

Recommendations

8. Prioritize renovation to improve the functionality of the District DR-TB Center in three months' time.
9. Consider relocating the CB-NAAT machine to a different room within the DH.
10. Strengthen counselling services.
11. Streamline recording and reporting.

Table 1: List of vacant positions in the district.

Position	In Place/Sanctioned	Impact
District Program Coordinator	0/1	Routine program management and monitoring.
Sr. DR-TB and TB/HIV Coordinator	0/1	Management and monitoring of DR-TB and TB/HIV patients.
Accountant	0/1	Financial management (esp. DBT).
TB Health Visitor	4/6	Treatment support and monitoring of patients in urban areas.
NIKSHAY Operator	0/1	DBT and NIKSHAY registration and administration
RNTCP Contractual LTs	0/3	TB diagnostics
LT – DMC (all sources)	26/28	
MO, Medical College	0/1	Diagnosis and management of TB patients in Medical College
LT, Medical College	0/1	
Counsellor	0/1	Counselling services available for patients and their families

Udaipur District

Team Members

Dr. Diana Weil, Dr. Ravindar Kumar, Ms. Erika Vitek, Dr. Ashok Bhardwaj, Dr. Sameer Kumta, Dr. Suman Vishvkarma, Dr. Oommen George, Dr. Sharath Burugina Nagaraja, Ms. Priyanka Grover, Dr. Rajesh Deshmukh, Dr. Vivek Mishra

KEY OBSERVATIONS

Achievements

- In engaging with health staff and
- volunteers, the team observed commitment at all levels to deliver care, prevention and support, and implementation of all basic elements of the programme.
 - Some of the impressive results are: reported over 100 percent of district case finding target; high treatment success rate; MDRTB care increase; expanding towards UDST, examples of strong contact tracing and preventive treatment for children; HIV and diabetes integrated care; NIKSHAY implementation and TB among major indicators monitored; DBT is being rolled out; and Multisectoral engagement.
 - The team also noted the impressive performance of some ongoing initiatives:
 - Multisectoral collaboration through SWACH (Tribal Areas Development financed NGO that offers large scale community-based TB case finding and treatment support as part of their health efforts) and SATIN (Rural Development Department).
 - Implementation of the Rajasthan Free Diagnostics Initiative that enables diagnosis of TB co-morbidities and TB diagnostic supplies.
 - Essential foundation for PPM: With private providers making significant contributions to increased case finding

in the District; and innovative individual example of engagement.

- Local innovation examples: Ayush doctor supervising health units and expanding paediatric case finding. Additionally, DMC is using visualization of clusters of cases to guide priority efforts.

Challenges and Opportunities

- Weaknesses in HR quantity, capacity and supervision; this directly impacts quality of results and coverage, including for diagnosis and quality of care for MDRTB, TB/HIV and paediatric patients.
- Capacity of, and access to, TB diagnostics requires strengthening. There are missed opportunities for early diagnosis placing undue burden on an already overburdened nodal lab, on patients, and on community workers needing to reach diagnostic services. CB-NAAT and microscopy & underutilization of X-Ray)
- DBT access, scaleup and consistent provision is somewhat hampered by some procedures and the limited flow of information regarding expected practices for STS and patients.
- Weakness in local information use, and overburdened staff due to requirements and management of NIKSHAY.
- MDR-TB care is challenging and requires more training and supervision for staff at the PHC and community level.
- Contact tracing and preventive treatment coverage is variable; there are examples of good performance in some rural, tribal areas suggesting it can be improved if staffing needs are addressed.
- Limited engagement of TB survivors and civil society health or TB advocates.

Recommendations

1. Urgently improve HR quantity, capacity and



Table 1: List of key facts on the State of Tamil Nadu.

	Key Facts
Population	790 Lakhs
Urban population	375 Lakhs
Districts (RNTCP)	35
Aspirational Districts	2: Ramanathapuram, Virudhunagar
Tribal Districts	Nilgiris
PPSA Districts	Coimbatore, Madurai, Salem, Tiruchirappalli,

Background

The JMM team spent one week in Tamil Nadu visiting various health facilities and speaking to patients. Below are the names of the specific sites grouped by category.

Table 2: List of public health facilities, providers, and patients visited.

Type of Public Health	Facility Number Visited	Name of Site
STDC	1	Chennai
STC	1	Chennai
DTC	1	Nagercoil, Kanyakumari
PHI	6	UPHC Vattavilai, (KK), PHC Nattalam (KK) PHC Kollemkode (KK), PHC Munchirai (KK) GH Padmanabhapuram (KK) UPHC Nanganallur (Chennai West)
DMC	9	UPHC Vattavilai, (KK), Block PHC Killiyur (KK), PHC Nattalam (KK), PHC Kollemkode (KK), Block PHC Arudesam (KK), PHC Munchirai (KK), GH Padmanabhapuram (KK), DTC (KK), UPHC Nanganallur (Chennai West)
TB Unit	2	Block PHC, Killiyur Block PHC Arudesam
CBNAAT/ LPA Lab	5	DTC (KK) 2 Labs, IRL Chennai NIRT Chennai, UPHC Nanganallur (Chennai West)
CDST	1	IRL Chennai
IRL	1	IRL Chennai
NRL	1	NIRT, Chennai

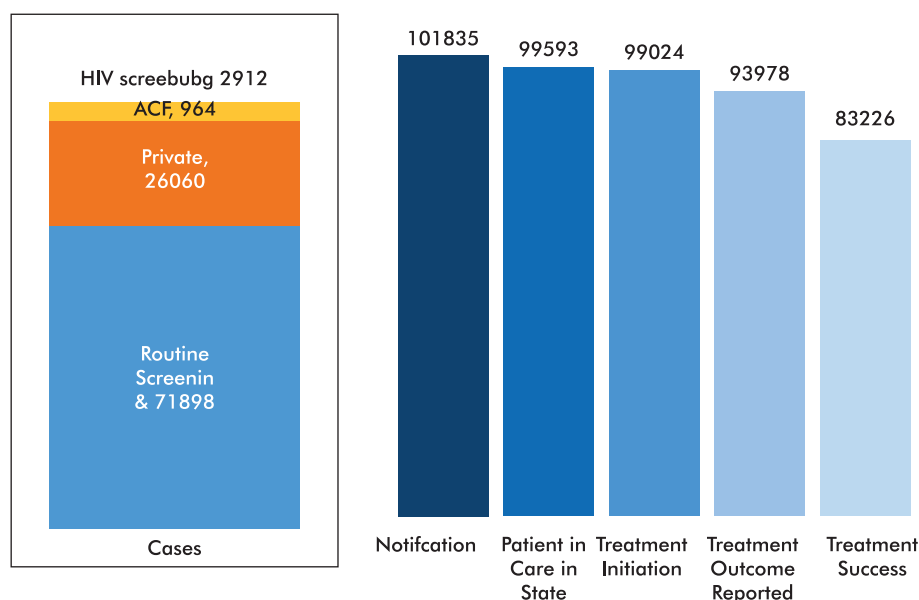
Mobile Diagnostic Unit	1	Chennai
ART Centre	1	KGMCH (KK)
DRTB Centre	2	DRTBC (KK), NDRTBC (GHTM, Tambaram)
Hospitals/ Nursing Homes	4	The Voluntary health Services (Nakshatra Centre), Taramani, Sankaralingam Hospital, Nagercoil (KK), Jayasekaran Multi Speciality Hospital, Nagercoil (KK), Immanuel Hospital, Arudesam (KK)
Private Practitioners/ Clinics	5	Dr Srinivas K, Pvt Clinic, Anna Nagar, Chennai, Dr K Deepak MS-Ortho, Anna Nagar West, Chennai, Dr S Subramaniam MBBS-GP, Shenoy Nagar, Chennai, Ramachandra Hospital, Nagercoil (KK) Chandrasekar Hospital, Thuckalay (KK)
Laboratory	1	DDRC-SRL, Nagercoil (KK)
Chemist	6	Vijaya Pharmacy, Ayanavaram, Chennai Rasi Medicals, Amjikari, Chennai, Apollo Pharmacy, Amjikari, Chennai, Babu Medicals, Chetpet, Chennai, Bawa Medicals, Nagercoil (kk), Sanmathi Medicals, Thuckalay (KK)
Patients Visited	16	DS-TB: 11, H-Mono/ poly: 1, MDR: 1 MDR with additional resistance: 0, XDR: 0, Private sector: 3

Table 3: List of stakeholder meetings the team conducted.

Name of Stakeholder	Number of Representatives	Type of Representatives
IMA	7	3 State and 4 District
Chemist Association	4	4 District
Drug Inspector	4	3 State and 1 District
TB Champions	3	1 State and 2 District

EPIDEMIOLOGY, SURVEILLANCE, SUPERVISION, MONITORING AND EVALUATION

Figure 2: HIV screening cascade.



Achievements

- Surveillance improved with private sector engagement, H1 Surveillance, and ACF.
- Over three years, there has been a 20 percent state and 100 percent city increase in case notifications largely from private sectors.
- NIKSHAY is utilized by all RNTCP cadres and public facilities.
- TB patients are notified at diagnosis (vs. treatment initiation). This has allowed the District to capture 60 percent of presumptive TB patients.
- In Kanyakumari, there has been a 2.5-fold increase in persons to be examined to detect one case; more than half of notified patients are over 55 years of age.
- State-specific prevalence survey is being conducted.

Challenges and Opportunities

- In 2018, the State's TB case notification from the private sector was 26,000 as

against the estimates of 90,000 (based on drug sales).

- Persisting operational and managerial challenges for NIKSHAY implementation.
- ACF and contact investigation information is far from complete – but that does not allow zero TB case reporting.
- IRL is maintaining spreadsheets for transmitting results to districts – no reminder of when different results should come.
- Double entry of data (paper and NIKSHAY) overburdening the field staff because users are focused on entering data but not always clear on how the system is helping them to do their job. NIKSHAY is also not helping PMDT reviews to present cohort data.
- In the sites visited, there was sub-optimal recording of DR-TB patient management. The Treatment Register is not available in KK and investigations were not updated.
- Without guarantee of residence, sputum

testing may not be done.

- Inconsistencies and persisting issues in data representation.
 - Tendency to show combined data on public and private for notification, but move to only public data for HIV testing, treatment outcomes, DM testing, etc.
 - DR-TB outcomes not presented as a cohort.
 - Data presentation formats not standardized.
 - Variable ACF analysis.

Recommendations

1. Analyze the percentage capture of private drug sales under notification to verify TB case notification data. As a first step towards this, STO to request the drug controller to forward state sales data (from drug clearing and forwarding agency).
2. Analyze age-specific population coverage of screening and testing.
3. Capacity building of TB/HV and peripheral health system staff on NIKSHAY data entry.
4. DTO to monitor care cascade on regular basis using NIKSHAY.
5. Address NIKSHAY issues on: ACF zero entry, diagnostic reminders, addition of dashboard, and analytic tools for mobile version.
6. Devise and implement a plan for transition to NIKSHAY-only and remove duplicate paper registers.
7. Collect iterative feedback from NIKSHAY users at all levels. Strengthen the design and/or clarify the use case of NIKSHAY for field-level workers such that it can make their daily tasks easier and more efficient.

PREVENTION

Achievements

- Contact investigations implemented as per guidelines: TB screening for household members and TPT for children under six

(68 percent State; 97 percent District).

- TPT is made available for PLHIV (71 percent in state; almost 100 percent in KK).
- Some screening for health workers was observed.
- At Chennai, TB patients' contacts are followed-up at six-month intervals for up to 1 year to screen for TB symptoms.
- Some AIC efforts are implemented: triaging present in some OPD facilities (this is not systematic) and health facilities are clean with green surrounding and ventilated out-patient areas.

Challenges and Opportunities

- IPT limited to children under six and few PLHIV with limited impact.
- "TB Free" movement in Chennai is a low yield ACF, without no ambitious prevention (TPT) targets
- Contact management is limited to families with no systematic coverage of adults. It is not extended to the workplace or schools.
- Incomplete contact investigation: only 61 percent of index cases in KK and 45 percent in Chennai South have completed contact investigations; only 2.5 contacts per index case (vs 4.2 household size); PPSA/PPSA-lite engagement struggles to implement contact investigation measures.
- While health worker screening is in place in REACH and GCC, it is not in place for all health workers in KK. For REACH, CXR is used for the screening and no cases have been detected so far; for the GCC verbal screening followed by CXR for the presumptive cases.
- Front-line staff do not have and/or use N95 masks even when treating DR-TB patients.

Recommendations

8. Systematically extend contact investigations beyond families to workplaces, prioritizing congregate settings like hostels, boarding houses, schools etc.
9. Link contact investigation efforts to more aggressive screening algorithms, TPT policies, and diagnostic tools (PPD/C-TB, CXR; follow-up contacts every six months for 2 years) (END TB).
10. Link the aggressive NCD (DM screening) program to LTBI because the proportion of DM among TB is high with one in every four TB patients presenting as diabetic in KK.
11. Systematically introduce screening for front-line health workers to provide them with adequate information on protection and prevention.
12. Consider beginning the distribution of AIC kits to patients

CASE FINDING, DIAGNOSIS AND LABORATORY SERVICES

Achievements

- A marked increased intensity of investigations (see Figures 3, 4, 5).
- ACF campaign ramp up including 1 mega campaign in the State and now weekly ACF campaigns in KK with volunteers that are supported by state funds, using village health nurses. The six mobile diagnostic units in Chennai are helping ensure the success of these campaigns.
- UDST is at 79 percent for the State in the public sector; this is supported by flexible financing for sputum transport.
- In 2019, there was an expansion from 839 to 1984 DMCs in the State (per 35K population). Additionally, there is at least one CBNAAT facility per district (per 1M pop). One DST per 17 million population with three machines to be added.

Figure 3: Graphs depicting the increase in the examination rate for presumptive TB and the trend in the TB case notifications.

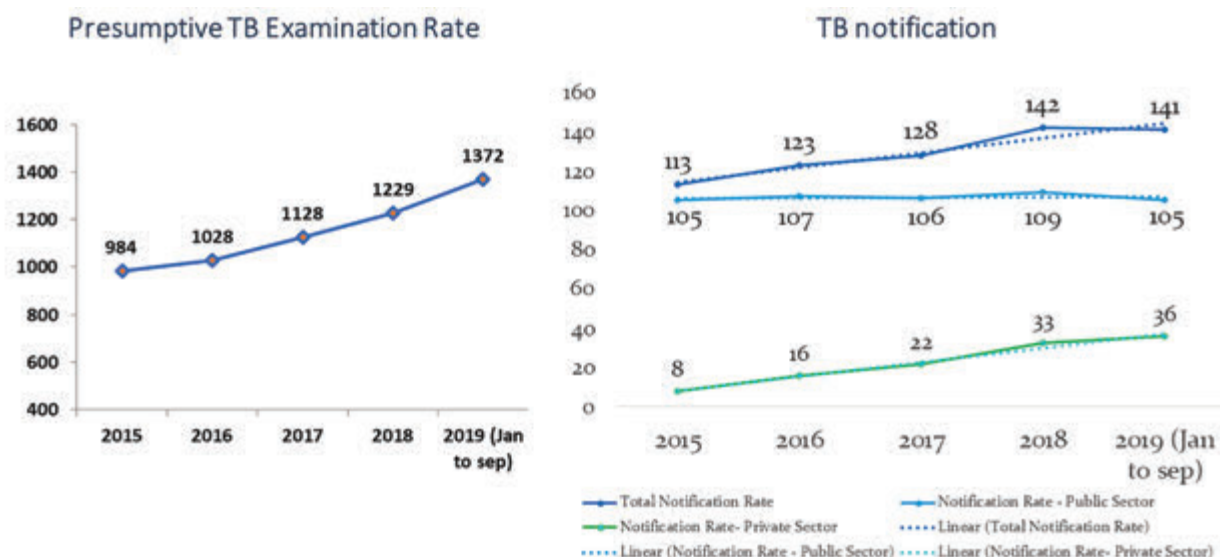


Figure 4: Graph depicting the increase in the examination rate for presumptive TB and the trend in the positivity rate.

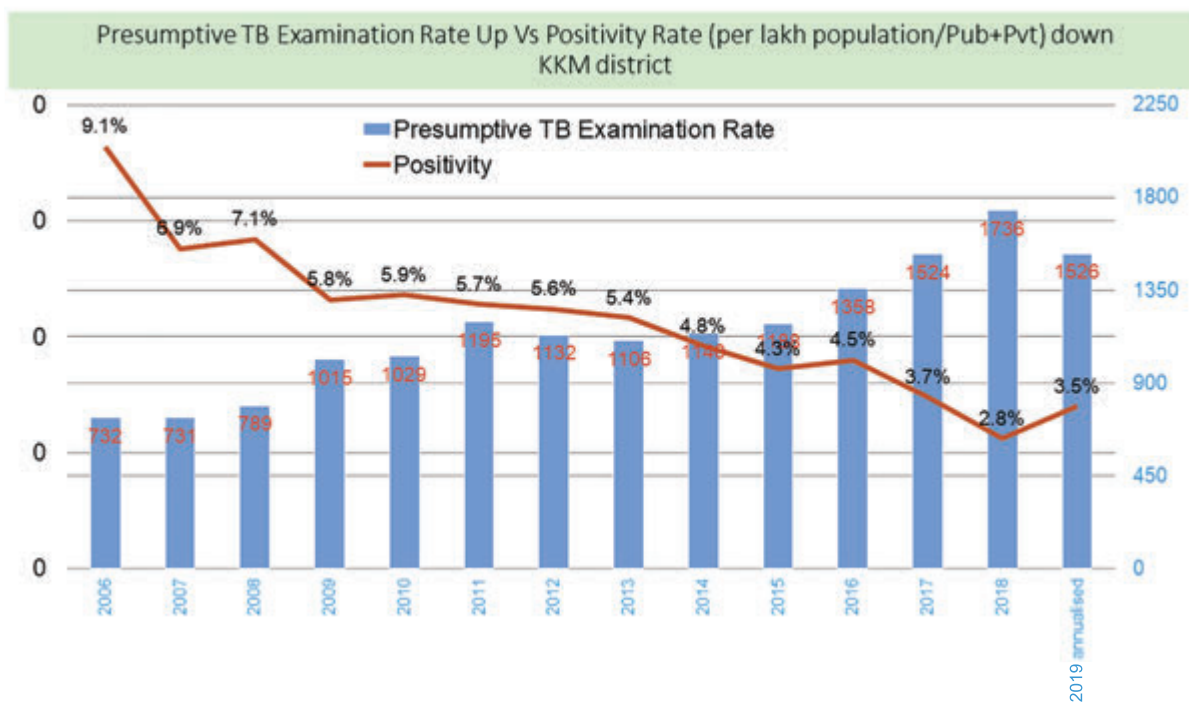


Figure 5: Table depicting the active case finding (ACF) efforts in Tamil Nadu.

Active case finding efforts – Key Population wise 1Q19-2Q19

Name of the District:						
Key Population	Target population mapped (Number)	Number of Persons screened	No. of Presumptive TB tested	No. of Microbiologically confirmed TB Patients diagnosed	No. of Presumptive TB examined for CXR (other than those diagnosed as Microbiologically confirmed TB)	No. of TB patients diagnosed based on CXR (other than those diagnosed Microbiologically confirmed TB)
Contacts of TB/DRTB Case	147577	80379 (54%)	5248 (6.5%)	75 (1.4%)	359	6
Tobacco	4451	2863 (64%)	194 (6.8%)	11 (5.6%)	20	1
Prison inmates	3163	2456 (77.6%)	414 (16.8%)	1 (0.2%)	34	0
Miner	1217	462 (38%)	33 (7.1%)	0	0	0
Migrants	19189	13098 (68.2%)	678 (5%)	9 (1.3%)	75	2
Refugee	14544	6410 (44%)	414 (6.4%)	7 (0.2%)	16	0
Urban Slum	2776970	520734 (18.7%)	24831 (4.7%)	455 (1.8%) (2.3% total)	27329	138
Health Care Worker	12680	10278 (81%)	663 (6.4%)	14 (2%)	286	0
NACO/SACS identified High Risk Groups	170810	48290 (28.2%)	1977 (4%)	70 (3.5%)	212	3
Closed Settings (Orphanages/ old age homes/ destitute homes)	52852	43727 (82.7%)	909 (2%)	27 (3%)	238	1
Other (Mention)	371705	174969 (47.0%)	4755 (2.7%)	140 (3%)	436	4
Total	3575158	903666 (25.2%)	40116 (4.4%)	809 (2.4%)	29005	155

Challenges and Opportunities

- Lack of integration of TB screening into NCD screenings by village health nurses and health inspectors. Additionally, there is a lack of use of data in family health register for vulnerability mapping.
- While much progress has been made in ACF, some challenges remain:
 - Low yield: 49 diagnosed from 90,946 screened in KK;
 - Limited impact on notifications;
 - Labor- and time-intensive efforts for all field level staff;
 - Limited targeting of priority populations with a mix of multiple models; and
 - Access to CXR is challenging (e.g., DMCs: CXR is 10:1 in Chennai) though most public health facilities are equipped with X-ray facilities.
- Some of the new DMCs facilities are using general lab staff with limited awareness of smear microscopy issues; this could be a contributing factor to the low yield.
- Insufficient CBNAATs for case finding (vs UDST). 23 out of 68 CBNAAT machines have more than 100 percent monthly utilization with 16 machines performing 4-500 tests per machine per month (~5 cycles).
- EQA training and supervision unit is not operational, this could be a contributing factor to the current 20 percent errors in quality.
- 26 percent UDST in the private sector.

Recommendations

13. Integrate the TB program into the general health system more holistically.
14. More focused ACF campaigns around mapping of existing cases.
15. Implement Xpert algorithm for NCD population.
16. Increase in RNTCP LT and STLS staff to cover the gaps identified in external quality assessments of the new DMCs.
17. Focus future efforts on Xpert expansion as opposed to DMC expansion.
18. Expedite the procurement of 16 additional cartridge machines to be provided at high utilization sites.

DRUG-SENSITIVE TB (DS-TB)

Achievements

- Medicines dispensed for ten days. Calls by HV and STS, Health system MOs are involved in care specially at the PHCs visited.
- Private sector patients are being followed-up by PPSA staff wherever available, otherwise the majority of follow-up visits are done by HV at the district visited.
- ADR monitoring referral happening at the district level by HVs/treatment specialists available at district.
- Impressive treatment outcomes 'public' in the last five years: DS new, 86-90 percent; previously treated, 65-75 percent; private overall, 73 percent.

Challenges and Opportunities

- Funds available for 99DOTS but there is a procurement delay.
- Too many data entries on multiple registers which leaves little time for patient follow-up in high burden settings
- Many LTFU due to alcoholism and migration issues.
- Extension of treatment (4FDC) by PP for up to nine months. No flexible guidelines as per physician recommendations leading to management issues in the private sector.
- No systematic death audit; checklist review committee not operating.
- Undefined tools for the quality of care.



Recommendations

19. Prioritize the procurement of digital technology on time and validate the STAMP pill dispenser technology.
20. Transition to exclusively online/electronic reporting to save time for patient follow up.
21. In the context of LTFU, focus on migrants and those suffering from alcoholism.
22. Long term follow-up for up to 2 years to be implemented for KK under the 'TB Free KK Initiative'.
23. Implement a system for TB death audits including a designated review committee.
24. Establish a standard identification system for treatment supporters, with linkage to village health nurses to address any patient treatment issues.

DRUG-RESISTANT TB (DR-TB)

Achievements

- There are 31 District DR-TB Centers established.
- At the district level, there is an efficient sample transportation mechanism in place.
- Short regimen implemented since the second quarter of 2018 – 88 percent of eligible patients were initiated.
- H-mono is implemented with 85 percent of eligible patients initiated.
- BDQ-regimens available and have been dispensed to 54 percent of eligible patients.
- In 2019, 64 percent of XDR patients were initiated on treatment.
- All-oral regimen protocols in place with 15 patients receiving this regimen.
- Short regimen success rate for the second and third quarter of 2018 was 64 percent, and the H-mono coverage for the first and third of 2018 was 72 percent

Challenges and Opportunities

- In KK, there is no DR-TB coordinator, sub-optimal R&R, and patient interviews indicated missing tests.
- 259 (14 percent) patients were pre-treatment LTFU.
- The rapid change in guidelines is confusing to staff.
- ADR monitoring and follow-up is in place, but incomplete. ECG monitoring is limited to a few PHCs. Audiometry services only available at district level with incomplete implementation.
- Patient transportation charges not 100 percent covered.
- Patient out-of-pocket expenditures remain (e.g. Mg, TSH).
- LTFU for short regimen in the second and third quarter of 2018 is 16 percent, H-mono converge for the first and third quarter of 2018 is 17 percent, and death rates are 13 percent and 6 percent respectively.
- No clear strategy for private providers transitioning to PMDT providers (sourcing and training providers); there is a low DR-TB awareness among PPs.
- Unclear if cohort/chart reviews are structured.
- Quality of clinical care issues are not documented. Framework exists in excel but not discussed as a priority
- Lack of patient groups and psychosocial support systems.
- Guidelines on follow-up schedule/daily dispensing of medicines by treatment supporter not in place.
- Most PPs refer DR-TB patients to the public sector. Awareness on MDR-TB in PP is low.
- Multiple data entry processes (data entry in three places, including google spreadsheet) that monopolize staff time.
- No hot spot mapping for MDR-TB was observed.



- Contact tracing and screening tools for MDR-TB not in place.
- Drug shortage issues.

Recommendations

25. Implement consistent chart reviews, including check-ins between health visitors and the DR-TB coordinator, to ensure all tests are completed and all patient complaints are addressed. These reviews should be driven by systematic review of the existing data on completed tests.
26. Prioritize the filling of key DR-TB positions within the next three months.
27. Expand private sector DR-TB coverage, including possible private DR-TB center at VHS hospital in Chennai.
28. Introduce patient support groups and psychosocial support systems including specialized counselling (e.g. model of five counselors at the nodal TB centers).
29. Explore use of call centers to improve treatment adherence.
30. Lab reports for CDST should have an alert/message to quickly get the results.
31. Implement DR-TB guidelines for treatment of comorbidities.

CO-MORBID CONDITIONS AND CHILDHOOD TB

Achievements

- Every PHC has an NCD register with bidirectional screening: 83 percent public TB patients with known DM status; and 21 percent of TB patients are diabetics.
- At the state-level, the public sector achieved: 95 percent PLHIV screened for TB, 89 percent of TB patients are tested for HIV; and co-location of testing (UPHC) and treatment (at FICTC) available (though not used completely).
- At the state-level, 85 percent of presumptive patients are screened for HIV.

- IPT coverage for PLHIV is 98 percent for KK; Pyridox is available; and 96 percent of patients completed IPT.
- In KK, 88 percent treatment success for TB/HIV patients.

Challenges and Opportunities

- Continued challenges in pediatric case finding; only three percent in the public sector vs. 12 percent in the private sector.
- There is a declining pediatric trend in the public sector but there is no evidence on whether that is a good or bad thing.
- Only 17 percent of TB patients know their DM status.
- No linkage to de-addiction centers.

Recommendations

32. Advocate for, and monitor performance on, sample extraction for pediatric patients.
33. Conduct required assessments to develop targets and indicators for pediatric TB.
34. Establish linkages between TB programs and de-addiction centers and tobacco cessation clinics.

MULTI-SECTORAL ENGAGEMENT AND PATIENT SUPPORT SYSTEMS

Achievements

- NIKSHAY Poshan Yojana has been rolled out throughout the State with a monthly pay-out of INR 90 million.
- State provides additional Rs. 1000 per month pension to eligible farmers and agriculture laborers with TB.
- Chief Minister Insurance Scheme (CMIS) covers tertiary care expenditure for all TB patients.
- Multi-sectoral approach has started through a Government Order (GO) with various ministries/departments. A line listing of the department was prepared and a draft MOU has been developed.

Challenges and Opportunities

- While many patient support systems are in place, there is limited coverage for patients seeking private sector care.
- The patients interviewed by the JMM team, reported variable responses in receipt of payment, particularly after the initial payment.
- High out-of-pocket expenditures for both public- and private-sector patients in general and among vulnerable populations in particular.
- Lack of sensitization and prioritization of TB across all departments within district(s) to achieve zero TB/TB free status.
- ICT based adherence monitoring systems are not available in the district – 99DOTS, MERM Box, Call Center etc. TB/HIV patients only have access to 99DOTs.
- District TB Forum is weak and needs further strengthening.
- Persisting issues with DBT:
 - Time-consuming to manage which can lead to patient adherence measures suffering;
 - Staff becomes demotivated if they are not able to fix issues locally;
 - Low coverage of private sector patients;
 - For the last two months, DBT payments have been interrupted because of a change in district code resulting in a nearly 80 percent rejection rate;
 - Patients reporting missing subsequent payments even if first payment was made; and
 - Unclear guidance on prioritizing indicators to monitor (e.g. percentage with valid bank details; percentage getting at least one payment; percentage total due that was paid, etc.).

Recommendations

35. Establish a rapid response team at central level for any states or districts where the percentage of total DBT paid falls below a certain threshold (to be determined at central level).
36. Implement a system to monitor NIKSHAY Poshan Yojana in two cohorts – at notification and at treatment completion to ensure full payment.
37. Promote state-level flexibility to use alternatives to DBT (outsourcing, ration shops).
38. Capitalize on opportunities in other sectors. For example, collaborate with existing schemes outside of TB (Rashtriya Kishor Swasthya Karyakram (RKSK) on adolescents and/or work with Mahila Arogya Samiti (MAS) on issues specific to women.
39. Rectify the lack of call centers to allow patients to express grievances. Consider studying different methods to accomplish this goal and tailor said methods to district/state gaps/needs.
40. Ensure that TB Forums are functional at all levels and further strengthen existing TB forums by engaging TB champions in the planning, coordination, and implementation of TB activities; involving local groups like the SHGs, youth associations, districts level statutory committees etc.
41. Consider implementation of the standard treatment adherence medication protocol (STAMP); maybe by first running a pilot with approximately 200 devices. This system works as follows: patient presses button; the machine dispenses the correct number of pills; and then sends an SMS to the supporter/electronic dashboard.
 - The cost for the machine is 1500 per machine, and 500 rupees every six months thereafter for the SIM





Figure 6: Picture of the standard treatment adherence medication protocol (STAMP) machine.

PARTNERSHIPS AND URBAN TB

Achievements

- The REACH Chennai model: one PPSA can contribute 70 percent of all private notifications; ownership by the private health sector through provision of free

space in Nakshatra centers; and inexpensive adherence solutions.

- Great use of the H1 system to surveillance the sale of TB drugs.
 - This resulted in a 13 percent increase in private notifications from pharmacies in 2018 (vs zero percent in 2017).
 - It has reduced the number of pharmacies selling anti-TB treatments – only 10 percent in KK.
 - DTO informs health visitors of all related patients in their block.
- Approximately 67 percent of the 28,776 registered allopathy facilities are mapped in NIKSHAY.
- In KK, the private sector contributed 20 percent even without PPSA.
- Resources are identified for four PPSA districts (though delayed with RO).
- In Chennai, case finding has increased from 8,278 in 2015 to 13,680 in the first three quarters of 2019 with 90 percent of the increase coming from the private sector and 70 percent of that from one PPSA.

Table 4: A table depicting the Schedule-H1 implementation within the State.

Schedule – H1 Implementation (Jan - Sep 2019)

District	No. of patients purchased Anti TB Drugs	No. of Patients double entries	No. of Patients invalid address	Others	Number of patients valid	No. of patients entered in NIKSHAY
Coimbatore	11339	5398	3305	1086	1550	649
Central Chennai	6001	3249	325	158	2238	1300
North Chennai	612	149	91	70	302	227
East Chennai	1235	572	87	181	390	305
South Chennai	270	28	54	20	177	134
West Chennai	6524	3563	842	347	1772	1475
Cuddalore	519	108	91	0	320	320
Dindigul	4453	2598	868	418	569	393
Dharmapuri	1248	266	89	43	850	816
Erode	2240	1353	94	28	765	650
Kanniyakumari	655	326	81	0	248	248
Krishnagiri	572	190	76	0	306	329
KANCHIPURAM	1434	525	140	3	756	529
Karur	900	360	269	0	286	286
Madurai	6489	4871	648	0	970	970

Challenges and Opportunities

- In KK, without PPSA, private sector contributions are flatlined at 18-20 percent for four years with 74 percent having unknown outcomes.
- Clients and PPs vary greatly which require adaptive models to be implemented (e.g. prefer to retain patients vs. not; advanced disease and migrants vs. not, etc.).
- Only 12 percent of private facilities in the State are notifying; from REACH: 50 percent of the case notifications are from 46/900 PPs – 75 percent of the 46 are GPs.
- At the state-level, indicators, other than case notifications remain low: 17 percent of private patients on public FDCs; 28 percent of TB patients with known HIV status: 26 percent UDST.
- Even where PPSAs are in place, pre-treatment patient costs remain very high.
- In Chennai, there are overlapping PPSAs which leads to inefficiencies.
- The contribution of JEET lite is not apparent.

Recommendations

42. Consider implementation of PPSA in KK and in other cities/towns with more urban populations.
43. Enhance the screening of HIV patients in the private sector.
44. To address the issues with FDC in the private sector, consider using private pharmacies and/or hospitals as DOT centers.
45. Identify and address the issues around the low UDST coverage.

COMMUNITY ENGAGEMENT AND ACSM

Achievements

- NIKSHAY Poshan Yojna was launched by the Honorable Chief Minister and Honorable Health Minister of the state.

- Sensitization training on TB for MLAs of state was held along with a signature campaign. All the MLAs who attended the event took an oath to end TB in their respective constituencies.
- Grama Sabha' meetings were held in all the Panchayats of Tamil Nadu with RNTCP staff participation in 731 of these meetings.
- State working to release TB 'jingles' in both the audio and visual media shortly.
- Through project Akshya, the Ayurveda & Siddha doctors are being sensitized to TB issues.
- TB forums are established and at least one meeting has been held in 30/32 revenue districts.

Challenges and Opportunities

- Poor utilization of funds earmarked for ACSM; through June 2019, only 15% of the approved funds were spent.
- No guidelines in place for providing RNTCP services to migrant or mobile populations.
- Lack of TB awareness and use of services particularly among the middle socio-economic class.
- Persisting social stigma particularly in the lower socio-economic class.

Recommendations

46. Immediately use the funds available for ACSM to:
 - a. Increase the visibility of RNTCP through mass media campaigns;
 - b. Meaningfully engage with other sectors (e.g. railways, State Road Transport Corporation etc.); and
 - c. Use audio and visual media to address the wider public while also including tailored messages to address issues specific to different socio-economic classes



HEALTH SYSTEM STRENGTHENING

Achievements

- Current staffing levels are sufficient for modest case load which allows vertical staffing to support public health tasks. However, post-diagnosis support requires the attention of the whole health system.
- State funds are available for financing specific district-level TB initiatives; all district funds are utilized.
- TB program review is conducted by the Chief Secretary on a monthly basis.
- State conducts a state common review mission to review all health programs; TB is one of these programs.
- System in place to monitor district performance using key indicators, and recognizing the high-performing districts.

Challenges and Opportunities

- At the state level, there are many key vacancies including: Epidemiologist, TB HIV Coordinator, DR-TB Coordinator, Microbiologist IRL, and Lab Technicians IRL.
- At the district level, there are also so many key vacancies including: District Program Coordinators, PPM Coordinators, Senior Treatment Supervisors and Lab Technicians, Medical Officers, and District Pharmacists (total of 298 positions).
- STDC is not functional. Capacity building of key staff is largely affected.
- In many of the storing places visited, it was observed that the spaces were inadequate, ill-lit, non-ventilated without racks.
- Invariably all the stores (including the Government Medical Stores Depots) are operated by a skeletal regular staff. Most of the staff is under contract with low salaries; this insecurity and insufficient financial compensation leads to suboptimal service delivery.

- Staff levels are low and inadequate.

Recommendations

47. Completely integrate the TB program within the general health system with program implementation and monitoring under the DPH and clinical care management and supervision under DMS/DME.
48. Conduct an analysis on the current HR situation and immediately implement actionable outcomes including approval and recruitment of the correct number of staff needed.
49. Prioritize and fill all key vacancies at the state- and district-level within three months.
50. Fill all posts in STDC to ensure optimal functionality.
51. Reevaluate staff financial compensation levels. Compensation commensurate with skills possessed and job security will truly motivate high staff performance.
52. In addition to the inhouse training exercises, further build staff capacity by appointing a key official to be in charge of capacity building.
53. Reassess the viability of key storing points (e.g. Government Medical Stores Depots, State Drug Stores and District Stores) focusing on storing capacity, infrastructure and implementation of Good Storing Practice and Distribution practices. Also assess the transport mechanism for drugs/diagnostics by transfer either inter- or intra-state with assured protection of the integrity of the drugs and diagnostics.
 - a. Address the existing gaps in the system to monitor and maintain the temperature and humidity within the storing premises. Including installation of air conditioners and dehumidifiers wherever not present.
 - b. Provide basic equipment to storage facilities like lifting forks, trolleys where the movement of the stores is considerably higher; GMSDs are priority.
 - c. Implement a system to properly dispose of



waste, expired drugs, and any other type of expired or used inventory. In all the sites visited, the JMM team observed that expired drugs were not only occupying valuable space but were also incurring latent additional inventory carrying costs.

- d. Implement a system for continued and sustained training to ensure the quality of service delivery at storing and distribution centers. The existing training programs should be reviewed, manuals should be updated, and modules should be developed and disseminated in a systemized periodical manner to identify and train all staff involved in PSM activities
- e. Additionally, consider implementing regular inspection exercises to ensure that stores have the proper security systems installed and all safety equipment/protocols are properly implemented (e.g. fire safety).

TECHNICAL ASSISTANCE

Recommendations

54. Develop a guideline document to address the programmatic management of TB among migrant populations.
55. Set indicators for monitoring TB progress in children.
56. Use the task list function in NIKSHAY for linking, tracking and following-up of contacts, especially the pediatric contacts, for TPT.
57. Ensure the availability of the TB death report in NIKSHAY.
58. Consider installing a mechanism for pop-up notifications in NIKSHAY to produce alerts when IRL results are ready.

RESEARCH AND INNOVATIONS

Recommendations

59. Include a pediatric component to all research activities, including validation of newer diagnostics and drugs.

60. Implement a system by which to measure household out-of-pocket expenditure on TB diagnosis and care, and develop strategies to address these expenses.

61. Employ a system to systematically analyze TB deaths.

3.1.6 Uttar Pradesh

State Visit

The Uttar Pradesh State team visited two districts: Agra and Gorakhpur. Below are the key findings from the various sites visited.

Achievements:

- State TB notification has almost doubled within two years; this is mostly associated with an increase in notifications by the private sector.
- Staffing level has improved over the last three years with dedicated, committed human resources.

Challenges and Opportunities

- UDST has improved but there is still scope for improvement.
- Among children, TPT for children contacts is not being implemented and pediatric TB diagnosis is much less than expected.
- ACF is happening but is lacking access to accurate and rapid diagnostic tools, like digital CXR and CBNAAT.
- Gaps in the specimen collection and transportation from non-DMC PHI for culture testing.
- Disconnect between massive amounts of data and its use to inform local decisions.
- DBT, especially for private sector patients, is less than 20 percent.

Recommendations:

1. Minimize/reduce turnaround time for CBNAAT results (averaging more than one week currently) by either involving diagnostic



services from the private sector or planning for more diagnostic facilities.

2. Ensure contact tracing and contact investigation is being done for all index cases. For TPT in children under six, State TB cell should draft a strategy to sensitize and train TB health care professionals.
3. Involve pediatricians to enhance pediatric case notification. For involvement of Indian Academy of Pediatrics and its local chapters, Districts should come up with plans in six months.
4. Strengthen mechanism for specimen collection and transportation from all health facilities.
5. Consider development of revised PP MOU to promote HIV testing in private sector SACS – within 3 months.
6. Ensure access to tools required for accurate and rapid diagnosis, such as X-ray and CBNAAT during ACF.
7. Strengthen RTPMUs.
8. Promote and implement capacity building for district level staff to analyze and use data for action.
9. Ensure implementation of additional efforts to ensure proper use of DBT for all eligible patients and providers.
10. Consider a waiver to reconsider NHM budget cap of 10 percent to enable the proper TB budget for accelerated progress.

TEAM MEMBERS

Agra: Prof. Kenneth G Castro (District lead), Dr. Sandeep Chauhan (Coordinator), Dr. Alka Aggarwal, Ms. Annabel Baddeley, Ms. Mona Balani, Dr. Shivani Chandra, Mr. Rajan Chauhan, Dr. Bharati Kalotee, Dr. Vithal Prasad Myneedu, Mr. Collin Pierce, Dr. MM Puri

Gorakhpur: Dr. Douglas Fraser Wares (District Lead), Dr. Umesh Tripathi (Coordinator), Dr. Dawran Faizan, Dr. Syed Imran Farooq, Dr. Avinash Kanchar, Dr. Suresh Kunhi Mohammed, Dr. Neeraj Nischal, Prof. Rajendra Prasad, Dr.

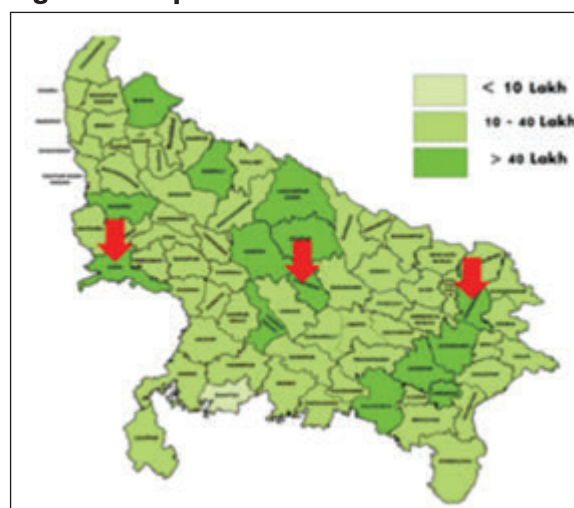
Kirankumar Rade, Prof. Rajesh Solanki, Dr. Guy Stallworthy, Mr. Ranjan Verma

BACKGROUND

With a population of 228,800,000 people, Uttar Pradesh accounts for 17 percent of India's population and 20 percent of the TB case notifications. The State is comprised of 75 total districts with 993 TB Units, 2063 DMCs, 38 ART centers, 40 ICTCs, and 992 FICTCs. Additionally, there are 1155 HIV testing facilities collocated with a DMC.

The JMM team visited the districts of Agra and Gorakhpur. Agra has a population of 4.4 million people. The district is comprised of 15 blocks and has a total of four CBNAAT machines, one Nodal DR-TB center and 1 Nodal ART center. Gorakhpur consisted of 19 blocks with a total population of 4.8 million people. The district has 21 TB Units, 48 DMCs, 3 CBNAAT machines, 5 LED microscopes, one Nodal DR-TB center, and one C/DST lab with another on the way.

Figure 1: Map of Uttar Pradesh.



The team visited various facilities during the trip. Table 1, 2, and 3 below provide a brief summary of the facilities visited at the districts- and state-level.

Table 1: A table listing all the sites visited in the Agra District.

Agra District Site Visits			
Public Health Facility/ Providers	Private Health Facility/Providers	Patients	Meeting with Stakeholders
<ul style="list-style-type: none"> - District TB Centre - District Hospital (including CBNAAT site and NRC) - Community Health Centre, Bah Agra - New Primary Health Centre, Holipura - Cantonment Hospital - S. N. Medical College (DRTB Centre, ART Centre, ICTC) - JALMA - First Referral Unit at Etmadpur, Agra 	<ul style="list-style-type: none"> - Private Practitioner - 3 - Private Chemist 	<ul style="list-style-type: none"> - Holipura PHC (3 patients) - Bah Agra CHC (2 MDR-TB patients) - District Hospital (8 patients) - Private sector patients - 3 	<ul style="list-style-type: none"> - Fixed group discussion (FGD) with IMA (including Officer bearers, Physicians, Pediatrician, Pathologist, Orthopedic Surgeon etc.) - FGD with ASHA workers - Representative of JEET
Debriefing with Chief Medical Officer and District TB Officer, Morning 14 November 2019 Debriefing with District Magistrate, Morning 14 November 2019			

Table 1: A table listing all the sites visited in the Agra District.

Gorakhpur District Site Visits			
Public Health Facility/ Providers	Private Health Facility/ Providers	Patients	Meeting with Stakeholders
<ul style="list-style-type: none"> - DTC, including CBNAAT lab - CHC Charganwa & CHC Pipraich (TU & DMC) - Harpur PHC (Non-DMC PHI) - BRD Medical College, Microbiology Dept (including C/DST lab) - ART Centre - NDR-TB Centre - DR-TB Ward, Paeds Dept, - DMC & DOT center 	<ul style="list-style-type: none"> - Private practitioners – 3 (2 formal, 1 informal) 	<ul style="list-style-type: none"> - Luhisi village Patients - 3 - 1 MDR-TB patient visited in Charganwa 	<ul style="list-style-type: none"> - IMA - AIOCD - TB Champions - Representatives of JEET, REACH, and WHP
Debriefing with District Magistrate, Evening 13 Nov 2019 Debriefing with District officers and staff, Morning 14 Nov 2019			

Table 3: A table listing all the sites visited in Lucknow City.

Lucknow City Site Visits	
Public Health Facility/Providers	Meeting with Stakeholders
<ul style="list-style-type: none"> - State TB Cell - State TB Training and Demonstration Centre - Regional TB Program Management Unit (Agra) - State Drug Store (Agra) - Uttar Pradesh State AIDS Control Society 	<ul style="list-style-type: none"> - State Task Force – Chairman - Intermediate Reference Laboratory – Agra And Lucknow - National Reference Laboratory – JALMA Agra - TB Champions
Debriefing with Principal Secretary, Secretary, Assistant Mission Director General, STO and other officials, Evening 15 Nov 2019	

KNOWLEDGE OF THE LOCAL EPIDEMIC, APPLICATION OF ICT AND PROGRAMME MONITORING

Achievements

- RNTCP and JEET staff trained in NIKSHAY to notify patients, resulting in doubling of notifications, primarily associated with private sector engagement.
- TB Index used for review of districts and ranking of performance.

Challenges and Opportunities

- While there has been an increase in notifications by the private sector, follow-up to ensure diagnostic accuracy, screening for key risk factors and comorbidities such as HIV, smoking, diabetes and alcohol use, as well as actions to ensure treatment completion was not evident.
- Data entry in NIKSHAY is described as a cumbersome and time-consuming process. Capturing presumptive cases may further burden the system.
- NIKSHAY captures a lot of information, but has limited analytic output for managers at different levels.
- Limited capacity to analyze the data to inform program management activities.

Recommendations

1. Implement schedule H1, use pharmacy surveillance data from chemists, expand PPSA and engage all providers to establish ICT enabled systems for a two-way channel between H1 data and NIKSHAY.
2. Optimize NIKSHAY server speed to cater to current and future needs of the program. Alternatively, RNTCP should consider outsourcing the service to a cloud service provider – if the latter is not subject to legal barriers.
3. Flexible reporting output options should be made available for customized reporting, based on the users' request.

UNIVERSAL HEALTH COVERAGE, HEALTH SYSTEM FUNCTIONS, INTEGRATION OF TB SERVICES WITH GENERAL HEALTH SYSTEM AND EQUITY IN ACCESS

Achievements

- Strong political will demonstrated at both the District and State levels.
- Adequate budgetary allocation for RNTCP in NHM PIP of 2019-20, and budgetary allocation for state RNTCP has seen a steady increase from Rs. 651 crores (2017-18) to Rs. 696 crore (2018-19) to

Rs. 729 crores (2019-20).

- Increase in TB notifications has been achieved through enforcement of Act IPC 269/270 and through implementation of DBT incentives.
- Monthly DHS meetings are conducted where RNTCP is reviewed by the DM, and performance is measured against the District TB index.
- TB task-force meetings are held once a year.
- Vacancy rate is only 15 percent, meaning 85 percent of all approved state-level and district-level positions filled.
- The STDC observed a 10-fold increase in training capacity in the last five years.
- Refresher training on PMDT, TB/HIV, NIKSHAY, EQA, NIKSHAY AUSHADHI, and ACF for RNTCP staff was completed this year.
- RNTCP is well integrated into the general health system in Agra and Gorakhpur; program components are reviewed in meetings of State Health Society, District Health Society, State PMDT meetings and State Task Force.
- Free diagnostic and treatment services are available for TB patients including private sector patients (should the private practitioners choose to offer these services).
- DBT payments have been initiated for patients and providers. In 2019, 64 percent of all eligible beneficiaries in the public sector and five percent in the private sector.

Challenges and Opportunities

- NHM cap of 10 percent for additional budget allocations (as compared to prior FY budget allocation) threatens to limit TB program scale-up plans.
- New initiatives (e.g. DBT, Universal DST,

ACF, roll out of NIKSHAY 2) have increased workload of field staff, indirectly impacting quality and focus of work activities.

- Current STDC is unable to cater to training needs of a large state like Uttar Pradesh, raising concerns about quality of cascade training (using TOT approach) at district levels.
- Regional TB program Management Units (RTPMU) dysfunctional due to frequent transfers and non-recruitment of consultants.
- Lack of equitable access to TB care for private patients – relatively low coverage of FDC, DST and DBT.
- Medicine and Pediatric residents at BRD Medical College are not rotated through DOTS center during training.
- Out-of-pocket expenses for private TB patients remain relatively high.
- Funds transferred from state NHM to district NHM in this fiscal year were delayed. First tranche received on 1 August 2019 (Gorakhpur). This has impacted the rate of expenditure.

Recommendations

4. Consider waiver of NHM 10 percent cap and increase financial envelope for FY 2020-21 to enable the increased funds required to scale TB program activities to achieve the ambitious TB elimination goal by 2025.
5. Add state level training units (focused on training and monitoring) STDC to monitor quality of cascade training in districts.
6. Reduce workload of field staff like STS by outsourcing non-core activities such as DBT.
7. Increase workforce and WHO consultants to improve monitoring and TA.
8. Improve functioning of RTPMUs by direct recruitment of positions by GoUP and by further clarifying the roles and responsibility of the RTPMU.
9. Add state level training units (focused on



training and monitoring) STDC to monitor quality of cascade training in districts.

10. Rotate and train Pediatric and Medicine residents through RNTCP facilities.
11. Ensure that private sector TB patients have access to all TB services that are available to public sector patients.
12. Give TB patients priority in receipt of available social protection schemes.
13. Resolve the impediments in funds transfer from state NHM.

PREVENTION

Achievements

- Coverage of TPT in child contacts increased from 1,626 (two percent) in 2018 to 39,870 (50 percent of contacts identified) during the first nine months of 2019 (public sector).
- AIC measures are implemented fairly well at high-risk care centres (Gorakhpur), but relatively limited in other settings (Agra).

Challenges and Opportunities

- Household contact investigations are not implemented systematically, with contact investigations conducted in less than a third of the TB index patients.
- No contact investigation conducted for TB patients in the private providers.
- TPT in children was not implemented among 50 percent of those child contacts identified.
- NIKSHAY issues: data missing on household contacts (and on treatment cards) and of TPT among children under six and among weaknesses in reporting on TPT people living with HIV.
- TB reported in healthcare workers (HCWs) – three doctors with MDR-TB, two staff nurses, and two other doctors with DS-TB in 2018 and 2019.
- No systematic policy for regular TB

screening of HCWs.

- Gaps in TB infection control: administrative procedures not in place; no fast tracking of patients with cough in waiting areas of health facilities; personal protection equipment (PPE) not used consistently in hospitals or CHCs and PHI.

Recommendations

14. Ensure linkages between TB ACF at facility/community level with TB preventive treatment. Systematic contact investigations will help ACF yield.
15. Enforce systematic initiation of TPT among child household contacts once TB disease is ruled out.
16. Ensure 100 percent coverage of TPT among eligible PLHIV.
17. Strengthen recording and reporting of contact investigation and TPT among child household contacts and for TPT among PLHIV.
18. Expand RNTCP/JEET activities to support public functions for TB patients notified from private sector
19. Increase efforts for TB case finding at facility/in community to also include provision of TPT
20. Expand the role of RNTCP/JEET partners to cover public health functions of contact investigations and provision of TPT for private TB patients (e.g. contact investigation and preventive treatment).
21. Put in place measures to enforce implementation of the hierarchy of infection control precautions, including personal protective equipment for HCWs involved in patient care.
22. Enforce periodic CXR screening of HCWs.

CASE FINDING, DIAGNOSTICS AND LABORATORY SERVICES

Achievements

- Between 2017 and 2019, there has been a doubling of notifications in Uttar Pradesh,

- and a tripling of case notifications in Agra.
- Having piloted the use of the public postal service for sample transportation, plans for formal engagement and statewide scale-up are in motion.
- Molecular diagnostics are being scaled-up, although primarily for UDST with up to 45 percent of DST conducted in sites visited.
- Efforts have been made to conduct ACF, including 56 million population mapped in 2019 resulting in 14,000 TB patients notified and hotspots identified in Agra.
- Staff is well trained and updated with the current guidelines.

Challenges and Opportunities

- Specimen collection and transportation from non-DMC PHIs is lacking in both districts.
- The standard one DMC per 100,000 people is not yet available (currently there are 2021 DMCs for 230 million population).
- In Agra and Gorakhpur there are only 4 and 3 CBNAAT machines respectively.
- ACF is happening but on a small scale, but the necessary tools like CXR and CBNAATs are not available.
- A high proportion of clinically-diagnosed TB notifications among privately notified patients (88 percent in Agra).
- Private engagement in rural areas is lacking with no involvement of AYUSH practitioners.

Recommendations

23. Strengthen and monitor mechanisms for specimen collection and transportation from all health facilities and monitor the engagement of the public postal service in sample transportation.
24. Increase CBNAAT coverage and diagnostic capacity in districts to meet the norms per

- population – increase number of machines, contract services of private laboratories, etc.
25. Strengthen capacity to process extrapulmonary clinical samples, as per RNTCP policy.
 26. Scale-up ACF activities in targeted populations at both the district- and state-level based on epi evidence, and ensure access to tools required for accurate diagnosis, such as CXR and CBNAAT machines.
 27. Strengthen capacity to ensure implementation and uptake of new RNTCP diagnostic algorithms in both the public and private sector.
 28. Systematically engage private practitioners in rural areas, including AYUSH providers, to ensure that all TB patients are notified, and maintain notification registers at all PHIs to facilitate monitoring.
 29. Maintain notification registers at all PHIs to facilitate monitoring.

DRUG SENSITIVE TB (DS-TB)

Achievements

- Reported TSR among notified TB patients is high in sites in the districts visited (89-90 percent); the State success rate overall was 70 percent in 2018.
- Adequate supply of first line anti-TB drugs is available with no reported stock-outs in the sites visited.
- Good treatment support and monitoring was noted among TB patients notified by the public sector (8/8 in Agra).

Challenges and Opportunities

- Large proportion of “clinically diagnosed” TB patients was noted in the private sector, associated with high treatment completion rates (90 percent in Gorakhpur) that were based on verbal reports and limited monitoring or follow-up (3/3 in Agra). Time from diagnosis to treatment initiation

was long in some patients, and as long as two weeks in certain cases.

- TB patients coming to private clinics for their diagnosis are registered as TB on treatment under NIKSHAY, based on the OPD slip without actual verification from the JEET staff.
- Digital adherence mechanisms such as 99DOTS are available to TB patients living with HIV but not to other TB patients.

Recommendations

30. RNTCP to increase capacity to ensure proper follow-up of all notified TB patients, irrespective of whether they are notified from the public or private sector.
31. RNTCP to monitor and ensure timely initiation of treatment after diagnosis.
32. Implement and monitor criteria for acceptable “clinically diagnosed” and “treatment completion” standards.
33. JEET staff to ensure visits and verification for each TB patient being registered under NIKSHAY; district PPM team should ensure proper monitoring and take regular feedbacks from JEET and other partners that are covering the private sector in the area of operation.
34. Ensure all treatment cards are complete.
35. Scale-up appropriate available digital technologies (e.g. 99DOTS) as an aid to support and monitor patient treatment adherence.

DRUG RESISTANT TB (DR-TB)

Achievements

- In both Agra and Gorakhpur, MDT has been implemented, scaled-up and is being decentralized with use of recommended regimens (H resistant-TB, Conventional MDR-TB, Shorter Treatment Regimen (STR), BDQ-containing and XDR-TB); almost 11,000 RR-/MDR-TB patients initiated on

treatment in Uttar Pradesh in the first three quarters of 2019.

- IRL (STDC) and JALMA Culture/DST in Agra and IRL at King George's Medical University (KGMU) in Lucknow, are fully functional and supporting 33 (8, 6, and 19 respectively) Districts; across the state there are: one NRL, two IRLs, and six C/DST laboratories with five additional new laboratories planned.
- Molecular diagnostics are being implemented – UDST started (45 percent combined with 65 to 70 percent in the public sector, but only 20 percent in the private sector).
- A courier system for specimen transport to IRL Varanasi has been established and is functional in Gorakhpur. The use of government postal services (NB issue of special stamp) has also been implemented.
- District health system is responsive to drug shortages for DR-TB patients by using local procurement as necessary.

Challenges and Opportunities

- Insufficient CBNAAT capacity in both Agra and Gorakhpur, and KGMU for UDST.
- Culture laboratory at BRD Medical College, Gorakhpur, almost ready to start providing services, but lacks adequate staff. Additionally, renovation, equipment, and staff for line probe assay laboratory at BRD Medical College, Gorakhpur, are also needed.
- There have been HR shortages of designated staff at the nodal DR-TB center and DR-TB ward in KGMU in Lucknow but staffing levels have been maintained by improvisation and relocation of staff.
- District DR-TB centers under nodal DR-TB center at KGMU are not fully functioning (established in 2018).
- SLD storage and management at

Gorakhpur DTC drug store is relatively limited space-wise and overall suboptimal. Likewise, drug supply management at SDS Agra is also suboptimal.

- Slow uptake of the new BDQ-containing regimens.
- In Agra, patients eligible for the STR are being admitted for up to a week in district DR-TB centers for treatment initiation.
- Few patients (approximately 20 percent) have samples for SL-LPA collected, with turnaround times for these results ranging from 2 weeks to more than a month at best (in Agra, Gorakhpur, and Lucknow); LPA results are not being sent to nodal DRTB center doctors (in Gorakhpur and Lucknow).
- The nodal DR-TB center has no access to the districts' NIKSHAY system (unless provided with District password), because of this the nodal center has no information on DR-TB patients in the districts.
- Suboptimal storage and management of SLDs at drug stores; this was observed both at the Gorakhpur DTC and Agra SDS.
- No DLM is available for pediatric (children under 6 years of age) DR-TB cases (Gorakhpur, Agra, and Lucknow).

Recommendations

36. Increase CBNAAT capacity as soon as possible and consider engagement of private labs at both the district- and state-level.
37. Implement urgent measures to recruit staff to ensure functionality of the C/DST lab at DRB Medical College functional and the LPA laboratory.
38. Monitor uptake of BDQ-containing regimens for all eligible DR-TB patients at the nodal DR-TB and state level. Consider having RTPMUs monitor drug stock management and supply to ensure drug availability.
39. Complete decentralization as per RNTCP policy to district DR-TB centers under the nodal DR-TB center, KGMU.
40. Increase staff capacity to ensure RNTCP guidance on admission of DR-TB patients is properly implemented.
41. Increase LPA capacity, with timely sample collection, transportation, and result delivery ensured.
42. Activate LIMS and link it to the RNTCP system; LPA results should be sent to nodal DR-TB center in addition to the relevant District.
43. Ensure accessibility of NIKSHAY systems for the nodal DR-TB center.
44. Ensure that drug stores are adhering to proper storage and management guidelines of SLDs.
45. Immediately ensure the availability of DLM for the treatment of pediatric (children under 6 years of age) DR-TB cases.
46. Ensure AIC measures are implemented completely in all health facilities, especially in high-risk settings.

PEDIATRIC TB

Achievements

- Pediatric dispersible FDCs are mostly available.

Challenges and Opportunities

- Six percent of notified TB patients are pediatric cases, indicating under-notified cases.
- In quarter three in Agra, 80 percent of the 459 pediatric notifications were notified by the private sector.
- A third of the 143 private pediatricians in Agra are not yet registered in NIKSHAY.
- No mechanism to track notification of children diagnosed by pediatricians.
- Limited ability to perform gastric lavage within medical colleges.
- Inconsistent understanding of the latest RNTCP guidelines regarding diagnosis, child TB prevention, and treatment.
- Lack of patient education on the importance and duration of treatment.

- H dose for children living with HIV is not available in Agra ART center, and staff are unaware of the current relevant policies.
- Inconsistent adoption policy/screening among malnourished children under Nutritional Rehabilitation Centre – (not implemented in Agra District Hospital Nutrition Rehabilitation Centre).
- Diabetes, tobacco, and alcohol use documented on TB cards reviewed and in NIKSHAY.
- Diabetes testing (in the public sector) increased, from 10 percent in 2017 to 46 percent in 2019; known tobacco use status also increased, from 19 percent in 2017 to 46 percent in 2019.

Recommendations

47. Implement the collection of accurate data on childhood TB and updated burden estimates.
48. Strengthen the engagement with Indian Association of Pediatricians and Nutrition Rehabilitation Centers.
49. Establish mechanisms to track the child TB cases detected at medical colleges.
50. Consider using the ECHO platform for capacity building of doctors in diagnosis and treatment of pediatric TB.

TB/HIV AND OTHER COMORBIDITIES

Achievements

- There is an overall upward trend in TB/HIV activities, and great collaborative action on TB, diabetes, and smoking.
- The majority of DMCs are co-located on the same campus with HIV testing facility, and CBNAAT co-located on the same campuses as most ART centers.
- Monthly HIV-TB coordination meetings are being held regularly.
- High-coverage of HIV testing among TB patients notified in the public sector in 2019: 92 percent in Gorakhpur, 95 percent in Agra, and 85 percent in the State.
- Intensified TB case-finding implemented and recorded in ART sites and ICTCs, and well-maintained line-lists to reconcile HIV status of TB patients.
- 99 DOTS implemented for PLHIV on TB treatment.

Challenges and Opportunities

- Late presentation of people with advanced HIV disease – reported average of CD4 count is 150 cells/cubic milliliters at enrollment in Lucknow ART center.
- No access to urine LAM testing for TB diagnosis in people with advanced HIV disease.
- As a low HIV prevalence state there is limited access to ART services – one ART center available for three districts (Agra, Firuzabad and Mathura), necessitating patients to return once a month to the ART centre for TB treatment and ARTs.
- Limited capacity to conduct joint supportive supervision.
- Symptom screening is not standard (as per four symptom screen) across all ICTCs and ART centers; this was deduced from patient interviews and ICTC interviews in Agra.
- Access to rifabutin and cotrimoxazole, and H for children living with HIV not available in all facilities in both Agra and Lucknow.
- Rates of co-management of TB and diabetes in the public sector is only at 37 percent.
- Reconciliation of data on TB and diabetes needs to be completed.
- Low coverage of HIV testing (27 percent), ART (11 percent) and CPT (three percent) among patients notified in the private sector.
- Limited uptake/reporting of screening or co-management of comorbidities in the private sector.

- NACO partnership guidelines and MOUs reportedly not conducive for HIV testing by individual private practitioners or laboratories.
- There are paper-based and digital recording systems for both TB and HIV which has resulted in increased administrative burden for all health care workers, and comorbidities such as DM, smoking, and alcohol being recorded only on HIV cards but not on TB treatment cards of the same individual or in NIKSHAY.
- No reconciliation of ART data at the district- or state-level, and no linkage of data systems. In NIKSHAY, ART coverage is 36 percent and cotrimoxazole is 24 percent in 2019 in public services in Uttar Pradesh, but NACO data suggests coverage rates of up to 90 percent.

Recommendations

51. Facilitate further decentralization of ART services by RNTCP and NACP so that there is at least one ART centre per district and through select CHCs.
52. Strengthen joint supportive supervision and mentoring.
53. Strengthen capacity for TB screening and disseminate posters with the four symptoms more widely.
54. Strengthen capacity and put in place measures to ensure scale-up, recording, and reporting of the full cascade of screening and co-management of HIV and prioritized comorbidities for TB patients notified in both the public and private sector.
55. Revise partnership guidelines so that RNTCP can better work with the NACP and enlist private labs to conduct HIV testing as partners of NACO/SACS.
56. Ensure availability of rifabutin, CPT, and H for children living with HIV.
57. Strengthen recording and reporting, and ensure reconciliation of reporting across TB and each comorbidity by creating linkages across reporting systems.

MULTI-SECTORAL ENGAGEMENT & PATIENT SUPPORT SYSTEMS

Achievements

- Children with TB are being “adopted” as part of a campaign sponsored by the UP Governor to encourage officials and departments across the state departments to promote diagnosis, supportive services, and completion of therapy.
- Social mobilization network (SMNet) for immunization is being utilized for ACF campaigns.
- Implementation of JEET project has increased the reach of DBT, and free diagnostic and treatment services.
- NIKSHAY Poshan Yojana, DBT extended to 57 percent of patients in public and 81 percent in the private sector.
- X-rays for all presumptive and on treatment TB patients are provided free of cost.

Challenges and Opportunities

- There is a lack of systematic planning for multi-sectoral engagement.
- There is outreach to various departments but no umbrella body.
- Intradepartmental convergence to extend available services to TB patients.
- Services heavily dependent on RNTCP resources at the level of healthcare; additionally, JEET services have not yet expanded as planned.
- TB service delivery in public sector facilities like railways, CGHS, ESI, police, defense, etc. – partnership activities restricted to the private health sector.
- Lack of health sector integration - CXR for all presumptive and on treatment TB patients being provided free of cost, but not this is not enough. Knowledge gaps were evident in health sector integration during field visits.

Recommendations

58. Convene meetings at the state-level with appropriate state leadership to promote and encourage multisectoral convergence under TB Haarega Desh Jeetega campaign.
59. Mandate District TB Forum so that they can further spread the messaging, monitor implementation of activities, and act as accountability mechanisms.
60. Organize a joint meeting between the District TB Forum and District Health Society on a (at least) bi-annual basis.
61. Expand widespread dissemination of framework.
62. Extend the use of TB tests and pre-treatment evaluations under the free diagnostics scheme to address reportedly high out-of-pocket expenditure.
63. Scale-up the IDAT initiative by prioritizing high burden urban areas and including the private sector.
64. Explore the ability for additional benefits through the PRI/PDS system for nutritional support (including in-kind support).
65. Extend clinical care at subdistrict-level to TB and Dr-TB patients at CHC and sub district hospitals free of cost to mitigate and avoid observed catastrophic costs incurred.
66. Implement enablers and support systems for patients, families, and providers with support from the Government, NGOs, and other sectors; consider implementing support (e.g. through financial, DBT, vocational, nutritional, counselling supports, etc.), and assess ways to limit, and eventually, avoid out-of-pocket expenses incurred by patients and their families.

PATIENT SUPPORT SYSTEMS - CALL CENTRE, NOIDA

Achievements

- In May 2018, a toll-free number with four target audiences was established: general

citizens, TB patients, public sector providers, and private sector providers.

- The call center has connected to around 150,000 patients.
- Inbound calls were mostly focused on information, grievances, case notifications especially from private doctors, and patient information updates from public sector providers. There are approximately 30 to 40,000 calls per month (48 percent from general citizens and 46 percent from TB patients).
- Outbound calls mostly focus on core roles related to DBT (often to get bank details) and counselling. More than a million calls connected (42 percent to Uttar Pradesh).

Challenges and Opportunities

- Only eight of the total 58 functions are covered currently; unclear if these functions are prioritized.
- There is limited dissemination of the toll-free number in all states, hence limited uptake.
- Currently, hoax incoming calls and unanswered outgoing calls account for 50 percent of all calls; there is a need to analyze the call data to find ways to reduce the number of unproductive calls.
- Random and erratic deployment of call center staff is currently focused largely on coordination of DBT for NIKSHAY Poshan Yojana.
- Non-systematic use of call center for outbound calls for treatment counselling, which was mainly in form of monologue and reading out a memorized script with unclear impact. Agents do not take any additional notes or actions if any critical gaps in information are detected

Recommendations

67. Disseminate information about the availability of call centre through TB Champions, patient



- networks and community groups
68. Prioritize functions of the call centre to focus from amongst current 58 functions, based on both program need and professional judgement that these are functions that lend themselves to call centre intervention
 - a. Then the agents should be deployed based on a rational and intentional plan, rather than ad hoc and at random as at present
 - b. Then their effectiveness and cost-effectiveness should be assessed continuously, with continuous adjustments in the light of data and experience
 69. Install professional management via the hiring of the two consultants to support the call centres (in Navi Mumbai and Noida) as soon as possible.

PARTNERSHIPS AND URBAN TB

Achievements

- Notifications from the private sector more than doubled.
- CHRI/Lepra, IMA, WHP and REACH are all active.
- JEET PPSA districts are performing better overall.
- Urban PHC staff are sensitized to TB.

Challenges and Opportunities

- Quality indicators for private sector notifications are poor even in the PPSA districts.
- Treatment success rate in private sector TB patients is of questionable validity. Particularly the private sector is under performing on the following indicators:
 - FDC coverage is only three percent;
 - NPY DBT coverage is only eight percent (vs. 57 percent for public sector patients);
 - PP DBT is only 14 percent;
 - DST is 17 percent; and
 - Very limited screening coverage and co-

management or reporting of prioritized comorbidities.

- Relatively few high-volume specialists and hospitals are engaged: 75 percent of PPSA notifications from just 364 providers (24 per district average 4.2m population).
- Partnerships are externally funded and centrally managed because there is no State or District budget.
- Only four out of 23 urban PHCs in Gorakhpur and five out of 40 in Agra offer TB diagnosis.

Recommendations

70. Budget for PPSAs in PIP and contract strong implementers per the new Partnership Guidelines.
71. Extend programme services to privately-notified patients.
 - a. Aim for more than 70 percent coverage of DBT for both private patients and providers, 70 percent coverage for DST, and 50 percent coverage for FDC.
72. Increase engagement of the private primary care sector to increase coverage and support patients earlier by:
 - a. Working with pharmacists' and druggists' associations to enforce Schedule H1, use data to contact and support private patients, and dispense FDCs (with appropriate incentives).
 - b. Engage more GPs, and informal providers, in the 10 to 100 cases per year range.
 - c. Make maximum use of the call center to support private sector notifications and treatment adherence.
73. Ensure field staff provide public health actions for all patients.
74. Improve the utility of NIKSHAY for monitoring private provider engagement by tracking payment of PP incentives, improving tracking of FDC and the standards for reporting private outcomes.

COMMUNITY ENGAGEMENT AND ACSM

Achievements

- There is intensive community engagement including with students from university and colleges, especially during ACF campaigns. Last four rounds suggest it has contributed to creating more awareness and increasing outreach.
- The mentorship program implemented by REACH has helped create a pool of TB champions (23 across 12 districts in Uttar Pradesh) who have conducted community engagement activities on their own and in collaboration with TUs in their area. REACH further linked them with NGO networks to help expand coverage.
- TB forum is operational with membership as per guidelines at the state and in all districts. Seven of 75 districts are yet to have the first meeting and about a third of districts have had their second or third meetings.

Challenges and Opportunities

- While there is a plan for ACSM and community engagement at district level, there are no such plans at the TU level. Hence many of the community engagement activities are ad hoc. There are also limited plans for advocacy activities.
- ACSM and community engagement is not providing information on social protection programs to reduce the vulnerability of TB patients.
- STC and DTC have no information on gender-framework for TB and its implementation.
- All IEC materials at the district- and state-level are in Hindi, but not in the regional languages (e.g. Bhojpuri, Bundelkhandi) common to the rural areas.
- There was a reduction in the ACSM budget

(one third of the previous year's budget) both at the district- and state-level; this poses a risk to continued, efficient ACSM and community engagement activities. In the last FY and the first three quarters of 2019, only 40 to 50 percent of the activities planned (and unplanned) could be completed. Wide variation across districts with minimal activities driven by budgetary constraints.

Recommendations

75. Implement and use TB Forums to raise awareness on the social protection programs.
76. Build awareness about TB Forums and their role in the community particularly among people affected with TB to help address field level issues and challenges.
77. Ensure that there are adequate budgetary provisions for community engagement and ACSM activities, including at the TU level.
78. Prepare compendium of social protection programs at the district- and state-levels along with details on eligibility and how to access benefits; this should be shared with all TUs, STS, and STLS during community engagement activities.

TECHNICAL ASSISTANCE

Recommendations

79. Procure help from the RNTCP Technical Support Unit at the state-level as planned.
80. Increase RNTCP consultants and/or other trained workers until 2026.
81. Rotate and train pediatric and medicine residents through RNTCP facilities at the state-level.
82. Use ECHO for pediatricians to provide support to the CHC level for the management of pediatric TB patients and consider use for wider support.
83. Train and hire TB champions and survivors to provide technical support to TB forums.



RESEARCH

Recommendations

84. Create awareness and demand for the use of existing research resources at the state-level.
85. Increase awareness of RNTCP supported operational research among medical college faculties and PG residents and encourage uptake of TB related thesis/dissertations and funding.

Suggested areas for research

- Assessment to identify criteria for “clinically diagnosed” amongst adult patients, especially in private sector patients.
- Assessment of the application of the definitions for 'clinically diagnosed' and 'treatment completion' in the private sector.
- Conduct surveillance of TB and MDR-TB among health care workers of DR-TB

centres at the state level and within different departments of medical colleges.

- Assess and identify factors associated with long turnaround time for DR-TB testing.
- Study factors for the delay in treatment initiation after confirmed diagnosis.
- Identify factors (and SOPs) for increasing the uptake of DST in the private sector.
- Enumerate barriers to, and enhance implementation of, contact tracing.
- Assess safety and efficacy of STR for RR- and MDR-TB patients (amended BEAT study using BPaL).
- Introduce mortality audit of TB patients to assess factors leading to treatment failure and/or death, and identify areas for improvement at the national level.



3.2 List of Participants

3.2.1 Thematic Groups

Overarching and guiding the thematic groups:

Name	Current Designation	Present affiliation
Dr Kenneth G. Castro (Mission Lead)	Professor of Global Health, Epidemiology, and ID	Emory University & USAID
Dr K. S. Sachdeva	DDG-TB	Central TB Division, Ministry of Health & Family Welfare
Dr Ranjani Ramachandran	NPO - TB Labs & Coordination	WHO India
Dr Malik Parmar	NPO - Drug Resistant TB	WHO India
Dr Kirankumar Rade	NPO TB Epidemiologist	WHO India

Theme 1. Epidemiology, Surveillance, Supervision, Monitoring & Evaluation

Name	Current Designation	Present affiliation
Dr Patrick Moonan	Associate Chief of Science, Global Tuberculosis Branch	US Centers for Disease Control and Prevention
Dr Mohammed Yassin	Senior TB Advisor	Global Fund to fight AIDS, Tuberculosis and Malaria
Dr Vineet Chadha	Director	Central Leprosy Teaching & Research Institute, Chengalpattu
Dr Sudarsan Mandal	Addl. Deputy Director General	Central TB Division, MoHFW, Govt. of India
Mr Avijit Chowdhury	IT System Support Executive	WHO India
Dr. Pankaj D. Nimavat	Senior Medical Officer	Government of Gujarat
Dr Vijayashree Yellappa	Consultant, Health	NITI Aayog, Government of India
Dr. Shamim M Mannan	TB Lead	Clinton Health Access Initiative
Dr Bhavesh Modi	RNTCP STF Chair Gujarat	Government of Gujarat
Dr. Manu E Mathew	National Consultant - Epidemiology	WHO-RNTCP TSN, New Delhi, India

Theme 2. Preventive Services

Name	Current Designation	Present affiliation
Dr Anand Date	Associate Chief, Global TB	US Centers for Disease Control and Prevention
Dr Avinash Kanchar	Medical Officer	Global TB Programme, WHO, Geneva
Dr SK Sharma	Adjunct Professor	Jamia Hamdard (Deemed to be University, New Delhi)
Dr Ameeta Joshi	Professor & Head Dept. of Microbiology	Grant Medical College & Sir J J Group of Hospitals, Mumbai
Dr Christine Ho	TB Branch Chief/Advisor	CDC India
Dr Mukta Sharma	Regional Advisor (TB)	WHO, Regional Office for South-East Asia, New Delhi
Dr Ravindar Kumar	TB Specialist	Central TB Division, Ministry of Health & Family Welfare
Dr Sarabjit Chadha	Regional Technical Director	FIND
Dr Avi Kumar Bansal	Scientist 'E'	National JALMA Institute for Leprosy Other Mycobacterial Diseases, Agra
Dr Anil Jacob Purty	Professor & HoD of Com Med, Vice-Chair RNTCP NTF	Pondicherry Institute of Medical Sciences
Dr Reshu Agarwal	Sr. Public Health Specialist - Care & Treatment	CST Division, CDC India
Dr Shibu Balakrishnan	Medical Consultant	WHO-RNTCP TSN, Kerala, India
Dr Rajesh Deshmukh	Public Health Specialist - TB	DGST Division, CDC India

Theme 3. Case Finding, Diagnostics & Laboratory Services

Name	Current Designation	Present affiliation
Dr Thomas M Shinnick	Independent TB Laboratory Consultant	TB Expert
Ms Amy Piatek	Senior TB Technical Advisor	USAID
Prof Urvashi B Singh	Professor, Dept of Microbiology	All India Institute of Medical Sciences, New Delhi
Dr Prabha Desikan	Director	BMHRC, Bhopal
Dr.Vithal Prasad Myneedu	Microbiologist (SAG) & HOD Microbiology and NRL	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr Sanjay Sarin	Head of FIND India	FIND
Dr Debadutta Parija	Medical Officer	FIND India
Dr Tarak Shah	Medical Officer	FIND India
Dr Himanshu Jha	Technical Officer	Central TB Division
Dr Shanta Achanta	Medical Consultant	WHO-RNTCP TSN, Andhra Pradesh, India
Dr Anand S	National Consultant - TB Laboratories	WHO-RNTCP TSN, New Delhi, India

Theme 4. Treatment Services for Drug Sensitive TB (DS-TB)

Name	Current Designation	Present affiliation
Dr Manoj Jain	Adjunct Professor	Emory University, Rollins School of Public Health
Rebecca Gupta Lawrence	Senior Programme Office, India Country Team	The Global Fund
Dr Rajendra Prasad	Vice Chairman	National Task Force
Dr Rupak Singla	Chest Physician & Head, Dept. of TB & Resp Diseases	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr. Yatin Dholakia	Hon'ble Secretary	The Maharashtra State Anti TB Association; The Foundation for Medical Research
Dr Ashwani Khanna	State TB Officer (Delhi)	Chief Medical Officer, Senior Administrative Grade
Dr M M Puri	Sr. Specialist	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr Salil Bhargava	Professor of Pulm. Medicine	M G M medical college, Indore MP
Dr Somasekar	Director	NTI, Bengaluru
Dr Neeta Singla	Senior Research Officer	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr Almas Shamim	Technical Consultant-PMDT	The Union
Dr Sandeep Chauhan	Medical Consultant	WHO RNTCP TSN, India

Theme 5. Drug Resistant TB (PMDT)

Name	Current Designation	Present affiliation
Dr Douglas Fraser Wares	Senior Consultant	KNCV TB Foundation
Dr Erika Vitek	Senior MDR-TB Technical Advisor	USAID
Dr Rajesh Solanki	Professor & Head	Dept. of Pulmonary Medicine BJ Medical College, AHMEDABAD
Dr Anuj Bhatnagar	Consultant Chest Specialist and HOD (Chest & TB)	Rajan Babu Institute of Pulmonary Medicine and TB, New Delhi
Dr Vineet Bhatia	MO-MDR TB	WHO SEARO
Dr Umesh Alavadi	Project Management Specialist, Health Office	USAID India
Dr Ritu Gupta	ADDG cum Consultant TB	Central TB Division
Dr Shivani Chandra	Medical Consultant	WHO - RNTCP TSN, India
Dr Deka D	Medical Consultant	WHO India
Dr Yogesh Patel	National Consultant - DR-TB	WHO India

Theme 6. Comorbidities and Childhood TB

Name	Current Designation	Present affiliation
Dr Annabel Baddeley	Medical Officer, TB/HIV & Community Engagement	Global TB Programme, WHO Geneva
Dr Senait Kebede	Consultant	Emory University
Dr Varinder Singh	Director Professor of Pediatrics	Lady Hardinge Medical College
Dr Sangeeta Sharma	Professor & Head, Pediatrics	NITRD, New Delhi
Dr Shobini Rajan	Representative NACO	National AIDS Control Programme, India
Dr Sanjay Mattoo	Joint Director (TB)	Central TB Division
Dr Pradeep Joshi	NPO - NCD	WHO India
Dr Suresh Shastri	JS IEC, Senior Specialist TB	Dept of Health and FW, Karnataka
Dr Rahul Srivastava	District TB Officer	Betul, Madhya Pradesh
Dr Shanoo Mishra	UNION Technical Consultant	Central TB Division
Dr RS Gupta	Consultant	NACO
Dr Suma KV	WHO Consultant	WHO India
Dr Anupama T	WHO Consultant	WHO India
Dr Lalit Mehandru	National Consultant - TB Co-morbidities	WHO India
Dr Deepak B		WHO India

Theme 7. Multi Sectoral Engagement & Patient Support Systems

Name	Current Designation	Present affiliation
Dr Diana Weil	Coordinator Policy/Strategy/Innovation	Global TB Programme, WHO Geneva
Mr Richard Cunliffe	Senior Fund Portfolio Manager	The Global Fund
Dr Anurag Bhargava	Professor of Medicine, Head Center for Nutrition Studies	Yenepoya Medical College, Yenepoya (Deemed to be University)
Dr Sameer Kumta	Country Lead, TB	Bill and Melinda Gates Foundation
Mr Amrish Shahi	Social Protection Specialist	The World Bank
Dr Neeraj Agarwal	Senior Program Director	Wadhvani AI
Dr B Ramesh Babu	District TB Control Officer, Chittoor, AP	District Programme Officer for TB in AP Medical and Health Services
Dr Pirabu Ramanan	National Consultant, M&E	WHO-RNTCP TSN, India
Dr Ravinder Kumar	WHO RNTCP Consultant	WHO-RNTCP TSN, India
Dr Nishchit KR	WHO Consultant	WHO-RNTCP TSN, India

Theme 8. Partnerships, PPE and Urban TB

Name	Current Designation	Present affiliation
Dr William Wells	Senior TB Technical Advisor	USAID
Dr Nevin Wilson	Senior Regional Project Coordinator	UN Migration Agency (IOM)
Prof. Venkatraman A	Professor	Faculty of Management Studies, University of Delhi
Dr Daksha Shah	City TB officer	Municipal Corporation of Greater Mumbai, Maharashtra
Dr Guy Stallworthy	PPM Consultant	Independent consultant to Gates Foundation, WHO and others
Dr Shibu Vijayan	Global TB Technical Director	PATH
Dr Lal Sadasivan	Director, ID - TB Portfolio	Global Health, FHI 360
Dr Di Dong	Health Economist	World Bank
Dr Syed Imran Farooq	Director Programs	The Union South East Asia
Dr Bharati Kalottee	National Lead- JEET Project	CHRI, New Delhi
Dr Raghuram Rao	Dy. Addl. Director General-TB	Central TB Division
Dr Bhavin Vadera	National Consultant - Partnerships	WHO-RNTCP TSN, India
Dr Sandeep Bharaswadkar	Medical Consultant	WHO-RNTCP TSN, India
Dr Rakesh PS	Medical Consultant	WHO-RNTCP TSN, India

Theme 9. Community Engagement, Advocacy, Communication, Social Mobilization

Name	Current Designation	Present affiliation
Dr Suvanand Sahu	Deputy Executive Director	Stop TB Partnership
Ms Miruna Mosincat	TB Communications Consultant	USAID
Ms Blessina Kumar	CEO	Global Coalition of TB Activists (GCTA)
James Malar	Programme Officer	Stop TB Partnership
Dr Nishant Kumar	DADG-TB	Central TB Division
Dr Jamie Tonsing	Regional Director- South-East Asia	The Union
Ms Smrity Kumar	Project Director	REACH
Mr Chapal Mehra	Public Health Specialist & Independent Writer	Survivors Against TB
Dr Oommen George	Director, Tuberculosis Control and Care	Abt Associates Inc.
Ms Deepti Chavan	Patient Advocate	Survivors Against TB
Dr V S Raja	Medical Consultant - TN	WHO RNTCP TSN India
Dr Palash Talukdar	Medical Consultant - Assam	WHO RNTCP TSN India

Theme 10. Health System Strengthening

Name	Current Designation	Present affiliation
Dr Ronald Mutasa	Senior Health Specialist/Team Leader	The World Bank
Ms Marion Grossmann	Country Supply Officer	Stop TB Partnership - Global Drug Facility
Dr Rohit Sarin	Director	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr Suresh Mohammed	Senior Health Specialist	The World Bank
Dr Himanshu Negandhi	Additional Professor	Indian Institute of Public Health - Delhi
Mr Sreenivas D	PSM	World Bank
Ms Tanya Gupta	PFM	World Bank
Dr Suman Vishvkarma	Deputy Civil Surgeon	Health Department Haryana
Mr Erulappa Thanaraj	Country Technical Advisor for India (GDF)	Stop TB Partnership/Global Drug Facility (GDF)
Mr Rajan Chauhan	Finance Consultant	Central TB Division
Mr Andualem Oumer	Consultant	GDF, Stop TB Partnership
Ms Priyanka Grover	Technical Consultant (Fin)	Central TB Division
Ms Neha Vats	Technical Consultant (HR)	Central TB Division
Dr Umesh Tripathi	WHO Consultant	WHO RNTCP TSN India
Ms Sheffali Sharma	Sr. Consultant - PSM	Central TB Division
Ms Kavitha Nair	National Consultant - PSM	WHO RNTCP TSN India

Theme 11. Technical Assistance to End TB in India

Name	Current Designation	Present affiliation
Dr Sreenivas A Nair	Regional Advisor	Stop TB Partnership
Dr. Yamuna Mundade	Technical Officer	FWC Cluster, WHO HQ
Dr L S Chauhan	Expert - TWG on PSE	MoHFW
Dr Alka Aggarwal Singh	Independent Public Health Consultant	Self Employed
Dr Manoj Toshniwal	Freelance Consultant	Self Employed
Dr Prahlad Kumar	Consultant TB (SAG)	National Tuberculosis Institute, Bengaluru
Dr. Reuben Swamickan	Division Chief, Infectious Diseases, Health Office	USAID India
Partha Pratim Mandal	Medical Officer - Tuberculosis	WHO, Regional Office for South-East Asia, New Delhi
Mr Venkatesh Roddawar	Sr. Program Officer	PATH
Dr Jyoti Jaju	National Consultant	WHO, Country office India
Dr Sanjay K Sinha	WHO Consultant	WHO India

Theme 12. Research and Innovation

Name	Current Designation	Present affiliation
Dr Puneet Dewan	Primary Health Care Lead	The Global Good Fund
Dr Dawran Faizan	Disease Fund Manager	The Global Fund
Dr DCS Reddy	Independent Consultant	Chairman, National OR Committee for RNTCP
Dr Somnath Karmakar	Senior Consultant	Central TB Division
Dr V G Rao	Consultant - Former Scientist G	ICMR - NIRTH, Jabalpur
Dr Ashok Bhardwaj	Professor and Zonal Chairman RNTCP	Dr. Radhakrishnan Government Medical College Hamirpur HP
Son Nam Nguyen	Lead Health Specialist	World Bank
Kayla Laserson	Deputy Director Infectious Diseases	Bill and Melinda Gates Foundation
Dr C Padmapriyadarsini	Scientist	NIRT, Chennai
Dr Srinath S	Deputy Director (Research)	International Union against Tuberculosis and Lung Disease
Mr Raghu Dharmaraju	VP, Products & Programs	Wadhvani AI
Dr Vivek Mishra	Medical Consultant	WHO RNTCP TSN India
Dr Vaibhav Shah	Medical Consultant	WHO RNTCP TSN India

3.2.2 Field Visit Teams

Assam State

State Lead: Dr. Patrick Moonan

Team: Tinsukia (12 members)

Name	Current Designation	Present affiliation
Dr Patrick Moonan (District Lead)	Associate Chief of Science, Global Tuberculosis Branch	US Centers for Disease Control and Prevention
Dr K. S. Sachdeva	DDG-TB	Central TB Division, Ministry of Health & Family Welfare
Dr Sreenivas A Nair	Regional Advisor	Stop TB Partnership
Dr Di Dong	Health Economist	World Bank
Dr Vineet Chadha	Director	Central Leprosy Teaching & Research Institute, Chengalpattu
Dr Somasekar	Director	National Tuberculosis Institute, Bengaluru
Dr Malik Parmar	NPO - DR TB	WHO India
Dr Sriram Selvaraju	Scientist C	National Institute for Research in Tuberculosis (NIRT), Chennai
Dr. Shamim M Mannan	TB Lead	Clinton Health Access Initiative
Ms Smrity Kumar	Project Director	REACH
Dr Pirabu Ramanan	National Consultant r M&E	WHO-RNTCP TSN, New Delhi, India
Dr Palash Talukdar (Coordination)	Medical Consultant	WHO-RNTCP TSN, Assam, India

Team: Kamrup Metro (12 members)

Name	Current Designation	Present affiliation
Dr Mukta Sharma (District Lead)	Regional Advisor (TB)	WHO, Regional Office for South-East Asia, New Delhi
Mr James Malar	Programme Officer	Stop TB Partnership
Mr Andualem Oumer	Consultant	GDF, Stop TB Partnership
Ms Miruna Mosincat	TB Communications Consultant	USAID
Dr Sangeeta Sharma	Professor and Head of Pediatrics	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr. Umesh Alavadi	Project Management Specialist, Health Office, USAID India	USAID India

Dr Avi Kumar Bansal	Scientist 'E'	National JALMA Institute for Leprosy and Other Mycobacterial Diseases, Agra
Dr. Anil Jacob Purty	Professor & HoD of Community Medicine, Vice-Chair RNTCP NTF	Pondicherry Institute of Medical Sciences
Dr Bhavesh Modi	RNTCP STF Chair Gujarat	Government of Gujarat
Ms Deepti Chavan	Patient Advocate	Survivors Against TB
Dr Reshu Agarwal	Sr. Public Health Specialist - Care & Treatment	CST Division, CDC India
Dr Deka D (Coordination)	Medical Consultant	WHO-RNTCP TSN, Assam, India

Chhattisgarh State

State Lead: Dr Richard Cunliffe

Team: Raipur (11 members)

Name	Current Designation	Present affiliation
Dr Anand Date (District Lead)	Associate Chief, Global TB	US Centers for Disease Control and Prevention
Dr Senait Kebede	Consultant	Emory University
Dr Manoj Jain	Adjunct Professor	Emory University, Rollins School of Public Health
Mr Amrish Shahi	Social Protection Specialist	The World Bank
Dr. Amar Shah	Project Management Specialist, Health Office	USAID India
Dr Neeraj Agarwal	Senior Program Director	Wadhvani AI
Dr Neeta Singla	Senior Research Officer	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr B Ramesh Babu	District TB Control Officer, Chittoor, AP	District Programme Officer for TB in AP Medical and Health Services
Ms Sheffali Sharma	Sr. Consultant - PSM (Domestic consultant)	Central TB Division
Dr Shanta Achanta	Medical Consultant	WHO-RNTCP TSN, Andhra Pradesh, India
Dr Nishchit KR (Coordination)	Medical Consultant	WHO-RNTCP TSN, Chhattisgarh, India

Team: Bilaspur (8 members)

Name	Current Designation	Present affiliation
Mr Richard Cunliffe (District Lead)	Senior Fund Portfolio Manager	The Global Fund
Dr Sudarsan Mandal	Addl. Deputy Director General	Central TB Division, MoHFW, Govt. of India
Bruce Thomas	Founder & Managing Director	Arcady Group, LLC
Marion Grossmann	Country Supply Officer	Stop TB Partnership - Global Drug Facility
Dr. Pankaj D. Nimavat	Senior Medical Officer	Government of Gujarat
Dr Tarak Shah	Medical Officer	FIND India
Dr. Manu E Mathew (Coordination)	National Consultant - Epidemiology	WHO-RNTCP TSN, New Delhi, India
Dr Kshitij Khaparde	Medical Consultant	WHO-RNTCP TSN, Chhattisgarh, India

Kerala State

State Lead: Dr Amy Piatek

Team: Wayanad (12 members)

Name	Current Designation	Present affiliation
Wilson Lo (District Lead)	Public Health and M&E Specialist	The Global Fund
Dr Christine Ho	TB Branch Chief/Advisor	CDC India
Dr Rupak Singla	Chest Physician & Head, Dept of TB & Resp. Disease	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr Ashwani Khanna	State TB Officer (Delhi)	Chief Medical Officer, Senior Administrative Grade
Dr. Yatin Dholakia	Hon'ble Secretary	Maharashtra State Anti TB Association; The Foundation for Medical Research
Dr Shobini Rajan	Representative NACO	National AIDS Control Programme, India
Dr Jamie Tonsing	Regional Director	The Union - South-East Asia
Dr Manoj Toshniwal	Freelance Consultant	Self Employed
Dr. Almas Shamim	Technical Consultant-PMDT	The Union, Central TB Division
Dr Ravinder Kumar	Medical Consultant	WHO-RNTCP TSN, Himachal Pradesh
Dr Himanshu Jha	Technical Officer	Central TB Division
Dr Rakesh PS (Coordination)	Medical Consultant	WHO-RNTCP TSN, Kerala, India



Team: Thrissur (9 members)

Name	Current Designation	Present affiliation
Ms Amy Piatek (District Lead)	Senior TB Technical Advisor	USAID
Dr Son Nam Nguyen	Lead Health Specialist	World Bank
Dr Prahlad Kumar	Consultant TB (SAG)	National Tuberculosis Institute, Bengaluru
Dr Salil Bhargava	Professor of Pulmonary Medicine	M G M medical college, Indore MP ,452001
Dr Himanshu Negandhi	Additional Professor	Indian Institute of Public Health - Delhi
Dr Rahul Srivastava	District TB Officer	Betul, Madhya Pradesh
Dr Sandeep Bharaswadkar	Medical Consultant	WHO-RNTCP TSN, Maharashtra, India
Dr Vaibhav Shah	Medical Consultant	WHO-RNTCP TSN, Maharashtra, India
Dr Shibu Balakrishnan (Coordination)	Medical Consultant	WHO-RNTCP TSN, Kerala, India

Rajasthan State

State Lead: Dr Diana Weil

Team: Ajmer (14 members)

Name	Current Designation	Present affiliation
Dr Lal Sadasivan S. (District Lead)	Director, Infectious Diseases	FHI 360
Dr Ronald Mutasa	Sr. Health Specialist/Team Leader	The World Bank
Dr Thomas M Shinnick	Independent TB Laboratory Consultant	TB Expert
Ms Tanya Gupta	PFM/Financial Management Specialist	World Bank
Mr Sreenivas Devarakonda	Procurement/Supply Chain Management	World Bank
Dr RS Gupta	Consultant	MACO, India
Dr Anuj Bhatnagar	Consultant Chest Specialist and HOD (Chest & TB)	Rajan Babu Inst. of Pulm. Med. and TB, New Delhi
Dr Ameeta Joshi	Professor & Head Dept. of Microbiology	Grant Medical College & JJ Hospitals, Mumbai
Dr V G Rao	Consultant Former Scientist G	ICMR - Nat. Inst. of Research in Tribal Health (NIRTH), Jabalpur
Dr Sarabjit Chadha	Regional Technical Director	FIND
Mr Chapal Mehra	Public Health Specialist & Independent Writer	Survivors Against TB
Dr Debadutta Parija	Medical Officer	FIND India
Dr Jyoti Jaju	National Consultant - ICT	WHO-RNTCP TSN, New Delhi
Dr Sanjay K Sinha (Coordination)	Medical Consultant	WHO-RNTCP TSN, Rajasthan

Team: Udaipur (11 members)

Name	Current Designation	Present affiliation
Dr Diana Weil (District Lead)	Coordinator Policy/ Strategy/Innovation	Global TB Programme, WHO Geneva
Dr Ravindar Kumar	TB Specialist	Central TB Division, Ministry of Health & Family Welfare
Erika Vitek	Senior MDR-TB Technical Advisor	USAID
Dr Ashok Bhardwaj	Professor and Zonal Chairman RNTCP	Dr. Radhakrishnan Government Medical College Hamirpur HP
Dr Sameer Kumta	Country Lead, TB	Bill and Melinda Gates Foundation
Dr Suman Vishvkarma	Deputy Civil Surgeon	Health Department Haryana
Dr Oommen George	Director, Tuberculosis Control and Care	Abt Associates Inc.
Dr Sharath Burugina Nagaraja	Assistant Professor; Chair, State OR committee	ESIC Medical College and PGIMSR, Rajajinagar, Bengaluru, Karnataka
Ms Priyanka Grover	Technical Consultant (Finance)	Central TB Division
Dr Rajesh Deshmukh	Public Health Specialist - TB	DGST Division, CDC India
Dr Vivek Mishra (Coordination)	Medical Consultant	WHO-RNTCP TSN, Rajasthan, India

Uttar Pradesh State

State Lead: Dr Kenneth G Castro

Team: Agra (11 members)

Name	Current Designation	Present affiliation
Dr Kenneth G. Castro (District Lead)	Professor of Global Health, Epidemiology, and ID	Emory University & USAID
Dr Annabel Baddeley	Medical Officer, TB/HIV & Community Engagement	Global TB Programme, WHO Geneva
Collin Pierce	Specialist, Risk Management	The Global Fund
Dr.Vithal Prasad Myneedu	Microbiologist (SAG) & HOD Microbiology and NRL	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Dr M M Puri	Sr. Specialist	National Institute of Tuberculosis and Respiratory Diseases, New Delhi
Mona Balani	National coalition of PLHIV	National coalition of PL HIV (NCPIPLUS)
Dr Bharati Kalottee	National Lead- JEET Project	Centre for Health Research, Innovation
Dr Alka Aggarwal Singh	Independent Consultant	Self-employed
Dr Shivani Chandra	Medical Consultant	WHO-RNTCP TSN, New Delhi, India
Mr Rajan Chauhan	Finance Consultant	Central TB Division
Dr Sandeep Chauhan (Coordination)	Medical Consultant	WHO-RNTCP TSN, Uttar Pradesh, India

Team: Gorakhpur (12 members)

Name	Current Designation	Present affiliation
Dr Douglas Fraser Wares (District Lead)	Senior Consultant	KNCV TB Foundation
Dr Avinash Kanchar	Medical Officer	Global TB Programme, WHO, Geneva
Dr Dawran Faizan	Disease Fund Manager	The Global Fund
Dr Guy Stallworthy	PPM Consultant	Independent consultant to Gates Foundation, WHO and others
Dr Rajendra Prasad	Vice Chairman	National Task Force
Dr Rajesh Solanki	PROFESSOR & HEAD	Dept. of Pulmonary Medicine BJ Medical College, AHMEDABAD
Dr Syed Imran Farooq Syed Irshad Ali	Director Programs	The Union South East Asia
Dr Kirankumar Rade	NPO TB (Epidemiologist)	WHO India
Dr Neeraj Nischal	Assistant Professor	All India Institute of Medical Sciences, New Delhi
Dr Suresh Kunhi Mohammed	SENIOR HEALTH SPECIALIST	THE WORLD BANK
Mr Ranjan Verma	Social Development Specialist	World Bank
Dr Umesh Tripathi (Coordination)	Medical Consultant	WHO-RNTCP TSN, Uttar Pradesh, India

Tamil Nadu State:

State Lead: Dr William Wells

Team: Kanyakumari (10 members)

Name	Current Designation	Present affiliation
William Wells (State Lead)	Senior TB Technical Advisor	USAID
Nevin Wilson	Senior Regional Project Coordinator	Middle East Response, IOM
Dr Daksha Shah	City TB Officer	Municipal Corporation of Greater Mumbai, Maharashtra
Dr Ranjani Ramachandran	NPO - TB Labs & Coordination	WHO India
Dr Shibu Vijayan	Global TB Technical Director PATH	PATH
Venkatesh Roddawar	Sr. Program Officer	PATH
Mr Erulappa Thanaraj	Country Technical Advisor for India (GDF)	Stop TB Partnership/Global Drug Facility (GDF)
Dr Bhavin Vadera	National Consultant - Partnerships	WHO-RNTCP TSN, New Delhi, India
Dr Suma KV	Medical Consultant	WHO-RNTCP TSN, Tamil Nadu, India
Dr Anupama T (Coordination)	Medical Consultant	WHO-RNTCP TSN, Tamil Nadu, India

