

# Report of the Joint TB Monitoring Mission, India, 2015

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### List of Abbreviations

ACSM	advocacy, communication and social mobilization
AIC	airborne infection control
ANM	auxiliary nurse midwife
ART	antiretroviral therapy
ASHA	Accredited Social Health Activist
C/DST	culture and drug susceptibility testing
CBCI-CARD	Catholic Bishops' Conference of India–Coalition for AIDS and Related Diseases
CBNAAT	cartridge-based nucleic acid amplification test
CBO	community-based organization
CCT	conditional cash transfer
CDR	case detection rate
CLHIV	children living with HIV/AIDS
CPT	co-trimoxazole preventive therapy
CSO	civil society organization
CTD	Central Tuberculosis Division
DALY	disability-adjusted life year
DCGI	Drugs Controller General of India
DFID	Department for International Development
DMC	designated microscopy centre
DOT	directly observed treatment
DOTS	directly observed treatment, short-course
DRS	drug resistance surveillance
DR-TB	drug-resistant TB
DST	drug susceptibility testing
DTO	district TB officer
DTU	district tuberculosis unit
EQA	external quality assurance
FAQs	frequently asked questions
FDC	fixed-dose combination
FIND	Foundation for Innovative Diagnostics
FLD	first-line drug
FM	fluorescent microscopy
GDF	Global TB Drug Facility
GoI	Government of India
HRD	human resource development
IAP	Indian Academy of Paediatrics
ICDS	Integrated Child Development Services
ICT	information and communications technology
ICTC	integrated counselling and testing centre
IEC	information, education and communication
IGRA	interferon-gamma release assay
IMA	Indian Medical Association
IMNCI	Integrated Management of Neonatal and Childhood Illness
INH	isoniazid
IPC	interpersonal communication
IPT	isoniazid preventive therapy
IRL	intermediate reference laboratory

JALMA	National JALMA Institute of Leprosy and other Mycobacterial Diseases
JMM	Joint Monitoring Mission
KAP	knowledge, attitude and practice
LED-FM	light-emitting diode-based fluorescence microscopy
LIMS	laboratory information management system
LPA	line probe assay
LRS	Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases
MCH	maternal and child health
MCI	Medical Council of India
MDG	Millennium Development Goal
MDR	multidrug resistance
MO	medical officer
MoHFW	Ministry of Health & Family Welfare
MPW	multipurpose worker
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NCDC	National Centre for Disease Control
NEP	new extrapulmonary (TB)
NGO	non-governmental organization
NIFHW	National Institute of Health and Family Welfare
NIRT	National Institute for Research in Tuberculosis
NRHM	National Rural Health Mission
NRL	national reference laboratory
NSN	new smear-negative
NSP	National Strategic Plan
NTI	National Tuberculosis Institute
NTWG	National Technical Working Group
OTC	over the counter
PHI	peripheral health institution
PI	protease inhibitor
PLHIV	people living with HIV/AIDS
PMDT	programmatic management of drug-resistant TB
PP	private health-care provider
PPD	purified protein derivative
PPIA	private provider interface agencies
PPM	public–private mix
PPP	public–private partnership
PWB	patient-wise box
QA	quality assurance
RNTCP	Revised National Tuberculosis Control Programme
RSBY	Rashtriya Swasthya Bima Yojana
SACS	State AIDS control society
SAP	social action plan
SHG	self-help group
SLD	second-line drug
SL-DST	second-line drug susceptibility testing
STC	State tuberculosis cell
STDC	State TB training and demonstration centre
STLS	senior tuberculosis laboratory supervisor
STO	state tuberculosis officer
STS	senior TB treatment supervisor

TB	tuberculosis
TBHV	tuberculosis health visitor
TSG	technical support group
TST	tuberculin skin test
TU	tuberculosis unit
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNITAID	International facility for the purchase of drugs to treat HIV/AIDS, malaria and TB
USAID	United States Agency for International Development
WCO	WHO Country Office
WHO	World Health Organization
XDR	extensively drug-resistant
YLL	years of life lost

## Executive Summary

This report contains the findings, conclusions, and recommendations of the fifth Joint Monitoring Mission (JMM) of the Revised National Tuberculosis Control Programme (RNTCP). The JMM brought together national and international experts, affiliated Departments from the Ministry of Health, civil society, implementing partners, technical and developmental agencies to review the progress, challenges and plans for India's TB control efforts.

The Government of India (GoI), along with all the Member States of the World Health Organization (WHO), adopted the End TB Strategy in May 2014, thus committing to put an end to the global TB epidemic. This is a great responsibility for India, which bears a quarter of the global burden of the disease. Meeting the milestones and targets of the End TB Strategy will require implementing bold policies that guarantee access to high-quality TB care and prevention to all who need it. India will need to address persistent health system weaknesses and the determinants driving the TB epidemic. The country must also play its part in research and innovation to develop and use better tools and strategies for TB care and prevention. The End TB Strategy effectively calls for a major transformation of India's current approach to tackling TB. If it succeeds, India will lead the world in removing TB as a "Captain of the Men of Death".

### Achievements

India's achievements in Tuberculosis (TB) control over the past decade are remarkable by any measure. More than 80 million people have been tested, 15 million TB patients detected and treated, and millions of lives saved by the RNTCP's efforts. India has an ambitious National Strategic Plan (NSP) to achieve Universal Access to quality TB diagnosis and treatment; this NSP has guided activities and created accountability against results. India achieved complete geographical coverage for diagnostic and treatment services for multi-drug resistant TB (MDR-TB) in 2014, with a remarkable 66,000 MDR-TB diagnosed and put on treatment in the last three years. The nation's first national anti-TB drug resistance survey is being conducted by NTI, Bangalore.

The RNTCP and the National AIDS Control Organization (NACO) have made HIV-TB collaboration efficient and effective; most TB patients registered by RNTCP receive HIV screening, and more than 80% of HIV-infected TB patients receive anti-retroviral treatment (ART). The GoI boldly banned serological tests for diagnosis of active TB, saving countless persons from inaccurate test results and unnecessary expense. The Government has developed and adopted unifying 'Standards for TB Care in India', applicable for public and private sector alike. Since TB became a notifiable disease in 2012, private providers nationwide have notified nearly 230,000 TB patients. The RNTCP rolled out an innovative and visionary electronic recording and reporting system (Nikshay) across the country, with 98% of reporting units sending incase-based reporting of TB patients, including notifications from private providers. Innovative approaches, including interface agencies and e-voucher systems for free drugs, have been successfully deployed as pilots to engage more private providers and improve quality of care. Modern media are being creatively used for TB control with Amitabh Bachchan's campaign, "TB Harega, Desh Jeetega", with commendable investments by the Ministry and corporations to broadcast these messages.

Throughout, RNTCP has demonstrated unprecedented financial absorption capacity. While allocations have been lower than requested, whatever was allocated has been spent. During the

three years of the NSP it has managed to disburse (spend and release to states) all of the Rs.1,624 crores received. The health and economic benefits of the RNTCP have been enormous, with an estimated USD\$350 billion in economic gain over 2006-2015 relative to the absence of RNTCP services.

### **The Burden of TB**

Each year, 12 lakh Indians are notified with newly diagnosed TB and at least 2.7 lakh Indian citizens die. Some estimates calculate deaths twice as high. TB can affect any age, caste or class but cases are mainly poor people and mostly men. Slum dwellers, tribal populations, prisoners, and people already sick with compromised immune systems are over-represented among the cases, compared to their numbers in the population. Children comprise 40% of the population, but are currently under-diagnosed in India. The WHO estimates that another 10 lakh Indians with TB are not notified. Again, this could be even higher. Surveys have shown that many people with TB remain in the community, untreated. Yet case reporting has gently declined since 2009. MDR TB is emerging as a massive organisational and financial challenge to the RNTCP.

The economic burden is vast – between 2006 and 2014, TB cost the Indian economy a staggering USD340billion. The average cost to a family of any member with TB can amount to as much as 39% of annual household expenditure – a catastrophe for any family already impoverished. Yet every rupee invested in TB control has a one-hundred-fold economic return on investment.

### **The Challenges**

The JMM 2015 has observed that the implementation of the NSP for 2012-2017 is not on track: projected increases in case detection by the RNTCP have not occurred, vital procurements are delayed and many planned activities have not been implemented. Similarly, the JMM observed that of the recommendations of JMM 2012, about two thirds have not been fully implemented. For the most part, CTD has completed the policy work requested. Work is held up for lack of timely decisions, especially at central level.

The ambitious expansion of resources planned under the NSP, 2012-2017 would triple the expenditure of the prior plan, but has not been matched by allocations. While RNTCP expenditure has increased 27% since 2012, there is a growing gap between the allocation of funds and the minimum investment required to reach the goals of the Plan. If this trend continues, final expenditure on the Plan would reduce to Rs. 3,000 crores, or two thirds of the minimum required. Accordingly, while bold policies are mostly in place, many planned activities have not been implemented, and anticipated increases in case finding have not realized.

The private sector is massive, heterogeneous, and growing. Over 70% of people with TB first attend this sector, yet substantial diagnostic delays occur, and diagnosis and treatment are of variable quality. This, combined with the absence of drug quality controls, leads to drug resistance. In spite of mandatory notification, many patients are still not notified to the RNTCP. Two decades of attempts to improve collaboration between the public and private sectors, have not yet worked. The existing TB surveillance system lacks the capacity to count the large pool of privately diagnosed and treated TB cases, and what is not measured is unlikely to be improved.

Within the public sector, there is heavy dependence on an insensitive diagnostic test, microscopy of sputum, which, in addition, cannot diagnose drug resistance. The Standards for TB Care in India (STCI) and the NSP promote drug sensitivity testing for all presumed cases of MDR TB, and other groups, but progress is threatened by slow uptake of the new molecular test, which provides both a more sensitive test for TB and a test for drug resistance, and is endorsed by WHO. It is people with MDR-TB, those living with HIV, and children, who are mainly at risk. Yet procurement of these tests has been unaccountably delayed for two years.

While the expansion of treatment of MDR TB cases is a major achievement, the cost of providing services is approaching 40% of total RNTCP expenditure. This threatens the future of TB control in India and underscores the necessity to prevent drug resistance. Yet the RNTCP currently treats patients without knowing their resistance profile and its current treatment regimen of thrice weekly doses, when given to those with prior resistance, has been associated with failure and amplification to rifampicin resistance. This regimen is therefore likely, under programme conditions, to be generating more MDR cases. While there were excellent reasons to embark on thrice weekly treatment in 1997, circumstances have changed. Universal drug susceptibility testing and switching to a daily regimen with adherence support can address this problem.

National policy recognizes the diversity in India and very well articulates the need for special efforts to reach and address TB in special groups. These key affected population groups are vulnerable, face barriers in accessing care and deserve more attention for reasons of equity, social justice and human rights. There has been some progress in the form of special action plans for tribal populations and several local projects targeting special population groups, but implementation to date has not reached the scale of the need.

The enormous diversity between States, and even districts, in terms of the population, terrain, level of development, health systems, and epidemiologic variety pose problems for a uniform centralised approach to TB control. Yet parts of the RNTCP appear strangely reluctant to engage non-governmental agencies. TB patients, civil society leaders, and community-based organisations need to be meaningfully and intensively engaged in the TB response at all levels.

### **Opportunities**

The Prime Minister's new policy of 'cooperative, competitive federalism', with the aim of strengthening states with additional resource allocation, offers important possibilities for health sector development. TB control is an integral part of the National Health Mission with availability and use of flexi-pool funding among the key benefits. Together with innovative e-governance tools this offers strengthening of programme management at all levels. The presence of maternal and child health care within the National Health Mission creates new avenues for identifying patients, particularly children, and families who can benefit from preventive and curative care.

The Government is now facilitating enterprise and innovation. This complements the work undertaken in the last few years in intensifying innovative approaches to quality treatment for TB in the private sector, and minimizing related patient costs. The new STCI provide the anchor for guiding and monitoring quality in both public and private sectors and incorporating new tools to reach all patients.

The momentum in applying e-governance tools also provides a prime opportunity for faster procurement, strengthened programme management, improved monitoring and evaluation, real-time data use, interfaces between health and social services databases, and most importantly, the ability to serve patients and communities by enabling UID Aadhaar linkages and e-transfers.

The Nikshay system for TB has the potential to further link with systems within TB, and link beyond TB, and its further enhancement and utilization will be critical. Work done in support of polio eradication, including geographic mapping of population migration and communities, is also an asset as GoI moves to reach the missing cases.

India is a worldwide leader across the continuum of health research, and for TB specifically. Its basic science capacity and its special National Institutes for TB research and ICMR institutes can help drive global innovation for TB elimination. With other BRICS members, India has committed to this role. Recent improvements in prevalence survey techniques and capture-recapture studies provide opportunities for India to better understand the scale and trend of its TB burden.

Thanks to Mr Amitabh Bachchan's engagement as a TB Ambassador, and the penetration of his first mass media messages, the foundation is laid for a high-impact campaign for a TB-free India, with engagement of leaders, communities and all those affected by this epidemic.

All these new developments build up confidence that India can be a global pathfinder in reaching universal access on the way to the milestones and targets of the End TB strategy.

## **Recommendations**

The mission commends India for endorsing the global 'End TB' strategy, and on rallying to a unifying set of Standards for TB Care in India. To quote Amitabh Bachchan, "TB harega, Desh Jeetega" - controlling TB will yield enormous health and economic benefits for the nation. India has the chance to a leader towards 'End TB', and TB control success in India is critical towards achievement of the global 2020 milestones. The existing National Strategic Plan has bold targets of 90% diagnosis and treatment and provides a roadmap, but funding is insufficient.

### **1. The JMM recommends that GoI significantly increases funding for TB control in order to meet the targets of the NSP and achieve the goals of the END TB strategy.**

It is strongly recommended that the remaining part of the NSP be fully funded, allowing RNTCP to spend Rs. 1,500 crores per year to achieve the goals of the Plan. Additional Investment of at least 750 crores annually will be required to reach the ambitious goals of the End TB strategy. This will enable implementation of early and intensified case finding with the revised diagnostic algorithm and appropriate treatment to prevent drug resistance, benefiting especially children, people living with HIV (PLHIV) who also have TB, and people with MDR-TB. The full cost estimation of these additional investments should be undertaken immediately. These measures will save around an additional 2.5 lakh lives annually. In addition, every rupee invested in TB control will have a one-hundred-fold economic return on investment.

The MOHFW should also streamline procurement and decision-making processes to ensure it spends the external grants and credits on time, enabling additional international funding in the future.

The GoI should grant States financial flexibility as well as additional technical, managerial, and human resources to facilitate timely innovations and expansion of their TB efforts. Building on ongoing integration of TB Units with the block level of the general health system, the TB programme's

managerial functions at district and state level need to be further integrated within the general health system for greater efficiency.

**2. The JMM recommends that all patients receive the “Standards for TB Care for India” irrespective of where they seek services, along with enhanced social support, community engagement and response to the needs of special groups**

The mission applauds the GOI for developing the Standards for TB Care for India and for the RNTCP efforts to support implementation. Accelerated implementation will require both public and private sector engagement. Specifically, the Mission urges the MOHFW to:

- a. Accelerate implementation of the transition to daily dosing using fixed-dosed combinations, with a clear timeline addressing the necessary planning and procurements.
- b. Rapidly improve access for patients to rapid molecular diagnostics.
- c. Rapidly improve, expand, and systematize economic, social and nutritional support to all TB patients and affected families, working with all relevant platforms and partners currently providing social benefits.
- d. Systematically build capacity to engage communities in planning, service implementation and evaluation, including through enhanced budget, staff and coordination mechanisms.
- e. Build on the example of MDR-TB treatment access expansion to accelerate the response to childhood TB and TB/HIV.
- f. Design, fund and implement targeted interventions for special groups as described in the NSP, based on systematic mapping.
- g. Develop e-Nikshay, a planned advanced version of the existing Nikshay system and ensure it serves as a tool to monitor the quality of services provided by different health care providers, and the quality of field supervision and monitoring.
- h. Establish state-of-the-art surveillance for capturing all TB cases, public and privately treated, in order to capture and respond to local and focal epidemics.

**3. Recognizing that patients choose private providers, the JMM recommends that the MOHFW urgently ensures that patients in the private sector receive early TB detection, appropriate treatment, and sustained support for adherence, and that their out-of-pocket expenses are minimized. This can be achieved by:**

- Strengthening regulations on mandatory TB notification, with clear consequences for non-adherent providers. In parallel, attract and facilitate notification from private providers with convenient, patient- and provider-friendly services.
- Eliminating taxation on TB diagnostics and drugs as a response for this ongoing public health emergency.
- Scaling-up systems to provide free diagnostic tests and drugs to patients, based on the lessons of successful experiences. Minimize patient out of pocket expenses by supporting costs for TB testing and free drugs.
- Extending and scaling-up successful models of adherence support and monitoring to all TB patients managed by private providers.
- Measuring the quality of services provided by private providers, and engaging with them to improve the quality of care they provide to TB patients.

- Extending public health services to privately-notified TB patients, including free drug susceptibility testing, contact investigation, and co-morbidity screening and care
- 4. The JMM recommends that the MOHFW should take steps to expand its knowledge base through the development of a strong interagency “TB Research Consortium” around the core commitment of the MoHFW, ICMR/DHR, DST, DBT, CSIR, and the private sector, and ensure a better understanding of the size and trend of the TB burden.**

The consortium should drive the development of a pioneer national TB Research Strategy with the creation of scientific networks and development of a country specific prioritized research agenda that will allow India to be a model country for TB research, in line with the WHO End-TB Strategy.

The JMM recognised the debate between different methods to estimate the size of the TB burden, but did not feel itself competent to decide between prevalence surveys (national or local), capture-recapture studies, improvements to the notification system, etc. The JMM therefore urges the rapid establishment of a suitably qualified technical group of national experts to determine the best way forward so that work begins on whatever method is chosen before the end of 2015.

- 5. The JMM recommends a high level sustained national campaign on TB: “TB Free India/TB Mukht Bharat” with active leadership of national, state and local self-governments in coordination with corporate/private sector, NGOs, media and others.**

The JMM recognises the enormous need for better awareness, inter-sectoral engagement and community ownership in the TB response, which could be built on the ongoing ‘Swatch Bharat, Swast Bharat’ campaigns.

### Debriefing meetings, 22<sup>nd</sup> April, 2015

1. Secretary, MOHFW, DG Health Services and Joint Secretary, MOHFW.

A group of JMM members (selected by CTD) briefed the Secretary and his colleagues on the findings and recommendations of the JMM. The Secretary agreed that funding was an issue, but was optimistic that money can be found for implementation of the NSP and to honour India’s commitments to the END TB strategy, although ensuring that States contribute the 25% of matching funds would be a challenge. With respect to delays in procurement, he asserted that the CBNAAT procurement was not waiting for a test of Indian origin, and that he would “get that moving”, tapping the external funds already available. He agreed to implementation of the daily regimen in place of the thrice-weekly one currently in use. He asserted that awareness of TB was important and that the campaign around Amithab Bachchan was a good thing, sure to have impact. Finally, he expressed that India needs better monitoring systems for TB.

2. Honourable Union Health Minister, JP Nadda.

A group of senior JMM members (selected by the Minister’s Office) presented the main findings of the review to the Honourable Minister with a plea for the Minister’s support in increasing central allocation of funds to TB control. Specifically, the group requested that public funds be made available for patients in the private sector and that the Minister should himself advocate for greater investment in TB control. There was a risk that external funds currently available to India would not continue to be available if their utilisation did not accelerate. The Minister agreed that his Ministry had to take initiatives with the private sector to avoid further increases in drug resistance. He asserted that India will use new technologies and that he would address the delays in diagnostics’

procurement. He agreed with the Secretary that funding was an issue, but that the Ministry was serious and the recommendations had political support. However, there must be no money wasted; optimal utilisation of funding was essential, and India would seek the support of the partners in this. If strategies change, he said, so must we. Civil society must engage more and while World TB Day was a good initiative, it was insufficient.

## A. Introduction

### 1. A situation summary of TB control on the eve of the JMM

India's achievements in Tuberculosis (TB) control over the past decade are remarkable by any measure. More than 80 million people have been tested, 15 million TB patients detected and treated, and millions of lives saved by the RNTCP's efforts. Incidence, estimated in 2013 to be 171 per 100,000 population, is falling<sup>1</sup>. India has therefore met the 2015 Millennium Development Target for TB. Prevalence, currently estimated at 211/100,000 and mortality, estimated at 19/100,000, are both less than half the estimated in 1990, thus meeting the Stop TB Partnership targets for 2015. India reported 1.24 million new and relapsed cases in 2013, by far the largest burden of any country, and over 270,000 Indians died of TB in that year. Some estimates calculate deaths twice as high<sup>2</sup>.

Case notification is only 58%. Over one third of cases is not diagnosed; or diagnosed, but not treated; or diagnosed and treated, but not notified to the RNTCP. Again, this could be even higher - the WHO estimates that 1 million Indians with TB are not notified<sup>1</sup>. Yet case notifications have been declining gently since 2009. TB affects any age, caste or class but cases are mainly poor people and mostly men. Slum dwellers, tribal populations, prisoners, and people already sick with compromised immune systems are over-represented among the cases, compared to their numbers in the population. On the other hand, children comprise 40% of the population, but are currently under-diagnosed in India.

MDR TB is emerging as a massive organisational and financial challenge to the RNTCP. Nevertheless, India achieved complete geographical coverage for diagnostic and treatment services for multi-drug resistant TB (MDR-TB) in 2014. In 2013, 248,000 cases of TB were tested for drug resistance and 35,400 were found to have MDR or rifampicin resistant TB. However, only 20,700 received treatment in that year – a diagnosis:treatment gap of 43%. Yet these cases, about a third of the estimated number, cost over 40% of the annual RNTCP budget. This is a financially unsustainable situation and emphasizes the crucial importance of prevention. NTI, Bangalore is conducting the nation's first national anti-TB drug resistance survey.

The RNTCP and the National AIDS Control Organization (NACO) have made HIV-TB collaboration efficient and effective. Almost two thirds of TB patients registered by the RNTCP received HIV screening in 2013, and 44,000 (5%) were found to be infected. More than 80% of these received anti-retroviral treatment (ART) and 95% received co-trimoxazole preventive treatment (CPT).

The GoI boldly banned serological tests for diagnosis of active TB, saving countless persons from inaccurate test results and unnecessary expense. The RNTCP developed and adopted unifying 'Standards for TB Care in India', applicable for public and private sector alike. Since TB became a notifiable disease in 2012, private providers nationwide have notified nearly 230,000 TB patients. The RNTCP rolled out an innovative and visionary electronic recording and reporting system (Nikshay) across the country, with 98% of reporting units sending in case-based reporting of TB patients, including notifications from private providers. Innovative approaches, including interface agencies and e-voucher systems for free drugs, have been successfully deployed as pilots to engage more private providers and improve quality of care. Modern media are being creatively used for TB

<sup>1</sup>World Health Organization. Global Tuberculosis Report, 2014. WHO, Geneva.

<sup>2</sup>IHME

control with Amitabh Bachchan's campaign, "TB Harega, Desh Jeetega", with commendable investments by the Ministry and corporations to broadcast these messages.

The RNTCP incorporated these innovative approaches and many others in its ambitious National Strategic Plan (NSP) 2012-2017 which aims to achieve Universal Access to quality TB diagnosis and treatment. So far, this NSP has guided activities and created accountability against results. Further evaluation of the implementation of the NSP is one of the JMM's objectives (see section below).

The economic burden of TB is vast – between 2006 and 2014, TB cost the Indian economy a staggering USD340 billion. The average cost to a family of any member with TB can amount to as much as 39% of annual household expenditure – a catastrophe for any family already impoverished. Yet every rupee invested in TB control has a one-hundred-fold economic return on investment.

The RNTCP has demonstrated unprecedented financial absorption capacity. While allocations have been lower than requested, whatever was allocated was spent. During the three years of the NSP the RNTCP has managed to disburse (spend and release to states) all of the Rs. 1,624 crores received. The health and economic benefits of the RNTCP have been enormous, with an estimated USD\$350 billion in economic gain over 2006-2015 relative to the absence of RNTCP services.

## 2. Objectives of the JMM

### General Objective

To review the progress, challenges, plans and efforts of India's health care system to control TB, and to advise GoI and partners on the pathway towards achieving Universal Access to TB care, within the context of India's commitment to Universal Health Coverage (UHC) agenda.

### Specific objectives

1. To review India's progress in implementation of the National Strategic Plan and follow up on recommendations of JMM 2012.
2. To review TB care services as an integral part of a broader health care system, in the context of ongoing health system strengthening efforts and financial outlook, identify strengths and weaknesses, and assess resource mobilization needs to achieve the objectives of NSP 2012-17 for TB care, control and prevention.
3. To review TB situation in India with detailed epidemiological analysis including review of the programme M&E system, look at the strategies to rapidly reduce the burden as planned in TB-Mission 2020 and provide recommendations for implementation.
4. To review opportunity for collaboration in research and development in TB for the global goal of TB elimination as per End TB strategy, and to review medium and long-term technical assistance and coordination needs for TB control in India.

### Thematic areas

The JMM terms of reference also included thematic areas for the team to address:

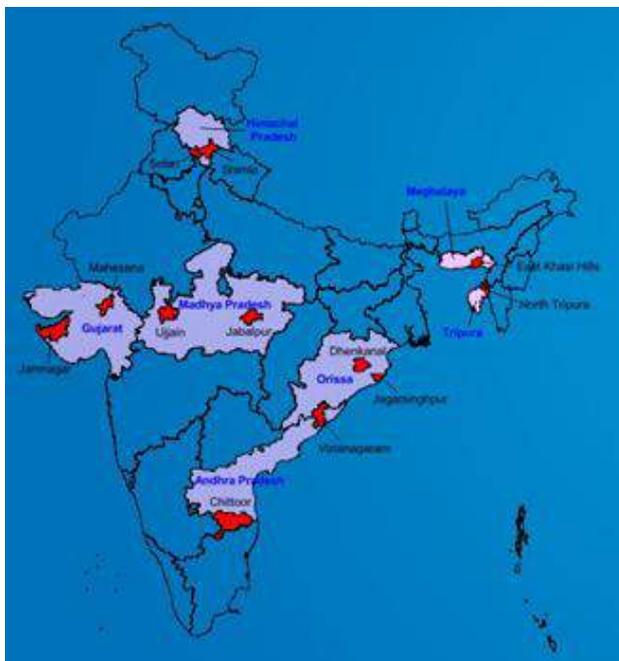
1. Epidemiologic analysis of TB: the magnitude of the epidemic with trends, including DR-TB and TB/HIV, the notification system, TB surveillance, monitoring and evaluation (M&E);
2. Health System Issues, including health care system strengthening and integration of TB services:
  - i. Governance, human resources, financing
  - ii. Social protection, patient support and UHC

- iii. Procurement and logistics
  - iv. Community engagement; advocacy, communication and social mobilization
  - v. Research
3. TB service delivery issues
- i. Early Diagnosis and case-finding for all types of TB, including laboratory services
  - ii. Treatment of TB
  - iii. Drug-resistant TB
  - iv. Engagement of all care providers
  - v. Interactions of TB with HIV and other co-morbidities
  - vi. Childhood TB
  - vii. Targeted interventions for special groups

### Process

The JMM 2015 was put together by the Central TB Division (CTD) of the RNTCP and the Country Office of the World Health Organization with financial support from the Global Fund against AIDS, TB and Malaria. It started its work on 10<sup>th</sup> April with briefings on the RNTCP implementation structure and core strategies by the national programme manager, and DDG-TB, Dr Sunil Khaparde and the emerging challenges and newer initiatives by the deputy programme manager, and ADDG-TB, Dr KS Sachdeva. Dr A Sreenivas from WHO presented the END-TB Strategy approved by the World Health Assembly in May 2014 and summarised the epidemiological situation of TB in India. The Team Leader, Dr Paul Nunn, laid out the procedures for the review including the reference checklist for the field visits.

**Figure 1. (Placeholder) Map of India showing the States and districts visited**



The States and districts were deliberately selected on the basis of their potential to inform deliberations on specific thematic areas, as well as the feasibility and safety of travel to the locations. Each State team (apart from those to Meghalaya and Tripura, which reviewed only one district) was divided into two groups, each of which visited one of two districts. The teams visited key institutions, including State TB Demonstration and Training Centres, government and private

medical colleges, intermediate reference laboratories, DR-TB centres, district TB centres, tuberculosis units (TUs), designated microscopy centres (DMCs), directly observed treatment (DOT) centres, pharmacies and medical shops. The team also visited private healthcare centres, including laboratories, private hospitals and practitioners. Patients, community members, DOTS providers, accredited social health activists (ASHAs), and State and district TB staff were interviewed. Each State team prepared a report on the field visit. This report described in brief the achievements, challenges and possible solutions, and assessed the degree to which the JMM 2012 recommendations had been implemented as well as the level of implementation of the NSP. The State teams conducted a debriefing meeting with the State officials once the field visits were over.

The teams discussed the findings of the field visits at a general debriefing meeting in New Delhi on 17<sup>th</sup> April 2015. Subsequently the State team leaders drafted brief written reports for transmission back to the States. On the 18<sup>th</sup> and 19<sup>th</sup> April, presentations and in-depth discussions took place on each of the thematic areas. The overall Team Leader and the thematic group leaders held two additional meetings on the 19<sup>th</sup> and 20<sup>th</sup> April to draft the Executive Summary (which also served as the debriefing note) and revised it by multiple iterative email exchanges. The thematic group leaders also later prepared a report for each thematic area.

Paul Nunn presented the summary findings and recommendations to the full JMM team on April 22<sup>nd</sup>, followed by a question and answer session. Later that day a group of JMM members (selected by CTD) briefed the Secretary, MOHFW, DG Health Services and Joint Secretary, MOHFW. Finally, also on the 22<sup>nd</sup> April, a smaller group of senior JMM members presented the main findings of the review to the Honourable Union Health Minister, JP Nadda.

From the State and thematic group contributions, the team leader drafted this report of the JMM 2015, which was finalised after one formal round of comments.

### Participants

The JMM brought together xx national and yy international experts on TB, health systems and related areas. These included MOHFW staff working on TB, as well as staff from affiliated Departments from the MOHFW. Members of civil society, communications experts, economists, epidemiologists, mathematical modellers, microbiologists, nutritionists, paediatricians, implementing partners, pharmacists, physicians and clinicians, policy-makers, procurement specialists, researchers, and social scientists were all involved. Among the agencies represented were foundations, non-governmental and community-based organisations, and technical and development agencies. For a complete list of individuals and their affiliations, see Annex 1.

## B. Findings

### 1. General observations with respect to the 1<sup>st</sup> term of reference

The JMM 2015 has observed that the implementation of the NSP for 2012-2017 is generally not on track. While some activities have achieved the target, or even exceeded them, key performance indicators such as the projected increases in case detection by the RNTCP have not been achieved (Figure 2). In particular, vital procurements of commodities and equipment have been delayed, for example light-emitting diode (LED) microscopes and cartridge-based nucleic acid amplification test (CBNAAT) machines. The consequence is a corresponding poor performance in the delivery of services to key affected populations, eg the percentage of chest symptomatics among PLHIV receiving a molecular diagnostic test (CBNAAT) was 2% in 2014 rather than the 50% target in the NSP. These delays will have cost lives, and they appear to originate from the levels between the CTD and the Secretary. What is also important is that no clear reasons for the delays have been provided to CTD staff.

The net effect of massive delays, apparent blocking of implementation of policies agreed in a national strategic plan, no good reasons given, and consequent significant loss of life, is a serious negative impact on the morale of the senior staff who put the files forward. Some very key personnel are considering a move to other fields.

The JMM recognises of course that procurement of large amounts of equipment from abroad is potentially contentious and entails some risk of litigation for the civil servants involved in making such decisions. However, this is a problem common to all large public health programmes and the MOHFW bureaucracy needs to find an efficient way of dealing with such large procurements.

**Figure 2. Selected targets from the NSP 2012-2017 set against actual performance.** *Source: NSP 2012-2017 and TB India 2014, Annual Status Report.*

Metric (selected)	14-15 target	Actual
Chest symptomatics examined (per 100,000 population)	172/lakh/qtr	172
Number of TB cases put on treatment (in lakhs)	16.5	14.2
Proportion of districts with TUs aligned with health system structure the block levels	50%	25%
Retreatment with DST at start of treatment	60%	80%
Number of M/XDR (thousands) started on Rx	30 / 0.5	26 / 1
% of DMC with LED microscopy	10%	<1%
% PLHIV chest symptomatics tested by molecular test	50%	0%
States with Private Provider Interface Agency contracted	6	2 (cities)

Similarly, the JMM observed that of the recommendations of JMM 2012, 26% have not been implemented at all and 40% only partially. Only 34% of the recommendations have been completely implemented. Thus, about two thirds (66%) have not been fully implemented. For the most part,

CTD has completed the policy work requested but work is held up for lack of timely decisions, especially at central level.

The paragraphs above have addressed delays in procurement, but the JMM observed other forms of delay. For example, a number of important policy approaches recommended by JMM 2012 were formulated in “Technical and Operational Guidelines” eg the registration of cases at the point of diagnosis. Because of delays in approving these Guidelines the policies have not yet been implemented. Some policies were prepared, eg the “screening pathway”, but only introduced with “early implementation pilots in a few districts” rather than the broad introduction across the country for clinical and social risk groups that was envisaged by the JMM 2012. Notification has been made mandatory and this has indeed increased notifications from the private sector, but a lack of enforcement means that notification of diagnosed cases remains low.

The inescapable conclusion is that the decision making process in the MOHFW, at least as it pertains to TB control, is broken. The fault appears to lie at the point that technical recommendations and policies arising from careful deliberations in the CTD require approval from the non-technical, administrative part of the civil service. While technical recommendations naturally require examination to ensure that they are affordable, feasible, politically acceptable, and ethically sound, the process of this examination should be transparent, and should not be unaccountably delayed. Furthermore, the criteria by which non-technical officers examine technical policy recommendations should be made public or at least made available to the officers responsible for preparing policy.

## 2. Tuberculosis epidemiology, surveillance, monitoring and evaluation

There has been an unprecedented scale-up of various TB control interventions in the country over the last 15 years. Though the available data suggest that the TB epidemic may be on the decline, India continues to be the highest TB burden country in the world in terms of number of cases and TB deaths each year. Mortality due to TB is the third leading cause of years of life lost (YLL) in the country.

### a) TB burden

Ten sub-national surveys, including nine district and one state level, conducted during 2006-2012 wherein about 760 000 individuals were investigated, gave a pooled prevalence of 3.2 million TB cases in the country. There are about 2 million new TB cases each year. Annual TB deaths in the country has been estimated to be between 270,000 and 550,000 depending upon the estimation process. The majority of these deaths occur in people who are active in the workforce, with men at two times the risk of dying compared to women. Additional deaths in PLHIV who die of TB are counted as HIV deaths. The incidence of HIV co-infected cases is estimated at 120,000 and there are 100,000 Multi-Drug Resistant (MDR) incident cases occurring each year. More than 10 million people acquire TB infection each year, thus adding to the latent pool of infection from which new cases will continue to emerge for a long time in the future.

State level surveys to find out the proportion of cases having MDR-TB have revealed that about 2-3% of new cases and 15-17% of retreatment TB cases registered under the program have MDR. A national level survey to find out the proportion of cases having MDR TB is in progress.

### b) Achievements

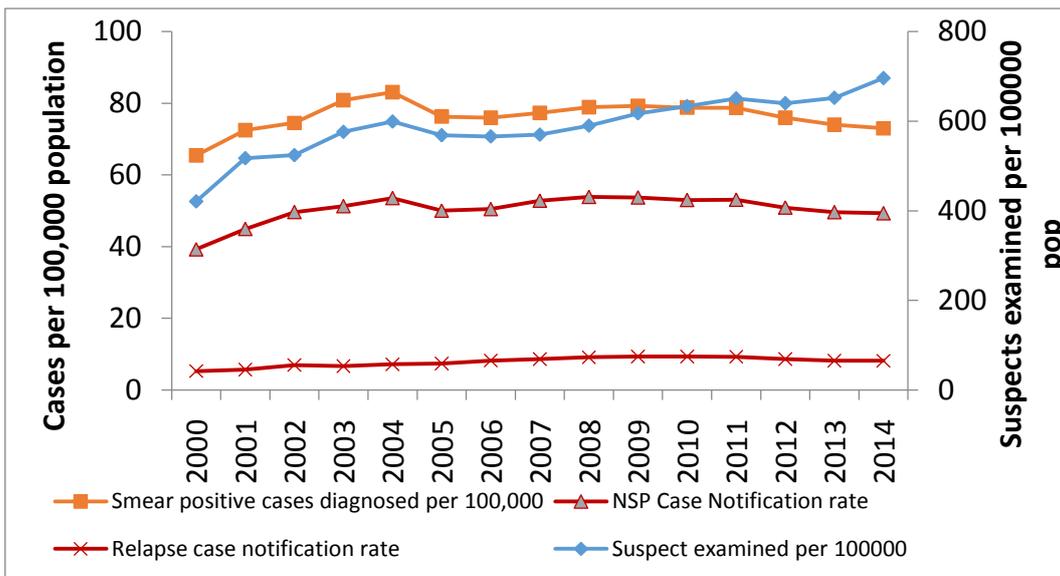
#### i. Routine surveillance under RNTCP

A robust surveillance system of recording and reporting has been in place since the inception of RNTCP, and is being continually strengthened. In 2012, a case-based electronic data recording and reporting system named Nikshay was introduced with the aim of capturing patient-level information from both public and private sectors for better program delivery as well as individual TB case management. Both the aggregate sub-district and case-based systems currently operate in parallel.

The routinely collected data has provided useful information on the trends in efforts of case finding, TB notification rates, proportion of different types of cases and their age-sex distribution.

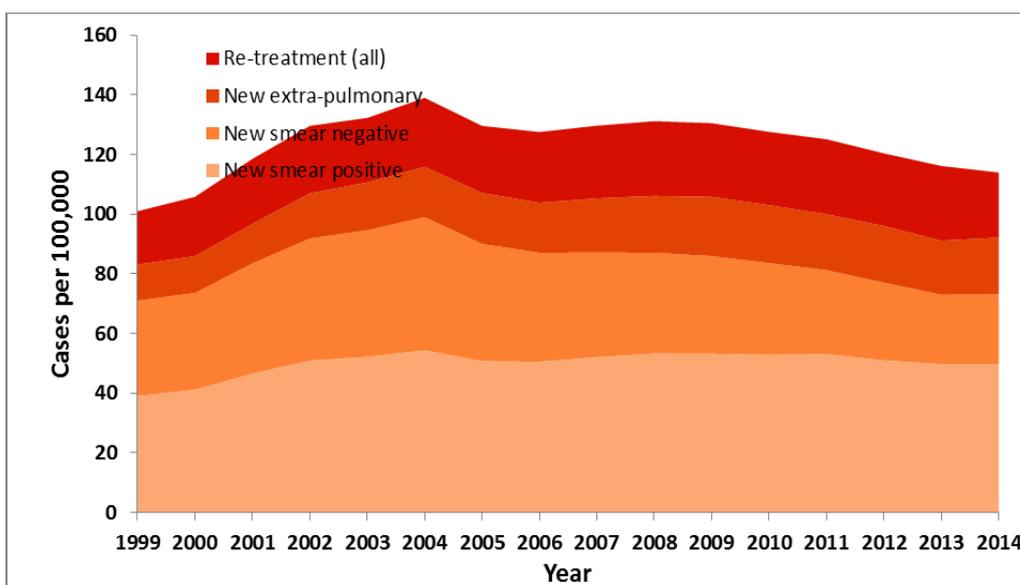
Case-finding efforts, as measured by the absolute number and the rate of persons examined by sputum microscopy per unit population, have consistently increased by an average of 4-5% per year since 2006 (Figure 3); about 8.4 million patients had their sputum examined in the year 2014. However, despite this increase in case finding efforts, the numbers of new smear positive cases as well as all smear positive cases per 100 000 population have been declining gently since 2009.

**Figure 3. Notification rates of new smear positive and negative cases and relapse cases, and rate of suspect smear examinations, India 2000 to 2014.***Source:*



Notification rates of all TB cases (all types) have shown a declining trend from 130 in 2004 to 110 per 100,000 in 2014 (Figure 4). During this period, notification rates of new TB cases (all types) declined from 116 in 2004 to 91 per 100,000 in 2014, primarily due to the decline in smear negative cases while the notification rates of smear positive and extra-pulmonary cases remained stable (Figure 2). About 1.4 million TB cases were registered for treatment under the program in 2014. Re-treatment cases constitute 18-20% of all registered cases while 20% of the cases have extra-pulmonary TB.

**Figure 4: Notification rates of new smear positive and negative cases, extra-pulmonary cases and relapse cases, India 1999 to 2014.** *Source:*

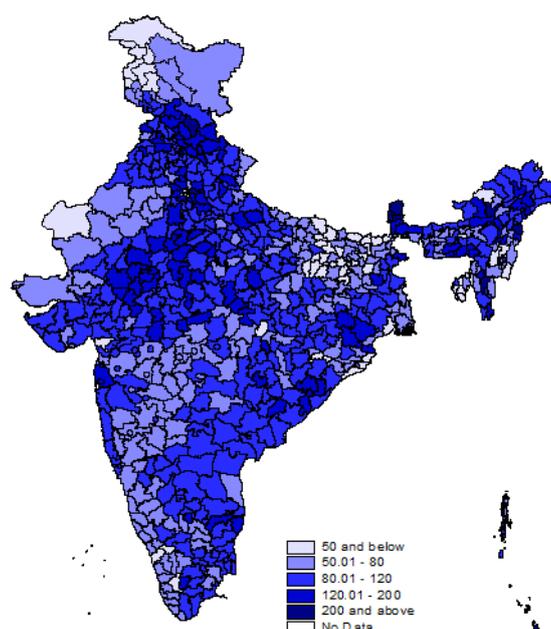


The age-and sex-wise analysis reveals that 74% of the new sputum smear positive cases in males and 78% in females are concentrated in the most productive age group of 15-54 years, with socio-

economic consequences for their affected families and the country as a whole. The most common sites of extra-pulmonary TB are the lymph nodes, pleura and meninges, as revealed by data available on Nikshay.

The large variation in notification rates reveals diversity in disease burden and/or efficiency of case finding between different districts of India (Figure 5). Notification rates are generally lower in the west and higher in the north, northeast and south, but with large variations within the regions of the country as well.

**Figure 5: Map of notification rates (per 100,000) by district, India 2014.** *Source:*



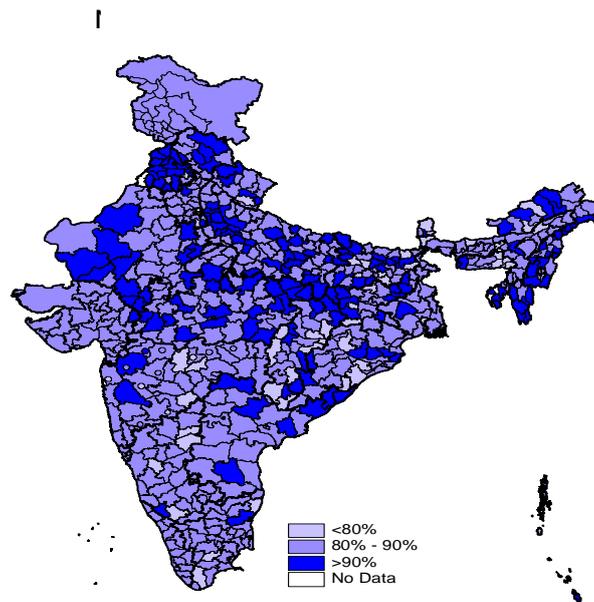
### *ii. Mandatory notification of cases*

The Government of India declared TB as a notifiable disease through a Gazette notification dated 7th May 2012. All public and private health providers are now required to notify TB cases diagnosed and/or treated by them to the District nodal officers. This is an ambitious and desirable initiative which is intended not only to improve epidemiological surveillance but also to extend the range of services available to patients regardless of whether they are registered under the public sector or treated in the private sector. These services are listed in the STCI. The RNTCP has developed a guide for notification which enables cases to be notified through email, mobile application or paper based records. The number of health facilities that have registered for notification has been growing steadily, as have the cases notified by the private sector.

### *iii. Treatment success*

Among all cases registered under RNTCP in the country, treatment success rates of about 85% in new cases (Figure 6) and 75% among retreatment cases have been consistently recorded.

**Figure 6. Map showing treatment success rates among new sputum smear positive cases of pulmonary TB registered in 2013, by district.** *Source:*



#### *iv. Evaluation*

A well-established and structured mechanism for state and central level internal evaluations is operational. In addition, regular external evaluations, including Joint Monitoring Missions, and Green Light Committee reviews are regularly conducted.

#### *v. Trends in disease burden*

Data on recent trends in prevalence, available from community-based surveys, reveal a decline in the prevalence of TB. In Thiruvallur, there was an overall decline of 36% in the prevalence of pulmonary TB in adults from the first survey in 1999-2000 following the introduction of RNTCP to the fourth survey in 2006-2008. However, the latter suggested a somewhat higher prevalence than the preceding survey in 2004-2006. In Wardha, two surveys carried out in 1986 and 2008 showed a decline of 61% in prevalence of TB. In rural Bangalore, the two surveys carried out in 1975 and 2008 observed a decline of 56%. It could be assumed that these declines in Wardha and rural Bangalore occurred after the implementation of the RNTCP in these districts from 2001 onwards, since several serial surveys in different parts of the country during the pre-RNTCP era had not shown any declining trend. Similar declining trends in the rates of transmission of infection at 4-6% per year were observed during the two rounds of national level tuberculin surveys in 2000-03 and 2009-10 respectively, as well as during repeat tuberculin surveys in selected districts.

According to the Global Burden of Disease study, TB mortality has been declining in the country at the rate of 3.5% per year since 1990.

An interpretation of the stable notification rates of smear positive cases per 100,000 population, while RNTCP efforts in case detection have increased, could be that this is a sign of decreasing incidence.

## c) Constraints

### i. *Routine surveillance*

The existing surveillance system still only counts patients in the public sector, and ignores initial default and referrals for treatment that never make it to registration. These losses of patients amount to about 100,000 smear-positive patients per year. Notification from private providers, as is standard practice worldwide, has been proposed but not implemented.

Currently, there is limited capacity at the local level for optimal use of the Nikshay system for public health action and for individual patient management. In addition, limited internet access in certain areas hinders timely case based electronic data entry. There is also the dual burden on the programme personnel of paper based as well as electronic data entry of individual patient records. No timeline or plan for transition from aggregate to case-based reporting was available.

The JMM observed delayed data entry and incomplete records. There were gaps between the reported and validated outcomes. There is a lack of monitoring on the follow up actions as recommended in the feedback on Performance Reports.

### ii. *Low rates of notification of private patients*

Even though the number of cases notified from the private sector has shown an increasing trend, only a small proportion of private providers participate in notification, and only a modest number of TB patients are notified currently. Notification of a case is not linked to any clear acknowledgement, services for patients, or follow-up action by the public sector; accordingly, private providers see little value in participation. Non-participation in notification has no adverse consequences for providers.

### iii. *Poor treatment success*

Though the treatment success rates among new cases are satisfactory at the national level, many districts report poorer success rates (Fig 6). The default and death rates among retreatment cases are unacceptably high. For the cohort of retreatment cases registered under the program in the entire country during 2013, 11% were lost to follow-up and 7% died during the course of treatment. The high rate of relapse among all reported incident cases in each of the States is another cause of concern.

### iv. *Evaluation*

In general, the response to recommendations of the state and central level evaluations was unsatisfactory, especially with respect to the pace of implementation of the suggested measures.

### v. *Estimating disease burden and diverse TB epidemiology*

#### 1. **Incidence**

The current estimates of incidence rely on the extent of under-reporting assumed at 40% based on expert opinion. However, private drug sales data suggest that a larger proportion of TB cases may be treated by private providers. While it is unknown how many of these cases were over-diagnosed, there are concerns that the true incidence is higher than has been estimated previously.

#### 2. **TB mortality**

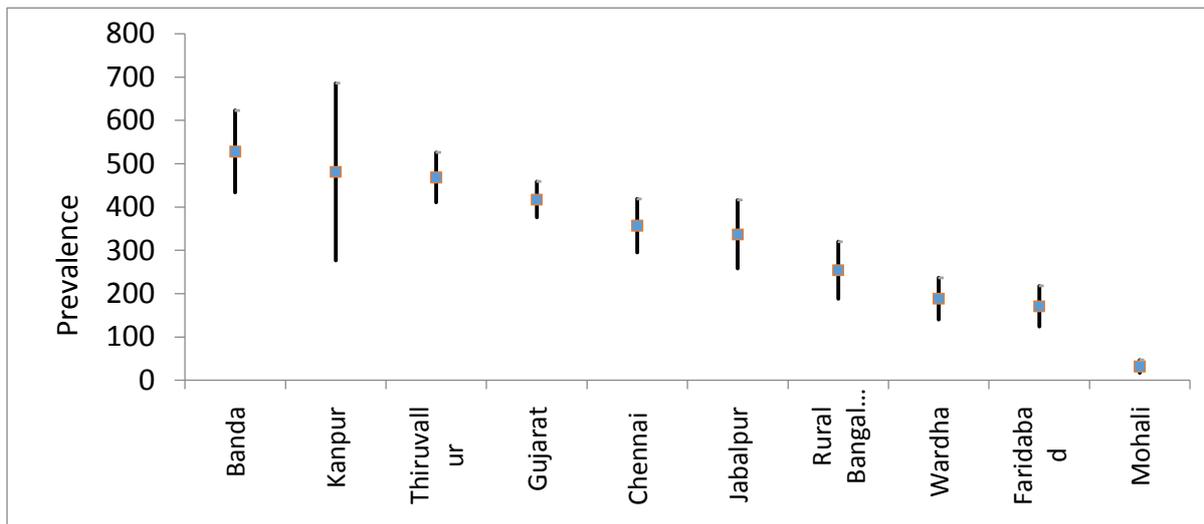
There is no complete reporting of the causes of death in India. Estimates have to rely on a subset of mostly urban vital registration deaths that have been medically certified and on verbal autopsy data from the Sample Registration System supplemented by isolated verbal autopsy studies. Less than 20% of deaths registered with civil registration, or less than 15% of the total deaths, have a medically

certified cause of death. This poses a risk of bias towards underestimation of TB deaths as medical certification is less likely in the poor who are most likely to die from TB. Validation studies of verbal autopsy (VA) have shown that they capture not more than 40-60% of true TB deaths. As the specificity is estimated to range between 95% and 98%, in India the estimated fraction of all deaths that is due to TB may be close to the true rate as false negative and false positive cases may cancel each other out.

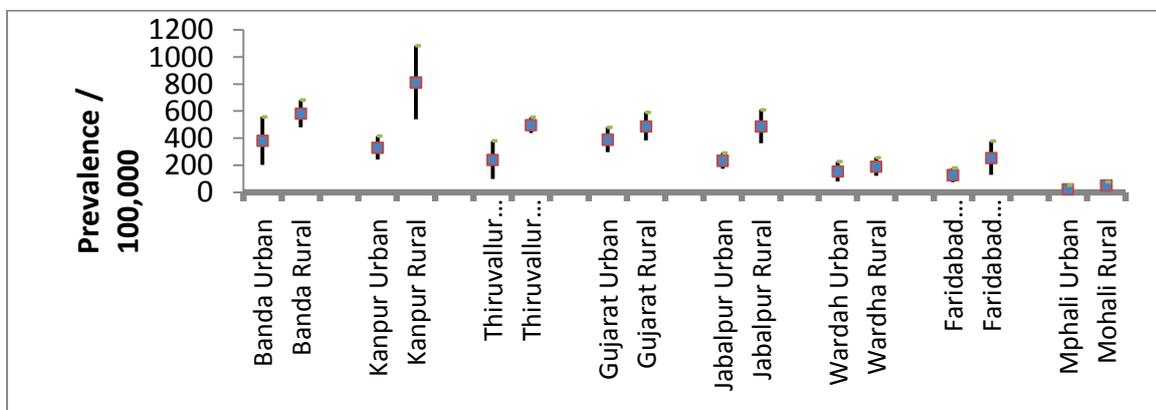
### 3. Prevalence

Sub-national prevalence surveys have revealed wide heterogeneity in the prevalence of TB across different districts (Figure 7). Another consistent and notable finding is the higher prevalence in rural compared to the urban areas (Figure 8), and higher prevalence in men compared to women. A limited number of surveys in tribal areas also observed a higher prevalence. Therefore, a single national level estimate is clearly not adequate to accurately describe the burden of TB across the country.

**Figure 7. Estimated prevalence per 100,000 population of bacteriologically positive pulmonary TB across different survey sites in India during 2008-2011.** *Source:*



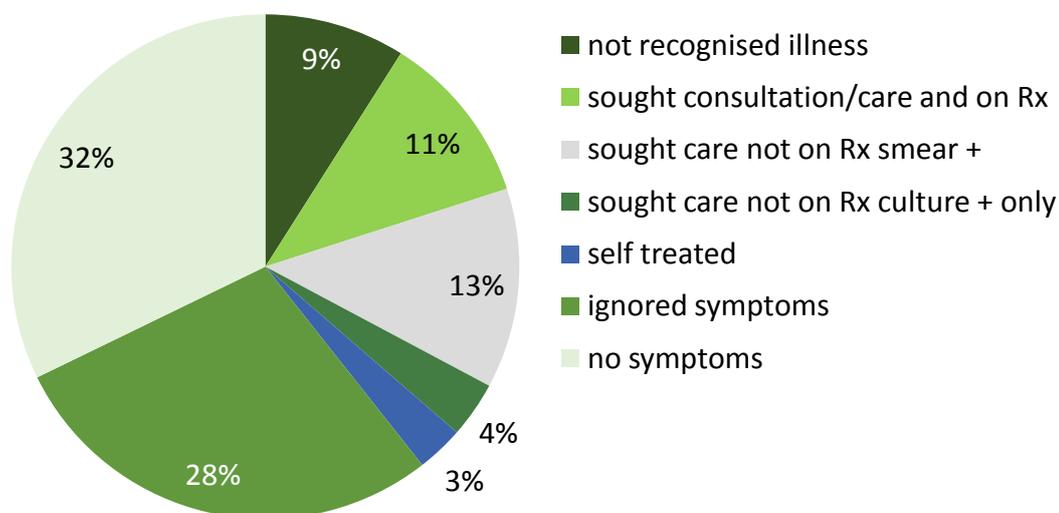
**Figure 8. Estimated prevalence of bacteriologically positive pulmonary TB by sex, across different survey sites in India during 2008-2011.** *Source:*



In the only state-wide prevalence survey in Gujarat, only 17% of bacteriologically positive cases were currently receiving TB treatment, but 31% had received treatment in the past, mostly within a few years of the time of survey. A third of the cases had no symptoms and 40% had ignored the symptoms or not recognized it as an illness (Figure 9). While there are legitimate concerns about the accuracy of reporting of symptoms, durations and treatments sought, these findings raise a number of concerns:

- The cure and success rates reported in RNTCP services may be overstated, given the large proportion of bacteriologically positive prevalent cases with a history of recent treatment
- Large numbers of people are infectious and transmitting disease in the community and thus maintain a steady stream of new cases to maintain the constant rates seen in the notification data
- The majority of bacteriologically positive people in the community either had no symptoms (yet) or did not recognize their symptoms as indicative of a serious illness requiring treatment. This suggests that the awareness of TB and its symptoms is low in the community. It also suggests that the duration of being infectious before people access treatment is long and that there may be a sizeable proportion of cases who never start treatment.

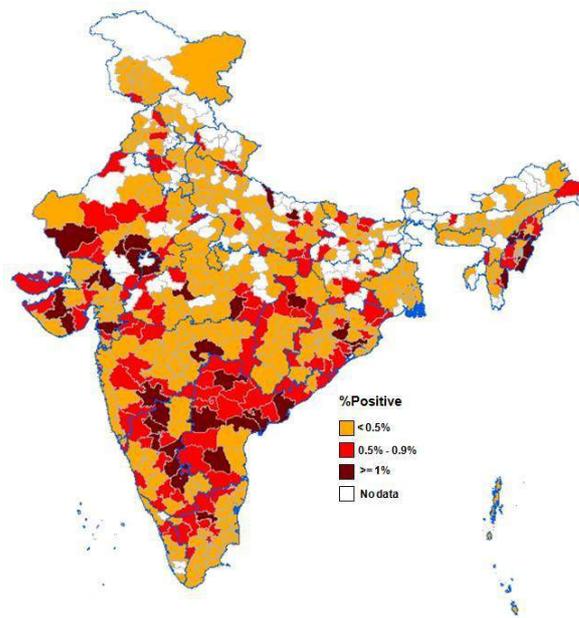
**Figure 9. Bacteriologically positive cases by treatment seeking behaviour, Gujarat 2011 (n=335). Source:**



#### 4. TB and HIV

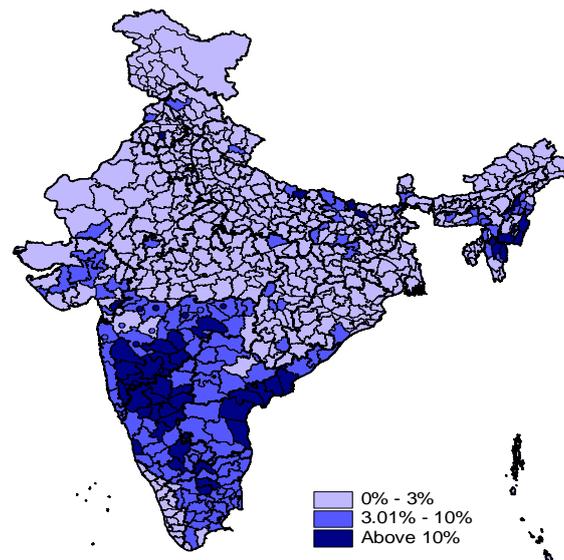
There is large variation in the prevalence of HIV sero-positivity in the general population as revealed by HIV testing among ante-natal patients (Figure 10).

**Figure 10. Map of HIV sero-positivity rates among ante-natal patients by district in 2010-11.**



The proportion of notified TB patients tested for HIV varies widely in different parts of the country. Among the cases tested in 2014, HIV sero-positivity rates varied between 0 and 45% across different districts (Figure 11). The districts of Bagalkot, Bijapur, Belgaum in North Karnataka and Sangli, Satara and Solapur in Southern Maharashtra had the highest burden of HIV among TB patients. In general, HIV levels are higher in Southern India and TB rates are higher in Northern India.

**Figure 11. Map of HIV sero-positivity rates among tested TB patients by district in 2013.**



## 5. MDR-TB

MDR-TB notification rates are very high in some areas, including Sikkim (340 per million), Mumbai (220 per million), Arunachal Pradesh (94 per million) and Delhi (84 per million) compared to the national average of 27 per million population. On the other hand, MDR rates are very low in areas such as Puducherry (14 per million) and Tamil Nadu (21 per million) even with increasing HIV testing among TB cases.

### 6. Childhood TB

Almost 40% of India's population is children under 15 years of age. An estimated 550,000 children become ill with TB each year and an estimated 80,000 children die of TB every excluding those children with HIV and TB<sup>3</sup>. Pulmonary TB still forms the largest proportion of the total TB cases among children, although children suffer the most from extra-pulmonary forms of TB compared to all other age groups.

Childhood TB in India is estimated to be 10.2%<sup>2</sup> of the total adult incidence but only 6% of the total cases reported to the RNTCP is children and this low level of case finding has remained flat for the last 9 years (Figure 12). The percentage of cases found in the private sector is closer to the expected proportion of child TB cases (Figure 2). However, although there is a large part of the private sector that deals with children with TB, most private practitioners do not notify cases to the program.

Figure 12. Number and proportion of childhood cases of TB, 2006-2014

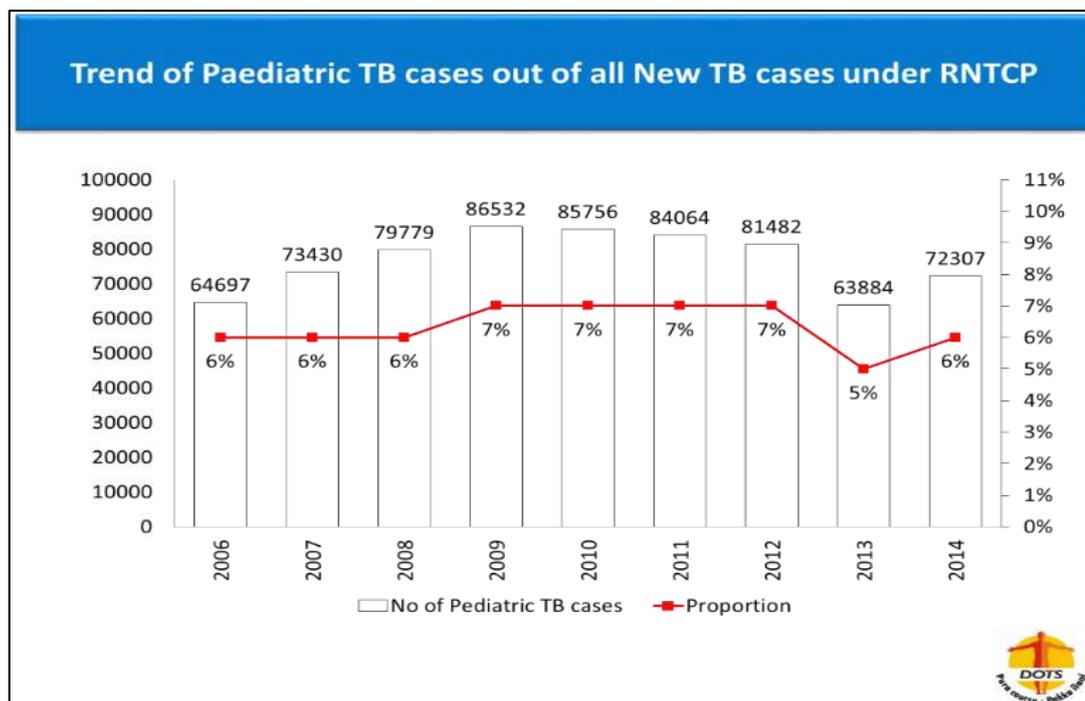
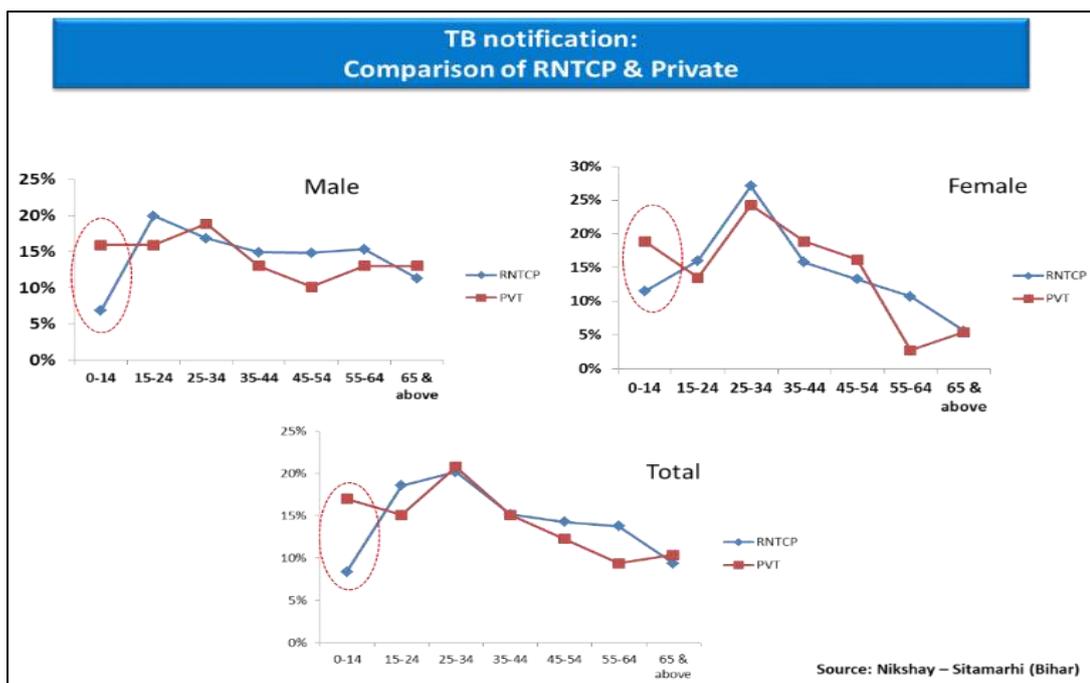


Figure 13.

<sup>3</sup> WHO Tuberculosis Report 2014

<sup>2</sup>Nelson LJ, Wells CD. Global epidemiology of childhood tuberculosis. Int J Tuberc Lung Dis 2004; 8: 636-47



### 7. Risk factors for TB

Poverty and other socio-economic factors, tobacco smoking, excessive alcohol intake, diabetes, under-nutrition, indoor/outdoor air pollution and occupational lung diseases (such as silicosis and coal worker's pneumoconiosis) are known risk factors for TB. The only quantification of the size of the contribution of these risk factors to the burden of TB in India comes from the Global Burden of Disease study which has quantified the contribution of tobacco, alcohol diabetes and pre-diabetes to the TB burden in India: 4%, 11% and 11%, respectively for the year 2010. No estimates are as yet available for the contribution of socio-economic factors, under-nutrition, occupational lung disease or indoor/outdoor air pollution.

#### d) Recommendations

##### 1. Urgently improve routine TB surveillance and monitoring

RNTCP's historical surveillance system has been adequate to efficiently operate and monitor public sector TB diagnostic and treatment services, but inadequate to meet the needs of TB surveillance in India. India's National Strategic Plan articulates a need to transition to notification at diagnosis, from public and private providers alike, and this should be pursued vigorously. Critical to improving surveillance is accelerated development of the user-friendly e-Nikshay system, which has been inexplicably underfunded and hence underdeveloped. This development should include an M&E framework to monitor and track access to, and delivery of, patient centred support and social protection, to TB patients

Deployment of strengthened surveillance systems should be accompanied by capacity building at the state level for timely performance review, identification of hotspots for TB, DR-TB and TB-HIV. Efficient use of the information for patient management will enhance TB control. It is also recommended to set a firm timetable and action plan to phase out the paper-based recording and EPI-CENTRE based aggregated reporting.

Deployment of portable digital devices to field staff working with the TB programme will enable real-time data entry and access, facilitate patient tracking when dropouts and patient transitions

inevitably occur, and lead to better program and patient management. When linked with geographic information for each patient, it will enable identification of transmission hot spots and vulnerable populations, and enabling targeted interventions to disrupt transmission chains and protect most-affected communities.

## **2. Improve notification of TB patients -diagnosed and managed by private providers**

Notification of TB patients diagnosed and treated by private providers is absolutely essential for improved TB control in India. Notification is the gateway to services and access for private patients to quality diagnosis, counselling, HIV testing, treatment adherence support, and social support services. Effective notification of TB patients treated by private providers will also enable dramatically improved burden estimation and impact assessment. Effective notification will require strengthening both enforcement, encouragement, and service quality. The existing notification order is celebrated but toothless, and requires legal backing. The key will be to engage private patients in these services that are successfully being provided by the RNCTP in a way that does not undermine the provider and require the patient to give up their choice for private treatment, but still offers a genuine value proposition for the provider and patient alike. A number of pilot projects (Mehsana, Mumbai and Patna) have shown that effective private provider engagement is possible at scale, can be facilitated by services like contact centres, and leads to a large increase in notification of private patients.

## **3. Improve TB burden estimates.**

Robust estimates of TB incidence, prevalence and mortality trends at the state level are absolutely necessary, not only to inform a more effective health system response to control TB in India, but also to help States for the first time to ‘know their epidemic’, and guide States to develop effective interventions and track the impact. The formation of an “India TB Estimation Group” is recommended, consisting of national and international experts. This group should facilitate development of a comprehensive information system framework related to TB that would include utilization of data from the following complementary sources:

- TB notification system – The e-Nikshay TB notification system has great potential in improving the understanding of the trends in new TB cases.
- Inventory studies – Such studies need to be strategically planned as they can greatly help to improve the assumptions related to the extent of under-diagnosis and under-reporting of TB, using empirical data.
- Prevalence surveys – a national level survey may not be useful for concerted actions at the state level. Prevalence surveys could be planned for major states initially. Global standard epidemiological methods and modern diagnostic tools should be used in these surveys.
- Cause of death data sources – Data from verbal autopsy studies on causes of death done as part of the Sample Registration System and from the Medically Certified Cause of Death system managed by the Office of the Registrar General of India need to be optimally utilized. In addition further strategic verbal autopsy studies using modern methods need to be planned to get a better estimation of mortality due to TB at the state level.

The above sources are complementary to one another in understanding the TB burden estimates, and the data from these sources needs to be brought together perhaps under the proposed “India TB Estimation Group” using modelling techniques for consensus estimates of incidence, prevalence

and mortality, nationally and sub-nationally, that take into account the limitations of each data source.

#### **4. *Quantifying risk factors for TB***

It is recommended that reporting of the proportion of the TB burden that is caused by major risk factors becomes a routine monitoring activity of the RNTCP.

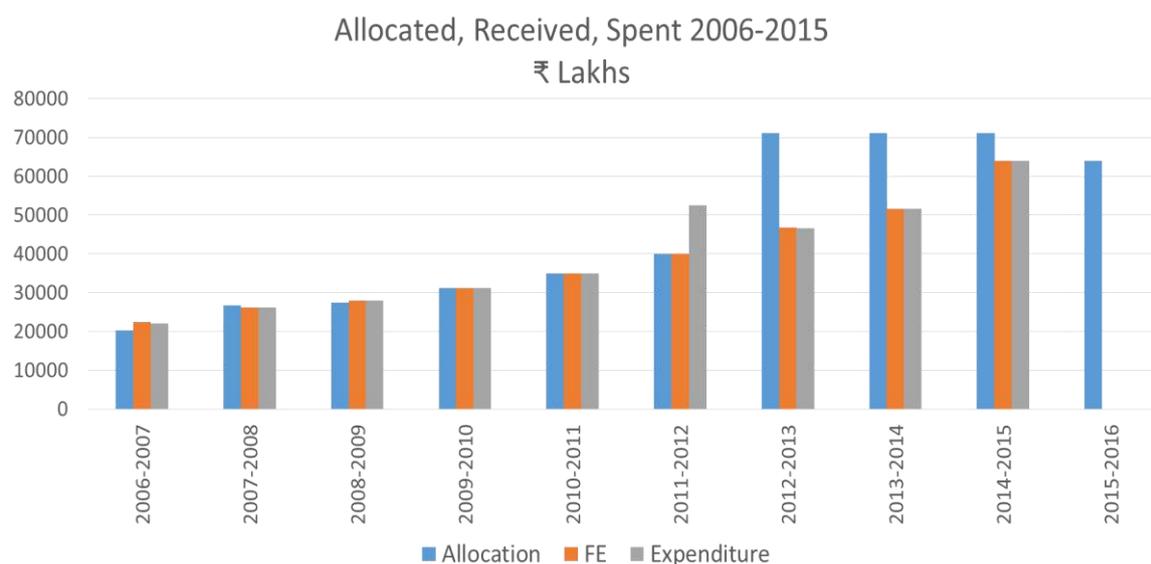
### 3. Financing

The ambitious goals of the NSP 2012-2017 required a corresponding expansion of financial resources, equivalent to tripling the expenditure of the prior plan.

#### a) Achievements

During the first three years of NSP implementation, the RNTCP has demonstrated high financial absorption capacity. In other words, whatever has been allocated has been spent. During this period, RNTCP has managed to disburse (spend and release to states) all of the Rs.1624/- crores received (Figure 14).

**Figure 14. Funds allocated to the RNTCP, and funds actually received (final estimates (FE)) and spent by financial year, 2006-7 to 2014-15.**Source:



Integration of RNTCP with the National Health Mission has presented two major advantages. On the one hand, States are now required to contribute 25% of the required RNTCP budget –and in some states like Gujarat this has gone up to 31%. On the other, access to the larger pool of NHM resources has allowed states to smooth the flow of funds to districts through a mechanism by which NHM makes short-term loans to RNTCP to bridge any time gaps in receipt of resources from the Centre.

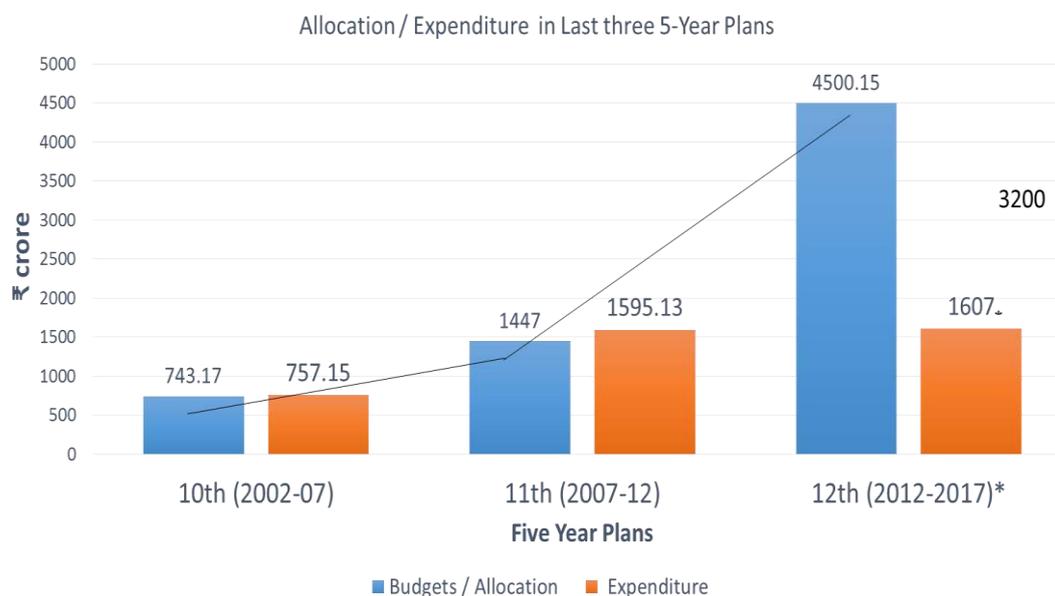
In at least one estimation, every rupee invested in TB control has a one-hundred-fold economic return on investment.

#### b) Challenges

The allocation of funds has not matched the ambitious expenditure increase in the NSP. While RNTCP expenditure has increased 27% since 2012, there is a growing gap between the allocation of funds and the minimum investment required to reach the goals of the Plan. If this trend continues, final expenditure on the Plan would reach Rs. 3,000 crores, or two thirds of the Rs. 4,500 crores that

the NSP established as the minimum required (Figure 15). As a direct result, while bold policies are in place, many planned activities have not been implemented, and anticipated increases in case finding have not occurred.

**Figure 15. Allocation and expenditure for the three 5 year plans for TB control since 2002.** *Source:*



In addition to initial allocations falling short of what is required, mid-year reductions (the difference between budget allocation and final estimate) impose restrictive budget ceilings and constrain the ability of RNTCP to spend, resulting in significant underinvestment in TB.

There have also been delays in release of funds to Societies hampering crucial activities and expansion of implementation; delays in submission of SOEs, Audited Accounts and other reports by Societies due to manual accounting; late submission of Consignee Receipts and delays in advance adjustments affecting reimbursement from funding agencies. Implementation of e-transfers has been uneven due to capacity shortfalls at state and district levels and desk financial reviews have not happened because data and reports were not available on line.

Until the financial year 2013-14, funds to NHM Societies were transferred directly from the Central Government Consolidated Fund. Restructuring of this system and routing of Financial Assistance to States through Consolidated Funds of the States, has resulted at present in grants to NHM Societies being released through State's Treasuries. The problem is that this new system has not worked as intended and actual releases from Treasury to Societies are taking about 4-8 months instead of 15 days. NHM Societies, who are the real implementers, are deprived of the needed funds, resulting in disruption of crucial activities and delays in remuneration of staff deployed for RNTCP work.

The RNTCP at Central Level, and State Societies at State and District levels, maintain books of accounts and records manually, and report to Central Level through scanned copies via e-mail or hard copies through post or courier. Manual accounting and reporting delay the processes and

funding agencies are not happy verifying the expenditures claimed by working through books of accounts and records.

The overall responsibility to run the Programme in States lies with the STO, and he/she is expected to be pro-active and manage all the programmatic, administrative, monitoring and evaluation and financial affairs. To maintain a smooth flow of funds for activities, he/she has to liaise with the Centre as well as all the levels in the State. The RNTCP has given certain financial powers to STOs/DTOs for proper and timely implementation of the Programme. Of late, a few of the States, on their own behalf, have withdrawn those powers, and have not sanctioned any imprest or advances to meet day to day expenditure. This in turn has significant negative impact on the implementation of the Programme.

Through the Annual Action Plan process, the amount of the State's share for TB activities is discussed, finalized and shared with respective States. However, the documents sent by States reveal that:

- Not all the State's share for TB activities is transferred to the Programme;
- If transferred, it often varies from the percentage approved in the Action Plan;
- If transferred, it often remains in NHM accounts;
- Timing of the transfer of the State's share varies from State to State.

Some of the posts of Accounts Officers/Accountants have been vacant for a long time. Further, many officers in post have not received any training for the last few years and are not well versed in the Financial Management Guidelines and Procurement Guidelines issued by the Ministry. Some staff presently handling accounts do not possess accounting qualifications or experience in accounting.

### c) Recommendations

#### **1. Increase budget allocations according to NSP priorities**

It is strongly recommended that the remaining part of the NSP be fully funded, allowing the RNTCP to spend Rs. 1500 crores per year to achieve the goals of the Plan and thus save a further 2.5 lakh lives annually. The MOHFW should also streamline procurement and decision-making processes to ensure it spends the external grants and credits on time, enabling additional international funding in the future.

#### **2. Mobilize additional funding to meet the goals of End TB Strategy**

Additional investment of at least Rs. 750 crores annually will be required to reach the ambitious goals of the End TB strategy. This will enable implementation of the revised diagnostic algorithm for early and intensified case finding, and introduction of a daily regimen to prevent DR-TB. Many children, PLHIV with TB, and many people with MDR-TB would be the immediate beneficiaries. The additional investment would also enable the introduction of new drugs for treating MDR-TB and support to the ambitions of the "TB Free India" 2020 Vision. The full cost estimation of these additional investments should be undertaken immediately.

#### **3. Streamline Fund Flow**

In view of the inordinate delays described above, a new procedure for release of grants through the Treasury route is urgently needed. The States, in consultation with their Finance

Departments,should draw up a plan, with clear timelines, for release of grants from the Treasury to Societies.

#### **4. Develop e-accountingthrough e-Nikshay Project Management**

The JMM recommends that the RNTCP develop its own computerized financial management system networked at Central, State and Society levels on web based technology (e-Nikshay). This will facilitate book entries and accounting, updating, consolidation and report generation at central level. A web based accounting package will augment efficiency and accuracy at all levels and also speed up accounting and reporting processes, which,in turn, will help timely releaseof funds, and verification of accounting actions at any time.

#### **5. Make full use of e-payments and transfers**

Most of the States have introduced e-payment of salaries to Programme staff; however, e-transfer of other payments is not usually done. States should immediately shift to e-transfer in all cases.

#### **6. Urgently delegate all appropriate project management and financial powers to STOs and DTOs**

**7. States should transfer the approved share for TB activities, to the NHM Societies, preferably in two instalments, one in the first quarter and the second immediately after audit of accounts. This should also serve to fill the gaps wherever centre funding is delayed.**

**8.Finance Units in States and districts should bestrengthened by immediate training of the Finance functionaries and filling of the vacant posts.**

## 4. Social protection<sup>4</sup> and support for patients and families affected by TB

### a) Achievements

At the World Health Assembly in May 2014, India endorsed the World Health Organization's END TB Strategy that sets the target of zero catastrophic costs for TB-affected families by 2020. WHO set the target because TB can impose such severe costs on patients and their families that outcomes are worse, transmission is aggravated, and social and economic impacts can be devastating. Furthermore, financial burdens can inhibit access to care.

However, India's constitution recognizes the right to social well-being, health and social assistance. The Government of India has the building blocks of a 'social protection floor' – a minimum array of social protection measures that all citizens need to survive. The total expenditure by the government of India on six of the major social protection related sectors (elementary education, health and family welfare, labour and labour welfare, social security and welfare, and rural development) increased from 1.06% of GDP in 1995-96 to 1.75% of GDP in 2010-11. The states spend almost twice as much as the central government on these sectors. Some of the social security and welfare schemes that likely have direct relevance to reducing the social and economic impact of TB are listed in Table 1.

The Government's current strong focus on improving e-Governance including for transmitting data and sharing data across elements of governments via rapid, secure online platforms and, even more importantly, roll-out of the unique identification (UID) card for persons living below the poverty line (BPL) and initiation of e-transfer and e-banking systems for provision of benefits to individuals, provides a powerful opportunity. In addition, the RNTCP's electronic reporting and surveillance platform (Nikshay) includes the potential to link with other government platforms.

India has a rich history of community support for those affected by TB. Many of the TB sanatoria established in the last century in the country were endowed by local landlords and princes and community owned lands were often set aside to treat and rehabilitate TB patients. The JMM observed that informal social assistance by local societies, NGOs and community members to those affected by TB patients still exists, however, there was wide variability of what was provided, how much and to whom.

The NSP prioritised equity and universal access in the delivery of TB services and articulated a vision of supporting socially and clinically vulnerable population through a social action plan (SAP) which included access to financial assistance, benefits and support. The SAP included specified action for tribal populations, malnourished children, women, PLHIV, people with co-morbidities such as diabetes, geriatric populations, tobacco users, prisoners and people in urban slums and workplace settings (including those occupationally at risk for TB). The RNTCP has adopted the 'Patient Charter'<sup>5</sup> that outlines rights to care, information, and security among other things. TB-specific services are available free of charge in the public sector. As recommended by JMM 2012 (2.2), the RNTCP operational guidelines have been partially revised to include support for transport for drug-resistant and TB/HIV patients.

The RNTCP has also initiated discussion with the Rashtriya Suraksha Bima Yojana (RSBY, a national insurance mechanism) to elaborate a package to support coverage of TB services. A recent experience in one state showed successful results for reimbursement for patients treated in public and private sectors.

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<sup>4</sup>Social protection is defined as access to essential social services and social transfers, in cash and in kind, paid to the poor and vulnerable to improve their food security and nutrition. It provides a minimum income security, as well as income replacement and social support, in the event of illness

<sup>5</sup>Patients' Charter for Tuberculosis Care © 2006 World Care Council / Conseil Mondial de Soins  
[www.worldcarecouncil.org/](http://www.worldcarecouncil.org/)

The Concept Note from India to the Global Fund under review (at the time of writing) includes funding to NGOs to facilitate access to social support by TB patients and affected families.

Provision of patient education and counselling is already program policy and training modules and materials have already been developed to assist this process. Treatment support is increasingly decentralised to the community with ASHAs and AWWs:

The RNTCP supports operational research on patient support and nutrition and there are several published studies estimating burden, costs and operational impact.

**Table 1: Illustrative list of social schemes and benefits relevant or potentially relevant for TB patients. The agencies which operate these schemes at the central level are Ministry of Social Justice and Empowerment, Ministry of Labour, Ministry of Health and Family Welfare Ministry of Consumer Affairs, Food and public distribution, Ministry of Women and Child development, Ministry of Rural Development, Ministry of Textiles, etc. Source:**

<b>A) Nutritional Support</b> (not solely for TB patients)	General : Antyodaya Anna Yojana (AAY), Food security Act 2013 implemented in 11 states in India, Integrated Child Development Services Scheme (ICDS), Mid-day meal scheme.
<b>B) Financial support:</b>	Departments of Social Welfare in certain states provide financial assistance to TB patients.
<b>C) Income Generation Activity (including Microfinance)</b>	Swarnajayanti Gram Swarozgar Yojana (SGSY), Mahatma Gandhi National Rural Employment Guarantee Scheme (MGNREGS)
<b>D) Health Insurance Schemes</b>	Rashtriya Swasthya Bima Yojana (RSBY) Employees State Insurance Corporation
<b>E) Benefits in case of death</b>	National Family Benefit Scheme : applicable to TB patients/ TB/HIV etc.  Compensation to silicosis/silico-tuberculosis patients ( e.g. National Human Rights Commission fixed Rs. 3 lacs as compensation in Rajasthan)  Group Life Insurance scheme for low income groups: Jan Shree Bima Yojana
<b>F) Benefits in case of disability</b>	In case of certified disability of >40% persons are eligible for low interest loans under National Handicapped Finance Development Corporation.
<b>G) Schemes for specific occupational groups</b>	Eg. Handloom Weavers Comprehensive Welfare Scheme
<b>H) Educational Support</b>	Sarva Siksha Abhiyan (SSA) Indira Gandhi Matritva Sahyog Yojana

## b) Challenges

Despite economic growth over more than six decades, poverty and deprivation continue to affect large numbers of people across India, and an estimated 80 per cent of India's population remains without access to adequate social protection.<sup>6</sup> Food security is fundamental to social protection. Malnutrition, which is endemic in India, is likely a major driver of the country's enormous TB epidemic. Worldwide, nutrition is estimated to be the top risk factor for tuberculosis disease. Studies have also documented serious levels of under-nutrition in Indian patients with active TB which increase the risk of mortality and are associated with poorer treatment results<sup>7</sup>.

There is a general lack of awareness of the scope and severity of the needs TB patients and communities have, and the barriers that patients face in accessing and adhering to therapy. There is an evidence base from research and field experiences, but it needs collation and further analysis. It does include knowledge of the prevalence of catastrophic costs incurred by patients and families affected by TB, background malnutrition and food insecurity, loss of livelihood, social vulnerability, stigma and poverty.

There is no specific policy or guidance for program officers and others which outlines the social support available to all TB patients (not just those with DR-TB), promotes equity in accessing services and addresses the elimination of catastrophic costs for TB patients and their families. Similarly with nutritional assessment and support, despite the availability of policy recommendations from WHO<sup>8</sup>. As a result, provision of social support and social assistance is ad-hoc and not systematic. There are no management directives, no clear standardized delivery schemes, no information on who is eligible for what, and no clear monitoring and evaluation of what patients actually get.

Program officers, health care providers, TB patients and communities are generally not aware of the many existing schemes and benefits of the Government of India that patients and families can avail (Table 1). Ministries and sectors managing these schemes and benefits are also not aware that TB patients and families are eligible for them.

Access to these schemes is often cumbersome, requiring TB patients, affected families and vulnerable communities to prove their eligibility with valid documentation, which often translates into failure or delays in accessing the benefits, and multiple visits to various government offices. There is usually no liaison to coordinate and facilitate access.

The specific needs for social protection and social assistance of a wide range of key populations affected by TB, including socially and economically marginalized groups, are not explicitly addressed in the SAP, beyond attention to some groups, such as tribal populations. Migrants and workers in specific industries, for example, face serious risks of TB and yet lack legal access to services or lack of compensation for workplace-related tuberculosis and loss of employment. Other groups may face stigmatization or loss of housing and other services because of TB. They, too, lack redress. See also the section on vulnerable populations.

Patient education and counselling is often done superficially, perhaps by someone with little training, and doctors and other medical professionals do not provide any leadership or models in counselling TB patients and their families. Health care staff are often inadequately trained and do not receive any support supervision to learn and improve their technique. There is too much dependence by the TB program on contractual staff for performance of core functions with regular health staff not taking responsibility for counselling of TB patients.

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<sup>6</sup>A social protection floor for India / Ravi S. Srivastava; International Labour Office, ILO DWT for South Asia and ILO Country Office for India - New Delhi: ILO, 2013

<sup>7</sup>Lonnoth xxx

<sup>8</sup>WHO. Guideline: Nutritional care and support for patients with tuberculosis, Geneva: WHO, 2013

### c) Recommendations

**1. In line with the RNTCP's NSP, and the WHO End TB Strategy, the MoHFW must rapidly ensure eligibility, expansion, and systematized economic and social support to TB patients and affected families.** To achieve this the JMM recommends that the RNTCP takes the lead across the Ministry of Health and across Government to build and expand on the social protection opportunities that already exist. It should collaborate, integrate and systematize the finance, design, delivery, monitoring and evaluation of TB patient support provided directly by TB services and, more importantly for sustainability, support that is accessible through the larger platforms noted above, especially for patients living under the poverty line and/or facing other vulnerabilities.

**2. The RNTCP must develop dedicated capacity to coordinate across all relevant departments and agencies<sup>9</sup> to identify already existing benefits and schemes provided by the Government of India, and ensure eligibility of TB patients, affected families and their communities to these benefits and schemes.**

**3. The RNTCP should advocate for social support to be delivered to patients or their families through a single window** in the health services to enhance synergy and avoid duplication. It should make use of Nikshay to ensure rigorous monitoring of the process, and to link to the larger initiatives of the Government of India including the Prime Minister's Jan Dhan Yojana, e-governance, Swachh Bharat, National Health Assurance Mission and RSBY to ensure patient support and patient centred care for all TB patients in the country.

**4. The RNTCP should develop national policy and guidance on implementation for TB and nutrition.** In doing so, it should work with relevant nutrition experts and counterpart authorities. This is justified as a priority, given the documented evidence on the prominence of malnutrition as a risk factor for tuberculosis, the severity of under-nutrition documented in Indian patients, and recent WHO recommendations on nutrition care and support for TB patients. To get this going, the RNTCP should pursue a baseline review and consultation process in the coming year, which should include the following:

- a) Comprehensive mapping of social support schemes and benefits currently available centrally, in States, NGOs, municipalities, Panchayati Raj, through taxation, CSR, etc; include lessons learned from HIV/AIDS program and other programs;
- b) Contract legal and administrative review of available entitlements for, and eligibility of, TB patients and their families including procedures to access them;
- c) Map current roles and responsibilities within and across Ministries and beyond Government in providing social support benefits or facilitating access to them;
- d) Initiate a representative survey on TB patient costs in pilot States<sup>10</sup>;
- e) Develop potential approaches to cross-review beneficiary databases across TB and social benefit programs to determine any overlapping coverage and the volume of clients "missed".
- f) Subsequent to the baseline review, and additional to recommendations 1-4 above, the JMM also recommends that the RNTCP:
  - i. Initiate discussions with NITI AAYOG and Ministries responsible for specific benefits to highlight the unmet needs of TB patients and affected families and make the case for their eligibility for these benefits and schemes, and necessary budgetary allocations;
  - ii. Organize expert consultations to guide the development of a policy on nutrition and TB;
  - iii. Initiate coordinated efforts to help TB patients and affected families systematically access social support and benefits and track and monitor patient centred care for all TB patients in the country;

<sup>9</sup> MoHFW departments, other relevant Ministries, State departments, district and municipal authorities, local government including Panchayati Raj, civil society, NGOs and representatives of patients and special populations

<sup>10</sup> WHO is piloting a protocol with other countries that may be useful.

- iv. Develop approaches for social support to specific vulnerable groups (eg, very poor, urban poor, rural poor, children, persons with silico-tuberculosis, specific labour groups (and their families such as in mining communities), persons with sequelae from TB illness, MDR-TB, TB-HIV, families or orphans of those who have died of TB);
- v. Prepare a compendium of best counselling guidance and materials for general health workers and for DOTS providers.

## 5. Community Engagement

### a) Achievements

The recent campaign with Amitabh Bachchan as brand ambassador launched initially in Mumbai and then nationally on WTBD 2015 has raised awareness of TB and helped reduce stigma.

An operational handbook on ACSM has been developed along with NGO schemes available for organizations to access. The central level has developed communication materials, and the team found examples of communication material on TB at the State level and in the districts.

The involvement of Accredited Social Health Activists (ASHAs), particularly in case referrals and DOT provision is very encouraging and in many places very successful. ASHAs are the first point of contact in the villages and have the trust of the community. A very committed and enthusiastic group, they support patients to complete TB treatments successfully.

### b) Constraints/Challenges

The last JMM in 2012 noted that community engagement and advocacy on TB were insufficient and limited to the areas of information, education and communication. Although conducted under the heading of "ACSM", the activities actually carried out had been restricted to communications. ACSM staff appointed almost always had a background in this area. Activities, particularly in the States, related mostly to printing information materials and hosting events on World TB day. JMM 2012 recommended disaggregating ACSM into three separate and distinct ideas: community mobilization, communication and advocacy and asked for separate strategies to be formulated for each of the three areas. There has been no progress in implementing this recommendation.

The current JMM finds that only two of the JMM 2012 recommendations have been implemented and these have had little impact on the strategic directions that were defined. The delay in renaming "ACSM" as "Community Engagement" is a missed opportunity. It could have made expectations clearer and allowed deeper understanding of the specific tasks and outcomes expected in the area of community engagement.

ACSM is plagued by being a low priority for the TB programme. RNTCP staff acknowledge that ACSM is the least priority in the basket of activities undertaken in States and districts. ACSM in almost all States receives a tiny allocation of funds in TB budgets (2%-3%) and the proportion of funds disbursed and actually spent on these activities is even smaller.

The low commitment to community engagement at all levels is of great concern. Some of this is due to lack of understanding of what community engagement entails and what needs to be done.

There is no systematic community engagement processes in place and the capacity in terms of both staff and skills is low at the state and the district levels. There is very minimal involvement of NGOs, CBOs, FBOs, CSOs and Panchayati Raj Institutions. Patient and community voices were absent. Community based DOTS provision was therefore weak and in need of more supervision. Engagement of community volunteers other than ASHAs, is missing. There was no concept of community monitoring of the TB services, which would go a long way in ensuring patient centred care.

Patient engagement was minimal. There was no outreach to patients and communities to educate and generate awareness, which would result in an increased demand for TB services. The understanding that cured patients could be our best advocates was missing. Formation of patient support groups or forums was not part of the ACSM plans. A couple of cured DR TB patients were being engaged in one or two districts to advocate for treatment adherence and completion of other

DR TB patients, but this was due to the proactive efforts of the MO at the Primary Health Care Centre rather than a systemic implementation plan in place for patient engagement.

Although communications and advocacy are supportive actions that can help increase awareness and fuel demand for services, information and communication material was limited at the district level and staff had little knowledge of what was available. There was no communication strategy that segments and addresses different groups. The quality of IEC material could be improved with attractive colourful messaging using pictures rather than heavy technical medical language. There was no community or patient involvement in the designing of the communication material.

Though the overall responsibility of Community Engagement lies with the RNTCP, Project Axshayais a Global Fund supported project which is being implemented in 374 districts (300 by The Union and 74 by World Vision India) with the objective of increasing access of vulnerable and marginalised populations to TB services through advocacy, communication and community engagement. This was not visible and falls terribly short in achieving the objective of increasing access through advocacy and community engagement in the districts visited and remains a huge missed opportunity.

### c) Recommendations

**1. The RNTCP should view Community engagement as a priority and urgently implement appropriate strategies at State and District level.** The RNTCP should engage in a systematic process of building partnerships with patient groups, community-based organizations, NGOs and other civil society organizations. This should include supporting appropriate staff at national, state and district levels to seek out such organizations and invite them to have a regular dialogue with the TB programme. Given the scarcity of organizations working with communities in TB, it also requires active outreach to organizations working in other areas of health such as HIV, MCH, PHC and NCDs as well as with vulnerable populations such as those who use drugs and alcohol. The RNTCP should actively engage these organizations to include community-based TB activities in their ongoing work, to maximize their own impact and the Programme should engage and involve them in planning and determining the course of community-based activities. The RNTCP should intentionally build the capacity to engage with communities through enhancement of budget, significantly increased human resources and establishment of mechanisms that enable collaboration with civil society organizations.

**2. Each State should develop and implement a formal strategy for Community Engagement in every state that has separate and explicit sub- strategies for engaging civil society, communication and advocacy.** *The community engagement strategy must make explicit provisions for the creation of collaborative forums for partnerships including:*

- State-level NGO coordination forums and regular meetings with STOs
- District-level NGO committees and regular meetings with DTOs
- Active outreach to NGOs working on MCH, HIV, PHC, NCD and WASH to integrate TB into their work and inclusion of such NGOs in state and district NGO committees
- Developing training materials to integrate TB into the ongoing work of community workers

*The communications sub-strategy must tailor different key messages relating to prevention, treatment, adherence and stigma. It should:*

- Define variables such as target group and choice of medium to convey the message
- Harness radio (including community radio), TV and local Cable TV for age- and sex-appropriate messaging (just as advertisers target consumers)
- Avoid terminology that stigmatizes patients – defaulter, suspect, high-risk population etc.
- Design messages that are pre-tested for user-friendliness and effectiveness, are locally relevant, and which clearly mention where persons with presumed TB may go to have their sputum tested in each district

- Adopt innovative approaches to communication such as TB messages painted on walls of school buildings, community halls, ration shops done by schoolchildren etc.
- Use all available opportunities to increase awareness amongst patients, families and communities including the involvement of schools and colleges and, in particular, use waiting areas in clinics to display videos such as “TB haarega; Desh Jeetega.”
- Develop a simple screening tool and ensure mass distribution to all doctors in the private sector as well as all chemists so that TV messages are reinforced

*The advocacy sub-strategy should ensure wider community ownership and action through:*

- Engagement of local leaders from the panchayati raj institutions, teachers, SHGs , AYUSH doctors and leaders in HIV as ambassadors of integration of TB with HIV
- Appointment of TB champions at local level
- Support for cured patients to become active in TB advocacy within their communities
- School health programmes
- Adoption of community-driven multi-stakeholder models for monitoring and evaluating TB services

**3. The RNTCP should support formation of patient groups and patient forums in every district for treatment adherence support and deliberately reach out to ensure patient voices are heard.** The RNTCP needs to establish mechanisms for this.

**4. The MoH should establish a high level sustained national campaign on TB: “TB Free India/TB Mukht Bharat” with active leadership of national, state and local governments in coordination with corporate and private sectors, NGOs, media and othersthat will aim to Reach, Treat, and Cure every TB patient in the next decade. The PM should lead it.**As part of the campaign, the RNTCP should develop a comprehensive communication and awareness-raising strategy to inform and educate TB patients, affected families, communities, health care providers and responsible program staff about the social needs of TB patients and the benefits and schemes available for them. It should advocate with ministries to increase allocations and eligibility of TB patients for these benefits and schemes including raising the priority of these needs with the Prime Minister’s Office. TB patients and their needs could also be a topic addressed by the Prime Minister in his monthly ‘Mann Ki Baath’ to the nation

## Procurement & Supply Chain Management

Background: Procurement & Supply Chain Management is one of the most critical activities of RNTCP. Ensuring reliable and an un-interrupted supply of good quality anti TB drugs and other commodities is the main objective of the supply chain management. The Procurement & Supply Chain Management Unit in Central TB Division (CTD) caters to the procurement and logistics functions at the Central level. This unit performs functions like procurement planning and monitoring, policy formulations, coordination with procurement agent, reporting and coordination with the Donors, implementation of procurement risk mitigation plan, handling day to day supply related issues and monitoring of the contracts etc. The procurement currently is being undertaken through an independent procurement agency and has been entrusted to Central Medical Services Society (CMSS), an autonomous entity under MoHFW, with a mandate to take independent decisions related to their procurement functions. The successful programme management would always rely on the effective procurement and supply chain management function in place. This is a vital activity and without which the implementation of the Programme is not possible.

### a) Achievements

1. **Availability of Anti TB Drugs:** First & Second line drugs are available all states except for a few loose drugs. However, the programme is in a position to take care of the supplies of loose drugs, too. Cap Rifabutin is now available with the programme for HIV/TB co-infection treatment and is being issued to states. Supply of Cap Rifampicin-150mg has been received at GMSDs and issued to all the states. Notification of award for Tablsoniazid-100mg & 300mg have been issued & supplies are expected by May/June-15 onwards.
2. **Procurement of Microscopes:** 2,500 LED & 1,500 Binocular Microscopes are being procured by the programme. First tranche of LED (755 NOs) & BM (500 NOs) microscopes have been issued.
3. **Procurement of CB-NAAT & Cartridges:** Cartridge based Nucleic Acid Amplification Testing machine (CB-NAAT) has been installed in 30 ART sites in 5 high-prevalence states. Further, procurement of 300 CB-NAAT machines & 7,80,000 cartridges through Global Fund is under consideration by the Ministry.
4. **Training on Supply Chain Management:** Training of Trainers of all states pertaining to supply chain & management had been done and completed by the programme during 2014.
5. **Consultancy Services:** Hiring of independent agency for ensuring quality assurance of antiTB drugs is under final stage. Similarly, process for hiring of Logistics & supply chain management agency, media agency and Technical Support Group has been initiated by the programme and is under consideration by the Ministry.

### b) Challenges/ Constraints

1. **Storage Condition:** Storage conditions are suboptimal at various levels. There are cases that Drugs are not stored as per their required storage conditions. Eg Cap Cycloserine which needs to be stored in cool temperature was stored outside the store due to inadequate space. Likewise, some injections which need to be stored under controlled conditions were not stored accordingly.
2. **Communication:** Communication gap still exists at various levels. Districts shortage of Inj. SM, RIF150, PC-13, PC-14, INH 100mg/300mg. e.g. Cap Rif available at SDS but neither supplied to districts nor DTCs were aware of Rif availability at SDS.
3. **Human Resource:** Few key positions especially DTOs & Pharmacists are vacant at various levels which are affecting the supply chain mechanism & drug logistics of states.
4. **Transport mechanism:** Transportation of drugs especially from Districts to sub-districts levels is inefficient. In some cases, drugs are being transported on motorbikes from districts to sublevels and concern person has to come back 3-4 times to collect their drugs requirement from stores.
5. **Preparation of MDR/XDR boxes:** With the increase in MDR/XDR patients, preparation of MDR/XDR boxes at State Drug Stores seems to be a big challenge within the available manpower & infrastructure at SDS. Due to shortage of manpower, MDR/XDR boxes are not being prepared at SDS and loose drugs are issued to districts.
6. **Procurement OF CBNAAT and Cartridges:** There is a significant delay in this procurement which was initiated by CTD about 2 years back.
7. **Introduction of Daily Regimen:** The programme plans to introduce daily regimen for FLDs which is expected to result in better outcomes, however, needs to be implemented in a phased manner, considering the challenges for feasibility, implementation, procurement and supply chain management.
8. **Procedural Issues:** Procedural delays at states level hampers supply chain mechanism like delay in issuing of road permits to suppliers and delay in executing Drug Transfer advice issued by Central TB Division results in loss of shelf-life of drugs.
9. **Limited capacity of the States on procurement:** The states whenever, entrusted the responsibility of undertaking procurement of drugs, find it quite challenging. Procurement of high quality anti-TB drugs at the states level, hence, needs to be restricted only in emergency situations.
10. **New Procurement agency:** A new procurement agency has been established and transition from M/s RITES to CMSS may be a challenge considering various aspects of procurement especially considering the maiden attempt of CMSS. An alternative mechanism needs to be kept as a standby arrangement if CMSS services are delayed to avoid any shortages / stockout of drugs.

## c) Recommendations

1. Introduce changes in diagnosis/treatment (e.g shift to daily regimen) in a targeted, phased manner - with consideration of (i) available stock of current products as well as (ii) supplies under the pipeline and (iii) procurement lead time required for scale up
  - a.
2. In order to maintain quality assurance, cost-effectiveness, and rational use of TB medicines:
  - a. Maintain procurement at central level as the standard practice for TB medicines. Reserve state procurement for emergency only; streamline procurement at state level through a procurement agency.  
Ensure preparation of MDR/XDR patient boxes at state level only, rather than delegating this to districts
3. In order to smoothen the flow of available products down to the lowest levels of the supply chain:
  - a. Strengthen communication about available stock between the different levels, with CTD in the lead
  - b. Strengthen transportation mechanisms from state level down (e.g. monitor if SDS has contracts in place for transport).
  - c. Resolve the issue of Road Permits through issue of general waiver by the Government of India for all Anti TB drugs at an appropriate level.
4. Nikshay:
  - a. Activate the LMIS module of Nikshay and roll it out in a phased manner over the next 2 years; introduce bar coding as soon as possible following the launch of the Nikshay LMIS module. Real time monitoring of all the supply chain management including the stock levels at various level through Nikshay is highly recommended.
5. **Human Resources:** In order to adequately address the expected complications in supply chain management as a result of planned changes in diagnosis and treatment approaches:
  - a. Strengthen HR at CTD (currently only one full-time PSM position);  
Strengthen HR at state level and below - by filling vacant positions (e.g. State level Technical Officer Procurement & Logistics) and refocusing/retooling existing staff/contractors
6. **Quality Assurance:** Guidelines for quality assurance needs to be ensured for drugs being procured locally by State/ districts in case of emergency. States may have quality assurance of these drugs at state / NABL accredited labs. Further, drug samples upto TU level may be recommended for sampling of quality assurance as storage condition at TU level may varies totally as compared to State/District Drug stores.
7. **Storage Conditions:** With the expansion of RNTCP activities like MDR & XDR, an action plan needs to be prepared for upgradation of state/ district drugs store, as per

requirement. An external level evaluation of the supplychain is required and the recommended corrections need to be implemented. Good Storage Practices (GSP) and Good Distribution Practices (GDP) need to be implemented and relevant training to all the key officials should be imparted.

- 8. Consultancy Services:** Expedite the process of hiring an Agency before 2015 to maintain the continuous momentum of managing the Drugs and Logistics issue without any disruption or gaps.
- 9. Use of Information Technology:** Use of software like NIKSHAY for collecting real time data regarding stock availability upto districts level needs is recommended within a time frame . This may result in eliminate the communication gaps at various levels within the state.
- 10. CB-NAAT procurement: Procurement process needs to be completed in** timeframe so that availability of new generation diagnostics is ensured at all levels by the end of 2015, especially the tribal areas.
- 11. All the relevant notifications for the exemption of payment of Excise and Customs Duty for procurement of anti-TB drugs issued by the Department of Economic Affairs (Revenue) needs to be relooked and extended beyond the current valid dates.**

#### Early Diagnosis and Case-finding for all Types of TB

The first pillar of the End TB Strategy includes a key component on case finding: “early diagnosis of TB including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups.”

#### Major accomplishments since the last JMM

- Serological tests were banned by the Government of India in 2012, and its use has dramatically declined since.
- The Standards for TB Care in India (STCI) were published in 2014, with 6 standards for diagnosis
- All WHO-endorsed TB tests are available and increasingly used (LED-FM, Xpert, LPA and cultures) in both RNTCP and private sectors (e.g. via Initiative for Promoting Quality and Affordable TB tests [IPAQT])
- New algorithms have been developed for PTB, EPTB and childhood TB, with CXR and CB-NAAT included
  - Laboratory capacity has been enhanced, especially for drug-susceptibility testing, with increase in the number of service delivery points
- New diagnostics are being validated in National TB Institutes (coordinated by ICMR)

Progress to reach major NSP goals

Although progress has been made since the last JMM, RNTCP has struggled to meet the milestones set out in the National Strategic Plan (2012–2017). This is illustrated in the table below.

Goal	Status in 2015	Likelihood of reaching NSP goal
By 2017 RNTCP expects to achieve the objective of early detection of 90% of all incident TB cases (which translates to 1.8 million TB cases per year diagnosed and treated as per national standards)	Current case finding is 60%	Low
Scale-up of CB-NAAT or equivalent DST is envisioned for the district level by 2017 (i.e. are deployed in all districts and medical colleges nationwide)	119 CB-NAATs are currently in the program (as compared to the 500 that were planned for by 2015)	Low
By 2017, all confirmed TB cases are screened at the outset or early in their course of treatment for drug resistance.	~25% of all confirmed TB cases are currently getting DST	Low

## Challenges and gaps

The following are the biggest challenges for TB case detection in India. First, an estimated 1 million cases are missing (not diagnosed or not notified), and TB case detection rate has flattened in the past few years.

Studies from India show significant diagnostic delays. Indian TB patients get diagnosed after a delay of nearly two months, and are seen by 3 different providers before a diagnosis is made (Sreeramareddy C et al. IJTLD 2014). Most poor patients begin seeking care in the informal private sector, including chemists and unqualified health providers (Kapoor S et al. PLoS ONE 2012). At this base of the healthcare delivery pyramid, patients rarely get investigated for TB, even when they present with classic TB symptoms. Instead, providers give broad-spectrum antibiotics (e.g. fluoroquinolones) and remedies such as cough syrups. By the time patients are detected to have TB, several weeks may have already passed. Thus, care seeking pathways are complex, with multiple missed opportunities for case detection.

Diagnosis in RNTCP is still heavily reliant on direct Ziehl-Neelsen smears (which are insensitive, and cannot detect drug-resistance). Sputum quality is an issue, and EQA has suffered in the recent past. In the private sector, physicians tend to order tests that are non-specific, such as complete blood count, erythrocyte sedimentation rate (ESR), Mantoux test or TB Gold, and chest X-rays. They rarely seek microbiological confirmation via sputum smear microscopy, culture or CB-NAAT (Satyanarayana S et al. IJTLD 2015). Among doctors, awareness about STCI is quite low.

In the public sector, although CB-NAAT is available, it is being used primarily as a DST tool, and access/uptake is quite limited (Qin Z et al. ERJ 2014). CB-NAAT use for extrapulmonary TB (EPTB) and childhood TB is low.

Progress towards expanding access to decentralized DST has been slow. Less than 40% of persons eligible for DST (under PMDT) are currently getting tested, and existing culture & DST labs are under-utilized. Access to second-line DST is low and a rate limiting step for the selection of appropriate evidence-based individualized treatment within PMDT. The STCI promote drug sensitivity testing for all presumed cases of MDR TB, and other groups, but progress is threatened by slow uptake of the new molecular test, endorsed by WHO, which provides both a more sensitive test for TB and a test for drug resistance. It is people at risk of MDR-TB, those living with HIV, and children, who are thus put at risk. Yet procurement of these tests is unaccountably delayed.

Systematic screening is hardly happening, even in vulnerable populations such as PLHIV and child contacts.

Recommendations

#### Recommendation 1: increase patient demand for TB testing

- Increase patient demand for sputum testing by running celebrity ads on TV (e.g. Amitabh Bachchan's ad campaign on "TB Harega, Desh Jeetega.")
- Approach Indian philanthropists and industries (e.g. CSR) to fund the ad. Campaign
- Consult with marketing experts for a communications and dissemination strategy

#### Recommendation 2: harness informal providers and chemists for identification of presumed TB

- Since informal/private providers, including chemists, are usually the first point of care, these providers should be engaged and incentivized to refer presumed TB patients for TB testing. This could be done by expanding the Private Provider Interface Agency [PPIA scheme] (learning from the PPIA pilots ongoing in urban areas).

In the public system, ASHA and CHWs can be incentivized to refer persons with presumed TB, or collect and send sputum samples to DMCs.

#### Recommendation 3: expand access to dCXR as a triage strategy

- Increase access to digital chest x-rays (perhaps with computer-aided diagnostic algorithms - CAD) in both public and private sectors as a triage test, and link persons with abnormal x-rays with microbiological testing (CB-NAAT)
  - CXRs are very popular among private practitioners; while they under-use and under-value sputum tests
  - CXRs are more sensitive than smears, and they are widely available in cities/towns, and affordable
  - If practitioners can order CXR early, then this could be used to shorten the diagnostic delay, if those with abnormal CXR can be referred to CB-NAAT testing sites
  - Provision of dCXR equipment (or CXR vouchers for purchasing from the private sector) to primary health centers will enhance TB detection as well as other conditions (e.g. childhood pneumonia, trauma)

#### Recommendation 4: update STCI and disseminate new algorithms

- Update STCI and publish 2<sup>nd</sup> edition, along with a simple, clinical practice guideline, aimed at practising doctors, with new algorithms for:
  - PTB
    - EPTB
    - Childhood TB
    - NTM
- Definition of "presumptive TB" in the new algorithm should match that in STCI
- Work with an advertising agency to develop a dissemination plan; seek help from marketing professionals
- Develop a mobile-based App for doctors in India with
  - STCI
  - Algorithms
  - Drug dosages, etc.
- Establish a hot-line for telephonic or WhatsApp consults, where doctors can get support
- Link up with pharma companies for free distribution of STCI and educational materials (e.g. mobile App)

#### Recommendation 5: Implement new algorithms and expand access to CB-NAAT in both public and private sectors

- Rapidly implement new algorithm and scale-up, based on lessons learnt

- Ensure that the new algorithm takes into account the point of contact (e.g. primary health center, community health center, district level)
- Increase the use of upfront DST using CB-NAAT, especially in children, PLHIV, and persons at risk of MDR
- Expand access to CB-NAAT for EPTB and children
- Expand access to CB-NAAT for patients in the private sector; scale up systems to provide free diagnostic tests in the private sector, based on lessons of successful experiences from pilot projects in Mehsana, Mumbai and Patna. **Minimize patient out of pocket expenses by supporting costs for TB testing**
- **Eliminate taxation on all TB diagnostics and thereby increase affordability for patients.**

#### **Recommendation 6: universal DST**

- Fully fund and implement the plan for Universal DST by 2019
  - In high MDR burden settings (e.g. Mumbai, selected states in the North East), universal DST should be implemented immediately (in 2015)
- Revised national lab scale-up plan (2014 – 19): needs to be fully costed and funded

#### **Recommendation 7: systematic screening**

- Increase capacity for systematic screening among household contacts, with under 5 children as the highest priority
- Develop systems for data capture and reporting, so contact investigations can be electronically tracked and monitored

#### **Recommendation 8: strategy for new tool introduction**

- Develop a clear, coordinated strategy for new tool introduction, and prepare the ground for launch of new drug regimens with companion diagnostics
  - Streamline regulatory pathway for new drugs and diagnostics; several new molecular diagnostics are emerging, and new TB drugs (e.g. bedaquiline and delamanid) are on the market as well. India needs a pathway for their validation and incorporation into policy.
  - Establish minimum standards for regulatory approval of new diagnostics
  - Link National TB Institutes to serve as multi-centric validation sites, coordinated by an agency such as ICMR

## **6. Treatment**

### **1. Achievements**

The most remarkable achievement by RNTCP and partners in the preceding years was the development of Standards of TB Care for India, through a large and consultative process, and subsequent endorsement by the Ministry of Health and Family Welfare. This for the first time acknowledged that patients would be treated by private providers, and gave genuine guardrails and responsibilities to private providers, rather than simply exhorting referral of unwilling patients to the public sector. The STCI notably go beyond the International Standards for TB Care in many areas of public health, and are a useful global model.

The Mission observed that in aggregate, program reported TB treatment outcomes remained adequate (Table). The RNTCP should take pride that over 13.5 million new cases have been treated with 87% treatment success, and 3 million re-treatment cases treated with 75% treatment success.

Table: Treatment Outcome of all types of TB cases for the period 1st qtr 1999-4th qtr 2013

Patient features	Number of patients evaluated (cumulative)	Cured,		Treatment completed,		Died,		Failed,		Defaulted,		Transferred out,	
		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
<b>New</b>													
Smear-positive	6,813,807	5741758	84%	173752	3%	296947	4%	145043	2%	412068	6%	46219	1%
Smear-negative	4,410,394			3875040	88%	155986	4%	29057	1%	322546	7%	29079	1%
Extra-pulmonary	2,354,372			2167769	92%	57811	2%	3630	0%	100718	4%	24148	1%
<b>Total New cases</b>	<b>13,578,573</b>	<b>5,741,758</b>		<b>6,216,561</b>		<b>510,744</b>	<b>4%</b>	<b>177,730</b>	<b>1%</b>	<b>835,332</b>	<b>6%</b>	<b>99,446</b>	<b>1%</b>
<b>Previously treated</b>													
Relapse	1,091,897	747106	68%	66072	6%	77921	7%	52199	5%	131246	12%	11375	1%
Treatment aftr failure	193,556	106982	55%	13272	7%	18679	10%	29001	15%	33495	17%	2449	1%
Treatment aftr default	826,099	533500	65%	64478	8%	70123	8%	36234	4%	155402	19%	17884	2%
Others	922,890	40559	4%	712928	77%	48681	5%	6855	1%	97705	11%	15036	2%
<b>Total Re-Treatment</b>	<b>3,034,442</b>	<b>1428147</b>		<b>856750</b>		<b>215404</b>	<b>7%</b>	<b>124289</b>	<b>4%</b>	<b>417848</b>	<b>14%</b>	<b>46744</b>	<b>2%</b>

The crucial decentralization of TB treatment supervision capacity and alignment with the block level was the most important shift in the National Strategic Plan, and it was noted that about a fifth of the country has done so. This decentralization brings the Block Medical Officer, in charge of all health staff, now to also be in charge of local TB treatment services. This is hoped to translate to better involvement of local health systems, improved treatment provider monitoring and follow-up. Decentralization of DOT services to community providers has improved, from 46% in 2010 to 54% in 2014. More importantly, DOT providers were observed to be diversifying beyond the easy-to-monitor ASHA/Anganwadi networks, to include AYUSH and other community providers. Remarkable progress has been made in PMDT, detailed elsewhere.

At a policy level, substantial progress was made. The RNTCP set out to tackle general discontent with standardized treatment regimens, hosting a meeting for DST-guided treatment in 2014. Updates to the diagnostic algorithms have created the opportunity to adjust treatment regimens based on DST results. Key recommendations of that meeting included expert-opinion formulated treatment options for INH resistant TB in particular, and other forms of non-MDR TB drug resistance as well. Adherence honoraria were improved four-fold, and now represent a rational honorarium for DOT providers instead of tokenism.

Important innovations were noted by field teams. With prior problems in ensuring that DOT providers got the promised honorarium, the system for e-Payments for DOT providers observed in MP was appreciated by all. Expansion of that approach would be feasible in most states, as transition to e-payment systems for honorarium for health workers is nearly complete nationwide. The State of Gujarat was observed to have made major reductions in initial default with routine initial default tracing integrated into basic program monitoring. In hard to reach areas, patient-friendly DOTS delivery services were found in Meghalaya.

On the treatment research front, important progress was made, buoyed by a growing portfolio of clinical research from NIRT, Chennai. While stable RIF resistance was noted from Tamil Nadu relative to a decade earlier, the high prevalence of OFX resistance among new TB patients suggested either substantial misuse in patients with presumptive TB (i.e. TB suspects) and/or the presence of high

levels of transmitted OFX resistance. Either results are concerning for the use of fluoroquinolones in future treatment regimens. Much of the research raised concern about the suitability of thrice-weekly TB treatment and in important patient groups, including HIV-infected TB patients and children.

Table: Key Indian TB treatment research reported, 2012 – 2014.

**NIRT-led 2012 repeat DRS for Tamil Nadu, from S+ patients at public sector DMC's – showed stable low RIF resistance, stable high INH resistance (10.4%, 30%), and high baseline OFX resistance (New 10%, RT 14% ) [Selvakumar et al, IJTL 2014]**

**Ongoing NIRT randomized controlled trial, showing lower culture conversion at 2 months (76% TIW vs 97% daily dosing) in HIV-infected TB patients on ART. [Narendran et al, presented at World Lung Health Conference, Barcelona, 2014]**

**Unacceptable levels of acquired RIF resistance in HIV-TB treated with RNTCP TIW regimen (9% without ART/ 4% with ART, vs <1% among HIV-) [Narendran et al, Clinical Infectious Diseases, 2014]**

**Retrospective cohorts showing high 12-15% relapse among NSP (Dang district), Gujarat (2 districts) [Dave & Shah et al, Presented at World Lung Health Conference, Barcelona, 2014]**

**NIRT RCT clinical trial (Study 24) – Non-inferiority of Moxi-containing daily IP 4 months regimen [Jawahar et al, Presented at World Lung Health Conference, Barcelona, 2014]**

**NIRT pharmacokinetics data showing low RIF serum Cmax in TIW regimen (children, HIV-infected) [Ramachandran et al, Antimicrobial Agents and Chemotherapy, 2015]**

The Mission was also enthused by what appears to be a grass-roots revolution to modernize TB treatment adherence monitoring and support. From small innovator and community-driven projects, a series of adherence innovations offer improved patient support, valid data, and patient empowerment. Innovations noted included smarter packaging (99DOTS, Pharmasecure, smart medication monitors), better counseling (family groups, Photovoice), patient reminders (multiple systems), Self-reporting (multiple systems), and ICT applications to help program and providers pro-actively reach out to

prevent loss to follow-up of patients. Most importantly, these innovations appear to be designed in many cases to be offered to privately-treated patients, as long as they are known to the system (i.e. notified). The potential of these systems for development and exportability as 'made in India'

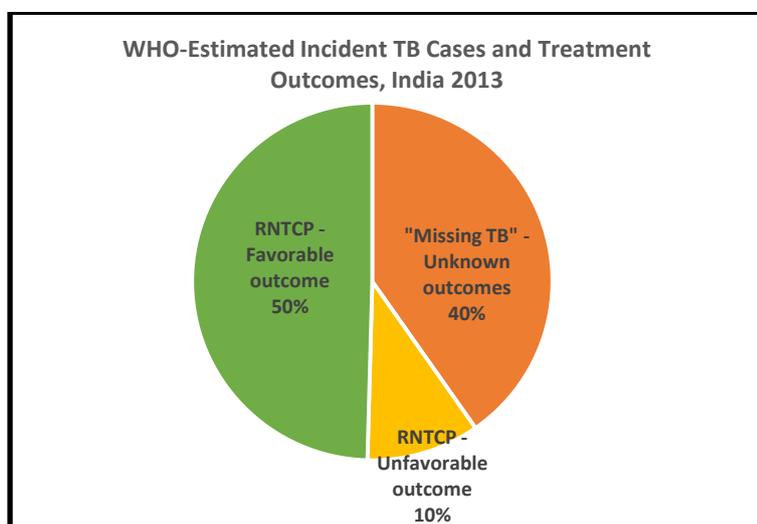


products and systems was noted. The mission was especially encouraged by potential linkage to social support systems, i.e. TB patient unconditional cash transfers as implemented in Kerala for all TB patients, or in a limited subset (OBC, BPL) in Gujarat.

### Challenges

The observed positive treatment outcomes reported were felt to be falsely re-assuring and largely misleading, for two reasons. First, the RNTCP treatment cohort represents only those patients who receive a RNTCP patient-wise box, and does not capture the treatment outcomes of TB in the community by private providers, which may include a cohort of patients larger than the RNTCP-treated cohort itself (Figure).

Figure: Notional TB treatment outcome cohort, 2013. Based on WHO estimated incident TB figure (2.1 million for 2013), against 'incident' i.e. new and relapse TB cases reported under RNTCP (1.25 million in 2013), and the proportion of favorable outcomes reported. It is noted that this estimate for "missing TB" would only account for approximately 1/3<sup>rd</sup> of anti-TB drug sales in the private sector nationwide.



Second, the treatment success outcomes reported masks problematic results of unacceptable relapse and, even more concerning, a stunning risk of amplification resistance to RIF during treatment (Table) found by programme analysis of routine DST results and follow-up of repeat DST results among previously-treated TB patients with non-MDR drug resistance.

Table: Treatment outcomes of mono and poly resistant TB cases (other than R) treated with standard first line anti-TB regimen under RNTCP. Source: Report on National Workshop on Drug Susceptibility Testing (DST) Guided Treatment for Drug Resistant Tuberculosis Patients in India, 26th to 28th August 2014

DST Pattern	Success	Failure	Amplification to Rif Resistance among failures
H Mono (LPA) n= 6426	53%	24%	41%
SHE n= 323	16%	67%	53%
HE n=100	31%	54%	64%
SH n=611	25%	54%	52%
SE n=68	24%	49%	46%
H Mono (Phenotypic DST) n= 819	31%	49%	40%
S Mono n= 442	26%	49%	35%

HIV-TB treatment outcomes also remain disappointingly poor, with unrelenting high proportion of death despite excellent overall coverage of CPTART during TB treatment during the same treatment cohorts (Table).

Table: Treatment outcomes among HIV-infected TB patients reported by RNTCP, along with correspondingly levels of CPT And ART reported by the end of TB treatment, RNTCP 2011–2013.

Year	Cured	Completed	Died	Failed	Defaulted	% HIV infected on CPT	% HIV infected on ART
2011	31.1%	46.4%	13.1%	1.3%	6.4%	92%	72%
2012	27.4%	49.9%	13.3%	1.2%	6.5%	91%	84%
2013	26.9%	49.3%	13.4%	1.2%	6.2%	94%	91%

The mission also observed frustrating persistence of poor treatment practices in programmatic practice in a few of the visited areas, including: selective registration (non-registration of patients perceived likely to default), weak pre-treatment counseling, spotty procurement of ancillary anti-TB drugs, non-standardized care of EP-TB. Patients continue to incur high out-of-pocket expenditures and loss of wages during DOT, and clunky reimbursement systems for travel (e.g. as in tribal action plan) are unlikely to be successful.

### Opportunities

The encouraging policy movement on daily anti-TB treatment was noted, although the decision to run a large-scale operational pilot of daily-anti TB treatment would need to be backed up with a timeline and procurement plan. The remarkable scale-up of rapid DST nationwide, from nearly nothing to nationwide coverage in 2 years, and the early-roll out of second-line DST at IRL's in 6 states has shown how India can rapidly accelerate the development of laboratory capacity with adequate resources and partnerships.

The beginning of TB notification from private providers was welcomed, and offers an opportunity to extend treatment support and monitoring services to patients treated by private providers. This may be self-reinforcing; with a genuine value proposition for 'why bother' to notify cases, providers may be more willing to notify. Real-world examples of how to monitor such patients were noted to be emerging from pilot projects for private notification and engagement.

In the regulatory landscape, Schedule H1 is a remarkable opportunity to deploy pharmacy surveillance for privately-treated TB patients, and to identify and engage the majority of providers who are not yet notifying TB cases. The provisional recommendation for bedaquiline licensure with distribution controls is also a model for how new TB drugs can be rationally introduced into the country, and needs to be met with careful program planning for roll-out. The inclusion of bedaquiline, delamanid, linezolid on the WHO essential medications list has put pressure on the country to allow access to the few patients who need these drugs, without permitting irresponsible use to destroy the transformation value of new regimens containing these extremely precious new classes of anti-TB drugs.

### Recommendations

7. Change dosing frequency to daily on priority in line with the STCI.

Ample evidence of potential harm in patient subgroups drives the recommendation that RNTCP transition from a thrice-weekly to a daily-dosing frequency on priority. The observation from clinical trials of acquired RIF resistance risks in HIV-TB (with and without ART), and the genuinely disturbing observations of RIF-resistance amplification in patients with INH resistance warrants change. It is acknowledged that daily dosing only reduces the risk of these outcomes, and alone is not a definitive solution. Yet even partial reduction of amplification risk would avert crucial morbidity and MDR treatment costs. It was also recognized that simultaneous daily/TIW usage would be operationally infeasible, and unnecessary. Furthermore, alignment of the public and preferred private treatment regimens would vacate a commonly cited barrier for private providers to refer patients to the public sector for treatment. The mission recommended proceeding with any necessary operational piloting *in parallel* with procurement for phased implementation, so that scale-up is not delayed by prolonged and unnecessary research studies and subsequent procurement timelines.

8. Transition to “Test and treat” approach with DST at baseline for all TB patients, and proposed DST-guided regimens.
9. Long-term solutions for poor treatment outcomes, particularly in non-MDR drug resistance, is not likely to be solved by daily dosing alone. While global guidance on treating such patients are based on very limited evidence, India has proceeded ahead and developed rational regimens with national experts. The rate limiting step to implementation of such regimens is clearly the capacity for rapid DST beyond RIF, i.e. for INH and FQ at the district level. The national laboratory scale-up plan will provide interim capacity to proceed with deployment of DST for all TB patients, till the next generation of CBNAAT devices from multiple vendors can include INH and FQ testing.
10. Modernize adherence support and monitoring.

The Mission suggests to consider that DOT is a *means* to monitor and support adherence, not an *end*. Accordingly, the Mission recommends that RNTCP modernize adherence support and monitoring systems, and in particular to extend successful models of adherence support and monitoring to TB patients managed by private providers. This means that the existing program policy of family DOT can be supported in implementation by ICT-supported systems to monitor DOT providers. It provides an important force-multiplier for health staffs, facilitating decentralization of TB treatment for both DOT provider and family custody of TB drugs. It is important to recognize that the solution should avoid a one-size-fits-all mentality, and should avoid compromising patient empowerment or autonomy; TB patients are not parolees to be subject to demeaning and heavy-handed monitoring. DepA multiplicity of options should be available, and the program and providers should help find the right solution for the right patient. The mission strongly recommends exploration of integrated e-payments for honoraria or social support for providers & patients. To be eligible for ongoing and regularly social support (for patients) or honoraria (for providers), pill-in-hand systems for adherence monitoring may be very useful.

11. Strengthen counseling for all TB patients
  - a. Integrate with digital platforms being used by ANM/AWW in MCH counseling
  - b. Standardize counseling tools in local languages
  - c. Include family in counseling and support
  - d. Develop& implement minimum clinical criteria for hospitalization / specialist consultation (e.g. hypoxic, high resp rate, BMI<16, etc)

- e. Including therapeutic nutrition for severe under nutrition (BMI less than 16)
- f. Train on pharmacovigilance, & include ADR's in R&R system.
- g. Develop and implement simple systematic relapse surveillance, with at least phone calls to patient cohorts at 6 and 12 months to ascertain potential relapse. This will be particularly important as a monitoring tool as regimens transition in the program.
- h. Develop criteria for 'high-risk' patients, for encouraging systematic referral to specialist consultants. For example, extensive radiologic disease, severe underweight, or comorbidity should include specialist consultation early, rather than waiting for clinical failure.

## 12. Childhood Tuberculosis

### a) Achievements

In line with global policy, the Indian government has made significant efforts to prioritize this vulnerable group within the RNTCP, with specific guidance for children included in the Standards of for TB Care in India published in 2014, and targets within the National Strategic Plan 2012-2017. The RNTCP is trying to diagnose and treat paediatric TB across the country and sensitize the national, state, and district levels on the issue, and on the guidance for children. There are also several forums addressing childhood TB, which involve representatives from the paediatric community, including the Indian Academy of Paediatrics (IAP), namely the National Technical Working Group (NTWG) on paediatric TB, the National Expert Committee on Paediatric TB, STCI, EP-TB guidelines focusing on childhood TB. However, this involvement needs expansion. There has been progress – many activities within the programme are now considering children:

- *Integration of TB Services with General Health System:* The general health system carries out treatment delivery, BCG immunization and contact tracing, and refers children to the RNTCP in many areas. The RNTCP has made a few patchy efforts to sensitise childcare providers to the strategies used for TB.
- *Early and Intensified Case-finding:* National policy that offers rapid diagnostics for the identification of children with TB is in place but implementation is still in a pilot phase. For example, a pilot to accelerate access to quality TB diagnosis for paediatric cases is being conducted in 4 major cities (Delhi, Chennai, Kolkata, and Hyderabad) with the purpose of identifying key hospitals, private clinics, and paediatricians to engage and establish a referral network. Nutritional Rehabilitation Centres (NRCs) are screening malnourished patients for TB.
- *Treatment of Childhood TB:* The patient treatment kits for paediatric weight bands are available and being used and with overall good treatment success rates. However, there are genuine concerns about these weight bands not offering low dosages to many children. In order to transition the country to the updated guidelines for paediatric treatment in the STCI, which follow the current WHO dosing guidelines, the government is planning a pilot in 100 districts of a daily dosing regimen using child-friendly fixed dosed combinations (FDCs). There has been dialogue with the RNTCP, the Drugs Controller General of India (DCGI), and manufacturers to fast-track the appropriate formulations for use in the pilot. The program has put in place the option for family members to provide DOTS to paediatric patients.
- *Drug-resistant TB:* The RNTCP is making efforts to detect MDR-TB early including extra-pulmonary TB, by providing CBNAAT. It also provides SLD treatment for the under 16kg weight band under programmatic settings.

- *HIV and TB:* Coordination mechanisms and service linkages exist with upfront molecular diagnosis offered to children in a limited number of facilities. Most children identified with TB get an HIV test.
- *Engagement of All Care Providers:* There is a strong partnership with the IAP on the development of policy for children, which produces regular updates of the guidelines. A comprehensive cascade training plan has been developed and was initiated in early 2015
- *Community Engagement:* Schools conduct activities to educate children on TB in a few states with the hope of the information filtering to the family and community at large.
- *Research Priorities:* Nikshay gives age desegregated data (ages 0-14 yrs) and there are some estimates of TB infection in children from the Annual Risk of TB Infection (ARI) surveys.

### b) Challenges

Although the policies required to address TB in children have progressed, implementation of these policies is lagging throughout the country, especially in early and intensified case finding and management of MDR-TB. There is a need to consider children much earlier for innovations and interventions introduced for TB control in adults, and as part of any broader initiatives of the program such as media campaigns and private sector engagement.

A change in perspective across the entire health sector that children are not 'miniature adults' and so cannot be treated exactly like adults, is badly needed. The RNTCP's focus is on microscopy with little or no provision of the diagnostic tools children particularly need, like chest radiology and fine-needle aspiration cytology (FNAC), to enable diagnosis of paucibacillary disease or EPTB.

- *Integration of TB Services with General Health System:* Although there is some engagement of the paediatric community at the national level for policy matters, this is not occurring at the operational level at state and districts. Even large paediatric institutions are not actively involved and have little communication with the RNTCP. The programme at all levels has little interaction or involvement with other NHM components, such as maternal and child health (MCH), NRCs, and immunization programs.
- *Early and Intensified Case-finding:* Case finding is still low with no improvements for close to a decade (Figure 12). This is due to several factors including inadequate levels of contact screening, limiting detection of cases to specialty health care settings such as Medical Colleges and bigger hospitals, and the poor deployment of diagnostic tools. There are also major knowledge gaps and a lack of skilled workers or equipped facilities to carry out appropriate sample collection and processing. Negligible involvement of both the public and private sectors reduces case finding still further. While the program has identified children as a priority area for use of rapid diagnostic tools like CBNAAT, the availability of such facilities is at present restricted to the pilot areas. The guidelines for optimal use of rapid diagnostics have already been developed - there is a need for a rapid scale up of these facilities.
- *Treatment of Childhood TB:* Even though children diagnosed with TB usually get treated, there have been some drug shortages observed (PC13, INH 100 mg) that affect referral for, and initiation of treatment. Inside the program, the new recommended weight bands and dosages are not followed. Outside the program, there are mixed practices for treating and managing children suspected or identified with TB: quinolones are often used for drug-sensitive patients

- *Drug-resistant TB:* Bacteriological confirmation of DRTB in many childhood forms of TB (particularly EP TB) remains difficult, but even when possible, it is often not performed in young kids and cases with EPTB, meaning that, in these cases drug-resistance cannot be diagnosed. The Programme has developed definitions for probable MDR-TB in children, but, once again, they are not much used in the field. One major barrier is the almost complete lack of involvement of the paediatricians in the PMDT strategy. Program managers at most levels are adult chest physicians who continue to retrofit adult-oriented diagnostic strategies to children, which often leads to delays or suboptimal therapy. Treating patients in lower weight bands for MDR-TB is difficult - child-friendly SLDs are unavailable.
- *HIV and TB:* Some of the weaknesses related to the management of TB/HIV in adults apply to children as well: limited case-finding, low implementation of isoniazid preventive therapy (IPT) and poor airborne infection control measures.
- *Engagement of All Care Providers:* There is low penetration and utilization of TB services by child care providers across all sectors and limited program schemes to involve private child care providers. Task forces within Medical Colleges focus mostly on adult forms of TB with little or no consideration of children.
- *Community Engagement:* The majority of community engagement activities, communications, and campaigns around TB are adult-centric. Amitabh Bachchan's campaign, "TB harega, Desh Jeetega", is praiseworthy, but such campaigns rarely include children or address the presentations and risks unique for children.
- *Research Priorities:* Data for childhood TB, including DRTB, TB/HIV and other co-morbidities are poor and there are none on the contribution of TB to under-5 mortality and morbidity. Children should be taken into account in the evaluation of newer diagnostics.

### c) Recommendations

If the RNTCP is to successfully address the epidemic of TB in children, children must benefit from innovative measures in TB in the same way as other groups, and not just as 'add-ons'. MDR-TB diagnosis and treatment was successfully scaled-up in a short period of time and serves as an example of lessons learnt from past programmatic experiences for adult TB that can be used to accelerate the response to childhood TB.

1. **The RNTCP should leverage other child survival strategies to expand paediatric TB care services (e.g. IMNCI, F-IMNCI packages to cover TB).**
2. **The RNTCP should work out ways to engage with large paediatric institutions, for example in the development of National and State-level model centres (COE) for paediatric TB that can address training, service delivery strategies and research.** The IAP and medical colleges should be engaged for the decentralized training of paediatricians. Medical College Task Forces should incorporate paediatric-TB into their agendas, allow faculty protected time to paediatric TB and ensure mandatory representation of paediatricians.
3. **The RNTCP should take all necessary steps to increase notification of TB in children, including:**
  - Capacity building, strengthening of referral services and treatment, and linking with molecular diagnostics services;
  - Making use of radiology services in the private sector and setting up the necessary mechanism for reimbursement;
  - Ensuring that a record of contact screening and IPT provision is included in the patient Treatment and Identity Cards and in Nikshay.

4. **The RNTCP should ensure the uninterrupted supply of quality drugs, diagnostics and other critical consumables needed to manage TB effectively in children, including follow-up on the dialogue with DCGI and the manufacturers to ensure that the child-friendly FDCs with WHO-compliant weight bands are fast-tracked in the next 6 to 8 months.** The agreement to shift from thrice to twice weekly dosage with FDCs (Debriefing meeting 1.) must simultaneously address those paediatric patients living with HIV/AIDS. In addition, all providers need to be informed about the updated treatment guidelines.
5. **The RNTCP should develop 'child friendly' guidelines for the management of DR-TB, and employ paediatric focal points in the RNTCP at national and state levels to help facilitate their implementation. The RNTCP should also establish DR-TB centres and child-friendly SLD formulations, as well as the representation of paediatricians in DR-TB forums.**
6. **The RNTCP should include all care providers in their program schemes for childhood TB (i.e., X-rays, TST, and pathology) and involve school health programs to help in the identification of children suspected of TB.** The RNTCP should ensure that providers receive appropriate training on childhood TB, including DRTB. Address the nutritional gaps for families with children with TB
7. **The RNTCP should support the development of a patient's charter for paediatric TB** which outlines the rights of the child to quality and timely care. Communities should be empowered on childhood TB through training on symptoms, contact tracing, reverse contact tracing, treatment, and changes and updates in policies.
8. **The RNTCP should ensure that childhood TB is included in the priorities for TB research; that data available in Nikshay is analysed to provide a better understanding of the TB epidemic in children; and that inventory study protocols are prioritized because these types of studies benefit children by providing understanding of underreporting.**

**Table 1. List of research priorities for paediatric tuberculosis**

<ul style="list-style-type: none"> <li>• Health seeking behavior of the children (and their caregivers) with presumptive TB and studying the determinants thereof.</li> </ul>
<ul style="list-style-type: none"> <li>• Prospective study of the burden of childhood TB in different parts of India using the new algorithm suggested by the IAP-RNTCP guidelines.</li> </ul>
<ul style="list-style-type: none"> <li>• Assessment of trends in case detection of pediatric TB using data available in the RNTCP program. (where and how are they diagnosed, what type of disease)</li> </ul>
<ul style="list-style-type: none"> <li>• Can pooling of specimens (different days or different specimens) improve yield and efficiency of bacteriological diagnosis among children?</li> </ul>
<ul style="list-style-type: none"> <li>• Is it possible to utilize MO/ MPW for pediatric respiratory sampling?</li> </ul>
<ul style="list-style-type: none"> <li>• Comparison of ADA and other pleural fluid characteristics in TB and parapneumonic effusions.</li> </ul>
<ul style="list-style-type: none"> <li>• Understanding nutritional changes prior to and after initiation of ATT among children with TB (weight, BMI, body composition, dietary intake, micronutrient levels)</li> </ul>
<ul style="list-style-type: none"> <li>• Assessment of ADR in children on new drug dosages and combination of drugs</li> </ul>
<ul style="list-style-type: none"> <li>• Assessment of ethambutol toxicity among children on short and long-term ethambutol-containing ATT regimens.</li> </ul>
<ul style="list-style-type: none"> <li>• Study of preventive therapy options for childhood contacts of adults with sputum smear negative and smear-positive drug-resistant TB.</li> </ul>
<ul style="list-style-type: none"> <li>• Evaluation of INH preventive therapy/ TB chemoprophylaxis among adolescents with TB infection: safety, adherence, efficacy</li> </ul>
<ul style="list-style-type: none"> <li>• Finding best strategy for identifying TB among childhood contacts (symptom based or investigative).</li> </ul>
<ul style="list-style-type: none"> <li>• Evaluating Alternative preventive therapies for childhood asymptomatic contacts</li> </ul>

<ul style="list-style-type: none"> <li>• Evaluation of the immunogenicity of BCG vaccine when given concomitantly with INH among TB-exposed infants.</li> </ul>
<ul style="list-style-type: none"> <li>• Evaluation of the tuberculin skin-test response in HIV-infected and non-infected children.</li> </ul>
<ul style="list-style-type: none"> <li>• Determination of the rates of adherence to TB treatment, treatment failure, recurrence and relapse in children with and without HIV.</li> </ul>
<ul style="list-style-type: none"> <li>• Pharmacokinetic studies for second-line drugs in children.</li> </ul>

## TB/HIV

Globally, HIV-related TB presents an enormous challenge for both the TB and HIV responses, and as India contributes the second highest burden, this becomes all the more relevant. People living with HIV are more at risk of developing TB, and have worse treatment outcomes. There has been a slow but steady decline in estimated HIV-related TB incidence and mortality in India since 2004 and India looks to be on track to achieve the UNGASS and Global Plan targets of halving TB deaths among people living with HIV by 2015. However, an estimated 14% of all TB deaths in India and a quarter of all HIV-related deaths were due to HIV-related TB in 2013. The case fatality rate among HIV-positive TB patients registered in RNTCP care in 2013 was 13%, more than three times higher than among HIV-negative TB patients. Eleven states reported at least 15% fatality rate among new cases in 2014. Intensified scale-up of the full package of collaborative TB/HIV activities with the appropriate screening, diagnostic, prevention and treatment technologies, as set out in the 2013 National Framework for joint HIV/TB collaborative activities and the STCI will be crucial in order to make any significant purchase on this dual epidemic, to meet the goals of the National Strategic Plan and in order to at least aspire to the targets set out in the End TB Strategy.

### Achievements and opportunities

The RNTCP and NACP have, together made tremendous progress in scaling up access to TB/HIV services since 2012, in particular in HIV testing and ART.

- Concerted efforts to provide a more integrated response have resulted in the co-location of 57% of the country's expanded network of Designated Microscopy Centres (DMCs) integrated with HIV care facilities, representing 7,742 co-located integrated testing and counselling centres (ICTCs), 470 ART centres and 960 Link-ART centres.
- 72% of registered TB patients knew their HIV status in 2014, representing a 25% increase from 821,807 in 2012 to 1,034,712 with known status in 2014. Provider initiated HIV testing and counselling among clients presenting with presumptive TB has begun in 194 identified districts. The coverage of ART initiation among HIV-positive TB patients has increased by more than 50% with 91% receiving ART in 2014. 70% initiate ART within 30 days (88% within two months). However there are some states with low coverage and 12% that are initiating ART after 2 months. CPT coverage increased from 91% to 94% in 2014.
- The four symptom TB screening algorithm has been revised and has been scaled up, mainly in high HIV burden settings.
- A policy for the provision of IPT among PLHIV identified as eligible with the four symptom TB screening algorithm was developed in 2012 and is ready for implementation and scale-up.
- The diagnostic algorithm for use of CBNAAT as the first diagnostic test for PLHIV was revised in 2014.
- The National Framework for joint HIV/TB collaborative activities was revised in 2013.

- The STCI holds promise for the promotion of a comprehensive package of collaborative TB/HIV activities both within and outside the public sector.
- A number of good state and NGO initiatives for the enhanced financial and nutritional support for HIV-positive TB patients should be taken to scale and made available for all TB patients.
- NIKSHAY could provide an excellent opportunity for improved real-time patient follow-up and to reduce the gaps in the more complicated HIV/TB care cascade.
- Networks of people living with HIV and NGOs supporting HIV targeted interventions are an untapped opportunity for expanding access to TB prevention, diagnosis and care services.
- The UNAIDS Fast-Track targets of 90-90-90 promote the earlier identification and treatment of PLHIV which will not only help in the prevention of HIV-associated TB but will also enable earlier engagement into services offering TB prevention, screening, diagnosis and treatment.
- The Global Fund new financing model and joint TB and HIV concept note lays a framework for initiatives to address some of the recommendations.

### Challenges

- Whilst joint monitoring and joint supervision is being conducted in some states it is not implemented regularly or at every level.
- The HIV epidemic is shifting and there are rising trends in some low and very low burden states as well as in districts. NACP is redefining districts based on recent surveillance. This needs to be monitored in the context of TB.
- Only half of the estimated total number of people living with HIV were in active HIV care (pre- or ART services) in 2013, and only 37% of estimated HIV-positive incident TB cases were reported by the RNTCP in 2013.
- The implementation of, and recording and reporting of TB screening is not routine in all states.
- The algorithm prioritising CBNAAT as the initial TB diagnostic tool for use among PLHIV is not yet being implemented. 10 month stock-outs of CBNAAT cartridges were reported in Andhra Pradesh.
- IPT is not yet available for initiation among PLHIV in any facilities throughout the country.
- Daily antituberculosis treatment and rifabutin are not yet freely available for PLHIV.
- Despite efforts to ensure co-location of services, patients still endure lengthy times queuing to receive more than one service. There is sometimes poor patient follow-up and no tracking mechanisms between HIV and TB facilities which are not co-located for HIV testing and for TB investigations. Not all private practitioners are aware of or carry out HIV testing and counselling among TB patients.
- PLHIV attending care facilities for TB and HIV, and PLHIV working in ART centres are being exposed to high levels of TB infection due to suboptimal infection control measures.

### Recommendations

1. RNTCP and NACP to ensure strengthened coordination at state and district levels, and implementation of regular joint supervisory visits and periodic reviews in all states, district and sub-district levels, including those with low prevalence of HIV.
2. To inform a strengthened response, RNTCP and NACP to conduct operational research into the reasons for higher TB case fatality rates among HIV-positive patients, compared with HIV-negative patients.
3. RNTCP and NACP to build capacity at state and district level for periodic review of the TB/HIV care cascade to identify areas of linkage loss and mechanisms to address the gaps.
4. RNTCP and NACP to ensure that the intensified TB/HIV response is aligned with the shifting dynamics of the HIV epidemic. **NACP and RNTCP to pilot and expand community HIV testing and counselling (Whole blood finger**

- prick test), and TB screening**, including among key populations affected by HIV, in districts and hotspots of high or of rising HIV prevalence.
5. RNTCP and NACP to increase capacity and ensure the systematic screening, and recording and reporting of TB screening are carried out among PLHIV in HIV facilities, including in prevention of parent to child transmission facilities.
  - 6. RNTCP to expedite, without further delay, the procurement and placement of CBNAAT for use as first test for TB diagnosis among PLHIV, and ensure sustained supply of cartridges in all health facilities with ART centres nationwide, and in co-located DMCs/ICTCs in districts of higher HIV prevalence.**
  - 7. RNTCP and NACP to expedite, without further delay, the procurement and distribution of IPT for nationwide implementation, ensure a sustained supply and monitor and evaluate uptake and adherence to IPT among PLHIV, according to the National TB/HIV framework.**
  8. RNTCP and NACP to coordinate more closely over exchange of data and consider the inclusion of referral, TB screening and IPT among PLHIV within the new electronic recording and reporting system (Nikshay) for use also by the HIV services.
  9. RNTCP to expedite, without further delay, the procurement of daily anti-tuberculosis treatment for nationwide implementation, according to the Standards of TB care in India.
  10. RNTCP and NACP to streamline procurement and distribution of rifabutin for use in all patients taking boosted protease inhibitor (PI)-based ART.
  11. NACP to roll out the initiation of antituberculosis treatment by ART Medical Officer's nationwide, beyond just 30 ART pilot sites.
  12. RNTCP and NACP to implement airborne infection control guidelines, expand training to all cadres of staff in facilities providing HIV and TB care, and monitor TBIC and HIV IC practices in facilities providing HIV and TB care during joint supervision visits to prevent nosocomial transmission to patients and staff, both HIV-positive and negative.
  13. RNTCP and NACP to develop strategies to incentivise and promote AIC best practice in HIV and TB care facilities.
  14. RNTCP and NACP to monitor the risk of TB among health care workers in HIV facilities relative to the general population and the proportion of healthcare facilities providing services for PLHIV that have TB infection control practices.
  15. RNTCP and NACP to build upon ongoing initiatives for physical co-location and decentralization of HIV Testing and counseling and ART services with DMCs, moving toward functional, more patient-centered care that offers HIV testing (all 3 tests) as well as ART initiation at sub-district level in high prevalence HIV districts (category A and B).
  16. NACP and RNTCP to ensure the scale-up of provider initiated HIV testing and counselling among people presenting with presumptive TB, as well as family contacts (adults and children) of HIV-positive TB patients in states with a high prevalence of HIV.
  17. Develop and implement a strategy to ensure HIV testing of TB patients by private practitioners and linkage to care and support services.
  18. Implement strategies to ensure timely initiation of ART for all HIV-positive TB patients along with systematic recording and reporting to the state and national level.
  19. RNTCP and NACP to consider adopting WHO recommendation to start ART within the first 2 weeks of initiating TB treatment among HIV-positive TB patients with CD4 count < 50 cells/mm<sup>3</sup>.
  20. RNTCP and NACP to systematically engage with NGOs and networks of PLHIV, in TB screening, prevention and care, monitor the implementation and impact of NGO involvement and promote best practice.
  21. NACP to include TB activities in the minimum package of activities for HIV prevention and care and monitor its implementation by the NGO and networks implementing targeted interventions for HIV key populations.
  22. RNTCP and NACP to assess the burden of HIV-associated TB and ways of improving access to services for key populations at risk of TB and HIV, e.g. prisoners, people who inject drugs, sex workers to inform the development of mechanisms to reduce drop-out in the care cascade for key populations.
  23. RNTCP and NACP to assess the joint burden of viral hepatitis, tuberculosis and HIV among PWID.
  24. RNTCP and NACP to conduct operational research to assess burden of HIV-related TB, access to services for TB/HIV in adolescents and consider integrating TB services into the ARSH (Adolescent, Reproductive and Sexual health) programme under NHM.

## Other comorbidities

### Background

**Diabetes Mellitus:** An estimated 63.1 million persons in India are affected by diabetes mellitus (DM), ranking India second globally. The prevalence of DM among TB cases in India is as high as 13 percent and the TB attributable risk of DM is between 15% and 25%, and even higher in MDR-TB cases. A study in India has found the TB incidence rate among DM patients less than 956/lakh. Diabetics who are diagnosed with TB have a higher risk of death during TB treatment and of TB relapse after treatment. Early detection of both DM and TB can help improve care and control of both.

**Tobacco use:** There are nearly 275 million tobacco users in India and 46% of TB patients have been found to use tobacco, compared with 35% of the general population. Smoking is strongly associated with increased rates of TB infection and tobacco use is associated with more rapid TB disease progressing and poorer prognosis.

**Silicosis:** Over 3 million workers are exposed to silica dust, whilst 8.5 million more work in construction and building activities, similarly exposed to quartz. Tuberculosis has been found to be up to 39 times higher among silicosis patients and is a common complication reported in Indian studies. The major industries placing workers at risk of silicosis in India are all stone quarries and crushers, quartz mining, foundries, sand blasting, ceramics industries, gem cutting and polishing, slate/pencil industries, construction, all mining industries and glass manufacture industries.

### Achievements and opportunities:

- A pilot to assess the feasibility of bidirectional screening of DM and TB was conducted in 2012 at eight tertiary care centers.
- DHHS issued directives to the National Program for prevention and control of Cancer, Diabetes, CVDs, and Stroke (NPCDCS) to screen all TB patients for DM in 142 districts where NPCDCS operates.
- A collaborative DM/TB framework, diagnostic, training, monitoring guidelines have been developed.
- Routine DM screening among MDR-TB patients is being carried out.
- Successful experience from Gujarat has provided evidence that 'Brief advice' for tobacco cessation can be easily and successfully incorporated into RNTCP activities.
- The National Action Plan and Monitoring Framework for prevention and control of NCDs aims to reduce the prevalence of tobacco by 25 percent and of alcohol by 10 percent. This provides a great opportunity to collaborate and mainstream TB into efforts to reduce alcohol and tobacco use.
- Silicosis is a notified disease under Mines Act 1952 and the factories Act 1948, although not yet a public health act.
- There is a large network of Employees' State Insurance (ESI) hospitals and outpatient facilities in 28 states of India managed by Ministry of Labour, that work with the RNTCP and that serve silicosis patients covered with ESI.

### Challenges:

- Bidirectional DM/TB screening is not yet routine and joint monitoring is not being carried out nationally.

- There is no national policy on the prevention and elimination of silicosis and a weak notification system.
- Industries that put workers at risk of silicosis tend not to be so organized and so not all will come under the purview of the ESI.

**Recommendations:**

- RNTCP and NPCDCS to develop a TB/DM monitoring and evaluation framework for target setting to promote the uptake and measurement of progress.
- RNTCP and NPCDCS to implement at scale the national TB/DM framework and routinize the recording and reporting of DM and TB co-infection.
- RNTCP is encouraged to take to scale the inclusion of tobacco use screening and cessation counseling as an integral component of TB care in India.
- RNTCP to develop and implement a multi-sectoral strategy, in coordination with the Ministry of Mining, Directorate General of Factory Advice Services Labour Institute, national Institute of Occupational Health, Tuberculosis Association of India and civil society organizations, to screen for and address tuberculosis among silicosis patients and among workers in silicosis risk industries.
- RNTCP to assess the burden, and yield and impact of screening for and addressing TB among other clinical risk groups e.g. those on immunosuppressive therapy, alcohol dependent, viral hepatitis, and/or vice versa, and develop and implement strategies accordingly.
- RNTCP to use existing screening initiatives for NCDs under the general health system for the screening of TB, and vice versa.

**Status of progress on NSP and JMM 2012 Recommendations on TB/HIV and other comorbidities**

<b><i>NSP Target/Indicator</i></b>	<b><i>Status</i></b>
14% case fatality among HIV-infected TB patients treated under RNTCP (2012 cohort)	13% died (range: 6%-25%)
70% of TB patients with known HIV status	72% with known status (range: 31% - 100%). 22 of 35 states have achieved > 70%.
80% of HIV-infected TB patients who received ART during TB treatment.	91% ART coverage (range: 61%-100%) 21/35 states above target.
80% of states where State Coordination Committee conducted meetings at least twice over four quarters.	<46% states had meetings
80% of districts with at least two District Coordination Committee meetings conducted over the past four quarters.	<30% districts had meetings
Increasing trend (baseline 400,000) of chest symptomatics identified at HIV care settings and referred to RNTCP	Trend increased. ART: 691,013 ICTC: 166,383 symptomatics identified in HIV care in 2014
50% of chest symptomatics among PLHIV screened using culture/molecular-based method.	2%
<b><i>JMM 2012 Recommendations</i></b>	<b><i>Status</i></b>
Implement the WHO 4-symptom algorithm for TB screening (prior to IPT initiation). Revise the diagnostic algorithm for TB for PLHIV (without inclusion of antibiotic trial) to expedite the diagnosis of smear-negative pulmonary and extrapulmonary TB. Prioritise the provision of molecular testing (CBNAAT) in all health facilities with ART centres and in co-located DMCs/ICTCs in districts with a high prevalence of HIV to ensure the diagnosis of smear-negative pulmonary and extrapulmonary TB.	Screening algorithm in use in high HIV burden state visited. Not routine elsewhere and poorly documented. Diagnostic algorithm revised and CBNAAT prioritized as first diagnostic test for PLHIV in policy but not being implemented. Available in 84 of 7,742 co-located ICTCs, DMCs and ART centres.
Implement the WHO four-symptom algorithm for TB screening (current cough, fever, weight loss and night sweats) and make IPT available at all ART and link-ART centres.	Algorithm in place. Feasibility study conducted. IPT approved. Policy developed in 2012. Order placed but IPT not yet available in facilities for implementation anywhere.
Consider changing the RNTCP regimen to a daily regimen based on a fixed-dose combination make it more acceptable for all care providers to refer cases to the RNTCP for treatment	Daily regimen approved and distributed to the USAID/WHO 30 ART centres in 6 high HIV burden states identified for intensified activities. Not yet procured or distributed nationwide. Challenge: ATT provided by TB services only which necessitates extra patient queuing.
Ensure the availability of rifabutin for TB patients who have been started on boosted protease inhibitor (PI)-based ART.	Rifabutin has been procured at national level, but not distributed to states. Some states purchasing but not available in all districts.

Accelerate the implementation of the national AIC guidelines and ensure that at least administrative measures are instituted in all co-located DMCs/ICTCs and ART facilities as a minimum standard.	Sensitization and training conducted and ongoing among certain cadres of staff. Patients in some districts were wearing masks. Otherwise limited AIC measures were observed in most facilities visited during the review.
Expedite the co-location of facilities for HIV testing in all DMCs and accelerate the provision of facilities for HIV testing in peripheral health institutions (PHIs) without DMCs in states with high prevalence of HIV.	57% of DMCs co-located with HIV testing facilities
Extend HIV testing to cover cases of presumptive TB, as well as family contacts (adults and children) of HIV-positive TB patients and outpatients in states with a high prevalence of HIV.	98% coverage among presumptive TB in AP/High burden state and Orissa (low burden). Phased rollout planned for 25-54 age group in low burden. HIV testing of family contacts under review.
Initiate ART among TB patients immediately after they are diagnosed with HIV, while they are undergoing baseline ART evaluation.	70% of co-infected patients receive ART within 30 days. <12% of selected sites initiated outside 2 months.
NACO and the CTD should strengthen TB case-finding under targeted HIV intervention projects.	Limited engagement of HIV outreach workers, HIV NGOs, networks of PLHIV and those carrying out targeted HIV interventions and HIV services for key populations (e.g. migrants, truckers, sex workers and people who inject drugs).
Active screening of clinical risk groups and socially vulnerable groups	Collaborative framework of care for TB and diabetes, M&E Guide and training modules developed. Bidirectional screening carried out in a number of states and more routinely among MDR-TB patients. Yet to be scaled up and routine data collection not being implemented.

## BACKGROUND

India has the world's highest MDR-TB burden country. The WHO Global TB Report 2014 estimated that 62,000 MDR-TB cases emerged annually in India amongst the notified PTB cases in 2013. This estimate is based on data available from population-based sub-national drug resistance surveys (DRS) conducted in 3 states of India (Andhra Pradesh, Gujarat and Maharashtra). WHO estimates that 2.2% of new PTB cases and 15% of previously treated PTB cases in India have MDR-TB. Amongst patients who were offered second line DST under routine PMDT services in the 3 initial states and amongst those MDR-TB isolates identified in the DRS surveys, the rates of FQ resistance was significantly high (any Ofloxacin resistance from 24 to 31%). The DRS survey in Gujarat (2005 to 2006) found XDR-TB in 4% of the identified MDR-TB isolates. While the extent and magnitude of the XDR-TB prevalence across India is still to be determined, it is estimated that a minimum of 2,000 such cases emerge annually.

The pooled results of various state level DRS revealed that the most common resistance among the previously treated patient group was isoniazid (H) resistance, which ranged from 60-80%. This implied that any H resistance was probably associated with additional resistance to other first line drugs. Hence, in addition to MDR-TB cases, previously treated cases with H resistance could be considered as a proxy of any poly-resistance to first line drugs (bar rifampicin). The next most commonly observed resistance was to streptomycin (S), with levels of SH poly-resistance of 23% seen.

The RNTCP has been implementing the component for the programmatic management of drug-resistant TB (PMDT- formerly known as DOTS-Plus) since 2007. In response to the "Call for action" at the Beijing ministerial meeting of high MDR-TB burden countries in 2009, ambitious national Laboratory and PMDT scale up plans were made to develop 43 LPA laboratories (with 33 liquid culture DST systems) and 120 DR-TB treatment centres, with at least 40,000 MDR-TB patients placed on treatment annually by 2014. Accordingly, an operational plan was developed, via a participatory planning process, with the states and partners in late 2010. After a modest scale up until 2010, the expansion of the PMDT services has been accelerated since 2011, with the result that complete geographical coverage of India with PMDT services was achieved in March 2013. Further scale up of services is provisioned in the National Strategic Plan for TB Control 2012-17.

### Vision of the National Strategic Plan for TB Control 2012-17

- Significantly reduce DR-TB burden in India by ensuring universal access to quality assured TB care: promptly diagnose and effectively treat all TB patients with DR-TB, through decentralized DST and PMDT treatment services integrated into RNTCP.

### Midterm objective

- By 2015, access to MDR-TB diagnosis and treatment for all smear-positive TB (new and re-treatment) cases registered under RNTCP early during their treatment.

RNTCP expects to treat about 160,000 MDR-TB and 4,100 XDR-TB cases between 2012 to 2017. Recently the RNTCP has updated and revised the National Laboratory and PMDT scale-up Plans, 2015-2019, which now aim for Universal Access.

### Goals

- To offer universal DST and DST guided treatment to at least 90% of all forms of TB cases.
- To enhance treatment outcomes of DR-TB patients (MDR-, XDR- and Mono-Poly DR-TB) managed both in public and private sectors.

### Activities

- Expansion of services in a phased manner to be able to offer by 2019 universal DST and DST guided treatment for to at least 90% of all forms of TB cases.
- Establish and strengthen at least 120 C-DST labs with liquid culture and FL-SL DST.
- Scale up access to CB-NAAT in at least 950 sites.
- Have the management capacity available to treat at least 60,000 MDR-TB cases annually.

### ACHIEVEMENTS

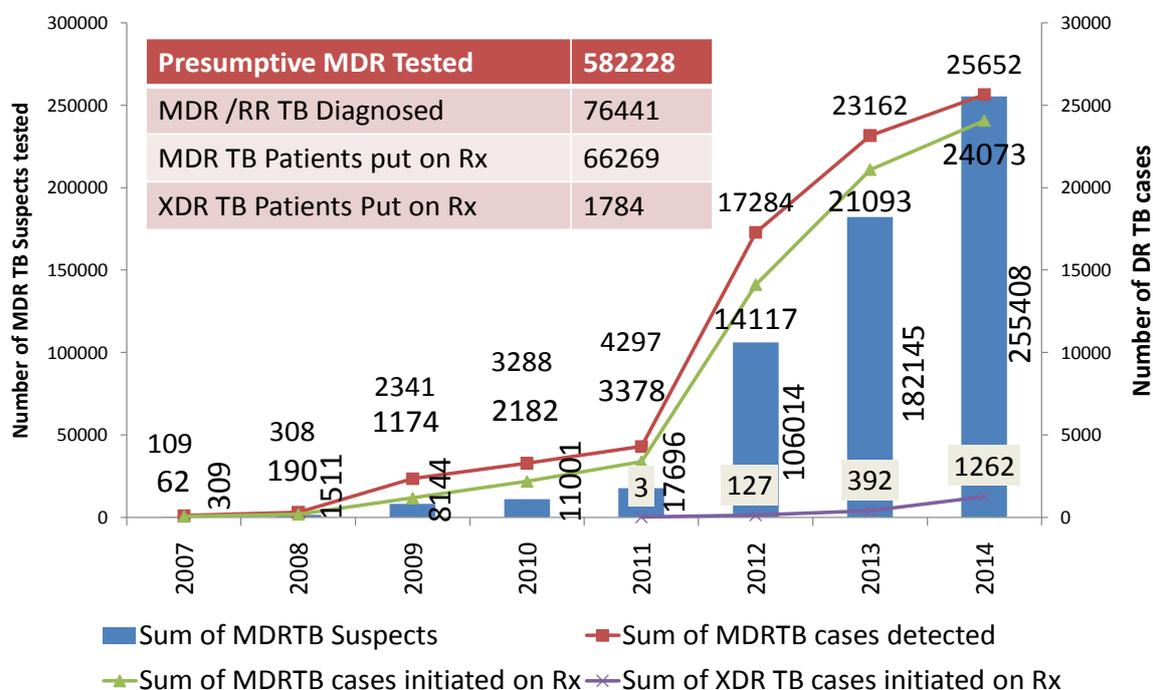
There has been remarkable progress in the expansion of PMDT services since the 2012

JMM.

- Nationwide geographical coverage of PMDT services by March 2013, with Criteria C (as mentioned below) implemented nationwide as from December 2014. With the scale-up of services, the RNTCP has expanded to test the following patients as Presumptive MDR-/Rifampicin resistant TB RR-TB) cases under Criteria C as follows:
  - All Pulmonary Retreatment TB case at time of diagnosis.
  - Any Pulmonary TB case that is positive by direct smear on follow-up.
  - All HIV-TB co-infected cases at the time of diagnosis.
  - Contacts of known MDR-/RR-TB cases.
- Improved access to laboratory diagnosis and DST via expanded network:
  - initial diagnosis of MDR-/RR-TB by rapid molecular test (CBNAAT/LPA); and
  - baseline SL DST introduced in 6 states (Delhi, Gujarat, Karnataka, Kerala, Maharashtra, Tamil Nadu), with strengthened MDR-TB regimen if baseline Ofx / Km resistance detected.
- Largely ambulatory treatment with standardized regimens for M/XDR-TB via 127 DR-TB centres and 50 linked DR-TB centres.
- Increase of MDR/RR-TB cases detected and started on treatment: 3,378 M/XDR -TB cases put on Rx in 2011 → 25,335 in 2014.
- Engagement of 13 Private / 80 IPAQT labs, ~2/3 DR-TB centres located in medical colleges.
- Support systems for MDR-TB patients through various state specific initiatives and National Health Insurance Policy (RSBY) in Chhattisgarh.

- Evidence based national policy update and planned field studies:

## DR-TB case finding and Rx initiation efforts, 2007-2014



- Use of CB-NAAT and its positioning in diagnostic algorithm (prioritized for diagnosis of TB among PLHIV, Pediatric, EPTB, Smear negative PTB groups);
- Daily FDC based regimen;
- DST guided treatment to address variants of DR-TB to improve outcomes.

### PMDT services in place in 2011 and in early 2015

Service Delivery Components	2011	March 2015
States with 100% coverage of PMDT	11	36
PMDT implementing districts	260 (65 Criteria B)	728 (100% Criteria C)
Culture-DST Labs with any technology	36	62
Labs with LPA	18	50
Xpert-MTB-Rif Sites	18	119
SL DST	3	16
Districts linked to WRD (LPA/Xpert)	167	728
DR TB Centers functional	50	127
Linked DR-TB Centers functional	0	50

Criteria B: All smear-positive, previously treated cases of PTB at the time of diagnosis; Any smear-positive patient (new or previously treated) with a positive follow-up result; Any new or smear-positive previously treated patient who fails treatment; and all PTB patients who are contacts of a known MDR-TB case.

### **ACTION ON JMM 2012 RECOMMENDATIONS FOR PMDT**

As per the 2012 JMM PMDT related recommendations, 3 have been achieved, 3 have only partially been achieved, 7 are ongoing and 1 was not done.

**Achieved (4):** Appropriate case definitions and definitions of treatment outcomes developed for paediatric cases, and included in RNTCP guidelines; lack of sufficient in-patient facilities has not been a bottleneck to the initiation of treatment; 1 culture is now done for follow-up; and updated laboratory and PMDT scale up plans up to 2019 available.

**Partially achieved (3):** Existing regulations related to anti-TB drugs have been strengthened with the inclusion of anti-TB drugs under Schedule H1, however this is yet to be strictly enforced; management of the contacts, adult and paediatric, of known MDR-TB cases included in 2012 update of PMDT Guidelines; and central procurement of quality assured second line anti-TB drugs continued.

**Ongoing (6):** National DRS survey ongoing; focus on prevention and "basic" RNTCP activities continued; stakeholders (funding and technical) support to scale up activities continued; development of laboratory capacity continues to be accelerated and expanded; alignment of diagnostics, drugs and treatment management improved in recent years; and bedaquiline to be introduced under strict conditions and only via RNTCP services.

**Not done (1):** WHO 2011 recommendations on MDR-TB treatment duration not considered.

As per the 2012 JMM Infection Control related recommendations, 1 has been achieved and 2 were not done.

**Achieved (1):** Coordinated with NACO, NRHM, National Centre for Disease Control and the National Institute of Health and Family Welfare to extend the implementation of the AIC guidelines beyond the setting of HIV care and DR-TB centres and laboratories, and into the wider general health system.

**Not done (2):** AIC guidelines not yet been updated since 2012 edition; and AIC guidelines not been integrated into the Indian Public Health Standards and MCI requisitions for the recognition of medical colleges.

As per the 2012 JMM DR-TB Research related recommendations, 2 have been partially achieved.

**Partially achieved (2):** Analyses conducted on available data in relation to outcomes of H mono-resistance and polydrug-resistant cases treated under the RNTCP. Research on actual management of such cases not yet conducted; and policy statement on the use of high-dose H in the treatment of MDR-TB cases has been made, however no research on this area has yet been conducted.

## Challenges AND CONSTRAINTS

### Epidemiology/Monitoring and Evaluation

- Epidemiological data (national / for majority of the states / for the private sector) are not known, and there is a lack of understanding of the drivers of the DR-TB epidemic.

### PMDT

- There is irregular review of PMDT activities at the State level, DR-TB Centres and District level.
- There is a lag in implementation of the NSP 2012-17 e.g. from 2012 to date
  - laboratory scale up not as planned (23 of 33 Liquid Culture laboratories, 119 out of 500 CBNAAT machines in place);
  - 25,335 M/XDR-TB cases placed on treatment in 2014, however NSP target was 30,000; and
  - Since 2012, gap between M/XDR TB cases detected versus placed on treatment (66,098/61,064 [92%]), however decreased to 6% in 2014.
- Presumptive M/XDR-TB cases identification and testing insufficient (only 60% of eligible under Criteria C were tested in 2014), in spite of the observation that the existing laboratory capacity for molecular DST (LPA/CB-NAAT) remains underutilized in many sites.
- Variable time to treatment initiation observed (up to 3 months in some districts), however in most districts times have been dramatically reduced since the introduction of rapid molecular diagnostic tests.
- Despite expansion in numbers, sample transport systems and DR-TB centres remain centralized with resultant access issues.
- Clinical and bacteriological follow up is often delayed or incomplete, leading to unnecessary prolonged IP and/or non-switching of patient on to an XDR-TB regimen in some cases.
- Half of patients have unfavorable outcomes (~20% deaths, ~20% LFR, ~8% failure) in early cohorts up to 2012 (predominantly Criteria A [footnote <sup>11</sup>] / Phenotypic DST), associated with the following factors:
  - Prior treatment episode,
  - Initial Ofx resistance among MDR/RR-TB cases at time of diagnosis
  - Under-nutrition (BMI<18)
  - Cavitary disease
  - Poor adherence (>7 days missed doses).
- High levels of H mono-resistance in new (~11%) and previously treatment cases (~30%), and ~30% of MDR-TB cases observed to have baseline FQ resistance.
- Weak patient counseling, pretreatment evaluation, and ADR management observed.
- Declining supervision and monitoring at all levels under the programme.
- Surveillance/digitalization of the MDR-TB data under NIKSHAY is incomplete, which greatly limits its use.

### Procurement and Logistics

- Interrupted supply of some second line drugs (levofloxacin, kanamycin) observed.

### Health System

- Non-enforcement of Schedule H/H1, F/SLDs still available OTC.
- Prevention of DR-TB:
  - Quality of services to DS-TB patients needs to be strengthened

- Limited implementation of airborne infection control (AIC) measures at all levels of the health services.

#### Human Resources

- Wide range of HR issues observed, including manpower, training, re-training, and retention of skilled staff.

#### Engage all care providers

- Medical College engagement is sub-optimal: Not all medical colleges have a DR-TB Centre and laboratory; and minimal TB related research being conducted.
- Private sector: Irrational prescription practices for TB and DR-TB continues; STCI and Partnership guidelines not widely disseminated yet.

#### Social support

- Lack of enablers and incentives for patients, families and health care workers, and limited awareness of and linkages to social support systems for patients and families.

#### Finance

Required funding to meet the necessary scale up plans (2014-19) not yet fully estimated nor secured.

## Recommendations

#### Epidemiology/Monitoring & Evaluation

- Disseminate results of national Drug Resistance Survey as soon as they are available. (By mid 2016)
- Plan study to understand the drivers of the DR-TB epidemic, including whole genome sequencing where appropriate. In addition, explore how the burden of DR-TB in the private sector can be assessed. (By end of 2015)
- Monitor the timely implementation of the revised laboratory and PMDT scale up plans (2015-19) to meet the targets set.
- Strengthen eHMIS, such as e-SMART, between diagnostic facilities, programmatic units and treatment centres to ensure timely transmission of DST results, initiation of treatment, adherence monitoring, and follow up, and link these systems to NIKSHAY. (By end of 2015)
- Implement Information and Communication Technology (ICT) based epidemiological surveillance and monitoring system for DR-TB (e-NIKSHAY). (By end of 2015)

#### PMDT

- Regular reviews of PMDT activities at State level, DR-TB Centres, and District levels to be conducted.
- Strengthen timely identification and testing of all eligible presumptive M/XDR cases under whichever criteria is implemented in the respective site, facilitated by decentralizing the sample transport systems to the DMC levels and optimizing use of all available capacity of rapid molecular DST (LPA/CB-NAAT). (By end of 2015)
- Continue expansion of DR-TB centres network and decentralization to the district level under strict appraisal mechanism to increase access to treatment and further reduce the gap between detected cases and those initiated on treatment. (By end of 2016)
- Urgently address the factors associated with unfavorable treatment outcomes through specific interventions like:
  - Continue building capacity to being able to offer DST at diagnosis in all TB patients, with prompt initiation of appropriate treatment;
  - Promote and monitor STCI in private sector;
  - Modify treatment according to DST results keeping in mind the variable reliability of the DST against some drugs (e.g. ethambutol, cycloserine, ethionamide, PAS);
  - Offer nutritional interventions to the patient and their family; and
  - Strengthen adherence monitoring and support via counseling, pharmaco-vigilance, and community engagement. Explore and implement alternative patient adherence

support systems, such as those that make use of ICT to monitor adherence for those who cannot be under direct observation.

- Implement scale up linked to local capacity for earlier detection, and move from the current baseline of Criteria C across the country towards universal DST as per the NSP 2012–2017 to cover the following:
  - Priority groups (PLHIV, Pediatric, EP–TB and Smear negative PTB) to be tested with rapid molecular diagnostic methods (CBNAAT) as part of diagnostic algorithm, with strengthened supervision and monitoring of PMDT services across whole of the country (By end of 2016);
  - Baseline DST plus initial second-line DST for all detected MDR–/RR–TB cases (By end of 2016);
  - DST for H and R in all registered TB patients using rapid molecular tests CBNAAT/LPA (By end of 2017); and
  - Any detected H–/RR–/MDR–TB case to have DST guided treatment using rapid molecular tests and liquid culture (To be guided by results of the 5 district pilot).
- Consider revisiting treatment duration as per the WHO 2011 PMDT guidelines.
- Introduce new drugs as per WHO recommendations (bedaquiline and delamanid).

#### Procurement and Logistics

- Procurement of second line drugs (SLDs) to continue from the Central level to ensure an uninterrupted supply of quality assured SLDs.

#### Health System

- As the CB-NAAT platform can be used for a range of diagnostic tests in addition to TB and RR–TB, the health system could consider planning in the future years to use it optimally to test for other diseases.
- Ensure continued focus on prevention of DR-TB, and "basic" RNTCP activities:
  - Maintain and strengthen quality of services to drug sensitive TB patients; and
  - Each health care facility, especially the DR-TB centres, should have appropriate infection control measures in place and monitored.
- Make the appropriate palliative and surgical care available where required.

#### Human Resources

- Review human resources across the programme to ensure sufficient, trained staff are in post at all respective levels of the health services.
- Assess training needs for the above activities and develop a plan for the required training needs.

#### Engage all care providers

- Strengthen the mechanisms for engagement of all uninformed Medical Colleges in RNTCP's PMDT activities.
- Widely disseminate the Standard of TB Care in India and Partnership guidelines, and monitor their implementation:
  - Use IT tools (e.g. SMS, whats-app, facebook, twitter and others) to reach all care providers.
- Private providers to have access to RNTCP's network of rapid diagnostic laboratories. Similarly laboratory services may be outsourced to RNTCP certified private laboratories as per the partnership guidelines wherever necessary.
- Use the Private Public Interface Agencies (PPIA) project lessons to engage all private practitioners in PMDT activities and STCI implementation.
- Enforce and monitor the existing regulatory measures, including mandatory MDR-TB case notification and Schedule H1 to protect F/SLDs.

#### Social Support

- Ensure timely payments of enablers and incentives as per policy.
- Leverage upon and establish better linkages to social support schemes such as the National Health Insurance Policy (RSBY), food security, additional nutrition through public distribution systems etc.

#### Finance

- Secure the required funding (Domestic and External) to support the PMDT scale up plans in India.

#### Research

Taking into consideration the important scale-up of the PMDT in India, implementation of diagnostic algorithms for DST guided treatment, expansion of new laboratory tools and introduction of new drugs etc., and the existing gaps in the programme, consider:

- Conducting a rapid validation of SL LPA DST.
- Conducting implementation research on shorter DR–TB regimen(s).
- Engaging in R&D on diagnostics, new drugs and vaccines.
- Building of evidence on the treatment of H mono– and poly non–MDR resistance.
- Adding of DST (pre– and post–treatment) in cases under the daily FDC treatment implementation study to see if the daily regimen reduces the risk of failure, relapse and amplification of DR in patients with initial H mono– and poly non–MDR resistance.
- Study of post–treatment sequelae during post–treatment follow up.
- Conduct international consultation once data of the national DRS, daily FDC treatment study, and DST guided treatment study become available.
- Document and disseminate the PMDT related experiences of RNTCP on the global stage.
- Consider OR to evaluate the impact of molecular TB diagnostics on the patients outcomes, in addition to access to diagnosis and treatment.

#### TECHNICAL ASSISTANCE

- In addition to the necessary capacity building, all required technical assistance to be estimated, requested, planned and provided by technical stakeholders to the RNTCP to facilitate innovations and evidence based scale up of successful interventions whilst moving towards the goal of universal access.
  - 1. The RNTCP should identify and work with other government agencies (in health and beyond health sector) and NGOs that serve special groups, at national, state and district levels. Act on opportunities for integrating TB services within other health and social welfare programmes.**
  - 2. Use different models to reach the special groups and diagnose TB. Four models have been suggested by the JMM thematic group (see table below). It is recommended that these be quickly finalized and used.**

Models	special population groups
<u>Model 1: Improve access by increasing service delivery points</u> More diagnostic centres, specimen collection centres, public and private access Better diagnostics Outreach – mobile teams / mobile diagnostic vans Flexi-time services – facilities open in the evening Symptom screening of health facility visitors	People who live in urban slums, prisoners, hospital visitors, migrants, children, refugees, and people from tribal populations
<u>Model 2: House-to-house community level activities</u> H-to-H information and identification of presumptive cases Referral of presumptive cases or specimen, to diagnostic facility. Ongoing throughout year (e.g. by integrating into MCH outreach services) / periodic	Contacts of TB patients, people who live in urban slums, refugees, people from tribal populations, hard-to-reach areas
<u>Model 3: Active screening</u> Screen with X-ray (with or without symptoms) Lab test for abnormal X-ray results to confirm TB On-going routine surveillance	Institutional and congregate settings and work place, silicosis Health care workers Contacts, PLHIV, very high prevalence settings like Saharia tribes, Tibetan refugees, etc

Model 4: <u>Managing co-morbidities</u> Bidirectional screening Treatment for both conditions	PLHIV, diabetes, undernourished population, Smokers
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3. **Recognizing that some of these groups face different challenges in adhering and completing treatment it is recommended to improve treatment adherence by the following actions:**
  - a. Systematic counselling and psychosocial support
  - b. training of health staff on counselling, use of call centres and radio
  - c. Treatment at home or in the community with flexible treatment support mechanisms
  - d. Implement new rates of incentives approved by Ministry
  - e. Better payment mechanisms for treatment supporters and patients
4. **Consider additional human resource for selected states and districts with high proportion of special populations.**
5. **Address socio-economic issues relevant to TB:**
  - a. Awareness generation customized to the needs of the group with a focus on stigma reduction
  - b. Provide travel allowance for accessing TB care
  - c. Reimbursement of out-of-pocket expenses of patients
  - d. Make all TB patient and their family (and community) eligible for nutritional schemes and actively facilitate access
  - e. Work with NGOs and other government agencies for social and economic rehabilitation of patients
6. **Implement tools and enablers that are needed to target interventions for special groups.**
  - a. Use of best diagnostics and most efficient diagnostic algorithms
  - b. Notification should include information on special sub-groups
  - c. Important programme indicators to be disaggregated by special groups - NIKSHAY should facilitate this
  - d. Implement E-payment for incentives
  - e. Link TB information with Adhar card / UID
7. **To ensure long term impact, empower communities and build their capacity to own and lead the fight against TB in their own community.**

JMM – 2015

Report Section 7: Research to Improve TB Care and Control

Methods of assessment:

Members of the team had access to a series of background documents, including the 'JMM 2012 report', 'Action taken report on recommendations of JMM 2012', and the 'National Strategic Plan for TB 2012-2017'. Members of the team participated in field visits between 11<sup>th</sup> and 16<sup>th</sup> of April, listened to the reports from all field teams on the 17<sup>th</sup> April, and probed as necessary questions on research aspects and needs. The team then gathered on the 18<sup>th</sup> and 19<sup>th</sup> to discuss findings and make recommendations to the JMM group.

In advance of the team meeting, Drs Soumya Swaminathan and Christian Lienhardt had a meeting with Dr Vijayraghavan, Secretary of the Department of Biotechnology. They presented the WHO End TB Strategy with a focus on the Research Pillar of the Strategy. They mentioned the 'Global Action

Framework for TB Research' that the Global TB Programme (GTB) at WHO is currently developing, and the idea of establishing 'model' countries for TB Research promotion and expansion. There was an enthusiastic response from Dr Vijayraghavan who suggested the development of a national TB research strategy involving all partners from the Ministry of Health, ICMR and Ministry of Science and Technology (DBT, CSIR) as suitable.

### **Recommendations from JMM 2012 - Research to Improve TB Care and Control**

(11-1) A National Research Cell for normative guidance, commission priority research, synthesize evidence, fund research institutions, manage and monitor research activities and conduct research dissemination and capacity building.

(11.2) The RNTCP needs to promote partnerships for the clinical and applied research in the country by engaging more deeply with the full spectrum of Indian research expertise including DBT, ICMR, CSIR and the private sector.

#### **Achievements**

The team noticed that some development took place mainly in the area of Operational/ Programmatic Research:

1. The Central TB Division has organized two workshops to develop strategies to strengthen and streamline the research component in the programme. During these workshops deliberations were about constitution and functioning of the National Research Cell. This is now under consideration with the Division.
2. The division has organized number of Operational Research workshops in collaboration with WHO-Union-CDC. There are certain collaborative research with other stakeholders, departments and organization like: NACP, ICMR, NPCDCS, National institutes (NTI, NITRD, NIRT), UNION, PATH, MSF, NGOs and with various developmental agencies. It is roughly estimated that about 200 persons have been trained on OR for TB.
3. Due to active and persistent effort put in by the division (CTD) and partners (WHO, Union, CDC), nearly 30 publications were published in peer reviewed journals since 2012. OR dissemination workshops were done by CTD, Union and NIRT. The findings from various ORs conducted by the programme were instrumental in key policy decisions such as reducing the number of follow up sputum examination, one sample for culture follow up, revising diagnostic algorithm, revised treatment policy, DST guided treatment for DR-TB, TB/HIV management, introduction of molecular diagnostics for MDR-TB on pilot basis, etc.
4. Four National OR expert committee meetings took place (June 2013; Sept 2013; March 2014; Feb 2015). This committee cleared 25 operational research proposals
5. Some states have taken the lead in funding state specific research projects (e.g. Gujarat)

#### **Observations and challenges**

Despite the above, however, the team noticed that the 2 major recommendations from the 2012 JMM had not been implemented:

- the National Research Cell (11.1) has not been established within the RNTCP. According to RNTCP staff, this was mainly due to a lack of clarity in its concept and remit
- the Indian research partnership involving the full spectrum of Indian research expertise (including DBT, ICMR, CSIR and the private sector) (11.2) has not been established. This seems related to the

fact that a proactive approach is required at different levels to involve full spectrum of research expertise and private sector in India – and this has not been possible so far.

- the 25 research proposals were approved by OR committees but their funding status was unclear at the time of the JMM. There are apparently long delays between the time of submission and the ultimate funding decision, with a process that is not streamlined. There is insufficient involvement from key players: for instance, there was no demand from medical colleges on OR, who are not aware of the needs of OR, and a general feeling that human resource capacity built for OR remained insufficient.

### **Opportunities in India**

With the call in Brazil in November 2014 by the BRICS Ministers of Health to foster research on TB, a unique window of opportunity is now opening to promote and expand research on TB in India. With a strong research base formed by a group of National Institutes exclusively focusing on TB (NIRT, JALMA, NITRD, NTI), the network of ICMR institutes, about 350 Medical Colleges, and the strong basic science institutes under DBT, CSIR and DST, India has a unique capacity to be a leader in basic, clinical, translational & operational research to advance TB control nationally and globally. In addition, the large burden of disease makes it a high public health priority and the former Health Minister called for improved TB control with global collaboration for TB research.

### **Recommendations**

1. The development of a strong interagency **“TB Research Consortium”** around the core commitment of MoH, ICMR/DHR, DST, DBT and CSIR, will allow Indian scientists to develop a national TB Research Strategy with the creation of scientific networks and development of a country specific prioritized TB research agenda that will allow India to be a model country for TB Research, along the lines of the WHO End-TB Strategy.

This Forum requires strong financial and technical commitment from all stakeholders including the above + others as appropriate (e.g. Ministry of Tribal Affairs, Women & Child Development, Pharmaceuticals, ...), including representatives from the private sector. It will be backed by a high-level technical *Steering Committee* responsible for framing a National TB Research Strategy covering the full spectrum of research (fundamental, translational, clinical, epidemiological and operational). The Secretariat of this Consortium needs to be mutually worked out between the partners. It will ensure the development of appropriate and thorough mechanisms for execution of the strategy proposed within a limited timeframe.

Responsibilities of the Consortium will include:

- creating a nationwide network of scientists, public health / programme officers, academia, and civil society engaged in TB research
- developing a prioritized national TB research agenda
- implementing the research agenda through relevant Task Forces and special committees
- identifying national and international collaborations
- identifying additional funding sources
- developing Centers of Excellence

High-level political advocacy will be solicited for fulfilling this agenda.

2. The importance of Operational Research is re-emphasized as the best means to improve TB control activities and should be carried out alongside RNTCP activities at all levels. For this, a fully trained focal point for TB OR should be appointed at each State level. It is proposed that **5% of annual TB budget be formally committed for research** through the above mentioned mechanism. Capacity building should be expanded through workshops, mentorship, training at all levels – target in particular junior faculty and students from medical colleges and RNTCP staff (all levels)
3. Lastly, the team stresses the importance of developing a systematic and fully transparent mechanism to ensure translation of findings from research into policy and practice.
4. Coordinate operational and impact research to assess delivery effectiveness and impact on cost reduction and treatment outcomes

## A. Reports from the Field Visits to the States

### 1. Andhra Pradesh

The state of Andhra Pradesh has an estimated population of 50.4 million inhabitants in 2015. It is the 8<sup>th</sup> largest state in India, with a literacy rate of 67%. The state recently split from Telangana, and the actual capital is Hyderabad. The bifurcation from Telangana caused several disruptions such as administrative, financial, institutional and HR vacancies, difficulty filling AP posts until post location is decided and some well-performing elements of the TB programme lost to Telangana. In October 2014, the cyclone "Hudhud" caused damage to the Vishakhapatnam laboratory, loss of samples and commodities, and fall in MDR-TB diagnoses in 4Q14. However, there was a post-cyclone resumption of services.

**Case finding:** There was a slight increase in total presumptive cases examined annually (2.8%), with a big dip in 2013 due to civil disturbance, but it rebounded in 2014. Total case notification rate fell gently, 2012-2014 especially in smear negative cases and initial loss to follow-up fell from 5% to 3.1%.

The quality of microscopy is good (both for LED and FM). X-Rays are not available freely limiting the use of them for diagnosing smear negative and paediatric TB in the public sector. There are two CBNAAT machines functioning (5 in process to set up) and the full procurement of NSP amounts are likely to be close to 15 machines. A cartridge stock-out from May 2014 - March 2015 has been documented.

Referral mechanisms for DR-TB are in place and working optimally. All Integrated Counselling and Testing Centres and some Targeted Intervention NGOs are referring presumptive TB cases for diagnosis. The case notification rates are still well below estimated burden and the MDR-TB case finding needs to be improved as all eligible cases are not being tested. Accompanied referral is done through the Axshaya project for early diagnosis at limited sites

Challenges: Limited CBNAAT linkages for clinical risk groups. Radiographic services are available at select CHCs. Sputum collection in Chittoor is delayed at times.

Recommendations: CBNAAT linkages for clinical risk groups need to be expanded. Radiographic services to be made available at CHCs and sputum collection centres for presumptive TB patients to be established for reducing the delays in diagnosis and missed cases with timely transport.

**Drug-Resistant Tuberculosis:** The DTOs are trained in PMDT at National Level. The district drug store was upgraded for temperature control. The DR-TB services are well integrated with the general health system where ANMASHA, AWW, and the Deputy DM&HO are directly supervising and monitoring the programme.

Challenges: Local NGO's are not optimally utilized, and contact screening is not always happening unless symptomatic, and only when an additional provider is involved.

Recommendations: To engage NGO's as per National Guideline for Partnership for integrated services for TB, DR-TB and HIV and carry out systematic contact tracing for early diagnosis of DR-TB.

**Laboratory Capacity for DST / CBNAAT testing:** Even with limited laboratory capacity, the programme was able to test current DR-TB suspects but not all prioritized group from JMM 2012. There was a post-cyclone resumption of services.

**Challenges:** There was only one functional Culture & DST lab in Visakhapatnam district, and CBNAAT testing throughout the state is underused. The laboratory capacity appears to be inadequate to reach the 90% target as set by NSP for case detection. The specimen transport to the labs is not optimal.

**Recommendations:** To engage additional labs in NGO sector which have capacity to provide services under various partnership options (LPA, Liquid and CBNAAT available). To enhance the use of CBNAAT for key populations, paediatric and extrapulmonary TB. The laboratory expansion needs to be reworked in line with the NSP targets. The specimen transport system to the labs needs to be strengthened.

**Paediatric TB:** Paediatric TB in Hyderabad ranged from 10-12% in 2 Qs 2014 and then fell; in Andhra Pradesh falling (4.2%- 3.8%) 2012-14. Partnership is encouraged with private paediatricians in Hyderabad who are given access to the public sector CBNAAT machine.

**Challenges:** Paediatric case-finding not optimal (below NSP target of 9%), the paediatricians are available at area hospitals but constrained due to lack of X-Rays. Sporadic linkages with private paediatricians for improving notifications, and not all aware that TB is a notifiable disease. Shortages of paediatric TB formulation and lack of research state institution.

**Recommendations:** To improve case-finding through newer molecular tools and linkages with PHCs e.g. induced sputum and gastric aspirate. To ensure access to X-Ray either by public or private sector. Systematic engagement and roll out using the Hyderabad example, and raise awareness of mandatory notification. Ensure buffer stocks in place and develop centres of excellence for research in paediatric TB

**TB/HIV and other comorbidities:** HIV testing among TB patients scaled up: 88% (2012) to 98% (2014); ART coverage among HIV positive TB patients: 83% though no increase since 2012. Sustained universal coverage of CPT over 3 years; 94% colocation for Designated Microscopy Centres and Integrated Counselling & Testing Centres; Operational research of diabetes screening among TB patients in Vizianagaram: 374 TB patients assessed, 3% newly diagnosed as diabetes and routine screening of TB reported to be implemented.

**Challenges:** Case fatality rate among TB HIV co-infected patients was 11% in 2014 (3 times higher than among HIV-negative TB patients); possible initial linkage loss from district ICTC to DMC but overall AP testing of presumptive cases 88%; Diagnostic algorithm with CBNAAT as the first diagnostic test for PLHIV not being used. IPT and daily ATT not yet being implemented. Infection control in HIV care facilities largely absent.

**Recommendations:** State specific strategy and plan to be developed to reduce the mortality among TB-HIV co-infected patients; better follow-up between district ICTCs and sub district level DMCs. Expansion of Nikshay to include referral and TB prevention for PLHIV; implement infection control guidelines and monitor TBIC practices in HIV and TB care facilities through joint supervision visits; expedite implementation of IPT and use of CBNAAT for PLHIV after presentation of any of the four symptoms. Opportunities to engage NGO hospital involved in the NACP services with lab diagnostic facilities to be tapped in district.

**Involving all care providers:** Provision of CMEs to private providers increases engagement, referrals, notification and care. A total 8,938 cases notified of Nikshay by private practitioners for the entire state.

**Challenges:** Involvement of private sector at a scale commensurate with their presence in AP not evident. Private sector has limited incentive for TB Care and control, capacity of programme to engage with private providers is limited. Lack of involvement of the AYUSH doctors.

**Recommendations:** There is a need to involve the private sector throughout the cascade of care. To strengthen HR and technical capacity within programme to engage with private practitioners. Expedite roll-out of daily fixed-dose combination and to develop strategy for broader engagement of other public sector bodies. AYUSH doctors should also be more involved as well as community pharmacists.

**Procurement and logistics:** All anti-TB drugs (First Line, Second Line and XDR drugs) with exception of PC-13, are available at all stocking points. There is good documentation, physical verification following good storage and distribution practices were in place. The temperature, humidity were well monitored with periodically validated instruments.

**Challenges:** The 3 month buffer stocks as per RNTCP guidelines were not available at the District level for almost all the first line drugs in Vizianagaram. The current space for the district stores is not always adequate. There is no State Drug Store in new Andhra Pradesh. The ADR data is not recorded.

**Recommendations:** A buffer stock of minimum 3 months at DTC level should be maintained to meet any eventuality. The district drug storage to be extended to take into account expected rise in MDR-TB case detection rates. To contract and establish state drug store for AP at Visakhapatnam at the earliest with qualified staff.

**Human resources for health:** High sense of motivation and devotion of the staff and the Medical Officers met by the teams-ASHAs, ANMs, Aanganwadi workers (AWW), STLS and STS etc. ASHA workers are more involved in TB and more accountable under incentive scheme.

**Challenges:** Objectives for HR in NSP are not met, on average vacancies are at 60% up to 100% for certain posts. Absence of a state training and demonstration centre. Delayed salaries and poor retention of trained people power. Limited training and career opportunities for ASHAs.

**Recommendations:** To review at state and districts levels of vacancies (especially STS of TB units) and for the concerned authorities to speed up the recruitment process. To establish a state training and demonstration centre for TB with suitable drug store. A Public Health management training should be essential for all supervisory functionaries at block/district/state levels. National and State authorities to ensure sufficient, sustained and timely resources available to facilitate a sustained and motivated workforce. Provide enhanced training and career opportunities for ASHAs.

**Financial support to TB Control:** The programme conducted essential activities within limited available resources due to bifurcation formalities and new system of release through treasury route. Presently the state and districts have funds for next 6-9 months.

**Challenges:** Forced underspending due to inadequate resources and delays in fund receipt. The programme conducted crucial activities within available resources, but some activities were curtailed. Contractual staff suffered delayed remuneration of at least 4 months. There are many vacancies of finance staff and finance staff posted were not well aware of financial management guidelines and procurement procedures.

**Recommendations:** To eliminate delays in making funds available for TB control to the District TB Societies. The State to provide DTO with an imprest account so that urgent day to day expenditures can be made. Working group at state level should address administrative problems and bottlenecks.

**Support systems for patients and families:** Integrated Tribal Development Agency offered protein rich food worth Rs 500 for every tribal patient reaching 220 patients until 12/2014; Financial assistance of Rs300 per month per patient offered to 20 patients by TB association of Andhra Pradesh; ICT enabled Aadhar card (unique personal ID) linked tool being piloted for the poor to instantly list out all social benefit schemes for which TB patients are eligible; HIV-positive TB patients receive Rs1000 per month, 50% bus pass compensation to ART centres and nutritional support.

Challenges: Some initiatives offering financial, nutritional and systematic support, but not to scale (per NSP); Patient and community interviews highlighted the need for nutritional support during treatment and financial assistance due to loss of wages for up to 4 months and there is some evidence of discrimination by both family and community post diagnosis.

Recommendations: Implement NSP recommendations; Develop a strategy for sustained and consistent provision of social support services; Counselling or awareness programme for families and communities to be organized by the ASHAs to help them combat stigma locally.

**Targeted interventions for special groups:** All ASHAs and AWW in tribal areas have been trained and were providing services, despite the remote rural location. The tribal patients approach the ASHAs rather than traditional healers when experiencing persistent cough. The Integrated Tribal Development Agency offered protein rich food worth Rs 500 for every tribal patient. NGO support for people in urban slums for treatment completion in Chittoor (i.e. Damian Foundation or TB Alert for MDR-TB).

Challenges: Targeted interventions only evident in some areas; not to scale.

Recommendations: As per NSP, map key populations e.g. prisoners, urban slum dwellers, old-aged, tribal, migrants, industrial workers, etc. to inform focussed response and community-involved interventions for early case detection and treatment support. Develop strategy for NGO engagement to address TB in identified key populations and NACO Targeted Interventions for key populations affected by HIV.

**Community engagement, ACSM:** There is Panchayat Raj (village leaders) involvement through community meetings in some areas visited, as well as sensitization and involvement of community leaders in DOT (for follow-up) in some areas visited. Limited advocacy programmes with district agencies, industry and priority government departments. Print and electronic media advocacy visible.

Challenges: Most NGO involvement is in TB/HIV activities and on MDR TB but no extensive engagement; only 33 NGO programmes in AP. Advocacy with Panchayats and other communities sporadic. Activities in Chittoor restricted to NGO and Axshaya project covered areas. Awareness of symptoms of TB, and services available in the community was limited. Self-help groups (SHGs) identified as an outlet for advocacy dissemination. Not all SHGs were well informed about TB and the programme.

Recommendations: Develop strategy and framework for sustained and systematic NGO engagement and systematic sensitization of all Panchayat and community leaders is recommended. To implement extensive promotion of services in regional language. To reduce stigma and raise awareness, patient-advocates could be encouraged to share their experiences. Use SHG monthly meetings for information, experience sharing and assure sustained financial support for NGO engagement. Partnering with community radio station for locally based programs.

**Research:** The following Operational Researches were conducted in Vizianagaram district (Andhra Pradesh): a) Linking HIV- Infected TB patients to Co-trimoxazole Prophylaxis and Antiretroviral Treatment b) Feasibility and effectiveness of provider initiated HIV testing and counselling of TB suspects c) screening of patients with Tuberculosis for diabetes mellitus. These OR led to policies at the National level in the programme. They are being implemented and are current practices across the country.

Challenges: Currently research is not part of programme core.

Recommendations: Develop centres of excellence for research in paediatric MDR-TB and key populations.

### **Some key recommendations from 2012 JMM that still need to be implemented**

There is a need for greater focus on care providers in the private sector; to work with the DCGI to restrict the availability of new anti-TB drugs; to establish strategies to improve retention and performance of staff; review NGO schemes and address the reasons for the low uptake of these schemes; engagement and strengthening of the community in partnership with CSOs; bottlenecks in human resources and the flow of funds need to be addressed; an empowered working group should be constituted to examine and address administrative problems and bottlenecks, as well as obstacles in HR management and financial management.

### **State Level briefing**

Increase case finding by: Expanding the radiological services available in the districts to ensure chest X-rays for the diagnosis of smear negative TB; work closer with the private sector to support mandatory notification and ensure all cases diagnosed in the private sector are notified; develop and implement plan that recognizes the primacy of NGOs in outreach and prevention and works closer with community groups ensuring they are sustainably supported to carry out TB work; provide paediatricians in public and private sectors with access to new CBNAAT diagnostics; increasing contact tracing and IPT for contacts under 5; engage proactively to seek cases in industrial hub sites.

Ensure TB control efforts are adequately staffed and equipped: Fill vacant posts at state and district levels especially those of Sr TB Supervisors; establish state training and demonstration centre for TB plus drug store.

Ensure adequate funding is available for TB control by: By eliminating delays in making funds for TB control available to district TB societies; provide DTO with an imprest account and provide financial support to drug-sensitive cases in poor people as well as MDR-TB cases.

Take advantage of AP's IT capacity to further develop E-smart platform and align with NIKSHAY to include referral and diagnosis

### **Team members**

<b><u>Vijayanagaram District</u></b>	<b><u>Chittoor District</u></b>
Paul Nunn (Mission leader) Annabel Baddeley	Jaime Bayona Amy Israel

K S Sachdeva V Kalaiselvan B B Rewari E Thanaraj Jyoti Jaju Shreelata Rao Seshadri R K Sachdev Umesh Alavadi Shanta Achanta	Gita Bamezi Pascal Zurn Rajesh Deshmukh Subhash Salunke Ranjani Ramachandaran Dharma Rao Reshu Agarwal
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### 3. Gujarat

The team visited State TB Cell, State TB Training and Demonstration Centre, State Drug Store, Intermediate Reference Laboratory and Drug Resistant TB Centre at the State level. Meeting with IMA representatives and Director of Food Drugs and Cosmetics Authority was carried out.

Jamnagar, Mehsana and Banaskantha Districts were visited. The team visited 2 District TB Centres, 7 TB units, 1 Medical College, TB C & DST laboratory and DR-TB Centre, 1 Sub-district hospital, 5 Community Health Centres, 6 Primary Health Centres, 6 Designated Microscopy Centres, 2 ICTC, 3 FICTC, 4 Drug store, 2 NGO, 1 Corporate hospital (DMC), 15 private practitioners, 12 chemists, 20 TB patients at district and sub-district level.

#### Achievements

- The state has highest level of administrative commitment reflected in budgeting, expenditure, procurements, insubstantial vacancies of HR under RNTCP reviews and process measures undertaken to ensure programme quality
- All TB units are aligned with blocks/taluka and optimum TB units are established in urban area.
- State has pro-actively implemented operational research, pilot interventions (e.g. UATBC in Mehsana) and conducted state funded TB prevalence survey
- Case-finding in public health facilities is strong. The state has taken proactive efforts to increase access to microscopy services by expanding its DMC network from 765 in 3Q14 to 850 in 4Q14.
- Proactive approach for TB case finding has been initiated in 2014. Enhanced case finding activities with house to house visit by health workers was conducted in high case load TUs. Systematic active TB screening activities are carried out in a few districts.
- Enthusiastic early response on private notification as reflected with increase in trend to more than 5000 patients notified in 1<sup>st</sup> Quarter 2015.
- To attract private notification effectively, the state has implemented pilot on universal access to TB care with use of advances in ICT to facilitate notification and providing e-transfers to pharmacists to facilitate access to free anti-TB drugs to patients. Total TB case notification rate has been doubled in 8 months period with stable notification from private sector.
- Extensive network of laboratories performing sputum smear microscopy. Sputum transportation mechanism has been established with available flexibility of funding from NHM to improve the access.

- DR-TB diagnosis services are provided through WHO- approved rapid diagnostics (WRD) to all districts by two TB C & DST and four CBNAAT laboratories. State has developed an in-house capacity of diagnosis of both first line and second line DST on liquid culture system at both TB C & DST laboratories duly quality assured and certified under RNTCP.State wide specimen transportation mechanisms is effectively utilized in cold chain for diagnosis and follow up of DR-TB patients to cover all district at six laboratories.
- Treatment offered to TB patients is of high quality. State has been able establish excellent and diverse decentralization of DOT services. Intensive efforts are put in to control initial loss to follow up.
- Efficient implementation and state wide expansion of Programmatic Management of Drug Resistant TB
- Services for TB-HIV collaborative services are well implemented and services for TB-DM is gaining momentum.
- Well-kept paper records at lower level health facilities and well-captured and collated at district and state level through EPICENTRE. Registration of TB patients in NIKSHAY is almost complete.
- Much appreciated social welfare scheme is implemented across board in the state. Through this, TB patients from SC, ST or OBC cast are given Rs. 500 per month. There is a movement in many districts to mobilize local resource to extend nutrition support to TB patients.
- The state has good absorption capacity and expenditure in TB control has grown 38% in real terms 2012-2015, with efficient fund disbursement.

### **Constraints**

- National Strategic Plan recommendation on HR is implemented, but HR needs not fully met. Number of patients that have to be handled by one STS range from as low as 19 to as high as 170 in visited district. Moreover, in area of high case load, comorbidities, drug resistance, scope of engagement of private sector are more; fixed allocation of staff by health block/taluka has resulted in less than optimal HR deployment and utilization.
- Public sector TB case finding is static. There is a recent surge in case notification rate in 2014 which has been driven by TB case notifications from the private sector.
- Burden of disease is demonstrably high, 417 bacteriologically-positive TB cases per 100,000 population, as reported in state conducted TB prevalence survey
- Patients are missed from surveillance, as 30% of bacteriological positive cases have not yet sought care for their symptoms (TBPS Gujarat)
- There is a huge private sector, which includes allopathic and non-allopathic health providers. Preliminary analysis of anti-TB drugs sales in Gujarat, it was estimated that at a given approximately 60% patients treated for TB are being treated by private providers.
- TB notification coverage is relatively low. Only a small proportion of private providers are notifying TB cases.
- High sensitive diagnostic tools are not yet utilized for diagnosing extra pulmonary diagnosis of paucibacillary TB like extra pulmonary and paediatric TB
- TB C & DST laboratories are not yet accredited in line with ISO 15189 but show promise moving toward this.
- There is a scope of strengthening some of the basics of getting quality sputum samples for sputum testing.

- High levels of second line drug resistance, >40% ofloxacin resistance at diagnosis, raises serious concerns on adequacy of all PMDT treatment regimens
- Proportion of paediatric TB cases out of all registered patients is only 5%.
- NIKSHAY and EPICENTRE operate as parallel systems. Reports and stats rely on EPICENTRE. Little use of NIKSHAY as periodic reports are not generated and interface is not user-friendly requiring repeated downloads into separate files and lack of flexibility.
- ACSM restricted to conventional activities like community meetings, patient provider meetings, Wall paintings etc.
- In the visited district, 26% patients were given benefit of social welfare scheme. But, nearly every TB patient interviewed claimed eligibility. Moreover, process to avail social welfare scheme support is cumbersome
- Nutrition support to TB patients is a welcome move but RNTCP can not become another public distribution system.
- There is a growing gap between needs and budget allocated as against planned and approved.
- Pressure on State to finance the Gap – ***the state share has gone up from 0-32% in last 3 years***
- There has been gradual deterioration of flow of funds. Funds releases have shifted towards last month of the year, presenting challenges to timely expenditure. This is partly due to delay in funds flowing to State Health Society from average 1.5 weeks in 2012-2013 to 10 weeks in 2014-2015.

### Assessment

The team recognizes and appreciates Gujarat's State RNTCP for the administrative commitment to building, implementation, and development of a robust public sector TB programme. In particular, the State has ensured a fully-funded programme with efficient need-based fund flows to districts, and aggressively filled HR vacancies. There are good process measures of program implementation, additional services, and basic public sector passive case finding.

Despite these efforts, the TB burden in Gujarat state is demonstrably higher than expected, at 417 per 100,000 adult population, or 1 in 239 adults. Preliminary analysis of Gujarat anti TB drug sales has suggested that on any given day, for every 2 TB patients treated by RNTCP Gujarat, 3 are treated by private providers. Notification 'coverage' of private patients is low.

Accordingly, the core recommendation of the JMM is to accelerate and expand engagement of private providers. This entails using the expanded TB workforce for new activities, not just more of the same. Specifically, expand access to quality assured services for private providers via UATBC (Mehsana model) expansion, and extension of free DST for all notified TB cases with sputum pickup and transport. Once engaged, encourage and monitor use of standard treatment practices. This is expected to be in line with existing case costs, but it is obvious that expanding the number of cases supported requires a commensurate expansion of the budget. In addition, targeted screening in high risk groups should be conducted, leveraging health staff for active case finding in slums, other high risk groups, along with systematic contact screening (using sensitive tools like CXR/LED/CBNAAT). We recommend tracking metrics of the percent of targeted providers who notify in the last quarter, and the percent of estimated privately treated patients notified (using models or private drug sales surveillance).

The JMM further recommends to strengthen social support services. Gujarat has laudable, country-leading social support initiative. But access is difficult and restrictive; other States, such as Kerala, have had more inclusive approaches to extending social welfare support to all notified TB cases

(public and private). Lastly, the JMM recommends to intensify community awareness, engagement & empowerment, in particularly to deploy demand generation campaign (e.g. TB harega, Desh jeetega) to drive early care seeking.

Perhaps more than any other State, Gujarat has the systems and commitment to be able to control the TB and MDR TB epidemic, and to serve as a model for the State commitment and resource requirement.

## **Specific Recommendations**

### Health System and Human Resource

- Use extended workforce for expansion of scope of TB services under RNTCP, such as enhanced case finding, scale up to effective treatment for drug resistant TB, engagement of private practitioners, extend public health services to patients diagnosed and treated in the private sector. Flexibly re-allocate treatment supervisory staff to high-need areas
- Highlight the bidirectional benefits of health system strengthening and TB control, to all stakeholders. All TB control efforts be supported by initiatives to strengthen health systems. Use Lab services as platform to increase attendance (and utilization) of public health facilities. An enhanced and assured package of lab services likely to attract more beneficiaries, provide opportunity to detect additional TB cases.
- Strengthen district level capacity in operational research – increased funding, Research on why people select a type of providers, care pathways and patient behavior.

### Case Finding

- Pursue immediate opportunities of case finding in public sector like use of high sensitive diagnostic tools (LED microscope, CBNAAT) at high work load settings to begin with. For this, scale up rapid diagnostics.
- Augment systematic contact screening with use of chest X-Ray or LED microscopes or CBNAAT for evaluation of TB
- Scale up systematic active TB screening in vulnerable and marginalized population. Consider use of mobile medical unit with digital chest X-Ray and rapid diagnosis to enhance the existing process of active TB screening. Use existing listing and mapping of marginalized population prepared for IPPI and notified slum area to target the coverage for active case finding activities.
- Accelerate, expand and pursue private sector engagement at a large scale. Leverage upon the expanded number of programme staff under RNTCP. Use new tools and tactics to complement existing sensitizations. Scale up UATBC to new districts. Extend services like DST for privately notified cases using district-level CBNAAT capacity.
- Consider Polio experience(Reporting and informer units) for engagement with private providers (both formal and informal) as ways to enhance case detection.
- Notification coverage needs tracking. Like of % of targeted providers who notify in the last quarter, % of estimated privately treated patients been notified (estimated based on model or sales based state-wise denominator) so on and so forth.
- Once engaged, encourage and monitor use of standard treatment practices

- Strengthen UATBC model with feedback to private providers for adhering to standards for TB Care in India for diagnostic practices emphasizing microbiological confirmation and prescribing rationale anti-TB regimens.
- Implement schedule H1 for surveillance and targeting providers prescribing anti-TB drugs

#### Laboratory Services

- Expand laboratories with high sensitive diagnostic tools to give benefit of early diagnosis of TB patients among those for whom microscopy examination has its limitation in detection. Priority should be given to extra-pulmonary TB, paediatric TB, smear negative TB to begin with.
- Strengthen & sustain HR capacity at C&DST labs. There is need of 2nd microbiologists to each TB C & DST laboratory.
- Start process of accreditation for C & DST laboratories in line with ISO 15189
- Increase volume of slide re-checking and frequency of supervisory visits in laboratories with low sputum positivity rates. Make sputum collection process on site observed by health worker and earmark designated space for collection of sputum samples at health facilities with display of visual aid materials adopted for the need of patients.
- Give private sector access to rapid TB diagnostic tests and DST results. Provide options for referral for sputum microscopy facilitate sputum collection and transportation or support microscopy centers in private health facility.

#### Treatment Services

- With reasonable strong foundation of existing strategies of RNTCP for TB care services, the state has a potential and should move to “test and treat”, for all public or private TB patients. Plan, budget, and implement universal DST for TB patients, i.e. include new smear positive & new smear negative TB cases for DST and initiate appropriate treatment
- Assess feasibility of long-term follow-up of cured TB patients as per ‘Standards for TB Care in India’ and offer symptom screening, sputum culture and DST and ancillary treatment. Assess cost effectiveness of such activities to guide the programme.
- Experience of tracking initial loss to follow up gives edge and state should move to notification and registration at diagnosis from public, and capture patient loss from death/loss to follow-up in treatment outcomes
- Enhance inter-sector coordination for patient support for nutritional supplementation, vocational rehabilitation and social welfare scheme support.

#### Programmatic Management of Drug Resistant TB

- Ensure all eligible patients receive DST. Decentralize Rif screening DST to District level with CBNAAT. Universal 2<sup>nd</sup> line DST crucial; expand the scope of DST.
- Avoid unnecessary extension of intensive phase. Use the liquid culture results for switching to continuation phase rather than waiting for solid culture result. Immediate communication and action by STS for switching patient to continuation phase.
- Reduce loss to follow up through intensive counselling services, identify and actively address adverse drug reactions, socio-economic support for all TB patients to cut down catastrophic expenditure

#### Paediatric TB

- Strengthen contact tracing and INH chemoprophylaxis for children <6 year of age
- Engage paediatricians to improve quality of diagnosis. Capacity of public health facilities should be enhanced to collect BAL, induced sputum, gastric lavage in case of children.
- Engage private paediatricians on notification and offer facilitating services, including CBNAAT.

#### Surveillance

- Set a deadline to phase out use of EPICENTRE and transition to a single notification system. Similarly, enhance functionalities of NIKSHAY like services of de-duplication of public/private notifications
- Use TB Prevalence Survey Data for further planning and monitoring

#### ACSM and Community Engagement

- Intensify community awareness, engagement & empowerment
- Deploy demand generation campaign (e.g. TB harega, Desh jeetega) with goals to achieve early care seeking and patient/provider acceptance for sputum testing. Use appropriate messages with less medical language more patient friendly and attention catching.
- Build capacity on planning and implementing ACSM activities. Undertake need based and contextual activities and measure impact
- Dissemination of information about schemes for patients and community. Engage more actively and meaningfully with cured patients and their families
- Empower ASHAs with input and knowledge about TB and comorbidities. Improve communication tools for ASHAs

#### Patient Support

- Availability of Social Welfare scheme is recognized as best practice and should inspire all States. Make access to and processing by social welfare department more convenient to patients. Remove filtering criteria; all notified TB patients should qualify for social welfare scheme.
- Pursue large-scale support from well-resourced and aligned charities. Develop innovative links to nutrition for all TB patients like food card without a new clunky PDS

#### Finance

- Action Plans and budget requests should reflect the funding needed to perform according to the aims of NSP rather than being "shaved" to match expected allocation
- GOI should release totality of the annual allocation by end of first quarter to compensate for longer fund flow from treasury to SHS
- Make expectations for State share clear earlier. Consider giving cash instead of drugs for States that want to change to daily regimen

### 3.Himachal Pradesh

#### Team Members

Sr. No.	Shimla	Solan
1	Dr Virender Singh Salhotra	Dr Sharat Chandra Verma
2	Dr Rakesh Dayal	Dr Manoj Toshniwal
3	Ms Amy Piatek	Dr Shantanu Kumar Kar
4	Dr R R Shinde	Dr Anuj K Bhatnagar
5	Mr Thomas Joseph	Dr Petros Isaakidis
6	Ms Smrity Kumar	Dr S Anand

#### State Profile

##### Demographic profile

		
<b>Population</b>		<b>71,41,141</b>
Population Density per sq. km.		123
Sex Ratio (Females per 1000 males)		972
Rural Population		89.96
Tehsils/Sub Tehsils		137
Development Blocks		78
Census Villages		20690
Gram Panchayats		3243
<b>Towns</b>		<b>59</b>
No. of PHC		497
No. of CHC		80
No. of sub-centres		2068
<b>Districts Visited</b>		
<b>Shimla</b>		<b>8,47,150</b>
<b>Solan</b>		<b>6,00,609</b>

##### Health Infrastructure

Health Infrastructure	State	Shimla	Solan
Districts	12		
Health blocks (BPMU)	73	8	5
Tuberculosis Units – Existing + Proposed	49 + 24	4 + 4	3 + 2
DMC – Public + Private sector	178 + 21	21 + 0	19 + 1
Medical Colleges – Govt.	2	1	0
Medical Colleges – Private	1	0	1
STDC (At Dharampur)	1	0	1
SDS (At Dharampur)	1	0	1
Ayurved Hospital & Dispensary	1100	151	90
ART Centres	3	1	0
Link-ART Centres	8	0	2
ICTCs	46	5	5
F-ICTCs	17	0	0
Co-located DMC	61	4	5
IRL (At Dharampur)	1	0	1

DR TB Center (At IRL Dharampur & RPGMC Tanda)	2	0	1
C&DST Lab (At IRL Dharampur & RPGMC Tanda)	2	0	1
LPA lab (At IRL, Dharampur)	1	0	1
CBNAAT (at IGMC, Shimla)	1	1	0

### Places Visited

Shimla	Solan
DTC Shimla	DTC Solan
DDU Hospital Shimla	District Ayurveda Hospital, Solan
IGMC, Shimla	MMU Medical College Solan
PHC, Shoghi, Maroug	Cantonment Hospital, Kausoli
Civil Hospital – Sunni & Chopal	CHC – Kandaghat, Chail, Baddi, Nalagarh, Arki, Kunihar
CHC/PHC – Dhami, Kumarsain & Mashobara	Government Ayurveda Dispensary – Barog, Gadkhal
MGMSC, Rampur	Private hospitals - Sai Sanjeevni Hospital, Dr Singhal Hospital
Aayush Health Centre, Duttnagar	ESI Hospital Parwanu, Katha
Tenzing Hospital	TBS Dharampur – IRL, SDS, DRTB Centre
HPVHA, Shimla	District Sub-Jail Solan

## 1. Local Epidemiology, application of ICT and program Monitoring

### Achievements:

- Steady rate of Presumptive TB examination & Case Notification Rate
- Total Case Notification - ~ 210/ 100000 for the past 8 years; declined to 196-199 in the past 3 years and increased again to 211 in 2014
- NSP case notification - ~ 78/100000
- Fortnightly SMS is sent to Ayush clinics, to refer the presumptive cases

### Gaps/Constraints

- STO and DTOs do not have full time responsibility for TB programme; having additional charges – hampering monitoring & supervision
- Gap between Smear positive cases diagnosed & put on treatment
- Usage of ICT is sub-optimal
- Pending entries in Nikshay

## 2. Universal Health coverage, Health system functions, Integration of TB services, general health system and equity in access

**Achievements:**

- Established general health system having high Community faith
- Alignment of RNTCP services with general health system
- Plan to align BPMUs with TU
- Funds of Rogi Kalyan Samiti (RKS) are being utilised for gap filling (support to patient)
- Guidelines for STCI shared with all stakeholders & programme managers and Initiation of trainings for STCI

**Constraints and gaps:**

- Vacancy under RNTCP at state and district level – both old & new positions
- Block level MO are untrained and provides little time for monitoring TB program.
- Non-functional DMCs in some HRA and far flung areas – vacant LT positions
- Sputum collection & transport mechanism lacking from difficult areas

**3. TB services****Achievements:**

- TB diagnostic & management services provided free of cost
- INH prophylaxis is being provided to eligible paediatric contacts
- Intensified case finding approach in select areas (such as Jails inmates, slums, industrial area, nomadic population etc.)
  - Model Central Jail Nahan, Solan, Shimla, Mandi , Kullu, Una and Kangra
  - slum area in TU Bhawarna in District Kangra in December 2014
  - Regular IEC activities in the hydropower projects areas in District Kullu, Chamba and Kinnour
  - Sensitization of weavers at Industrial area at Bhuthico Kullu, Industrial area of District Shimla, BBN area of District Solan and Pounta Area of District Sirmour, Cement factory in Darlaghat in District Solan, Industrial area in Una
- Involvement of Ayush clinics for referral of presumptive cases and DOT services

**Constraints and gaps**

- Very low NSN case detection rate & very high EPTB
- Non-functional DMCs - due to HR - lab technician vacancy
- Most DMCs are referring lower than expected number of TB symptomatics
- Underutilized CB-NAAT at IGMC, Shimla
  - Most of referrals are from the districts

- Not optimally utilized for PLHIV, EPTB, Children
- Treatment initiation and DOTS is centralized – Less than 10% of patients receiving DOT through a community provider
- There are few “transfer out” patients in spite of large migrant populations

#### **Recommendations (for 1, 2, & 3)**

- Placement of adequate HR
- To develop community-level sputum collection approaches and decentralized DOT
- ICF activity in high risk population like DM, Paediatric, slums, industry worker etc.
- Block level MOs to be trained and reviewed on monthly basis by CMO
- Update on algorithms for diagnosis among health care providers
- Sensitization regarding CB-NAAT testing algorithms for optimum utilization
- Evaluation of high percentage of EPTB cases
- Systematic implementation of “Referral for Treatment”, “transfer out” and “defaulter tracing” mechanisms to ensure all patients are followed-up

#### **4. *Drug resistant TB***

##### **Achievements / Observations:**

- DR TB diagnostic & management services provided free of cost
- Districts linked with 2 DR TB Centres at Tanda & Dharampur
- Pretreatment evaluation is done in DR-TB centres/District Hospitals
- Upgraded DDS for SLDs
- Use of 108 service for these patients
- Pharmacovigilance initiated in DRTB patients
- Sputum specimen transportation from District to IRL via - Human carriers due to absence of courier agencies

##### **Constraints and gaps**

- Low number of presumptive DR TB referrals & diagnosed DR-TB cases with wide variations among districts with varied knowledge of presumptive DR TB cases criteria.
- Gap between TB patients diagnosed and put on treatment
- Diagnosed RIF-resistant cases are referred to the DRTB Center for treatment (about 75 km away) from IGMC
- Accreditation of C& DST lab at RPGMC, Tanda is pending
- STS/STLS being used as human carrier (weekly)

- No Two wheeler for DR TB Supervisors
- Vacancy of key positions at DRTB Centre

#### **Recommendations**

- Line listing of presumptive DR TB cases with prompt referrals
- Tracing all diagnosed cases and initiating treatment
  - Pre-treatment evaluation & initiation of treatment of all DR TB patients diagnosed at IGMC with intimation to DR TB Center
  - Developing mechanism of sputum transport without using STS/STLS
  - Procurement of Two wheeler for DR TB Supervisor
  - Provision of ICTC / F-ICTC at DRTB Centre
- To expedite for accreditation of C& DST lab at RPGMC, Tanda

### **5. Paediatric TB**

#### **Achievements:**

- The state/district are highly sensitized on pediatric TB/DR-TB
- Systematic contact tracing is conducted in parts of the district, including children, which is commendable (BEST PRACTICE)
- INH prophylaxis is also being offered to Paediatric contacts (BEST PRACTICE)

#### **Constraints and gaps**

- No systematic monitoring of chemoprophylaxis
- Low Paediatric TB cases proportion: ~5%
- Revised paediatric guidelines not yet disseminated
- The capacity on gastric aspiration/BAL is limited at state level
- Mixed practices for Pediatric cases management at IGMC with regards to regimen and notification
- PPD vials not available

#### **Recommendations**

- Make the use of CBNAAT for TB diagnosis in children routine practice ASAP!
- Increase state capacity in pediatric TB diagnosis, including gastric aspiration/BAL/sputum induction
- Improve the contact-tracing/INH prophylaxis data collection tools and DOCUMENT the experiences and outcomes of this innovative intervention
- Use of new paediatric guideline after training and sensitization

- Need based procurement of PPD vials
- Ensure uninterrupted supply of INH
- Ensure TB/DR-TB counselling at all levels of care for children/care-givers and ensure trained staff is delivering such service
- Improve recording and reporting for children in general

## 6. *TB/HIV and other co-morbidities*

### **Achievements:**

- Increasing trend of known HIV status of registered TB patients (64% in 2014) but having wide variations among DMCs/blocks
- Excellent up-take of HIV testing among TB/DR-TB patients (>90%) in specific district
- TB-Diabetes: In Districts (Solan, Sirmour and Kangra), blood sugar examination of all TB patients is being carried out from 1<sup>st</sup> quarter 2015
- Recording of Smoking history on treatment cards initiated

### **Constraints and gaps**

- District Coordination Committees establishment is pending at 8/12 districts
- Infrequent DCC meetings
- Less number of co-located facilities
- Intensified Case Finding (ICF), Infection Control (IC), Isoniazid prophylaxis (IPT), Cotrimoxazole prophylaxis (CPT) and antiretroviral therapy (ART) are not at all streamlined – IPT for TB/HIV co-infected not available
- The CBNAAT facility is seriously underutilized for HIV patients and EPTB patients (if at all) – Staff at ICTC were not aware about use of CB-NAAT in TB symptomatic among PLHIV
- TB/DR-TB treatment outcomes are not segregated for HIV patients and overall the TB/HIV reporting is poor

### **Recommendations**

- Regular DCC meetings with adequate actions on the minutes
- All TB patients should be offered ICTC/HIV testing
- Diagnostic algorithm for TB diagnosis among PLHIV to be disseminated
- All the TB/HIV co-infected must be screened for DRTB
- Enhancement of co-located health facilities
- Implement the “3 Is” strategy for HIV patients (ICF/IC/IPT) and co-ordinate with HIV services for the whole cascade of care for co-infected patients. ART initiation should be prompt

- Ensure TB/DR-TB counselling at all levels of care for HIV patients and ensure that trained staff is delivering such service
- Improve recording and reporting for co-infected patients. Report separately outcomes for HIV/TB/DR-TB co-infected patients

## **7. Engagement of All care Providers**

### **Achievements:**

- Notification of TB cases from Private hospitals increased in 2014
- Engagement of Aayush clinics

### **Constraints and gaps**

- Institutional implementation present but community involvement initiatives yet to develop
- Private practitioner and NGO involvement sub-optimal
- Linkage with NHM concepts of CBM, Rogi Kalyan Samiti and VHSNC committees inadequate
- PPM Positions (PPM Coordinator, TBHVs) are vacant at state and districts
- Private hospitals are not reporting treatment outcomes of notified cases

### **Recommendations**

- To promote mandatory notification of TB cases & STCI among private health facilities
- Community DOTS should be promoted more as ASHAs are also are poised to be in place now

## **8. Role of Medical Colleges (MC), Research & Technical Assistance**

### **Achievements**

- All 3 MC are involved & providing advanced medical care to TB patients
- STF & Core committee mechanism in place
- There is research capacity at the medical colleges in specific districts in the State

### **Constraints/gaps**

- There is no operational/implementation research “culture” at the State level and research seems a low priority
  - Documented OR studies lacking
  - The state OR committee seems inactive
  - There are fragmented OR ideas at different levels but no OR agenda at the State
- Inadequate inter-departmental coordination
- Many diagnosed TB patients are missed from notification

### **Recommendations**

- Timely Nodal department, core committee & STF meetings
- Involvement of Community medicine department of MC for coordination, training, , monitoring , supervision & research in RNTCP
- Contact OR training courses using well-established models (e.g. UNION/MSF/WHO-SORT-IT) in order to gain a critical mass of staff trained in OR / Nomination in OR courses
- Activate the State OR committee and decentralize responsibilities and ownership at the State level
- Involve medical colleges in capacity building/training, in collaborative OR projects, ethics committees, and scientific advise/ Technical support
- Document BEST practices already existing in the State (contact-tracing, INH prophylaxis, Gate Pass/TB services at work-place)
- MDR TB cases to be essentially treated at medical colleges itself
- Strengthening Referral and feedback mechanism with support from DTC
- Involve UG and PG students in research studies and community mobilization
- Faculty to be trained as TOT
- Participation of MC in State Internal Evaluation

## 9. ***Support systems for patients and families***

### **Achievements**

- High political commitment by the State to support TB patients – New proposal to provide MDR-TB patients with food packages
- Nutritional support is provided to all in-patients
- An ambulance service is available free-of-cost on a simple telephone call (108) (BEST PRACTICE)
- There is a patient welfare fund at all health facilities (BEST PRACTICE)

### **Constraints and gaps**

- Fear of Loss of income/loss of jobs
- TB is not included in RSBY
- No linkages with different social schemes
- Varied practice of reimbursement of travel cost to DR TB patients and old rate of honorarium for community dot provider
- Work place restrictions hampering access to DOT at some places
- Consider direct financial support to TB patients, especially DR-TB patients

### **Recommendations**

- Inclusion of TB in RSBY
- Inter-departmental coordination for linkages with different social schemes
- The nutritional support is to be expanded to all TB patients in the State
- Consider food packages for families with TB patients who are BPL; not just for MDR-TB patients with support from other departments
- Implementation of Revised rates of honorarium to community dot provider
- Reimburse transport costs
- Directives from appropriate authority (DG-FASLI) enabling workers to access DOTS (Work place DOTS)

## **10. *Advocacy and communication***

### **Achievements:**

- There is an active agenda of ACSM activities, especially at the district level (including school based activities, patient providers meetings, community based awareness activities, printed material)
- There was an active ACSM activity in slum/migrant populated areas (BEST PRACTICE)

### **Constraints and gaps**

- Limited range of activities in communication and even less in advocacy
- Sub-optimal community as well as patient provider interaction meetings
- Paucity of ideas and mechanisms to deliver effective IEC
- Produce a specific strategy for advocacy and communications for TB in Himachal Pradesh
- Very low expenditure on Advocacy and Communication

### **Recommendations**

- Produce a specific strategy for advocacy and communications for TB in Himachal Pradesh

## **11. *Community Engagement***

### **Achievements:**

- Sensitization workshop for NGOs conducted

### **Constraints and gaps**

- Only 4 NGOs in 2014 engaged in TB program, not formally under signed scheme
- The involvement in TB/DR-TB of local NGOs at the district and State levels is extremely low (mainly due to lack of funding)

### **Recommendations**

- Create an NGO coordinating body for TB at state and district levels as per revised guidelines and engage NGOs systematically and formally in the TB programme – not just in service delivery but also in policy development, planning, monitoring and evaluation.
- Follow up on agreed actions to allow such systematic and regular interaction to strengthen TB Programme-NGO relationships
- Ensure funding for community NGO to participate in TB activities
- Support NGO participation at all levels of care from community awareness to diagnosis to treatment
- Ensure NGO participation in defaulter tracing and adherence support using a patient-centered approach

## **12. Targeted interventions for special groups**

### **Best practices/Achievements/Innovations**

- The state/district are highly sensitized on TB in special groups (especially migrants, slums and factory workers)
- The attitude of the health staff (DMC, OPD, DOTS centers, private DOT providers) towards special groups was excellent (especially towards migrants who constitute 2/3 of the population in parts of Solan district)
- ACSM activities at slums are systematic, regular and done by highly motivated staff
- A “Gate pass” is issued to factory workers on DOTS so they can attend their respective centers during working hours without risking their jobs (BEST PRACTICE)
- DMC/DOTs centers are opened in large factories bringing TB services to the workplace (BEST PRACTICE)

### **Challenges/Constraints**

- No targeted activities among special populations in the areas we visited (In Solan district – only ACSM/No ICF)
- The working hours (9.00-16.00) of TB services (especially DOTS centers) are not convenient for workers.

### **Possible solutions/Recommended actions**

- “Open a DOTS center or issue ‘Gate passes’” should be a clear message to all employers in high TB burden pockets and hot-spots
- Legislation to protect patients with TB/DR-TB and facilitate the use of services
- Contact systematic ICF activities in slums, large factories
- Ensure TB/DR-TB counseling at all levels of care for special groups and ensure that trained staff is delivering such service
- Think ‘out of the box’ and pilot non-DOT adherence support practices

## **13. Drugs and supplies**

**Achievements:**

- Procurement of INH and few 2<sup>nd</sup> line drugs at state level

**Constraints and gaps**

- Pharmacist and Store Assistant at SDS are vacant
- Inadequate space at SDS
- TU drug store at DTC Shimla is maintained by STS
- No established mechanism of drug transport to districts and TU

**Recommendations**

- Appointment on two posts under RNTCP for SDS
- DDS Shimla needs to be maintained by Pharmacist
- Logistics Management of drugs needs improvement

**14. Programme financing****Achievements**

- NHM releases fund from its pool to STC irrespective of fund receipts from GoI for RNTCP (after receipt of ROP from central NHM)
- No delay in release of funds from STC to districts
- Mechanism of loans from NHM to RNTCP at district level also

**Constraints and gaps**

- Districts not updated on approved activities
- Revised rates of “remuneration to contractual staff” & “incentives” to beneficiaries not implemented
- TA/DA of STS/STLS have not been paid for the past few months affecting mobility for field supervision
- Staff morale is low and programme objectives are being adversely impacted
- The funds required for training are provided through the districts to STDC and expenditure booked by respective districts - This mechanism carries risk

**Recommendations**

- Implementation of New financial norms of RNTCP
- STDC should provide the training calendar and budget
- Release of fund directly to STDC

**15. Human Resources for Health****Achievements**

- Appointments through outsourcing &/or deployment from general health system
- LT support from RKS at few high load facilities

#### **Constraints and gaps**

- Untrained DTOs, MO-TCs & other key staff
- Approved HR positions in the ROP of 2014-15 are yet to be filled
  - Majority of contractual positions at State & District levels are vacant
  - At state level 3 key positions APO; MO-STC and DRTB coordinator are vacant.
  - Position of microbiologist is lying vacant for the part one year
  - Vacant position of SDS & DRTB centre
- Untrained DTOs, MO-TCs & other key staff
- All trainings are done at State level (no mechanism of district level training)

#### **Recommendations**

- Fast tracking of HR recruitment process at -state and district level
- Training:
  - Hostel facility at STDC Dharampur to be established at the earliest
  - Training of the health personnel to be undertaken on war footing in 2015-16
  - Staff trained 3-5 years back, should be given refresher training.
  - Trainings to be decentralized at District level
  - District level sensitization for all the doctors (comprehensive including PMDT, Paediatric TB, TBHIV) to be undertaken.

### **16. Governance and Health information system**

#### **Achievements**

- Supportive State & District administration and regular review conducted including in NRHM and mission meetings
- State has increased RSBY limit to 1.75 lakhs from 30000

#### **Constraints and gaps**

- Inadequate manpower at the State TB Cell
- Sub-optimal M & E activities and irregular DTO review meeting only one SIE and one DTOs quarterly review meeting in last year
- No visit by State IRL Team to Districts for EQA for the last two years due to non-availability of microbiologist
- District level OSE visit report, feedback & Action Taken Report not properly documented
- Crucial component of mobility support with provision of 2-wheeler vehicle along with POL support is lacking in field. Most of the patients are not being visited at home impacting field supervision.

- Non alignment of TUs with BPMU
- Suboptimal involvement of Municipal corporation in program

### Recommendations

- Municipal councils to be involved fully under program
- Involvement of other sectors to be worked out
- Strengthening of M & E mechanism
  - Regular State level DTOs review meeting, supervisory visits at all levels & State level Internal Evaluation to be undertaken as per the norms
  - District level review meeting of Block Medical Officers by CMO on monthly basis to improve the TB control. Review by DM on quarterly basis will help the program.
  - STDC Dharampur to ensure supervisory visits to each district at least twice a year. The required mobility support (vehicle & POL) for field visit to be provided from state.
- Proper documentation of District level OSE visit
- Immediate procurement of the 2-wheelers as per guidelines

## 4. Madhya Pradesh

The Joint Monitoring Mission visited the State headquarters at Bhopal and districts of Ujjain and Jabalpur.

State Profile:

Madhya Pradesh is located in central India with a population of 77.8 million of which 23.3 million is urban and 54.5 million is rural. It has 1.65 million tribal populations with 4 districts with majority of tribal population and 19 districts with scattered tribal population. There are 51 revenue districts and 50 RNTCP districts.

TB services:

There are 202 functioning Tuberculosis Units (TU), there are 313 revenue blocks, it means an additional 111 more TUs need to be created for full decentralization of TUs to align with revenue blocks. There are 799 designated microscopy centres including 11 in NGO/private sectors. There are 34631 DOT centres.

For Programmatic Management of Drug Resistant TB (PMDT), there are 6 DR-TB centres including one in a private medical college, 3 more are under development. For diagnosis of MDR-TB patients there are 6 gen Xpert Labs and 2 LPA labs are there. One more LPA lab is upcoming at Gwalior Medical College. For follow-up cultures 4 solid culture labs and 1 liquid culture facilities are available. One more liquid culture lab is under accreditation process at BMHRC Bhopal.

For TB/HIV services, there are 186 Integrated Counseling and testing centres (ICTCs) and 425 F-ICTCs, providing HIV testing services, 76% of them are co-located with DMCs. There are 17 ART centres including one ART-plus centre and 37 Link ART centres providing ART care.

### Epidemiology:

Out of total population in the state, the percentage of tribal population is 22. Among the primitive tribal groups, Saharia is an important tribe and its total population is 417171 implying 2.70 percent out of total tribal population of the state. There are a number of epidemiological studies conducted among 'Saharia' tribes in Madhya Pradesh including prevalence studies and ARTI studies. A community-based cross-sectional TB prevalence survey in 2009 showed overall prevalence of pulmonary TB disease was 1518 per 100 000 population.

### Case Finding and TB notification:

MP has more case notification at all age/sex group than National average. Though the symptomatic examination rate of MP has been increasing and is above the national average, the distribution across districts are not uniform. There are many districts with very low examination rate, while district like Dindori has done exceptionally well with more than 1500 examination per 100,000 population with a corresponding increase in the smear positive TB cases diagnosed.

External quality assurance system in place in all designated microscopy centres, initial lost to follow up is only 4%, data quality was found to be generally good. Weekly monitoring of targets for case finding with estimated missed cases has showed good improvement in programme management resulting in increased case notification efforts and correspondingly the case detection rate has also increased. Symptomatic examined per 100,000 population has increased from 158 to 186 in the last year-the rate of change being 18%.

Major Challenges/Constraints are: considering the higher prevalence of TB in MP especially in rural and tribal areas, the case finding efforts still need augmentation, case notification is not uniform, there are many districts where the symptomatic examined and cases diagnosed are very low. Most of the case finding is at major hospitals like DTC, TB hospitals and medical colleges. At least 60% of the DMCs are grossly underutilized. Data entry in NIKSHAYA is not complete and use of NIKSHAYA data for programme analysis is generally lacking.

Possible Solutions/Recommended actions are to do in-depth analysis of programme data, with focus on districts with low examination rate, capacity development of programme managers for data analysis and action, focus action plan for low performing TUs and training for private sector for TB notification. Decentralized NIKSHAYA entry at PHC/ CHC need to be facilitated along with provision of PDA to STS and mobile sim cards to TB workers. Intensified TB case finding in high risk groups especially Saharia tribes should be a priority. Focused action plan for underperforming DMCs

### Universal Health Coverage, Health System Functions, integration of TB services with general health system and equity in access:

There are a number of good practices MP state has initiated such as monitoring of all programmes by Principal Secretary every week, availability of flexi pool funding from NRHM and smart utilization of the funding by TB programme. Online portal for recruitment of staff and e-transfer of payments of salary to staff and honorarium for DOT providers, local procurement of drugs- online system- through GMSD or TNMSC and good infrastructure development in general health system are other good examples.

Major Challenges/Constraints is due to insufficient fund flow to state and districts, only 60% of PIP submitted gets allocation. This led to delay in initiating new activities envisaged as per NSP in the state. Delay in release of fund in 2014 resulted in delay in payment of salaries to contractual staff. NHM management structure's involvement in TB care is suboptimal. There are many staffs recruited under NHM including the staff at DPMU, BPMU etc, however the focus is mainly in RCH services. No coordination between TB programme staff and NHM staff as both finds the jobs are different. This silo approach is not advantageous to any. There are no direct benefit schemes for TB patients in terms of social support or financial support except an NGO initiated project for nutritional support to few poor MDR TB patients in Indoor.

Possible Solutions/Recommended actions include: NHM staffs need to be sensitized and involved in TB care activities proactively. In order to strengthen integration of TB care with general health system and NHM, there need to be a structure for collaboration at State and district levels similar to TB/HIV coordination committee. There are different types of counsellors in the district, every programme put in one more counsellor and now TB programme also has a counsellor planned in the NSP. These resources can be pooled and effectively decentralized to provide integrated counselling services to all patients. Explore possibility of e-transfer of honorarium through linking with Nikshay

#### Treatment of TB:

Standard treatment regimens being administered through a mix of public and private providers with linkages are in place to provide services for TB/HIV and drug-resistant TB. DOT services are decentralised through ASHA and community volunteers

Major Challenges/Constraints are: delay in treatment initiation owing to practices of service provision by concerned geographically-located service delivery points, sub optimal treatment monitoring and offer of adjunct services to improve quality of life and treatment outcomes. Adverse drug reactions monitoring is not systematic. Drug shortages especially paediatric formulations leading to delay in treatment initiation as well as prevention activities were noted with concern. Due to shortage of INH, contact tracing and IPT is not happening. Delayed payments of honorarium to community DOT providers noted in some districts and local procurement of drugs are delayed due to system issues.

Recommendations include: Consider local procurement at State/District-level as per national directives, as and when required to ensure availability of all necessary drugs for treatment including INH and paediatric drugs. All community DOT providers to be paid honorarium regularly, use e-transfer mechanism linking to NIKSHAY. Need enforcement of schedule H1 by drug regulatory authorities.

#### TB/HIV

Main achievements include formation of TB/HIV coordination committees, State coordination committee meeting held in 1<sup>st</sup> qtr 15 and TWG in 3 qtr 14; co-location of services has increased substantially in the last two years, now 73% of facilities are co-located (from 42% two years back). 66% of TB patients know their HIV status, which is a leap of 50% compared to last year. Out of the tested TB patients 1% is HIV positive. 85% of co infected patients are on CPT and 94% are on ART.

Major challenges/constraints are: one third of TB patients do not know their HIV status, intensified case finding for TB among PLHIV found deficient, no IPT to PLHIV without TB, there is knowledge gap on use of CBNAAT for PLHIV among medical officers, district level

coordination meetings are infrequent and there is Shortage of HIV 2<sup>nd</sup> and 3<sup>rd</sup> test kits with zero stock at state level. Linkages are not available for other comorbidities i.e., TB – diabetes/ TB – tobacco

Recommendations include: streamlining of procurement and distribution of both HIV test kits and all necessary drugs should be prioritized along with expansion of co-location facilities for effective TB and HIV care. CBNAAT to be preferentially used for TB diagnosis in PLHIV presumptive TB, necessary communications and trainings for intensified TB case finding among PLHIV to be imparted to medical officers. IPT to non-TB PLHIV to be implemented to reduce incidence of TB in PLHIV

#### Pediatric TB

Main Achievements include active involvement of nutritional rehabilitation centres with active screening of malnourished children for symptoms of TB. Contacts are screened and referred to the TB control programme for further evaluation and treatment.

Major Constraints are: Diagnosis of pediatric TB mostly limited to speciality healthcare settings; diagnosis mostly dependent on clinical judgement and radiological evidence. There are stock outs of INH and shortage of pediatric drug formulations in the programme especially for children less than 6 kg. Additional tools for bringing out sputum such as BAL/induced sputum etc are not practiced.

Recommendations include: Revised algorithm for childhood TB to be practiced by proper dissemination/training of paediatricians and medical officers, equip manpower and provide facilities for microbiological confirmation of paediatric TB; CB-NAAT to be utilized for diagnosis of pediatric TB, INH to be procured and made available for prophylaxis, training of staff administering the Manteux test for better utility of TST and recommend and use of other tools like aspiration and nebulisation for sputum extraction and use of CB-NAAT for diagnosis

#### Drug Resistant TB Services:

Main Achievements are: PMDT services have been scaled up to entire state with availability of rapid diagnostics for all presumptive DR TB cases.

Major Challenges/Constraints are: sub optimal sputum collection and transport mechanisms and lack of decentralized treatment services. The initial clinical work up of the DR TB patients is not being offered at district level despite availability of facilities resulting in delays and prolonged stay at DR TB centre, Bhopal. Avoidable delays observed in identification, offer of DST and treatment initiation. The vacancies in RNTCP including DR TB staff are adversely affecting the quality of DR TB services. Although the ADR monitoring centre has been established at medical college, effective linkages are not in place. Delayed or no second-line DST observed.

Recommendations include: Promote early DST through rapid collection and transportation of samples. Consider enhancing NIKSHAY to include DR TB module, thus case-based electronic reporting and analysis system can be established. Planned three DR TB centres in the medical colleges to be made operational at the earliest, consider opening more DR-TB centres. Initial clinical workup and initiation of DR TB treatment to be decentralized at least up to district level. DR TB treatment services and ADR monitoring should be available in all medical colleges. Vacancies need to be filled at earliest. Laboratory upgrade to include second-line DST. State TB Cell to actively monitor all DR TB centres at State level to reduce diagnostic & treatment delays

PMDT trainings and retraining of staff along with regular supervision. Services of DR TB counsellor to be utilized for both facility and home-based counselling

Engaging all care providers:

Main Achievements include improving private sector notification of TB cases and involvement of few private hospitals and NGO hospitals in RNTCP. Many private providers are aware of TB notification and are willing to notify

Major challenges are: mechanisms for complete TB notification from all departments of medical college not established. Medical college faculty untrained in basic TB as well as PMDT services. Sub optimal utilization of partnership provisions in programme to increase reach and improve service delivery. No active measures have taken to engage private sector in a big way. There is no IMA engagement in the state. Awareness on Standard for TB care in India is poor among the practitioners.

Recommendations: Major initiatives need to be taken to sensitize and engage private practitioners in the state involving stakeholders like IMA and other professional associations. Training on STCI and ICT enabled solutions (IVRS, Mobile app, etc) should be utilized to promote complete TB notification. Training of all faculties dealing with TB care and control in medical college should be a priority.

Finance and Human Resource Management:

Main Achievements are: State has taken advantage by utilizing NHM funds for programme funding deficit and e-transfer of salary to staff and honorarium to DOT providers.

Major Constraints are: Long standing vacancies at state and district level adversely affecting the programme. The powers of re allocation of funds lie with the state health society hence districts don't have flexibility of re allocations as per need. STDC Bhopal doesn't have adequate infrastructure/HR to conduct state level trainings/supervisory visits.

Recommendations include: Fill vacant positions on priority. Delegation of financial powers (as per NHM framework) to the district health societies for flexibility and prioritization of activities as per local needs

STDC Bhopal to be made functional with all components (trainings, bacteriology, programme monitoring, review and analysis, ACSM etc.)

Governance and HIMS

Main Achievements are: Basic TB services are well decentralized in the state and the programme is able to advocate with NHM for incremental funding.

Major Constraints are: There is a gap in re alignment of TB control units and integration within the NHM framework of activities. The local self-governments have limited involvement in TB care and support.

Ownership of general health system for TB control services was found be lacking and dependency on contractual staff in overall TB programme management was observed in the state. The involvement of Department of Medical Education and research in TB control is sub optimal

Recommendations: State should expedite realignment of TB services within NHM framework. Local self-government to be actively engaged for advocacy and extension of various welfare schemes to the TB patients

Procurement and logistics:

TB drug stores are established at various levels including 2<sup>nd</sup> line drug stores (with temperature control)

And drugs stocks are being monitored for utilization within shelf life

Major Constraints noted are: the existing state Drug Store is space constrained for both 1<sup>st</sup> and 2<sup>nd</sup> line drugs. Nil stock of Prolongation pouches, PC 13, INH 100mg, INH 300 mg observed at state and facilities visited in the district. No mechanisms in place for procurement of drugs as and when directed by Central TB Division leading to non-availability of loose drugs and Inj streptomycin. No proactive mechanism of drug transportation from state to District Drug stores for 2<sup>nd</sup> line drugs. The CBNAAT cartridges were short in supply and required relocation of cartridges from various sites and projects to keep the machines running. Recommendations include: Urgently establish 2 more additional State Drug Stores. Streamline mechanism for procurement of drugs as and when directed by centre. Ensure adequate availability of CB NAAT cartridges to for seamless services. The resource available at State TB cell to be utilized for proper supply chain management. Capacity building in drug management at all levels, including e-learning and blended learning solutions

Patient Support systems: There are no established patient support systems except some NGO supported nutritional support for few patients.

Recommendations: Link TB patients with existing social schemes and livelihood options. Proactive engagement with local self-governments and other departments are required for patient support services.

Advocacy Communication and Social mobilization:

Major Achievements include TB awareness creation efforts at state level including advertisement in electricity bills. 'Gain & gap study' done to analyse knowledge, awareness and community issues pertaining to TB. RNTCP IEC activities closely linked to State Health IEC activities.

Major Constraints include: There are various affinity groups for case detection, treatment, follow-up and support but their collaboration cum cooperation is not initiated. There is no effort to map the key informal/formal CBOs involved in active case finding and there is lack of strategic direction for following-up community engagement.

Recommendations include: to have mechanisms to forge coordination between RNTCP staff and NGOs as well as collaboration among different NGOs providing services. Focussed activities to improve awareness in rural and tribal populations and structured measures to assess the outcome of ACSM activities being performed by different players

## 5. Meghalaya

The state of Meghalaya in the north-east India caters a population of 3.3 million covering an area of approximately 22,430 square kilometers and is predominantly inhabited by the tribal population (95%). About 70% of the state is forested.

Districts: 11

Topography: Hilly

Male-Female Ratio- 1000:1011

Adult Literacy Rate: 75%

Per Capita Income (INR): 29000 (38000 National)

Proportion of child population= 40%

Infant Mortality Rate: 49 per 1000 live births

Complete geographical coverage of TB services under the Revised National TB Control Programme was achieved in the year 2003 and accessibility to drug resistance diagnostic and treatment services was established in the end of year 2012.

The Joint monitoring Mission 2015 team members (Annexure-I) have strategically reviewed the program implementation status by analyzing the outcome of the field visits and interactions held from 1<sup>th</sup> to 16<sup>th</sup> April 2015 at East Khasi Hills as enlisted below:

**State:**

- State TB Cell, State Drug Store, State DR-TB Centre, Culture & DST Laboratory (Nazareth Hospital), ART Centre (Civil Hospital)

**District (East Khasi hills):**

- District TB Centre, District Drug Store, 3 TB Units (Shillong, Mawphlang, Sorah), 6 DMCs (including Medical College and Nazareth Hospital, CBNAAT Lab (H Gordon Robert Hospital), DOT Centres, Prison and Private Clinics (Holy Clinic and Woodland Hospital)
- Patient Home visits and meeting with DOT providers
- Meeting with the staff of AxshyaProject
- Debriefing meeting with the Additional Chief Secretary, Secretary Health, Mission Director (National Health Mission), Commissioner Health, Director General Health services, state and district RNTCP team

**Key Observations:**

**a. Epidemiological situation:**

The state of Meghalaya is reported as a **High burden state for TB, including MDR-TB**. The trends in Case Notification rates of all forms of TB and Presumptive TB examination rates have remained stable over the last 5 years.

As per the program data of 2014,

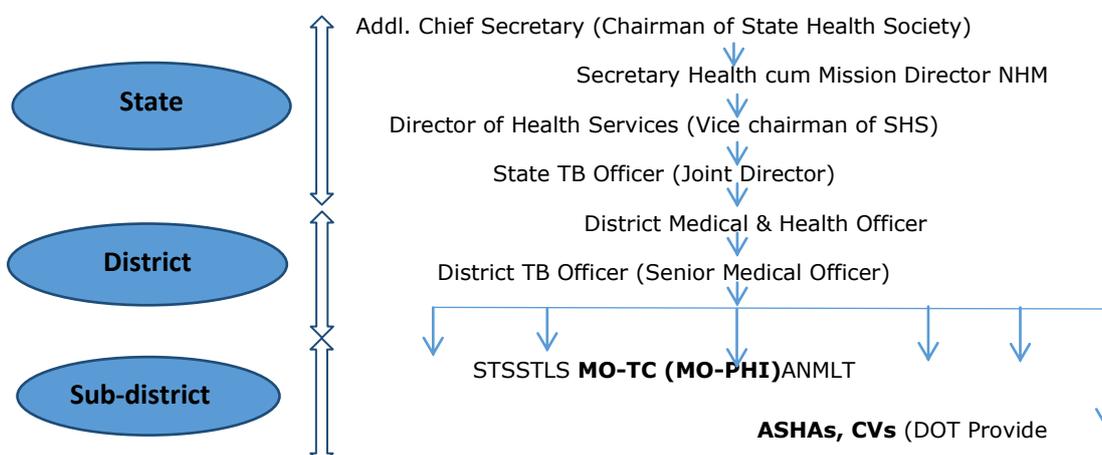
- Total TB case notification rate = 154/1,00,000/year.
- New Sputum positive case notification rate = 54 /1,00,000/yr;
- Amongst all diagnosed TB cases, 37% were Extra Pulmonary cases
- 84 % have been notified in the age group of 15- 54 years
- Among registered TB patients, less than 30% had HIV testing done
- Of all registered TB patients tested in the year 2014, 2.4 % were found to be HIV positive..
- MDR TB rates among Presumptive MDR-TB cases is high up **to 38% at state level and 57% noted in East Khasi Hills.**
- 82% of the new sputum positive cases are getting cured with 54% of success rate in previously treated TB cases. High failure rates (**up to 18 % in previously treated cases in EastKhasi hills**) have been noted in the state.

**b. Universal Health Coverage:**

**Progress towards NSP 2012-2017:** The state RNTCP is implementing the **Tribal Action Plan** and the activities are planned and budgeted in the Program Implementation Plan under NHM annually to achieve universal access to quality TB diagnosis and care.

RNTCP has re-organized its structure along the health block lines, aligning and integrating sub-district programme management and supervision with NRHM. The pending re-engineering of 4 new districts and 4 TB units had been approved in the budget for FY 2014-2015 but has not been established, thus planned for FY 2015-2016. The MDR-TB diagnostic and treatment services are available in the state with the support of IRL Guwahati. There is an alignment with general health staff for improved treatment supervision by ASHA workers. A comprehensive HRD plan to update and develop the skills of both program personnel and general health system staff involved with service delivery is not in place. Most of the key health staff is in place at state and district level. Accessibility issue of TB services both for diagnosis and treatment was quoted by 90% of the patients interviewed by the team members. Engagement with other care providers is appreciable in the state as well as in district of East Khasi Hills which is discussed in detail under PPM section.

**Health System Organization (RNTCP Integration)**



### **Organization of Health services**

<b>Organization of Health services in the state</b>
Medical College and Hospital-1
Civil Hospital-7 (one at each District)
Chest Hospital-1
Government Children Hospital-1
CHC-29
PHC-108 (10% shortfall)
Subcentre-397 (~50% shortfall)
PSU (ESI, Railway Hospital)
Private Health Facilities-61 (Hospitals-9)
Large number of traditional healers
<b>Organization of RNTCP services in the state</b>
RNTCP implementing districts -7
Tuberculosis units -17
Designated microscopy centres-65 (including 5 private)
Intermediate Reference Laboratory-0
<b>Organization of DR-TB services in the state</b>
State Culture & DST laboratories-1(Nazareth Hospital) supported by IRL Khaparde
State DR-TB centres-2 (RP Chest hospital, Shillong&Tura)
<b>Organization of TB-HIV services in the state</b>
ICTCs-16 & 3 <b>mobile ICTCs</b>
ART centres-1 & Linked ART centres-2
DMCs with co-located ICTCs-18

#### **Challenges/Constraints in achieving universal health coverage:**

- **State TB training and Demonstration Centre (STDC) has not been established**
- **No Intermediate Reference Laboratory available in the state.**The culture facility is being utilized from IRL Guwahati
- **X ray facilities not available in the entire East Khasi hills district except at Civil Hospital Shillong.**
- Minimal involvement of general health system staff
- Vacant Positions: 2nd MO at DTC, Pharmacist & Store assistant at SDS for SLDs, specialists at CHCs, ANMs, long leave-TBHV and LTs
- **None of the DTOs are trained in TB/HIV.**Last MOTC training was held in 2013
- **MO-PHIs mostly untrained including PMDT**
- High staff turnover especially LTs. Some LTs have not been trained since 2003

#### **Recommendations:**

- Re-engineering of all TUs along the Block level health facilities as per the PIP of FY 2015-16, completing their civil works and should become functional during this financial year.
- the State of Art health facility being established for the relocation of State TB Cell, STC, DR-TB Centre, DTC and state drug Store should also have the provision for establishing a STDC to streamline trainings, Culture & DST and monitoring activities which are not adequate presently in the state
- Recruitment of all key staff should be completed within 3 months especially to streamline second line drug management
- All health staff require **urgent** training / retraining in all components of TB control (EQA, PMDT, TB -HIV and STCI)
- The district should establish sputum collection centres by involving more NGOs/Community volunteers under the various schemes proposed in the new Partnership guidelines 2014
- Decentralization of treatment services needs further strengthening to achieve universal access to quality TB care.
- Linked DRTB centres to be established in districts for improving treatment accessibility of DRTB patients.
- Recruitment of all key staff should be completed within 3 months especially to streamline second line drug management

#### **c. Diagnosis and Case Finding(including Paediatric TB, key vulnerable populations and comorbidities):**

The majority of the population for the state of Meghalaya is tribal which resides in hard to reach areas. The pediatric population under 6 yrs of age is 5.6 lacs which constitutes 25% of the total population. The key

vulnerable group includes the tobacco users (smoking and tobacco chewing) which constitute 54% of more than 15 yrs of population. 73% of males and 36% of the female population are tobacco users currently. Overcrowding, poor living conditions and limited engagement with RNTCP is evident in the prison of Shillong. There are 50,000 Coal miners and 30,000 cement workers employed in the state. Migratory population from neighbouring states like Tripura and international border of Bangladesh are accounting for nearly 6% of the initial defaulters in the program.

#### **Best Practices/ Achievements:**

- The Medical Officers are generally aware of diagnostic algorithms but not in intensified case finding guidelines
- Satisfactory Presumptive TB sputum examination rate
- The proportion of TB cases amongst children is 8% in 2014 in the state which is higher than the national data of 6%. In EKH, 9.7 % of all TB cases are reported as pediatric TB in the year 2014
- The health staff have been oriented on the Revised Pediatric guidelines
- PPD vials are being used for diagnosis of TB in children
- Pediatricians with PG qualification following correct practice for diagnosis and treatment, using gastric aspirate, induced sputum
- Lymph node TB diagnosis by FNAC, culture and DST (LPA in one private hospital)

#### **Challenges/ Constraints:**

- Symptomatic screening unsatisfactory at some places and key vulnerable populations, Contact tracing is not happening
- Low sputum positivity rate noted at few DMCs, overall satisfactory
- Diagnostic facilities for smear negative pulmonary TB, Extra pulmonary & Pediatric TB not available in peripheral areas.
- Functional Binocular microscopes not available in many DMCs
- The External Quality Assurance system for TB diagnosis is not in place
- Presumptive Pediatric TB cases are referred to Government Children Hospital in Shillong majority of which fail to reach
- General physicians not using gastric aspirate, diagnosis empirical
- Newer technology (LPA, CBNAAT etc.) not frequently used by General physicians
- Most of the practitioners are aware about Standards of TB care in India
- No Smoking Cessation clinics or De-addiction clinics available.

#### **Recommendations:**

- EQA training for all key staff to be conducted on priority
- Accessibility to sputum diagnostic services to be improved by establishing sputum collection centres
- Proactive approach for repeat sputum examination to be adopted
- Availability of X-ray at CHC to facilitate diagnosis of sputum negative cases
- Create infrastructure for Pediatric TB and EP TB diagnosis at CHC
- General physicians need to be sensitized for diagnostic tools and use of newer technology (LPA, CBNAAT etc.)
- Screening of TB in children who are contacts of all TB patients should be done by the Medical Officers
- Intensified case finding should be carried out for detection of MDR-TB in children who are contacts of MDR-TB patients
- A district level sensitization should be carried out for all paediatricians in all districts to intensify case finding activities.
- Smoking Cessation clinics or De-addiction clinics to be established
- Sensitization of cement and coal mining companies on TB
- Establish DMC or sputum collection centres for coal miners and cement workers
- Enhanced & regular screening, including staff : at entry & periodic
- Isolation of diagnosed TB patients in prisons
- Refer TB patient on discharge from prison, to RNTCP DOT centre under intimation of DTO, contact tracing
- Mechanism of tracking/transferring migrant population to be strengthened
- Blood sugar testing facility for TB patients to be scaled up as per National programme for non-communicable diseases

#### **d. Treatment of Drug sensitive TB:**

##### **Best Practices/ Achievements:**

- First line drugs were available except Injection Streptomycin
- Community DOT providers available near patient home. Mobile DOT services were available

**Challenges/ Constraints:**

- Treatment success rate is 85% with 5% death rates and 6% default rates in new sputum positive cases
- Treatment outcome in re-treatment case: success =54 %, failure =10 %, default= 16%, Death = 7 %.
- Patient travel long distance for injections incurring high out of pocket expenditure and loss of wages
- Smear positives at follow up- not always subjected to DST
- INH prophylaxis not initiated in majority of child contacts
- Some pediatricians are adding quinolones for serious TB cases.MDR-TB treatment is being done using non standardized regimens

**Recommendations:**

- Ensure initial home visits and reduce treatment delays and initial defaults by fixing accountability of health staff
- Relevant Investigation reports to be attached with treatment cards
- Involve Community DOT providers in urban areas and strengthen patient counselling
- Strengthen mobile DOT services especially for injections
- Develop mechanism for monitoring IPT in individual child contacts
- Promote 'Work place " DOT for factory workers

**e. Programmatic Management of Drug Resistant TB (PNDT):**

Complete geographical coverage of PMDT services was achieved by the state in end of 2012. All districts are implementing Criteria C for presumptive MDR-TB diagnosis. The DR-TB diagnostic services are being provided by 2 C-DST labs using LPA Technology at Nazareth hospital, Shillong and Solid culture and liquid culture for follow up at IRL Guwahati, Assam. The treatment of patients is initiated at 2 DR-TB Centres: RP Chest DRTB Centre Shillong and Civil hospital, West Garo Hills.

**Best Practices:**

- State DR-TB Committee is in place and meetings are being held regularly
- The State DRTB coordinator is in place
- Second line drugs are available
- Most MDR- TB cases including from private sector are being treated in designated DR- TB center
- DOT providers are being effectively used
- Mobile injection facility for DR- TB patients in remote areas is appreciable

**Challenges:**

**The emerging incidence of MDR-TB in the state of Meghalaya needs immediate attention as indicated in the data below with an OR to analyze the reason for variation in the data of the two DR-TB centres:**

	DR-TB among Presumptive MDR-TB		
	2012	2013	2014
<b>Meghalaya state</b>	<b>57%</b>	<b>32%</b>	<b>30%</b>
<b>DR-TB Centre Shillong</b>	<b>75%</b>	<b>52%</b>	<b>47%</b>
<b>DR-TB Centre Tura</b>	<b>24%</b>	<b>7%</b>	<b>5%</b>
<b>Shillong district</b>			<b>56%</b>

- No IRL or CBNAAT lab available in the public sector
- New cases are being diagnosed based on single LPA report: MDR-TB treatment is given, against guidelines
- Some Presumptive MDR case, LPA not done: MDR-TB cases are being missed (field and report findings)
- Some Presumptive XDR, culture/DST not done: XDR-TB is being missed
- The collection of sputum sample is centralized at the DTC.
- Delay in initiation of treatment upto 1-4 months
- Patients travel long distance for injections, sometimes hospitalized for giving injections
- Follow up cultures not done as per schedule / delay in receiving reports: most MDR-TB patients get 8-9 months injection
- XDR-TB with DST report available: sometimes wrong regimen chosen by DR-TB committee
- Inadequate number of beds in MDR-ward. N-95 masks not available at DR-TB center
- AIC measures are not adequate :Sufficient windows present, but closed
- Treatment cards at DR-TB center: not updated for months which raised the authenticity of quarterly reported data from these centres

- One CBNAAT facility available at H. Gordon Robert Hospital at private sector, not utilized by RNTCP
- Poor contact tracing happening although there is evidence that in n 2014, 36% MDR –TB was detected amongst the contacts

**Recommendations:**

- Laboratory capacity needs to be strengthened. IRL for the state needs to be established. CBNAAT facility to be utilized from H Gordon hospital under partnership schemes
- Decentralization of sputum collection and transportation at TU level with the use of human carriers if courier service is not available. NGOs can be involved under the partnership schemes to increase accessibility to diagnostic services
- Counseling of DR-TB patients for ADRs
- DR-TB committee needs sensitization: Regimens for XDR-TB cases to be based on DST
- Streamline transportation of follow up sputum specimens to IRL Guwahati & timely receipt of results
- Cross checking of quarterly reports from DR-TB centre to be done to ensure that authentic data is reported

**g. TB-HIV collaborative activities:**

**Best practices:**

- The state has rolled out the TB-HIV intensified package in 2011.
- The TB-HIV collaborative services have been organized by 16 ICTCs, 1 ART centre, 2 Linked ART centres and 3 mobile ICTCs .There are 18 co-located DMCs at ICTCs.
- State TB- HIV coordination committee & State Technical Working Group are in place.
- Intensified TB acse finding is being conducted for HIV patients at ART centers
- No shortage of ART kits was reported recently

**Challenges:**

- Last State TB-HIV coordination committee meeting in March 2014
- Only one third TB patients were tested for HIV in 2014
- ART centers are congested which emerges a challenge for air borne infection control
- Uninterrupted supply of HIV testing kits is a challenge as shortage of kits had been noted few months back

**Recommendations:**

- State TB-HIV coordination committee meeting need to be held quarterly
- ICTCs Counsellors to participate in RNTCP monthly review meeting at district level
- SACS to provide HIV testing facility at all DMCs
- Airborne infection control measures at ART center to be strengthened
- Training of key health staff in TB-HIV intensified package

**h. Engagement of all care providers (including Medical college):**

**Best Practices:**

- There are 61 Private Health facilities including nursing homes, laboratories, and private clinics supporting the program and notifying TB cases being treated by them. Till date, there are 1828 TB cases notified to the program from the private sector, which is appreciable
- Good support and collaboration with Nazareth hospital has helped the drug resistant TB diagnosis in TB patients
- One medical college (NEIGRIHMS) is involved in the program and has a DMC and DOT Centre
- Medical college core committee, State OR committee, State Task Force are in place & meeting regularly
- In 2014, out of the total cases registered for treatment, medical college has contributed to 21% of the cases

**Challenge/Constraint**

- Not all Private Practitioner are sensitized in STCI
- Culture& DST facility not available at Medical college although running PG course in Microbiology
- No paper published on TB except a multicentric study conducted along with the state of West Bngal to evaluate the involvement of Medical colleges in RNTCP

**Recommendations:**

- Training/ CME of all Private Health care providers on STCI.Sensitize informal providers also
- Notification needs strengthening
- Expedite C&DST facilities in Medical college on priority

**i. Operational research:**

The burden of TB in the state as well as the poor treatment outcomes in the TB patients could be evaluated by conducting ORs in the following areas of concern:

- How to decrease high default and failure rate especially in retreatment cases?
- Is it true that more than one third of all incident cases are EPTB?
- What are the reasons for high level of drug resistance in presumptive MDR-TB ?
- How is it that about 35% of new EPTB cases have Multi drug resistance

#### **i. Drug & Logistics management:**

##### **Achievements:**

- The upgradation of state drug store and district drug for stocking of SLD is as per RNTCP guidelines;
- Records at the state drug store are well maintained for first line drugs (FLD) and second line drugs (SLD), but the index should be included as the first folio of the drug stock register;
- District Drug store has well maintained record for first line drugs (FLD);
- Reconstitution of MDR-TB drugs of default / died patients is being done, but only in one district
- There is a good practice for packaging of second line drugs, including recycling boxes

##### **Challenges/constraints:**

- A stock-out of injection streptomycin was observed at state and district drug stores, as on 10 April 2015;
- The post of contractual pharmacist and store assistant for second line drug management is vacant since the roll-out of PMDT services;
- The drug stock is being maintained by a BCG technician, public radiographer at the district drug store, who are not efficient in drug and logistics management;
- The Drug store register for second line drugs is not available at district drug store;
- Transportation mechanism for distribution of drugs from State to Districts and within the districts is not in place; Transportation of drugs is being done by the supervisory staff of RNTCP
- Demand and supply of drugs is not as per the QRPML (Quarterly Report on Program Management and Logistics);
- Supply of MDR-TB drugs is being done based on the initiation of treatment of a patient to the respective district – this supply may involve daily distribution of MDR-TB drugs to the same district;
- Reserve stock for first line drugs and second line drugs are not adequate both at State and District level
- Regular power supply is not available for air conditioning in the State drug store;

##### **Recommendations:**

- The State should immediately inform the CTD about the requirement on injection streptomycin and do emergency procurement, if necessary, as per instruction of the CTD. The state is also requested that in future, CTD should be informed, at least one month prior to expected stock-out;
- Appointment of a pharmacist and store assistant should be done on a priority basis (3 months period);
- The district authorities are suggested to ensure that all drug stores at district and periphery levels are manned by a pharmacist;
- Drug stock register for maintaining second line at district and TB Unit stores should be made available (Immediately)
- The State needs to strengthen its transportation system for distribution of drugs to the districts.
- The DTO should ensure that all drugs and logistics are supplied up to the TU level by the district and not transported on two-wheelers by the contractual (STLS) staff;
- It is suggested that the MDR-TB drugs are issued to the districts on a monthly basis based on the QRPML received from the districts and not on a day-to-day basis to ensure efficient drug management;
- The State should analyse the supplies received from the centre have enough reserve stocks and in situations where stocks are not adequate an additional drug request should be sent to CTD;
- Reconstitution of MDR-TB drugs is not happening in 6 districts and this needs to be initiated on a priority basis;

It is suggested that the State budgets the procurement of back-up generators for the State drug store in the PIP (Project Implementation Plan) for the FY 2015-16

#### **k. Patients Support Systems:**

- No strongly established patients support systems are in place in the state;
- Some nutritional support was being provided to selected TB patients under Project Axshya. Project Axshya workers are also providing counselling services to the MDR-TB patients.
- TB-HIV co-infected patients registered in the Meghalaya State network of PLHIV get nutritional support from the State Social Welfare Department;
- DOTS providers do not seem to be well trained in supporting MDR-TB patients during occurrence of adverse drug reactions for prompt management;
- The State should develop and/ strengthen the patient support system by developing linkages between RNTCP and Social Assistance Programs (Social Welfare, nutrition, counselling, etc.)

##### **Recommendations:**

- The State should develop and/ strengthen the patient support system by developing linkages between RNTCP and Social Assistance Programs (Social Welfare, nutrition, counselling, etc.)
- Counselling of TB patients, especially MDR-TB patients, needs to be strengthened and standardised at the level of Medical Officer, health staff and DOTS providers;
- Comprehensive training needs to be provided to DOTS providers, especially for identification of adverse drug effects for early and prompt management;
- Travel costs to the MDR-TB patients and one attendant for treatment initiation and follow-up examinations has to be reimbursed as per the RNTCP guidelines on a priority basis.

#### **l. Finance:**

- The status of fund utilization for the FY 2014-15 in the state is 67%. Only one instalment of Rs. 4.33 cr. released by MoHFW to the state Treasury of Meghalaya out of which Rs. 2.36 cr. was released to the districts
- The fund flow mechanism is smooth within the state with strong support from NHM
- In majority of districts fund utilization was zero in Civil works
- There are substantial unspent balances in training in EK, WKH, Ribhoi, EGH which suggests that regular Trainings are not happening, as observed during interaction with the health staff;
- Substantial unspent funds in Honorarium, and Patient Support and transportation charges, NGO support, ACSM/ IEC are sensitive issues and if taken care can give a good boost to the outcomes

#### **m. Procurement:**

- The State procurement committee is in place
- State level procurement includes procurement of anti-TB drugs on an emergency basis, while procurement of logistics, lab reagents and equipment is done at the district level;
- Central TB Division does the overall procurement of the RNTCP drugs. As observed, supply of drugs at State and District level seems sufficient. However, shortage of Streptomycin was observed;
- Two-wheelers provided to the RNTCP staff for supervisory visits (by the district TB Officer) are in a state of condemnation and should be replaced.
- The state should ensure that all emergency procurement of drugs follows quality assurance protocol.

#### **n.ACSM:**

##### **Best Practices:**

- IEC material displayed in local languages at the health facilities visited
- ACSM activities under Axshya includes sensitization of local political leaders, opinion leaders, AxshyaSamwad

##### **Challenges:**

- Low motivation of volunteers under Axshya project due to payment issues
- Limited reach of Axshya workers

##### **Recommendations:**

- Increase advocacy at all levels including sensitization of MLAs and village heads

#### **O. ICT Application for Surveillance:**

- All 7 districts are reporting in Nikshay. No data analysis being conducted at state or district level for performance review
- There is a back log of data entry pending in the state. For 04qtr14, 78% of the data entry is completed.
- 61 private health facilities have been registered under Nikshay

***As an overall recommendation, the political commitment of the state needs to be enhanced. It is suggested that Intensified monitoring of TB services in the state needs to be done by conducting regular review meetings under the Chairmanship of Hon'ble Secretary Health at least once a quarter for next six months. The district reviews should be held monthly under the chairmanship of the District Medical Health Officer involving all MOs of PHIs and a DMC wise analysis should be conducted during the review. Urgent training needs should be fulfilled to improve quality of TB services in the state .State should build their HRD and special population coverage plan in consultation with the Central TB Division at National level.***

**ANNEXURE-I****Team Meghalaya :**

1. Dr Vineet Chadha, Head Epidemiology and Research, NTI Bangalore
2. Dr Rajendra Prasad, Vice-chair, National Task Force, RNTCP India
3. Dr Rupak Singla, Head, Deptt.of Pulmonary medicine, NITRD, New Delhi
4. MsBindu Sharma, Director , IFD, GoI
5. Dr AshwaniKhanna, State TB Officer, New Delhi
6. Dr Pradeep Joshi, Technical Officer Non -Communicable Diseases, WHO India
7. Mr John Mcharo, Program Officer, Grant Management Division,The Global Fund,  
Geneva
8. Dr Bharati Kalottee, Grant Manager-The Global Fund, Central TB Division, New Delhi

**6. Odisha****1. Organization of TB services****Findings:**

Core components of TB services are in place in the State and the general health services are also engaged to though partly. There are gaps in leadership, supervision, HR, quality of services. STO's position is at the level between CMOs and DTOs and therefore lacks authority. Only 2/31 DTOs are full time and the DTOs demonstrate suboptimal involvement in the programme. In a total of 549 DMCs, 82 lab technician positions are vacant. Many contract medical officer positions are vacant. ACSM officer and PPM coordinator positions at state are vacant. Many medical officer positions in the general health services are also vacant. While the State is eligible to have 314 TUs by virtue of 314 blocks, only 159 TU are functional. Funds for civil work up-gradation of additional 75 is provided in the current year but there is no allocation for HR and two wheelers. Collaboration between TB and HIV programs is good.

**Recommendations:**

STO's position needs to be upgraded at least at par with other programmes like malaria. Central government should approve supplementary PIP for HR and two wheelers for 75 TUs and ensure protected funding for accelerated scaling up of the remaining 80 TUs to complete decentralization.

**2. Programme Monitoring****Findings:**

Monitoring, reviews and evaluations are conducted regularly. However, TB program review gets low priority at district level. Programme at all levels in the State still follows old 70/85 targets while the 2012-17 NSP's targets are 90/90. The state is using Nikshay, the case-based web-based software for entering data of TB patients in the public as well as the private sector. Only the patient registration module is being used and there is a back log of entries across the state on the status of HIV, follow up examination and result of treatment. It was observed that Nikshay is being used more as a data entry tool and there wasn't sufficient evidence regarding its use as a monitoring tool. Presently data entry at every level is being done by the contractual staff-STs, STLS etc. All the payments in the state from the public sector to ASHA is through e-payment gateways. In pilot modes, biometrics and mobile phones are used in the state. There is a possibility of duplication of data due with ICT applications. The usefulness and ethical aspects of the ICT pilots are not clearly demonstrated.

**Recommendations:**

Program should get priority for review especially at the district level. State should follow NSP's target of 90/90 at all levels of the programme. District should explore possibility of making data entry at Block/TU level for timely registration of the TB patients in Nikshay through DEOs placed /Pharmacist/HA etc. Line listing of all the private health facilities/laboratories and private practitioners should be done; subsequently these facilities and private providers should be registered in Nikshay to enable these facilities to notify TB patients. The program should also line-list all health care providers, register in Nikshay, sensitize, share notification format, follow-up with each facility and then subsequently the patients diagnosed and treated by private health facilities. Usefulness and ethical issues of ICT models may be considered.

**3. Case finding****Findings:**

Total presumptive TB patients screened by the RNNTP is showing a gradual decreasing trend from 135/100,000/quarter in 2009 to 121/100,000/quarter in 2014. In the same period the total TB case notification has also declined from 129 to 105/100,000/quarter. Of the 1357 PHIs, only 453 (30%) have a referral of more than 2% of its adult OPD. Diagnosis of Tuberculosis is restricted to CHCs though many of the PHCs also have Microscope and Laboratory technicians. Case finding activities are passive. There is a persistent gap of about 7-8 smear positive cases/100,000 population who are diagnosed but not being initiated on treatment over the last 6 years. Paediatric TB diagnosis is restricted to DTC and the patients registered was dependent on availability of paediatric drugs. Only 2/31 DTOs are full time who are not engaged with any responsibility other than TB Control

**Recommendations:**

TB referrals for testing need to be monitored from the programme management report and shared with the CDMO. As per the program need, provide diagnosis facility in PHCs which have an LT and a microscope. Case detection should not be confined to sputum positive cases only and should

encompass around detection of NSN and EP cases as well. Wherever available, X-ray facilities should be encouraged and utilized for diagnosis of smear negative cases. Efforts for community awareness to be prioritized using village-wise mapping of TB suspects using Laboratory registers. State needs to intensify the efforts to address the low case detection in coastal areas and focus on intensified case finding activities involving HWs, Health supervisors and ASHAs as well as practicing infection control measures at all microscopy centres, district Hospitals and DRTB centres with ensuring implementation of various components of RNTCP in line with National Strategic Plan and ensure better coordination and linkage with NHM. Large number of vacancies of lab technicians in designated microscopic centres need to be addressed with priority. RNTCP should liaise and coordinate with NUHM to benefit from the mapping of urban slums and refurbished urban health facilities by NUHM. To provide improved services to the Tribal populations, Inter-sectoral convergence with other programmes and departments other than health has to be initiated by the District TB officers at the Block level.

#### **4. TB and health systems**

##### **Findings and Recommendations:**

There is significant integration of TB services in the general health system. However, overall the health system of the state is weak, primarily due to significant human resources shortages. The TB programme as well as the broader health system is also not able to perform fully as a result. The state authorities are cognizant of the general issues but there is no clear timeline for when issues are likely to be resolved. Issues like degree of reliance on contractual staff and related salary issues should be considered in this context.

Some additional performance issues arise from low engagement with private sector providers. Existing platforms such as the CEA should be used where possible but more initiative is needed. Leadership from the state as well as national authorities is needed to push for systematic engagement with private providers for general health systems as well as TB care. All states, including Odisha, should map private providers and systematically come up with plans to engage with different types of providers and providers in different geographic areas. With regards to the RNTCP, there is in fact a financial incentive provided for notification for example, which if implemented would have huge implications for TB notification and care in the state.

Certain features of the integration of TB activities with the general health system also require some re-thinking. There are shortages of some types of staff like lab technicians. In some districts existing lab technicians across the health system are underutilized because of restrictions from the RNCTP programme while in other districts, RNTCP programme LTs are overburdened. The state as a whole and districts need to focus on rationalizing the workload of LTs across different programs to respond better to local needs.

Similarly, there is a high and logical reliance on ASHAs to deliver many components of TB care. However, support systems for ASHA are weak and there is often unnecessary task shifting to them which causes inefficiency (e.g. transport of sputum from ASHA all way to CHCs). These issues need to be urgently addressed. Additionally, ASHA remuneration is low as compared to their workload, which is extensive and further funding is needed to ensure that ASHA motivation to carry out NHM as well RNTCP activities remains high. Overall, it would be logical to design the ASHA incentive payments such that the overall remuneration of well performing ASHAs is in line with that of Aganwadi workers.

There are also some limitations in the financial management systems used by the RNTCP and NHM that cause inefficiencies. The RNCTP uses paper-based financial management systems, while the

NHM uses paper-based financial management systems at the district level and below. Computerization of these systems will be extremely beneficial. Additionally, there are dual financial reporting formats needed for the RNTCP program and NHM. These issues also need to be addressed in a streamlined computerized financial management system across all levels and programs in the State.

A similar issue is the lack of computerization of patient records in the general health system. Simple paper registers are kept in public health facilities, even at the level of medical colleges. This makes it very difficult to systematically keep track of re-visits, etc. Computerization of at least basic patient records at PHC, CHC and higher levels will be key for monitoring and improving quality of services. This computerized system should of course be inter-operable with NIKSHAY. Additionally quality assurance mechanisms at the public providers are also necessary and could be easily incorporated into a computerized patient record system. Overall, there should only be reliance on training of health workers but supervision and clinical auditing mechanisms should also be used.

Finally, there was no evidence of implementation of procedures to control the over the counter sales of Schedule H1 drugs in the state at private chemists. This of course has significant implications for the treatment outcomes as well as broader issues such as anti-microbial resistance for TB drugs. As such, there is an urgent need for implementation of norms to control the sale of Schedule H1 drugs.

## **5. Procurement, Supply Chain Management**

### **Findings:**

There was no stock out of adult or paediatric medicine boxes at peripheral level. Due to short supply of medicines (Inj. SM & INH, some of the districts had to procure loose anti TB drugs. There has been no quality assurance for local procurement as this is done in emergencies where the district cannot wait for the quality assurance process which takes 3-4 months. Transport mechanism for drugs from districts to sub-levels is not efficient. In some cases, stock is transported on motorbikes from districts to sub-levels without adequate safety measures and the concern person has to come 2-3 times to collect their complete stock. Further, storage conditions are sub-optimal. Cycloserine received by the State was kept outside the drug store for 4-5 months due to lack of storage space. Some of the injectable drugs were kept outside refrigerator. System gaps were visible in drug management e.g. low buffers, shortage of SM, RIF 150, PC-13, PC-14, INH 100mg/300mg. Also, Rifampicin was available at state drug store but DTOs were not aware of it.

### **Recommendations:**

Quality assurance of locally procured drugs needs to be done at State / NABL - accredited labs. Block Management Units have to take the responsibility of transport of drugs. State may also consider annual contract with transport or courier agencies to strengthen its transport mechanism. RNTCP should link with the state agency OSMC for interim procurements from other states, if required. Physical verification and monitoring of drug stores to be done routinely. Storage conditions needs to be improved. Information regarding drugs availability at SDS may also be shared with districts, so that they can request for the same accordingly.

## **6. Treatment and treatment support**

### **Findings:**

Overall treatment outcomes under RNTCP are good. Community DOT providers engaged in 80% of cases treated. However, supervision of community DOT providers work is sub-optimal. Large number of TB patients are managed with inadequate standards in private and public sector and they remain un-notified. Only 1158 were cases notified in NIKSHAY from the private sector last year.

### **Recommendations:**

Health staff in the general health services should be used for improved supervision of community DOT providers. State should take immediate steps to engage the private sector and to notify cases treated by the private sector through Nikshay.

## **7. Drug Resistant TB**

### **Findings:**

PMDT services are available in all districts of Odisha with rapid molecular diagnostics through RNTCP certified labs (2 LPA, 3 CB-NAAT) and treatment with second line drugs (3 DR-TB Centers– Cuttack, Behrampur, Burla) free of cost. Intermediate reference laboratories (IRL) Cuttack is certified for all DST technologies (Solid Culture, Liquid Culture and LPA) for first-line drugs (FLD). It advanced to DST for second-line drugs (SLD) in March 2015. A National Reference Laboratory (NRL) for east India is located at RMRC Bhubaneswar and certified for LPA & Solid Culture while advancing for Liquid Culture for FL & SL-DST. Till 2014, ~7200 presumptive MDR-TB patients were tested, 668 MDR-TB patients & 20 XDR-TB patients were put on treatment. ~80% of enrolments in national drug resistance survey from 4 selected TB unit clusters of Odisha completed. MDR-TB drugs adequately supplied, XDR TB drug procured locally.

There are many unresolved issues affecting access and quality of PMDT services with limited monitoring from the state and district levels. Key staff positions sanctioned for PMDT services like 1 Senior MO for DR-TB Center Cuttack, 3 Counselors for DR-TB Centers and 5 District PMDT –TBHIV Coordinators.

At IRL Cuttack, the following challenges were unaddressed since nearly six months 1) Maintenance and repairs of 6 critical lab equipment's including the air handling unit of bio-safety level BSL III facility compromising bio-safety of lab staff 2) National training of lab staff appointed by FIND India was pending due to issues of travel allowances from RNTCP 3) Stocks of lab consumables for LPA and liquid culture would last for only a month 4) CB-NAAT sites not monitoring by IRL Cuttack 5) CB-NAAT site at Koraput sub-optimally utilized. Only 150 tests were done in 2014 against an optimal capacity of ~3000. This lead to expiry of 59 cartridges 6) ~50% eligible patients were offered MDR-TB diagnosis in 2014. Access to sample collection is available only at district level in most districts 7) Existing laboratory capacity of 5 labs sub-optimally utilized.

Issues with MDR-TB treatment services: A total of 25 bed capacity was saturated at existing three DR-TB Centers with an average duration of stay of 13 days per patient. This is clearly insufficient for scaling up services towards universal DST by 2017. Expansion of DR-TB center at Cuttack sanctioned but held-up since a year due to administrative reasons. Three more DR TB centers sanctioned in the budgets of 2014-15, however, the contractual staff proposed were removed during budget negotiations at NHM level. Thyroid Function Test as part of the pre-treatment investigations is not available at the government health facilities. MDR-TB patient have to pay for this test and are reimbursed later, however, many poor patients can't pay and do not get the test. Only 76% lab confirmed MDR-TB patients were initiated on treatment. Only 7/31 districts initiated >95% diagnosed MDR-TB patients on treatment, lowest being in Rayagada 29%, Sonepur 57% and Bhubaneswar 66%. Coordination and information exchange between DR-TB centers and district staff compromising monitoring patient's progress on treatment was a neglected area. Linking MDR-TB patients to existing patient support systems was observed to be an untapped opportunity.

Digitalization of MDR TB patients data from labs (417 -10%) and DR TB centers in NIKSHAY was minimal. Second-line anti-TB drugs like Levofloxacin, Amoxy-Clav were found to be sold over the counter at pharmacies without prescription.

**Recommendations:**

The State PMDT Committee should meet regularly to monitor progress and trouble-shoot to resolve issues precluding improvements in quality and access of services to MDR-TB patients in the state.

IRL Cuttack - Repairs of laboratory equipment need to be urgently addressed particularly air handling unit of BSL III, resolve bottlenecks for lab staff training, optimize and monitor CB-NAAT site utilization

Key vacant staff positions for PMDT need to be filled and trained

Resolve bottleneck in expansion of DR TB center Cuttack, expedite initiating services at 3 new DR TB centers, plan District DR TB centers in district hospitals (train specialists, reserve 4-6 beds) in phased manner

Decentralize sample collection and transport to block level and involve ASHA/ANM/MPW in transport, engage PHC staff in patient tracking and care to improve treatment initiation of MDR TB patients.

Contract out Thyroid Function Test from State level to relieve the patients of financial burden.

Instruct DRTB-TBHIV coordinators of all districts to regularly meet the concerned DR-TB Center staff each month for updating patient's progress on treatment to improve care.

Extend social welfare schemes to MDR-TB patients irrespective of below poverty line levels or HIV status and develop systems to automatically link them (nutrition, pension, shelter, RSBY, free public transport etc.)

Expedite and monitor digitalization of MDR TB patient data from labs and DR TB centers in NIKSHAY Strengthen stringent implementation and monitoring of Schedule H1 at all pharmacies in the state through state drug controller and drug inspectors

**8. Engaging all care providers**

**Findings:**

Large numbers of patients those presumptive TB cases are accessing care from the non-public health care health facilities of the State. In the districts visited, patients and community members told that when they have cough, they first seek care from pharmacies. All pharmacies visited in the peripheral areas were using levofloxacin as the first option to treat cough. If the cough remains, people then prefer to visit Homeopathy practitioners. The community in general believes that cough for more than a month can be due to TB. Many such patients them prefer to go to nearby cities to seek care from medical colleges or bigger private hospitals. Even in the Port Trust hospital, owned by the central government, patients suspected to have TB are referred directly to a tertiary care private hospital for further care. Cuttack medical college was visited which gave more evidence for the above pattern and the engagement in RNTCP was limited. There are many private hospitals and about 170 pharmacies around the medical colleges. Many of the medical college faculty members are working in these private hospitals where the diagnostic and treatment practices are different from the RNTCP. Majority of the patients treated in such private hospitals and many patients seen in the medical college are given prescriptions to buy medicines from private pharmacies. All the pharmacies visited were stocking different brands of anti-TB drugs as FDCs. Prescriptions include drugs like levofloxacin. So, fare only 19 cases notified since Jan'2013 from the private sector in Cuttack.

Despite the above described situation, there were very limited efforts by the RNTCP especially at district level to engage all care providers with the RNTCP. The private sector mapping is not done although the state has a good presence of PSUs and private sector companies. No efforts were made to engage with the Chemists or Pharmacists in the state although the RNTCP has clear guidelines and

training modules to engage Pharmacists in the program. The State commented that they were unaware of any such mandate given by CTD or the training modules also there were no funds allocated for the initiative. Similarly health care providers like nurses and ANMs were not engaged to optimally utilize their capacity and outreach. The State has no Technical Support group for PPM – as recommended under the NSP. The State also does not have any assigned Public Private interface Agency (PPIA) for the urban areas private sector coordination. The PPIA were to be assigned in 2013. PPM coordinator position at the State is vacant. Engagement with professional organizations like IMA is very limited despite the presence of a Global Fund project implemented by IMA.

**Recommendations:**

The state TB program needs to engage private sector extensively. As an initial and basic step, a detailed mapping of the private sector should be done. The state immediately needs to put in place a PPM coordinator and ensure that his/her expertise is utilized to put in place a plan for engaging all care providers. Nikshay should be used more widely to get notification form the private sector. The State should also engage the centre to get a PPIA in place and learn from the models in Mumbai, Patna and Mehsana. Collaboration with the IMA project, with district wise analysis of low reporting from high presence of PPs should be done and prioritized. The State TB Office also should work closely with the Drug Control Authorities to ensure the implementation of the Shedule H1. The Chemists and RHCPs (less than fully qualified providers) should be engaged for referral and treatment supervision of patients in the private sector. If needed the Department should join hands with the OSACS to jointly approach the industry for their support and engagement. The NGO sector and civil society needs to be engaged and supported for reaching the key population. They should be invited to participate in the program and partnership guidelines should be used to engage them. PPIAs should be engaged to play a crucial role in the engagement of the private providers in the urban centers and help find the missed cases, increase awareness of STCI and TB notification. Strong efforts are essential also in the perspective of occupational health issues in the state.

**9. TB-HIV and other co-morbidity**

**Findings:**

The State has a good TB/HIV Coordination. 68% of TB patients know their HIV status. There is high death rate of TB-HIV patients (17% New, 19% PT) mainly due to access issues and delayed diagnosis and ART initiation. Intensified package started in 2009 and State level SCC & SWG meetings are conducted regularly. DCC meetings are conducted in most of the districts (In Cuttack 2 meetings per month). Integrated HIV/TB services in the CHCs and the Medical College visited. ICTs and DMC are co-located. TB patients identified are sent across for HIV testing. HIV patients tested at ICTs/ART centers are sent for TB testing. Good numbers of TB patients know their HIV status as per shared reports. Good numbers of co-infected patients are receiving CPT & ART as per the extract of the Coordination meeting held in Feb 2015. Good record keeping on HIV/TB co-infected patients. On the other hand, there is very limited infection control measures applied in co-located facilities, DMCs, ICTs and ART centers visited. For example, waiting rooms are shared by both HIV/TB patients and are not properly ventilated in ITCs, ART and DMCs visited; providers for both HIV/TB patients are not taking adequate infection control measures (No masks, gloves for LTs; and no masks were provided to MDR patients. There is high death rate of HIV/TB patients (No clear reason given for this). There is no easy access to the diagnosis centers (patients have to travel more than 30 km to get access to CHCs and ICTs). There is no early initiation of treatment due to stock out and shortage of drugs. IPT was not available. There was stock out of HIV test kits at ICT centers. Counsellors were not available for co-infected TB HIV patients.

**Recommendations:**

State should implement infection control guidelines and monitor TBIC practices in HIV and TB care facilities (Ensure measures such as designated AIC focal points in each HIV (and TB) facilities, facility AIC plan, AIC check-lists, patient education and AIC in local language on cough etiquette, availability of masks, cough monitoring, fast tracking, training of staff on TB and HIV infection control). Research to find out the reasons for high death rate among TB/HIV patients should be encouraged. State should ensure that it receives IPT procurement from CTD, implement and monitor the uptake of IPT among PLHIV according to the National TB/HIV framework. ORISSA SACS should request NACO to supply HIV test kits to ICTs and ART centers.

## **10. Pediatric TB**

### **Findings:**

The state has made significant effort to address tuberculosis in children especially around contact screening, identification of cases through bacteriological examination, treatment, and HIV testing. The major challenge that the state faces is the low case finding with only 4% pediatric cases among total TB cases, which is below the current national average of 6% and far below the 10-20% of new pediatric cases that are estimated to occur in India. In relation to contact screening, initial visits to household of newly diagnosed TB patients is consistently conducted and an innovative initial home visit form has been developed to assess all contacts in a household including children. The contacts under 6 years of age are recorded on the treatment card, but the ability of the state to effectively provide IPT is hindered by stock outs of INH 100 mg and the lack of tracking and monitoring the completion of the full course of IPT among these contacts. One district visited Jagatsingpur was successful in procuring INH 100 mg and maintaining their stocks, although there was no records that indicated the children completed IPT.

The low identification of children through diagnosis has many reasons and is a combination of issues related to poor use or lack of use of available tools and the negligible interaction with public and private providers engaged with childcare. The state merely provides bacteriological examination to identify children with TB and has almost none to limited availability of other tools such as TST, radiography, and rapid molecular diagnostics (CBNAAT). Because of the unique presentation of TB in children, one tool is not sufficient to adequately diagnosis a child. Within the program, facilities are not only poorly equipped but many also have inexperienced and poorly trained technicians, therefore children suspected of having TB are not adequately investigated.

In addition to these weaknesses within the program, it is apparent that many cases of pediatric TB are identified and diagnosed outside of the RNTCP within the public and private sectors. Even given this reality, the program has little to no interaction with these providers (both public and private) and these providers are not notifying their patients to the program. A prime example of this is the lack of involvement with Shishu Bhawan, the largest pediatric healthcare institution in the state. The diagnostic practices among the doctors involved in child care in the private sector were also poor as they largely relied on clinical tools.

One of the more neglected areas is the management of children with or exposed to drug-resistant TB. Currently, there is improper investigation and treatment (i.e., given Cat. I treatment without any effort for a bacteriological diagnosis) throughout the program and state. Within areas and wards where DR-TB patients are present there is little to no infection control exposing children to a serious threat of DR-TB infection for which not many treatment options available.

### **Recommendations:**

There is an opportunity through Nikshay to gain a better understanding of pediatric TB in the state to better address the issues; but Nikshay must be expanded to include large pediatric institutions, as well as, its data analyzed further to understand additional data points such as numbers on types of TB in children, types of samples collected, where children are being diagnosed, how many children

given IPT, etc. In order for the critical initial visits to households to continue and be consistently employed across the state, the travel allowance to TBHV must be protected within the budget and paid which did not happen during the 2014-2015 fiscal year. Instead of declaring a case as negative just because a smear is negative children would should be diagnosed using a multitude of tests, using the guidelines provided by the programme. Shishu Bhawan should be actively engaged and involved in providing TB Services but in order for this to happen: They require support for diagnostic facilities [TST, bacteriology-smear or CBNAAT] and linkage with the DMC [DST, culture] as well as training of their doctors in childhood TB diagnostics. They need to be registered for notifications and need to be a provider for DOTS. There is a strong need to provide pediatric-specific training of the public and private providers and efforts to actively involve the willing partners to improve case detection. The RNTCP must give greater attention and urgency to addressing deficiency around DR-TB management due to its fatal consequences for children and their families. The capacity building of the focal points like interested faculty in Shishu Bhawan is needed to create a skill bank for not only better service delivery but also as the leaders and trainers for the rest of the fraternity in the city and state.

### **11. Targeted interventions and Special groups**

#### **Findings:**

There were several small scale initiatives for systematic screening for active TB disease targeting special groups (AIPH TB-REACH, Jagatsinghpur). RMRC, a research institute is estimating TB burden among tribal population and diabetics. There is evidence to say that there is significant burden of undetected TB among tribal population. A survey among children in a tribal school showed that the prevalence is 4 times compared to the State. Prisons are engaged in RNTCP but systematic screening of inmates and infection control are not in place.

#### **Recommendations:**

State should support RMRC the estimation of TB among tribal population. There should also be efforts to estimate the TB situation among other relevant special groups. RNTCP should install systematic screening and infection control measures in prisons.

### **12. Support systems for patients and families**

#### **Findings:**

Most of the patients visited were undernourished. Social protection schemes for BPL and PLHIV (nutrition, pension, shelter, RSBY, transport) exist in the State. However, there is no access for TB patients to most of the social support systems for TB patients and families unless they belong to the above said special groups. There were some small-scale attempts to provide nutritional support by NGOs

#### **Recommendations:**

Social protection schemes for BPL and PLHIV should be extended to TB patients.

### **13. Community engagement and ACSM.**

#### **Findings:**

There was high visibility to the extension branding of the logo of DOTS, stressing on treatment compliance. There is limited involvement of some NGOs and their networks at the state level has taken place and the arrangement is mutually beneficial. School health programme is used to good effect to spread message of spread, treatment and control of TB in the community, but needs to be further developed and expanded. Some health educational material (posters, wall-writings) were available at most health institutions. "Swasthya Kantha" (regularly updated blackboard messages) were seen at village common areas.

There is no formal policy for community engagement and ACSM at the state and district level. This may affect the planning, implementation and monitoring of the different components of this aspect of the RNTCP in the state. ACSM Officer position at state level is vacant for the last few years, with important implications for implementation of the ACSM strategies. ACSM budget is only 2-3% of RNTCP budget and expenditure is about 45 to 50% of this amount. Involvement of AYUSH doctors in RNTCP is inadequate. Though the work in PHCs, they are not given proper orientation to identify and refer presumptive TB cases to RNCTP. IEC materials, particularly those for mass distribution (pamphlets, leaflets, patient guidelines) were inadequate at the peripheral levels. There was inadequate use of media. RNTCP is not utilizing several opportunities for health education – at health institutions (OPD waiting areas, inpatient wards), colleges, groups in villages. Stigma against TB is still very common at different levels. There is low awareness of adult women in the community on TB and its prevention, as compared to men.

**Recommendations:**

RNTCP should increase budgetary provisions and capacity to utilize funds fully for ACSM activities. There should be focussed targeting of women of all age groups for IEC activities. Women's groups of various kinds (mothers, SHGs, mahila mandals, adolescent girls) should be used for this. NGO involvement should be increased at district level, and forums for these organisations participating in the RNTCP at the state and district levels should be encouraged. Media use needs to be increased manifold with regular radio talks, TV spots, short films and documentaries. Patient groups should be set up with cured / ex-patients invited to facilitate group sharing sessions. IEC strategies should vary with the region of the state – different ones for tribal and non-tribal areas should be worked out.

**14. Research & Technical Assistance**

**Findings:**

Technical assistance to RNTCP is provided by WHO, FIND, IMA and other partners. Awareness drives and community based active case finding done in 10 coastal districts resulted in 11% incremental increase in case notification. Intensified case detection in Jagatsinghpur led to incremental increase of 8/100,000 cases. Zonal OR committee is not meeting regularly. There is limited OR capacity in the State. There is no focal point or specialist in the state for research.

**Recommendations:**

OR committee should meet regularly. State should take measures to strengthen the OR capacity by recruiting a focal point or by collaborating with research institutions or medical colleagues.

## 7. Tripura

### State profile

Population:	3.67 million
Literacy rate:	88%
Administrative set-up: DMCs	8 districts, 6 RNTCP districts/reporting units, 11 TB Units, 56
RNTCP: services initiated in	Full state coverage under RNTCP in October 2005, PMDT
CBNAAT 0; DR-	2012. C/DST labs: 1 (but not yet certified by RNTCP); LPA 0;
Trends in key programme indicators: 36 per 100,000	TB Centre 1 Annual (2014) new smear positive PTB case notification rate (national 50); Treatment success rate of new smear positive PTB cases 88% (2013)
Districts and state level facilities Kailasahar; DTC and TU, visited by JMM: Manu Valley	Unokoti District: District Hospital and RGM Hospital,  Kailasahar, Panisagar CHC; Irani PHC; Kanika Memorial PHC;  sub-centre; District Jail; 1 Tea Garden; and 5 TB patients interviewed, and >10 tea garden workers interviewed (at health facilities and home) North Tripura: District Hospital, Dharmanagar; Kadamtala PHC; Kanchanpur Sub-Divisional Hospital / PHC- TU; Jampui PHC (tribal area, >3,000 feet above sea level); Pharmacies in Dharmanagar market; and 4 TB patients interviewed, including 1 MDR-TB patient, and 6 non-TB patients in general wards (at health facilities and at home). In Agartala (State Capital): State Drug Store, Agartala Government Medical College (DR-TB Treatment Centre, Dept of Microbiology, ART Centre); NACP Community Support Centre; Private laboratory and pharmacy; and 3 MDR-TB patients interviewed (at health facilities and at home)

### Key Observations

#### Political and administrative commitment for Universal access of TB Care

- TB is a state health priority, including large advances (Rs 1 crore) to TB work from the common flexi pool of NHM funds, IEC materials on all health programmes including RNTCP distributed among the Panchayati Raj Institutions (PRI) members by the Minister of Health during district level review meetings.
- Districts increased – 8 districts now up from 4.
- Number of TUs increased with decentralization and use of norms for hilly districts in Tripura.
- TB HIV and PMDT services are in place in Tripura.

#### Epidemiology (burden, notification system, M&E, etc)

- High level of treatment success amongst the new smear positive pulmonary TB cases maintained, with a relatively high level of treatment success amongst smear positive pulmonary

TB retreatment cases with a slight decline in lost from treatment, but mirrored by slight increase in death (NB: small numbers of patients).

- Significant increase in identification and examination of presumptive MDR-TB cases from 2014 onwards.
- Nikshay introduced in all districts, and 90% of cases were registered in Nikshay in 2014.

#### **TB Care: Early diagnosis and case finding**

- Good coverage by DMC network.
- EQA system in place and done well.
- Minimal initial default observed.

#### **TB Care: Treatment of TB**

- 878 DOT Centres functioning.
- Majority of cases initiated on treatment within 2 days of diagnosis
- MPWs and ASHAs actively involved as DOT Providers (DPs) in the districts, with half of patients receiving DOT from community volunteers in 2014.
- Good treatment success rates maintained.
- Virtually no ATT (even FLD) available in private pharmacies.

#### **TB Care: Drug resistant TB**

- As across the whole country, Criteria C is being used for identification of presumptive MDR-TB cases.
- Rapid increase in number of presumptive MDR-TB cases examined from 2014 onwards, mainly due to resolution of sputa transportation and logistics issue.
- 100% of detected MDR-TB cases placed on treatment, most within 1 week of sample being sent for DST, virtually all within 2 weeks.
- All investigations provided free to patient, as are all ancillary drugs for ADRs (including reimbursements of any prescribed purchase from a private pharmacy).
- Airborne infection control measures (AIC) in DR-TB Treatment Centre mostly adequate.

#### **TB Care: Engagement of all care providers**

- Within the state, the vast majority of health care (95%) is provided by the public sector. There are very few solely private providers in the state, and most private healthcare facilities are already registered in Nikshay.
- There are a large number of tea gardens in the state, most of whom have their own independent primary health care facilities supported by governmental/private/special services. Many have established links with the RNTCP services.

#### **TB Care: HIV and TB**

- 18 DMCs have a co-located ICTC, and 37 are co-located with a FICTC.
- Across state, around 70% of TB patients know their HIV status, which has been steadily increasing annually since 2011.
- 85% or more of HIV-infected TB patients are placed on CPT and ART.
- Screening of HIV-positive clients for TB disease is ongoing.

#### **TB Care: Paediatric TB**

- Sensitization activities to the relevant officers on the RNTCP Paediatric TB Guidelines have been conducted.
- AGMC collecting alternate specimens (GA, induced sputum, etc) for the diagnosis of TB in children.

**TB Care: Targeted interventions for special groups**

- DOT centre set up in the Central Jail of the state.

**TB Care: Support systems for patients and families, social protection, UHC**

- From the State Government, all TB patients under RNTCP who successfully complete treatment are entitled to Rs 900.
- Reimbursement of transportation cost as per actual to TB patients who are referred to DTC for consultation and investigations via the Tripura TB Association is available.
- A proposal has been submitted from Gomati District to the State for BPL TB patients to receive rations at subsidized rate.

**Programme financing and health system strengthening**

- High percentage expenditure of disbursed funds in 2011-12, additional funds from NHM supported RNTCP in many activities.

**Advocacy and communication**

- Some IEC materials are available in the local language.
- Good knowledge of available services amongst community.
- Patient provider and ASHA meetings by NGO in North Tripura District.
- Daily health camps and monthly Village Health Nutrition Day (VHND) held.

**Other issues**

- Register kept in 1 DMC of North Tripura District with details of adult contacts of smear positive PTB cases since 2012.

**Constraints****Political and administrative commitment for Universal access of TB Care**

- STO also has other functions.
- Two currently undivided Districts (North Tripura and Unokoti) still function as one for RNTCP, which affects administration, reporting, logistics etc.
- Key HR vacancies in North Tripura District which impacts on both financing and activities (e.g. number of trainings conducted). Across the state, 15 STS and STLS posts are vacant out of 22.
- Many sub-centres have 1 MPW in post not 2, majority of time spent on MCH.
- No DTC in North Tripura district.
- Rigidity in financing structures.

**Epidemiology (burden, notification system, M&E, etc)**

- TB and MDR-TB estimated caseload extrapolated from national level estimates.
- Slow decline in both presumptive TB examination and notification rates across state and most districts.
- Monitoring and supervision observed to be weak in a number of sites, leading to poor practices in the field (e.g. quality of DOT, poor record keeping, late submission of monthly PM reports from PHI level, etc.).
- Challenges with Nikshay due to competing activities for the HMIS Assistants and poor internet connectivity in some sites.

**TB Care: Early diagnosis and case finding**

- Referral for testing of presumptive cases of TB from OPDs appeared to be low, with resultant drop in symptomatics tested and an observed decreasing case detection.
- LT vacancies in Unokoti district.

- Non-DMCs doing RNCTP smear microscopy work in North Tripura district.
- Number of binocular microscopes need replacing.
- No rapid diagnostic technology available anywhere in the state.
- Monitoring and supervisory activities were observed to be variable across the state and districts.

#### **TB Care: Treatment of TB**

- Virtually no buffer stock of PWBs in place in North Tripura District at Kanchanpur TU drug store
- No H 100 or 300mg available, shortages of R150 mg also.
- State Drug Store (SDS) has no electricity supply, SLDs kept in separate AC room.
- No DPs list, no duplicate Rx card with DP, delays in payments to DPs.

#### **TB Care: Drug resistant TB**

- Sputa samples from presumptive MDR TB cases need to go to Guwahati IRL for DST, and are transported by the Tripura State Bus Service.
- Detected MDR-TB patients need to go to Agartala for admission, with no enablers or incentives in place for patients and families, bar what is provided by the State TB Association.
- Poor awareness of staff of provisions for patients and families.
- No routine clinical monthly FU of patients once on treatment.
- Management of ADRs not being handled well.
- No adequate personal protection for staff on DR-TB ward at the Agartala Government Medical College (AGMC), staff are being provided only with single layer cotton surgical masks as for the patients.

#### **TB Care: Engagement of all care providers**

- Although there are only a few NGOs in the state and predominantly only government doctors are doing private practice after their governmental duty hours, there is no formal partnership between the private and public sector. The same is true of the other health facilities within the public sector and RNTCP.
- AYUSH doctors observed to have limited knowledge of RNTCP.

#### **TB Care: HIV and TB**

- There is no financial support provided to TB patients to attend ICTCs for HIV counselling and testing (outlay can be between Rs 80 to 100).
- Only 1 ART Centre at AGMC, and 3 Link ART Centres across the whole state.
- Whole blood testing for HIV not yet implemented in the state.
- In the Opioid Substitution Centre visited, no screening of clients for TB was being done.
- Counsellors stated that they had limited guidance and tools on how to screen the HIV-positive clients for TB.
- No tracking mechanism to monitor whether all TB patients are referred for counselling and testing, and whether they actually reach the ICTCs.

#### **TB Care: Paediatric TB**

- Paediatric TB cases contribute only around 2% of all TB cases notified in the state.
- PPD is not available.
- Paediatric PWBs are not available.
- Contact tracing in childhood contacts of infectious cases is highly variable, and H 100mg and 300mg are unavailable.

#### **TB Care: Targeted interventions for special groups**

- No formal linkages between RNTCP and the medical services in the prisons and tea gardens.
- Minimal emphasis on TB at NACP Targeted Intervention (TI) sites.

- Little documentation on TB situation within tribal populations within the state, and only one district within the state qualifies as a "tribal district" despite significant proportions of the population in the respective districts being tribal.

#### **TB Care: Support systems for patients and families, social protection, UHC**

- There are many delays in the processing and release of funds from the state Government support schemes to patients. Hence few patients actually access these benefits.
- Few patients appear to be actually entitled to reimbursement of travel costs or other enablers/incentives.

#### **Programme financing and health system strengthening**

- Funds available at the state and district levels are less than the amount requested in the PIP and approved amount.

#### **Advocacy and communication**

- TB and RNTCP not included in Health camp and VHND activities.

#### **Other issues**

- Register of adult contacts of smear positive PTB cases seen in North Tripura District showed not a single TB case detected since 2012.
- Where waste disposal pits were available, often the waste is scattered outside of and around the pit. In 1 site, it was observed that the general hospital waste was thrown out in the open directly opposite from the hospital staffs' residences.

#### **Key Recommendations**

Whilst the basic components of the RNTCP are in place, the focus and importance given to TB at the state level is not translated at the levels below. Greater attention needs to be paid to the quality of RNTCP services provided for drug sensitive TB cases, which requires better and strengthened supervision and monitoring at all levels. Whilst services for TB-HIV co-infected patients and DR-TB patients are available in the state, they require strengthening both by decentralisation of services and introduction of new technologies, particularly for diagnosis.

#### **Political and administrative commitment for Universal access of TB Care**

- Translate state level priority on TB to the field level, and to ensure that the patients are treated as the VIPs of the programme.
- Fully separate and equip the 2 undivided districts for optimal functioning of the TB programme.
- Fill key vacancies asap, and consider decentralisation of recruitment of key district level HR to the district level in future. As an interim measure, use existing LTs in more than 1 DMC on rotational basis, particularly for /and to areas with less laboratory load.
- Give some flexibility within NHM financing processes to allow for "innovative" RNTCP activities

#### **Epidemiology (burden, notification system, M&E, etc)**

- Visibility of TB and RNTCP needs raising at all levels across the state.
- PMDT services need to be closely monitored
- Strengthen training, monitoring and supervision at all levels and for all staff.
- Importance of timely general reporting and registration under Nikshay reinforced to the appropriate officers and staff.

#### **TB Care: Early diagnosis and case finding**

- Involve the PRIs at the village levels to strengthen case detection efforts.
- Strengthen training, monitoring and supervision at all levels and for all staff.

- Key vacancies to be filled urgently.
- Non-DMCs doing RNCTP smear microscopy work is to be stopped in North Tripura, instead establish effective sputum collection and transportation mechanisms. The current siting of the DMCs needs to be reviewed and DMCs maybe moved depending on workloads.
- Replace binocular microscopes as required, with LED where appropriate.
- CBNAAT and LPA should be made available to the state asap.
- Schemes that are in place such as daily health camps and the monthly VHND, can also serve as a platform for TB sensitization programmes as well as screening for presumptive TB cases.

#### **TB Care: Treatment of TB**

- Review drug stocks and delivery patterns from SDS to undivided DTC in Unokoti and to North Tripura District.
- SDS needs electricity supply urgently, and consider sending SDS storekeepers for retraining.
- Easier and timely system needed for DPs to access their honorarium.
- Monitoring of sale of ATT (FLD & SLD) to continue as per schedule H1.

#### **TB Care: Drug resistant TB**

- The practice of sending the sputa samples to Guwahati IRL by the Tripura State Bus Service to be stopped and alternative transportation arranged (e.g. via individual vehicle hiring).
- All State and RNTCP policy and norms to be implemented in regard to enablers and incentives for patients and families, in addition to those provided to staff.
- Recruit a counsellor at the AGMC DR-TB treatment Centre.
- Consider a 2nd DR-TB Treatment Centre in the northern part of state in the coming year.
- Monthly clinical follow up of patients at the AGMC DR-TB Treatment Centre (or District Hospital if a trained Chest Physician is available) is required to monitor progress and advise on treatment.
- Awareness of patient and family of MDR-TB, transmission, treatment, etc., needs improving.
- Strengthen training to DPs in regard to ADR management.
- N95 masks to be provided for staff in the AGMC DR-TB Treatment centre for personal protection.
- Monitor identification of presumed MDR-TB cases and detection of MDR-TB cases against the stocks of SLDs and supplies carefully as case detection is increasing rapidly.
- Consider 1<sup>st</sup> introducing LPA and CBNAAT at the AGMC Microbiology Department laboratory, whilst continuing to build capacity to do Culture and DST. 2<sup>nd</sup> CBNAAT location to be installed in Dharmanagar Hospital, North Tripura District.
- Review staffing needs at AGMC laboratory as plan for laboratory strengthening is finalised.

#### **TB Care: Engagement of all care providers**

- Continue work on raising awareness amongst the small private sector in the state on TB and RNTCP.
- Establish formal partnerships with those providers that do exist in the state, including complete documentation.
- As a priority, train the AYUSH doctors on RNTCP.

#### **TB Care: HIV and TB**

- Whilst HIV rates are currently low in the state, close monitoring of HIV infection trends needs to be maintained (for example STD rates seem to be high in some sites visited).
- Consider providing financial support to TB patients for travel to ICTCs for HIV counselling and testing until decentralised whole blood testing is implemented widely.
- Speed up decentralisation of ART provision to the district level.
- Better dissemination of and training on existing tools for screening for TB amongst HIV-positive clients at the ICTCs, and monitoring and supervision of implementation.

- Establish a tracking system to monitor TB patients who are sent to ICTCs for counselling and testing, and for TB–HIV patients referred to ART Centres for ART.

#### **TB Care: Paediatric TB**

- Continue sensitization and training of all relevant staff on the RNTCP Guidelines for Paediatric TB to ensure appropriate identification and detection of cases of childhood TB (and to avoid both over- and under-diagnosis).
- The Central level to resolve the issues of non-availability of Paediatric PWDs, H and PPD asap.
- Implement RNCTP policy on contact tracing in childhood contacts of infectious cases fully and across all sites.

#### **TB Care: Targeted interventions for special groups**

- Conduct sensitization activities for the medical staff of the prison and tea garden medical services, and establish formal linkages between them and RNTCP.
- Increase TB focus under NACP TIs.
- Districts with significant proportions of tribal populations need to document services and notifications. Consider mobile services linked to other such existing services.

#### **TB Care: Support systems for patients and families, social protection, UHC**

- Review all approved support schemes and proposed new ones, to ensure that all patients receive their entitlements as approved and on a timely basis.
- All health care providers to be sensitised on available support schemes, etc.

#### **Programme financing and health system strengthening**

- Review capacity for planning and preparation of PIPs, and financing mechanisms from Centre to State to District.

#### **Advocacy and communication**

- Use the cured patients as DPs and advocates for RNTCP.
- Promote involvement of PRIs in the activities of RNTCP.
- Include information on TB and RNTCP services in the Health camps and VHND activities.

#### **Other issues**

- The testing of adult contacts of smear positive PTB cases should be evaluated as a state-led operational research study to assess whether RNTCP policy on said area needs reviewing.
- Waste disposal and management needs strengthening. As an interim measure, it should be promoted that waste should be overnight soaked in phenol solution and buried in a deep pit.