



Ministry of Health
& Family Welfare
Government of India



World Health
Organization
COUNTRY OFFICE FOR India

**Report of the
Joint Monitoring Mission**

REVISED

**NATIONAL TUBERCULOSIS
CONTROL PROGRAMME**

April 2015

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Contents

Abbreviations	i
Executive summary	1
1 Health system and tuberculosis in India on the eve of the JMM	7
1.1 Health sector status and priorities	7
1.2 A situation summary of TB control	8
1.3 Objectives of the JMM	9
2 Observations of the JMM on the interaction of the health system and tuberculosis control	13
2.1 General observations with respect to the first term of reference	13
2.2 Tuberculosis epidemiology, surveillance, monitoring and evaluation	14
2.3 Financing	26
2.4 Social protection and support for patients and families affected by TB	29
2.5 Procurement and supply chain management	33
2.6 Community engagement	35
2.7 Human Resources for Health	38
2.8 Engaging all care providers	41
2.9 Research to Improve TB care and control	43
3 Observations of the JMM on the technical aspects of TB care, prevention and control	47
3.1 Early diagnosis and case-finding for all types of TB	47
3.2 Treatment	49
3.3 Childhood tuberculosis	56
3.4 TB/HIV and other co-morbidities	60
3.5 Programmatic management of drug-resistant TB (PMDT)	65
3.6 Target interventions for special groups	69
4 Reports from the field visits to the states	73
4.1 Andhra Pradesh	73
4.2 Gujarat	78
4.3 Himachal Pradesh	83
4.4 Madhya Pradesh	91
4.5 Meghalaya	97
4.6 Odisha	105
4.7 Tripura	114
Annexure	121

Abbreviations

ACSM	advocacy, communication and social mobilization
ADR	adverse drug reaction
AIC	airborne infection control
ANM	auxiliary nurse midwife
ART	antiretroviral therapy
ASHA	accredited social health activist
ATT	anti-tuberculous treatment
AWW	anganwadi worker
BAL	bronchoalveolar lavage
BPL	below poverty line
C&DST	culture and drug susceptibility testing
CBNAAT	cartridge-based nucleic acid amplification test
CBO	community-based organization
CHC	community health centre
CMSS	Central Medical Services Society
CPT	co-trimoxazole preventive therapy
CSIR	Council of Scientific and Industrial Research
CSO	civil society organization
CSR	corporate social responsibility
CTD	Central Tuberculosis Division
CXR	CXR
DCC	District Coordination Committee
DCGI	Drug Controller General of India
DM	diabetes mellitus
DMC	designated microscopy centre
DOT	directly observed treatment
DOTS	directly observed treatment, short-course
DR-TB	drug-resistant TB
DRS	drug resistance surveillance
DST	drug susceptibility testing
DTC	district tuberculosis centre
DTO	district TB officer

EPTB	extrapulmonary tuberculosis
EQA	external quality assurance
FDC	fixed-dose combination
FLD	first-line drug
FM	fluorescent microscopy
FQ	fluoroquinolone
Goi	Government of India
HR	human resources
HRD	human resource development
HS	health systems
HSS	health systems strengthening
IAP	Indian Academy of Paediatrics
IC	infection control
ICF	intensified case finding
ICMR	Indian Council of Medical Research
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
IPT	isoniazid preventive therapy
IRL	intermediate reference laboratory
JALMA	National JALMA Institute of Leprosy and other Mycobacterial Diseases
JMM	Joint Monitoring Mission
LED	light-emitting diode
LPA	line probe assay
LRS	Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases
LT	laboratory technician
M&E	monitoring and evaluation
MCH	maternal and child health
MDG	Millennium Development Goal
MDR	multidrug resistance
MDR-TB	multidrug resistant TB

MO	medical officer
MoHFW	Ministry of Health & Family Welfare
MPHW	multipurpose health worker
MPW	multipurpose worker
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NCD	noncommunicable disease
NGO	nongovernmental organization
NHM	National Health Mission
NIRT	National Institute for Research in Tuberculosis
NITRD	National Institute of Tuberculosis and Respiratory Diseases
NPCDCS	National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke
NRHM	National Rural Health Mission
NSN	new smear-negative
NSP	National Strategic Plan
NTI	National Tuberculosis Institute
NTWG	National Technical Working Group
NUHM	National Urban Health Mission
OOP	out-of-pocket
OR	operational research
OTC	over the counter
PHC	primary health centre
PHI	peripheral health institution
PI	protease inhibitor
PIP	project implementation plan
PITC	provider initiated HIV testing and counselling
PLHIV	people living with HIV/AIDS
PMDT	programmatic management of drug-resistant TB
PP	private practitioner
PPD	purified protein derivative
PPIA	private provider interface agency
PPM	public-private mix
PRI	panchayati raj institution
PTB	pulmonary tuberculosis

PWB	patient-wise box
QA	quality assurance
RCH	reproductive and child health
RNTCP	Revised National Tuberculosis Control Programme
RR-TB	rifampicin- resistant TB
RSBY	Rashtriya Swasthya Bima Yojana
SACS	State AIDS control society
SAP	social action plan
SC	sub-centre
SDS	state drug stores
SHG	self-help group
SL-DST	second-line drug susceptibility testing
SLD	second-line drug
STC	state tuberculosis cell
STCI	standards for TB care in India
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
UATBC	Universal Access to TB Care
UHC	universal health coverage
UID	unique identification number
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
VVHND	village health and nutrition day
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 Sixth 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 tuberculosis (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 nearly a quarter of the global burden of the disease. Meeting the milestones and targets of the End TB Strategy will require implementing bold policies with access to high-quality TB care and prevention to all who need it. India will need to address health system weaknesses and the determinants driving the TB epidemic. The country has the potential to play a part in research and innovation and to develop and use better tools and strategies for TB care and prevention. The End TB Strategy calls for additional efforts in 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 TB control over the past decade are remarkable by any measure. More than 80 million people have been tested, more than 17 million TB cases 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 multidrug-resistant TB (MDR-TB) in 2013, with a remarkable 66 000 persons with MDR-TB diagnosed and put on treatment in the last three years. The programme is now 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; most TB patients registered by RNTCP receive HIV screening, and now 90% of HIV-infected TB patients receive antiretroviral 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 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 is being creatively used for TB control with new focus - 'TB harega, desh jeetega campaign' with commendable investments by the Ministry.

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 INR 16 240 million (1624 crores) received. The health and economic benefits of the RNTCP have been enormous, with an estimated USD 350 billion gain to the Indian economy in the 10 years from 2006 to 2015, relative to the absence of RNTCP services.

The burden of TB

Each year, 1.2 million Indians are notified with newly-diagnosed TB and at least 270 000 Indian citizens die from TB. TB can affect any age, caste or class but cases are mainly in poor people and mostly men. Slum dwellers, tribal populations, and malnourished people already sick with compromised immune systems are more at risk of developing TB. Children comprise 40% of the population, but are currently possibly under-diagnosed with TB in India. The WHO estimates that nearly 1 million Indians with TB are not notified. Surveys have shown that many people with TB remain in the community, untreated. Case detection in the programme appears to be stagnating since 2009. MDR-TB is emerging as a massive organizational and financial challenge to the RNTCP.

Despite the gains from TB control, the economic burden of TB is still vast – between 2006 and 2014, TB cost the Indian economy a staggering USD 340 billion. 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 lagging as against plan, the projected increases in case detection by the RNTCP have not occurred, certain procurements have been delayed. Some of the recommendations of JMM 2012, have not been fully implemented

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 by 27% since 2012, there is a growing gap between the allocation of funds and the investment required to reach the goals of the Plan. If this trend continues, final expenditure on the Plan would reduce to INR 30 000 million (3000 crores). Accordingly, while bold policies are mostly in place, anticipated increases in case finding have not been 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. 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 sector have been unsuccessful. The existing TB surveillance system lacks the capacity to count the large pool of privately diagnosed and treated TB cases.

The Standards for TB Care in India (STCI) and the National Strategic Plan (NSP) promote drug susceptibility testing (DST) 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. People with MDR-TB, those living with HIV, and children are mainly at risk.

While the expansion of treatment of MDR-TB cases is a major achievement, the cost of providing services is approaching 40% of the total RNTCP expenditure. This threatens the future of TB control in India and underscores the necessity of preventing drug resistance. The current treatment regimen of thrice-weekly doses, when given to those with prior resistance to any drug,

has been associated with failure and amplification to rifampicin resistance. 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.

The enormous diversity between states and even districts in terms of population, terrain, level of development, health systems and epidemiological variety pose problems for a uniform centralized approach to TB control. TB patients, civil society leaders and community-based organisations need to be meaningfully and intensively engaged in TB response at all levels.

National policy recognizes the diversity in India and articulates very well the need for special efforts to reach and address TB in special groups. 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.

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. Collaboration of the TB programme with maternal and child health care within the National Health Mission offers new avenues for identifying patients, particularly children and families who can benefit from preventive and curative TB care.

The Government is now facilitating enterprise and innovation. This complements the work undertaken in the last few years to intensify innovative approaches to quality treatment for TB in the private sector, and minimize the cost to patients. 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 linkages and e-transfers that use the Universal Identification number (UID).

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

India is a worldwide leader across the continuum of health research, and specifically for TB. Its basic scientific capacity and its special institutes for Research in Tuberculosis and Indian Council of Medical Research (ICMR) 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.

All these new developments build the 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. Controlling TB will yield enormous health and economic benefits for the nation. India has the chance to be a leader towards the End TB Strategy and TB control success in India is critical towards achievement of the global 2020 milestones. The existing NSP has bold targets of 90% diagnosis and treatment and provides a roadmap, but funding is insufficient.

- The JMM recommends that Gol significantly increase 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 INR 15 000 million (1500 crores) per year to achieve the goals of the Plan. An additional Investment of at least INR 7500 million (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 250 000 lives annually. In addition, every rupee invested in TB control will have a one-hundred-fold economic return on investment.

The Ministry of Health and Family Welfare (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 Gol 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 levels need to be further integrated within the general health system for greater efficiency.

- The JMM recommends that all patients receive care according to the STCI 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 Gol for developing the STCI and for the RNTCP's efforts to support implementation. Accelerated implementation will require both public and private sector engagement. Specifically, the Mission urges the MoHFW to:

- o accelerate implementation of the transition to daily dosing using fixed-dosed combinations, with a clear timeline addressing the necessary planning and procurements
- o quickly improve access to rapid molecular diagnostics for patients
- o rapidly improve, expand and systematically link economic, social and nutritional support to all TB patients and affected families, working with all partners currently providing social benefits
- o systematically build capacity to engage communities in planning, service implementation and evaluation.
- o build on the example of MDR-TB treatment access expansion to accelerate the response to childhood TB and TB/HIV
- o design, fund and implement targeted interventions for special groups as described in the NSP, based on systematic mapping

- o 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
 - o 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.
- Recognizing that patients often choose private providers, the JMM recommends that the MoHFW urgently ensure that patients in the private sector receive early TB detection, appropriate treatment and sustained support for adherence, and that their out-of-pocket (OOP) expenses are minimized.

This can be achieved by:

- o 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
 - o eliminating taxation on TB diagnostics and drugs as a response to this ongoing public health emergency
 - o scaling-up systems to provide free diagnostic tests and drugs to patients, based on the lessons of successful experiences. Minimize patient OOP expenses by supporting costs for TB testing and free drugs
 - o extending and scaling-up successful models of adherence support and monitoring to all TB patients managed by private providers
 - o measuring the quality of services provided by private providers, and engaging with them to improve the quality of care they provide to TB patients
 - o extending public health services to privately notified TB patients, including free drug susceptibility testing, contact investigation, co-morbidity screening and care.
- 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 its core commitment. The consortium should include the ICMR, National TB institutions, Department of Science and Technology, Department of Biotechnology, Council of Scientific and Industrial Research, other academic/research institutions and the private sector.
- o The consortium should ensure a better understanding of the size and trend of the TB burden.
 - o 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.
 - o 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.
- The JMM recommends a high level, sustained national campaign on TB called “TB-free India/TB-mukt Bharat” with active leadership of national, state and local self-governments in coordination with the corporate/private sectors, NGOs, media and others.

The JMM recognises the enormous need for better awareness, intersectoral engagement and community ownership in the TB response, which could be built on the ongoing “Swatch Bharat, Swast Bharat” campaign.

1

Health system and tuberculosis in India on the eve of the JMM

1.1 Health sector status and priorities

India has a population of over 1.2 billion people, of which three quarters live in rural areas. Nearly 400 million people in India live on less than USD 1.25 (PPP) per day, and 44% of all children are malnourished. Infant and maternal mortality rates are still unacceptably high despite earnest efforts by the government. Strong economic growth in the last few decades has fuelled migration from rural to urban areas. Health care is one of India's largest service sectors. The health-care system is primarily administered by the states in India. The health-care infrastructure in rural areas has been developed as a three-tier system: sub-centres for every 3000–5000 population, primary health centres (PHCs) for every 20–30 000 population and community health centres (CHCs) for every 80–120 000 population. Apart from this, there are tertiary referral hospitals, medical colleges, etc. offering health care to the population. The health-care providers in India can be broadly classified into public and non-public sectors. The public health sector includes health facilities under the Central Government and the state governments, and health facilities under other ministries, e.g. Railways, Labour, etc. The non-public sector includes the private sector, nongovernmental organizations (NGOs) and the corporate sector.

The challenges that India's health-care system faces in providing care to its citizens are substantial. There is a rise in infectious diseases as well as in noncommunicable diseases (NCDs), giving India's health-care system a double burden to combat. At the same time, India's public spending on health is extremely low. In 2009, it amounted to just 1.1% of GDP. If public funds, private funds including patients' OOP expenditures and external flows are combined, the total health expenditure amounts to 4.1% of GDP. With a capacity crunch in the public health-care system, patients have become dependent on private health-care providers who currently treat 78% of outpatients and 60% of inpatients. Further, high OOP expenditures for health care result due to an underdeveloped health-care insurance system, which can be prohibitive for access to care or drive people into poverty.

In 2005, the Government launched the National Rural Health Mission (NRHM), a health programme, in mission mode, to improve the health system and the health status of the people, especially for those who live in the rural areas, and provide universal access to equitable, affordable and quality health care. Despite the supposed proximity of the urban poor to urban health facilities, their access to such facilities is severely restricted. In order to address the health concerns of the urban poor population, the Ministry launched the National Urban Health Mission (NUHM) in 2012. The NUHM and NRHM have been clubbed together under the National Health Mission (NHM) from 2013. The concept of the NHM is that it should be a community owned, decentralized health delivery system with simultaneous intersectoral action on a wide range of determinants of health such as water, sanitation, education, nutrition, social and gender equality. It is intended as a platform that will enable Universal Health Coverage (UHC). The Revised National Tuberculosis Control Programme (RNTCP), one of the National Disease Control Programmes (NCDPs), has been subsumed in the NHM under the Twelfth Five-year Plan. Given the differences of the health systems in rural and urban areas, the TB programme will have to use

different approaches in the coming years to achieve health system strengthening in these two areas. Broadly speaking, in rural areas it needs to continue to strengthen engagement through the NRHM. In urban areas the need is to continue its current efforts to integrate with general health services and augment these efforts by partnering with the urban private sector.

1.2 Asituation summary of TB control

India's achievements in tuberculosis (TB) control over the past decade are remarkable by any standards. More than 80 million people have been tested, more than 17 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.¹ With this, India has met the 2015 Millennium Development Goal (MDG) Target for TB. Prevalence, currently estimated at 211/100 000 and mortality, estimated at 19/100 000, are both less than half the numbers 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 as twice as high.²

Case notification for incident TB cases is only 58%. Over one third of cases are not diagnosed, or diagnosed but not treated, or diagnosed and treated but not notified to the RNTCP. Again, this could be even higher – WHO estimates that 1 million Indians with TB are not notified.¹ Case notifications have been declining gradually 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 TB among them is currently under-diagnosed in India.

Multidrug-resistant TB (MDR-TB) is emerging as a massive organizational and financial challenge to the RNTCP. Nevertheless, India achieved complete geographical coverage for diagnostic and treatment services for MDR-TB in 2013. In 2014, 255 000 cases of TB were tested for drug resistance and 25 748 were found to have MDR or rifampicin resistant TB, of whom 24 073 (93%) received treatment in that year. 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. National Tuberculosis Institute (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; 90% of these received antiretroviral treatment (ART) and 95% received co-trimoxazole preventive treatment (CPT).

The Government of India (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 (STCI), 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 control, TB harega, desh jeetega campaign, with commendable investments by the Ministry and corporations to broadcast these messages.

¹World Health Organization. Global Tuberculosis Report – 2014. Geneva: WHO;2014.

²Murray CJL, Ortblad KF, Guinovart C, Lim SS, Wolock TM, et al. Global, regional and national incidence and mortality for HIV, tuberculosis, and malaria during 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2014; 384:1005–70 ([http://www.thelancet.com/journals/lancet/issue/vol384no9947/PIIS0140-6736\(14\)X6102-7](http://www.thelancet.com/journals/lancet/issue/vol384no9947/PIIS0140-6736(14)X6102-7), accessed 21 September 2015).

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 USD 340 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 INR 16240 million (1624 crores) received. The health and economic benefits of the RNTCP have been enormous, with an estimated USD 350 billion in economic gain over the period 2006–2015 relative to the absence of RNTCP services.

1.3 Objectives of the JMM

1.3.1 General objective

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

1.3.2 Specific objectives

- To review India's progress in implementation of the NSP 2012–2017 and follow up on recommendations of JMM 2012
- 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
- To review the TB situation in India with detailed epidemiological analysis, including review of the programme monitoring and evaluation (M&E) system, look at the strategies to rapidly reduce the burden as planned in the TB Mission 2020 and provide recommendations for implementation
- To review opportunities for collaboration in research and development in TB for the global goal of TB elimination as per the End TB strategy, and to review medium- and long-term technical assistance and coordination needs for TB control in India.

1.3.3 Thematic areas

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

- Epidemiological analysis of TB: the magnitude of the epidemic with trends, including drug-resistant TB (DR-TB) and TB/HIV, the notification system, TB surveillance, and M&E;
- Health system issues, including health-care system strengthening and integration of TB services:
 - o Governance, human resources, financing
 - o Social protection, patient support and UHC
 - o Procurement and logistics
 - o Community engagement; advocacy, communication and social mobilization
 - o Research.

- TB service delivery issues
 - o Early diagnosis and case finding for all types of TB, including laboratory services
 - o Treatment of TB
 - o DR-TB
 - o Engagement of all care providers
 - o Interactions of TB with HIV and other co-morbidities
 - o Childhood TB
 - o Targeted interventions for special groups.

1.3.4 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 (WHO) with financial support from the Global Fund against AIDS, TB and Malaria. It started its work on 10 April 2015 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 K.S. Sachdeva. Dr A. Sreenivas from WHO presented the End-TB Strategy approved by the World Health Assembly in May 2014 and summarized 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.

Fig. 1. Map of India showing the states and districts visited

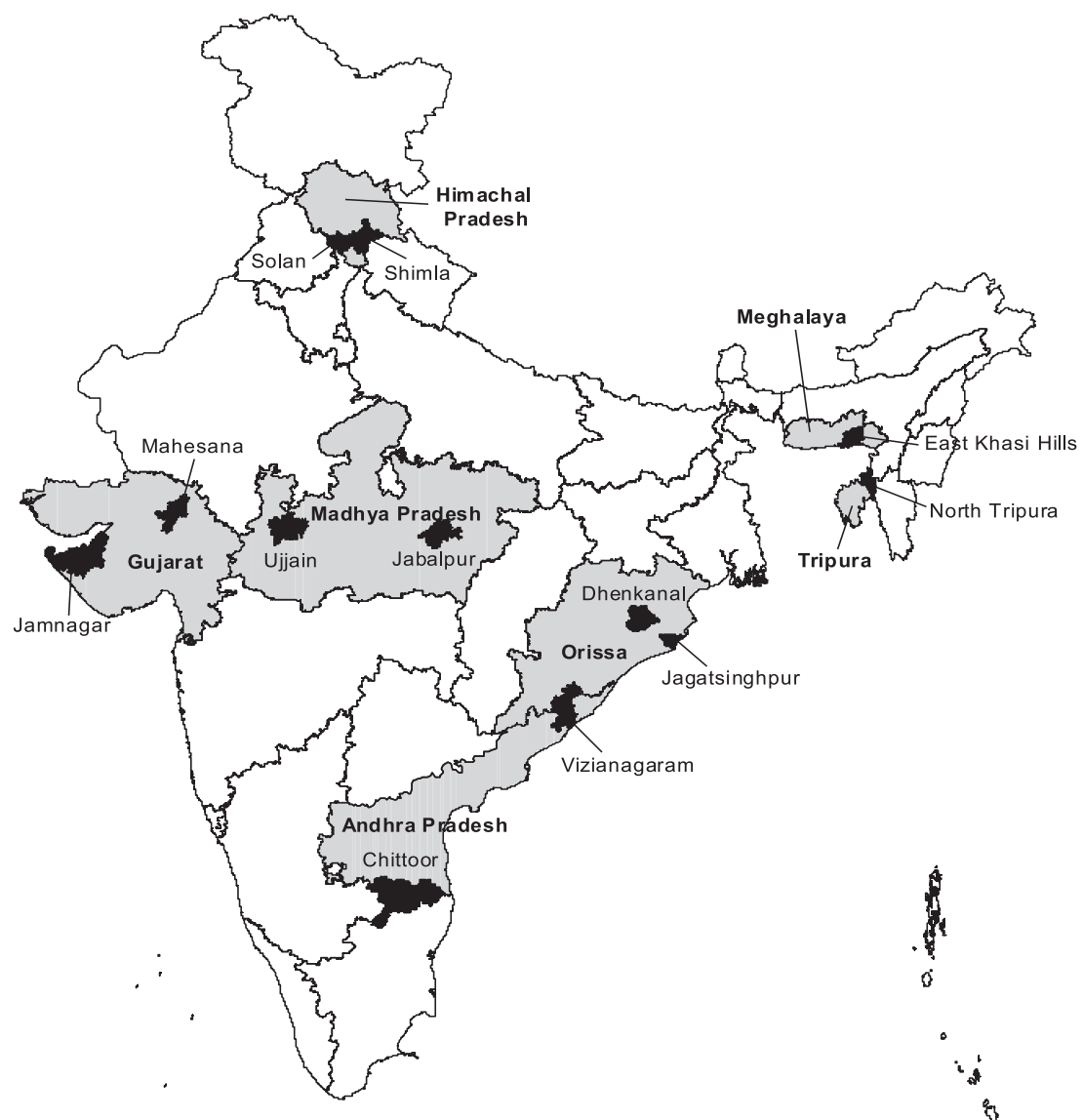


Fig. 1 shows the states and districts visited. States and districts were deliberately selected on the basis of their potential to inform deliberations on specific thematic areas and represent programme conditions nationwide, as well as the feasibility and safety of travel to these locations. Each state team (apart from the teams 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 health-care centres, including laboratories, private hospitals and practitioners. Patients, community members, directly observed treatment, short-course (DOTS) providers, accredited social health activists (ASHAs) and state and district TB staff were interviewed. Each state team prepared a report based on observations made during field visits. These reports (reproduced in Chapter 4) describe in brief the achievements, challenges and possible solutions, and assess the degree to which the JMM 2012 recommendations had been implemented as well as the level of implementation of the NSP. At the conclusion of the field visits, the state teams conducted a debriefing meeting with the state officials, discussed the findings of the local review and offered potential recommendations and solutions.

The teams also discussed the findings of the field visits at a general debriefing meeting in New Delhi on 17 April 2015. Subsequently, the state team leaders drafted brief written reports for transmission back to the states. On 18–19 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 19 and 20 April to draft the Executive Summary (which also served as the debriefing note) and revised it by multiple iterative e-mail exchanges. The thematic group leaders also later prepared a report for each thematic area.

Paul Nunn presented the summary findings and recommendations³ to the full JMM team on 22 April, 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 22 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, and subsequently edited by the WHO Country Office TB team.

1.3.5 Participants

The JMM brought together 96 national and 41 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, TB programme managers, 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, nongovernmental and community-based organizations, and technical and development agencies. For a complete list of individuals and their affiliations, see Annex 1.

³Available at www.tbcindia.gov.in

2

Observations of the JMM on the interaction of the health system and tuberculosis control

2.1 General observations with respect to the first term of reference

The JMM 2015 has observed that the implementation of the NSP 2012–2017 had started well but was generally not on track. While some activities have achieved their targets, or even exceeded them, key performance indicators such as the projected increases in case detection by the RNTCP have not been achieved (Table 1). In particular, procurements of commodities and equipment have been delayed; for example, procurement of light-emitting diode (LED) microscopes and cartridge-based nucleic acid amplification test (CBNAAT) machines. The consequence has been a poor performance in the delivery of services to key affected populations, e.g. the percentage of chest symptomatics among people living with HIV/AIDS (PLHIV) receiving a molecular diagnostic test (CBNAAT) was 2% in 2014 as against the 50% target in the NSP.

Table 1. Selected targets from the NSP 2012–2017 set against actual performance

Metric (selected)	14-15 target	Actual
Chest symptomatics examined per 100,000 population	172/quarter	172
Number of TB patients put on treatment	1650000	1420000
Proportion of districts with TUs aligned at block level	50%	25%
DST for all previously treated cases at start of treatment	60%	80%
Number of M/XDR TB patients (thousands) started on treatment	30/0.5	26/1
% of DMC with LED Microscopy	10%	<1%
% of PLHIV chest symptomatics tested by molecular test	50%	2%
States with PPIA contracted	6	2 (cities)

Sources: NSP 2012–2017 and TB India 2014, Annual Status Report

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

The JMM observed delays in areas apart from procurement. For example, a number of important policy approaches recommended by JMM 2012 were formulated in “Technical and Operational Guidelines”, e.g. 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, e.g. 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.

2.2 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.

2.2.1 TB burden

Ten discrete sub-national surveys, including nine at district and one at state level conducted during 2006–2012 wherein about 760 000 individuals were investigated, gave a pooled prevalence of 3.2 million TB cases in India. Mathematical models estimate about 2 million new TB cases each year. Annual TB-related deaths in the country were estimated to be between 270 000 and 550 000 (depending on the estimation process). The majority of these deaths occur in people who are active in the workforce, with men at twice the risk of dying compared to women. TB is also one of the top killers of women – rivalling maternal causes – and more women die from TB in India than in any other country. Additional deaths in PLHIV who die of TB are counted as HIV deaths. There are an estimated 120 000 incident cases of HIV-associated TB, and 100 000 incident MDR-TB 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.

Several 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 programme have multidrug resistance. A national level survey to find out the proportion of cases having MDR-TB is in progress.

2.2.2 Achievements

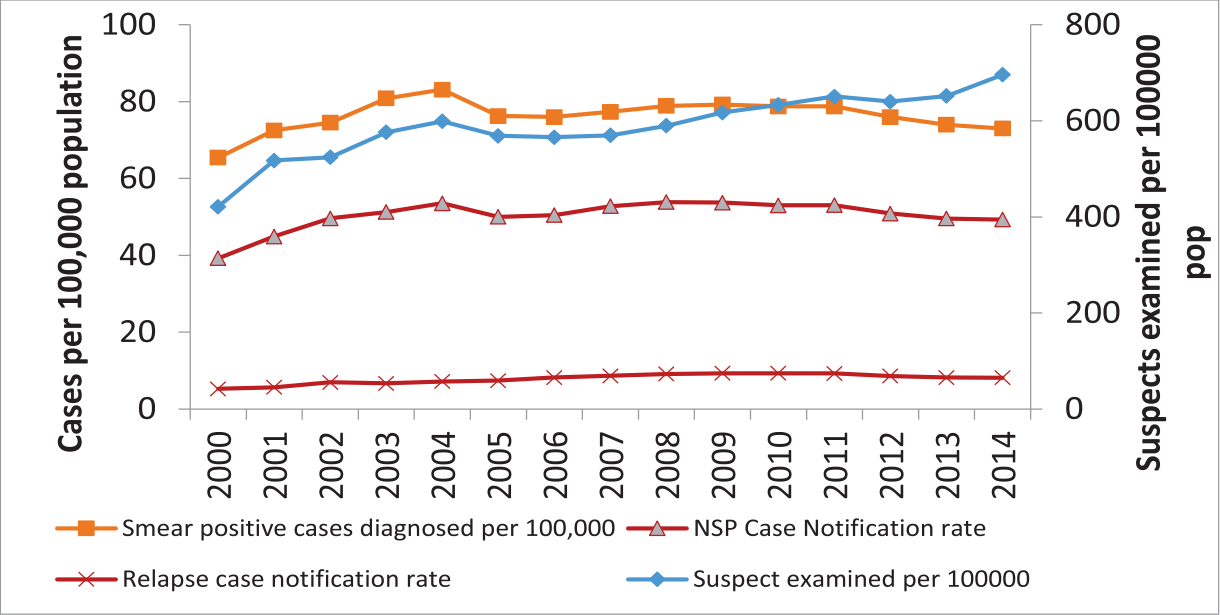
Routine surveillance under RNTCP

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 programme delivery as well as individual TB case management. Both the sub-district system, which aggregates data, and the case-based system currently operate in parallel.

The routinely collected data has provided useful information on the trends 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 (Fig. 2); 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 gradually since 2009.

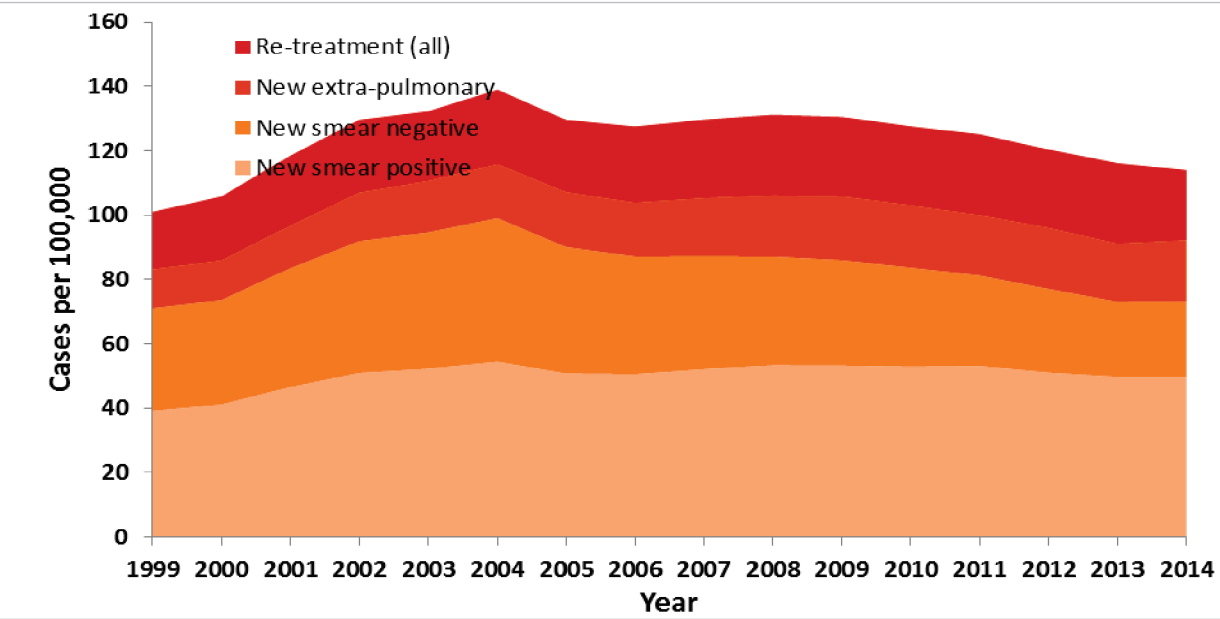
Fig. 2. Notification rates of new smear-positive and smear-negative cases and relapse cases, and rate of suspect smear examinations, India 2000 to 2014



Source: Central TB Division, Directorate General Health Services, Ministry of Health and Family Welfare, Gol, TB India 2015, RNTCP Annual Status Report (<http://tbcindia.gov.in/showfile.php?lid=3166>)

Notification rates of all TB cases (all types) have shown a declining trend from 130 in 2004 to 110 per 100 000 in 2014 (Fig. 3). During this period, notification rates of new TB cases (all types) declined from 116 per 100 000 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 (Fig. 2). About 1.4 million TB cases were registered for treatment under the Programme in 2014. Re-treatment cases constitute 18–20% of all registered cases while 20% of the cases have extra-pulmonary TB.

Fig. 3: Notification rates of new smear-positive and negative cases, extra-pulmonary cases and relapse cases, India 1999 to 2014

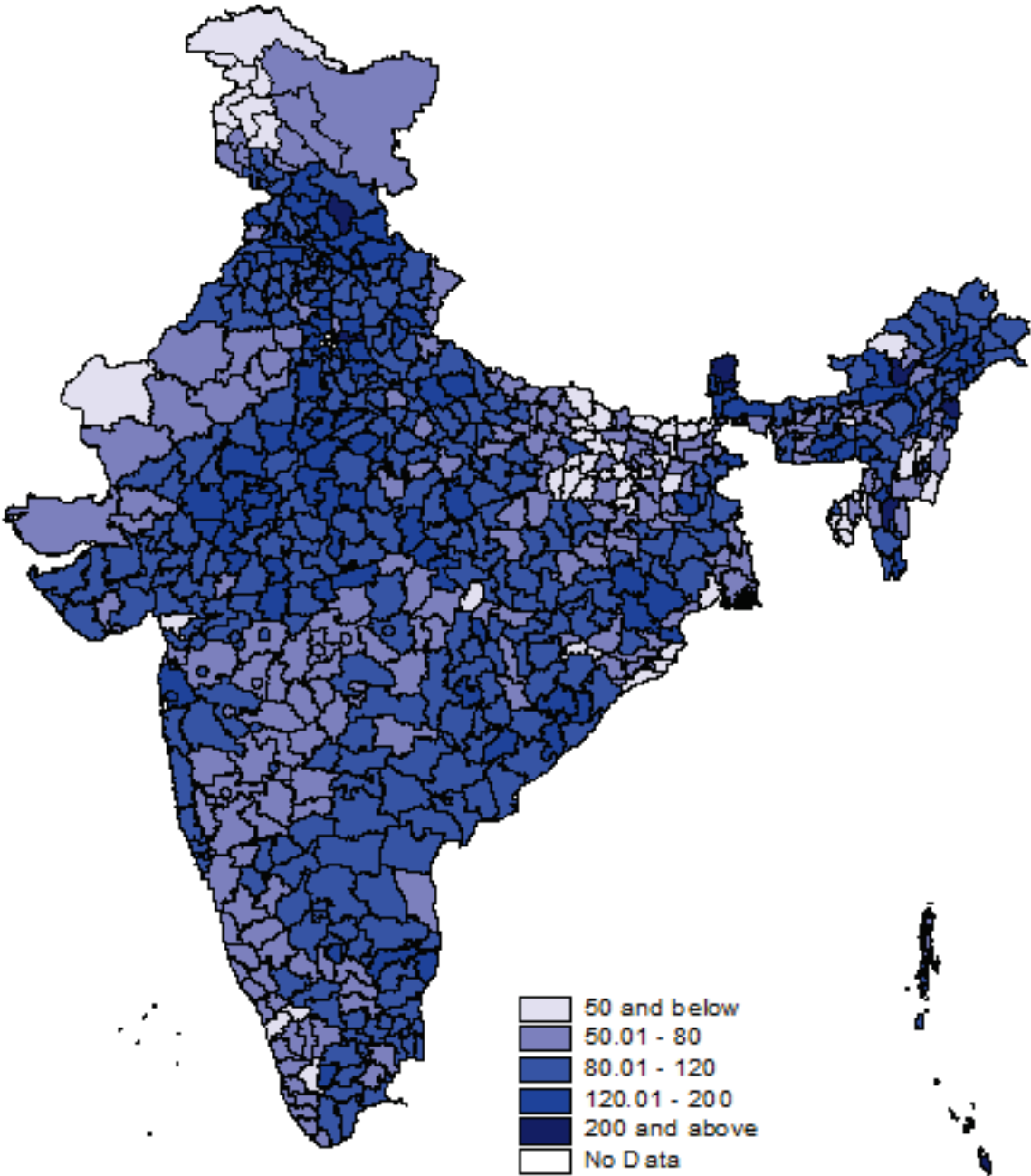


Source: Central TB Division, Directorate General Health Services, Ministry of Health and Family Welfare, Gol, TB India 2015, RNTCP Annual Status Report (<http://tbcindia.gov.in/showfile.php?lid=3166>)

The age- and sex-wise analysis reveals that 74% of the new sputum smear-positive cases among men and 78% among women are concentrated in the most productive age group of 15–54 years, with socioeconomic 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 diversities in disease burden and/or efficiency of case finding between different districts of India (Fig. 4). Notification rates are generally lower in the west and south and higher in the north and northeast, but with large variations within the regions of the country as well.

Fig. 4. Map of notification rates (per 100 000) by district, India 2014



Source: Central TB Division, Directorate General Health Services, Ministry of Health and Family Welfare, GoI, TB India 2015, RNTCP Annual Status Report (<http://tbcindia.gov.in/showfile.php?lid=3166>)

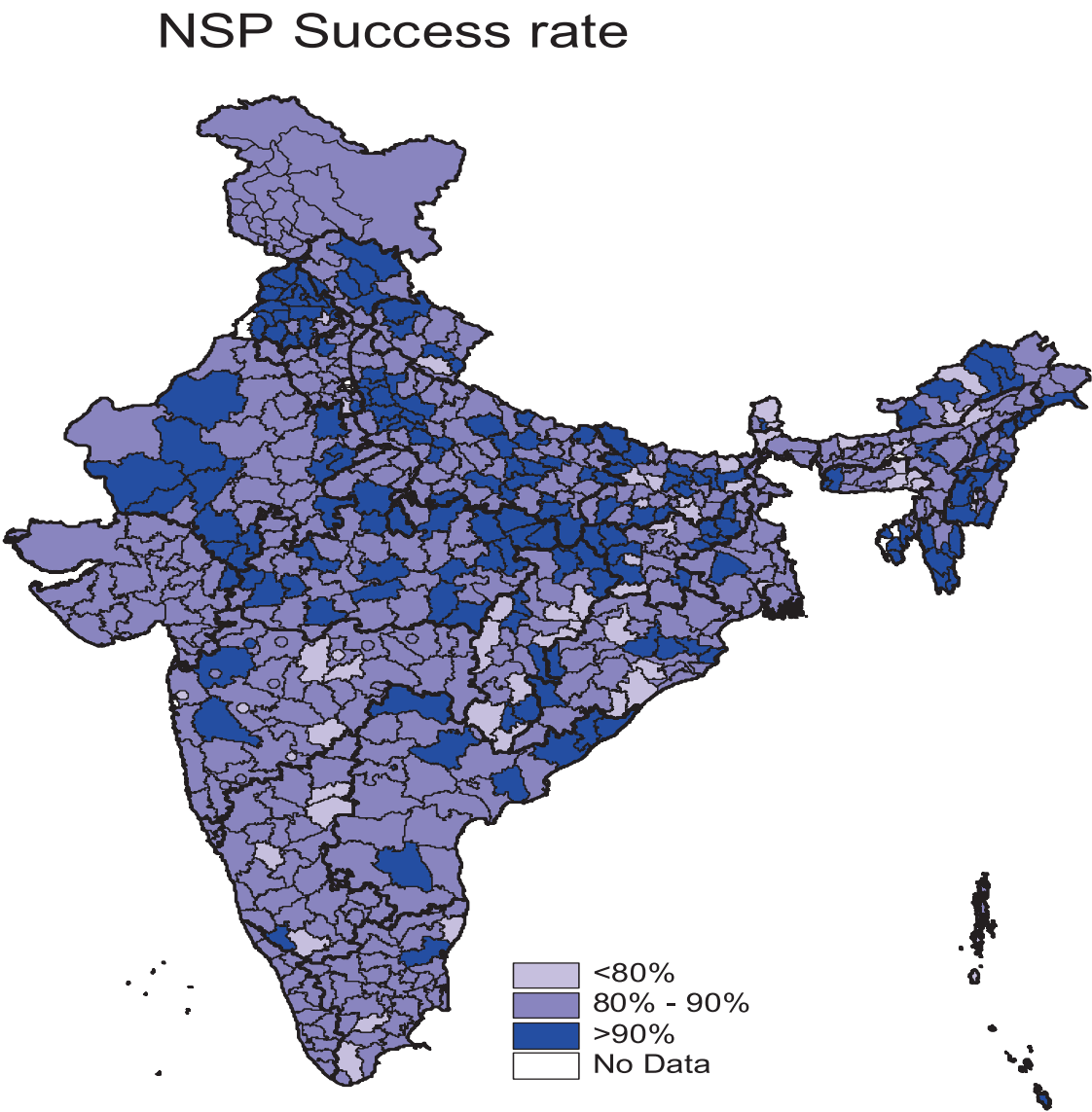
Mandatory notification of cases

The Gol declared TB as a notifiable disease through a Gazette notification dated 07 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 that enables cases to be notified through e-mail, mobile applications or paper-based records. The number of health facilities that have registered for notification has been growing steadily, as has the number of cases notified by the private sector.

Treatment success

Among all cases registered under the RNTCP, treatment success rates are consistently about 85% in new cases (Fig. 5) and 75% among retreatment cases.

Fig. 5. Map showing treatment success rates among new sputum smear-positive cases of pulmonary TB registered in 2013, by district



Source: Central TB Division, Directorate General Health Services, Ministry of Health and Family Welfare, Gol, TB India 2015, RNTCP Annual Status Report (<http://tbcindia.gov.in/showfile.php?lid=3166>)

Evaluation

A well-established and structured mechanism for state- and national-level internal evaluations is operational. In addition, regular external evaluations, including joint monitoring missions and green light committee reviews are conducted regularly. As part of the supervision and monitoring strategy of the programme, internal evaluations are conducted both by the state and the Central TB Division. Internal evaluation acts as a tool to evaluate if good programme practices are adopted and quality services are provided to the community. Data validation is an important component of the internal evaluation. The evaluations also offer an opportunity for programme managers to look into all aspects of the programme critically and swiftly. Central TB division selects one state per month for evaluation based on the performance so that all big states are visited once in every 2 years. In the selected state at least two districts are evaluated. Central Internal Evaluation (CIE) provides an opportunity to review performance in select districts and to review overall performance of the state. It facilitates the Centre to understand, address and support actions for improving the quality of RNTCP implementation in the state. The CIE team consists of representatives from CTD, NACO, WHO, state tuberculosis officers (STOs) from other states, civil society, partners, etc. In a similar fashion, the states conduct evaluations of at least two districts per quarter.

In 2014, a total of nine states were evaluated by the CTD and state-level internal evaluations were also conducted in 28 states. The programme was also reviewed in terms of state coordination committee meetings for TB–HIV and review of programmatic management of drug-resistant TB (PMDT), both at the state and regional level.

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 district in Tamil Nadu, 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 district of Maharashtra, two surveys carried out in 1986 and 2008 showed a decline of 61% in the prevalence of TB. In rural Bangalore in Karnataka, 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 2000–2003 and 2009–2010, respectively as well as during repeat tuberculin surveys in selected districts.

According to the Global Burden of Disease study,² 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 a sign of decreasing incidence.

2.2.3 Constraints

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. Some estimates suggest this could be as many as 1 million patients per year.

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. Accountability is low. There is a lack of monitoring on the follow-up actions recommended in the internal evaluation reports.

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. Besides, non-participation in notification has no adverse consequences for providers.

Poor treatment success

Although treatment success rates among new cases are satisfactory at the national level, many districts report poorer success rates (Fig. 5). The lost to follow up and death rates among re-treatment cases are unacceptably high. For the cohort of re-treatment cases registered under the programme 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.

Estimating disease burden and diverse TB epidemiology

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 private providers may be treating a large proportion of TB cases.⁴ While it is unknown how many of these cases were diagnosed incorrectly, there are concerns that the true incidence is higher than has been estimated previously.

TB mortality

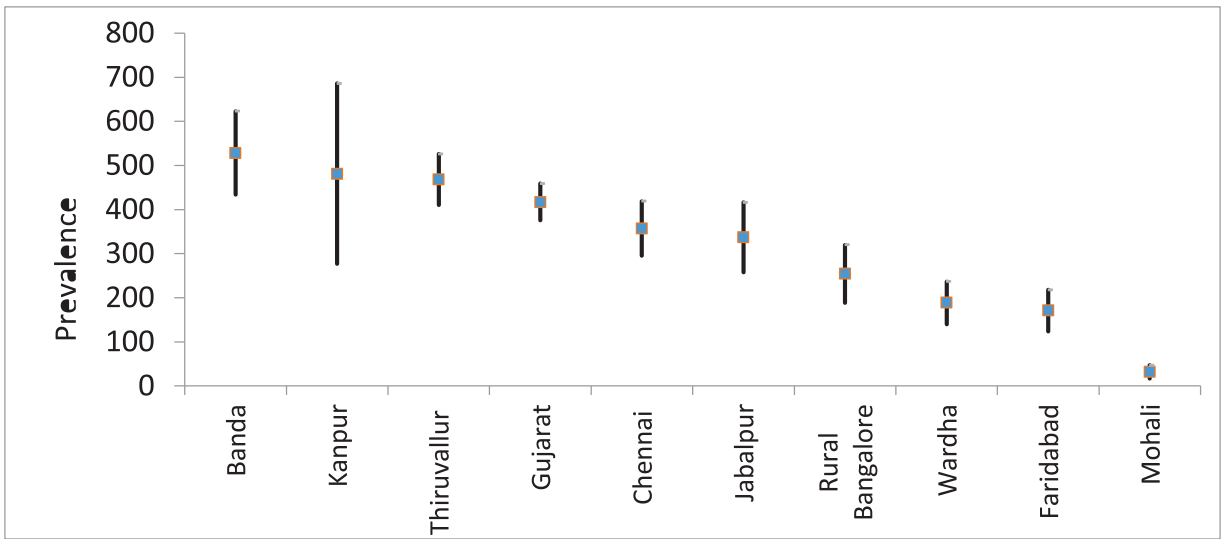
There is no complete reporting of the causes of death in India. Estimates have to rely on a subset of mostly urban vital registration deaths that have been medically certified, and on verbal autopsy data from the Sample Registration System supplemented by isolated verbal autopsy studies. Less than 20% 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 have shown that they capture not more than 40–60% of true TB deaths. As the specificity ranges 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 tend to cancel each other out.

Prevalence

Sub-national prevalence surveys have revealed wide heterogeneity in the prevalence of TB across different districts (Fig. 6). Another consistent and notable finding is the higher prevalence in rural areas as compared to urban areas (Fig. 7), and higher prevalence in men than in women. A limited number of surveys in tribal areas also observed a higher prevalence. Of course, a single national-level estimate could not accurately describe the burden of TB across the country, and state-level surveys in all the states of India would be resource intensive. However, state-level surveys, specifically in the most populous and economically weaker states, would provide a valuable contribution to the evidence base for assessing the TB burden.

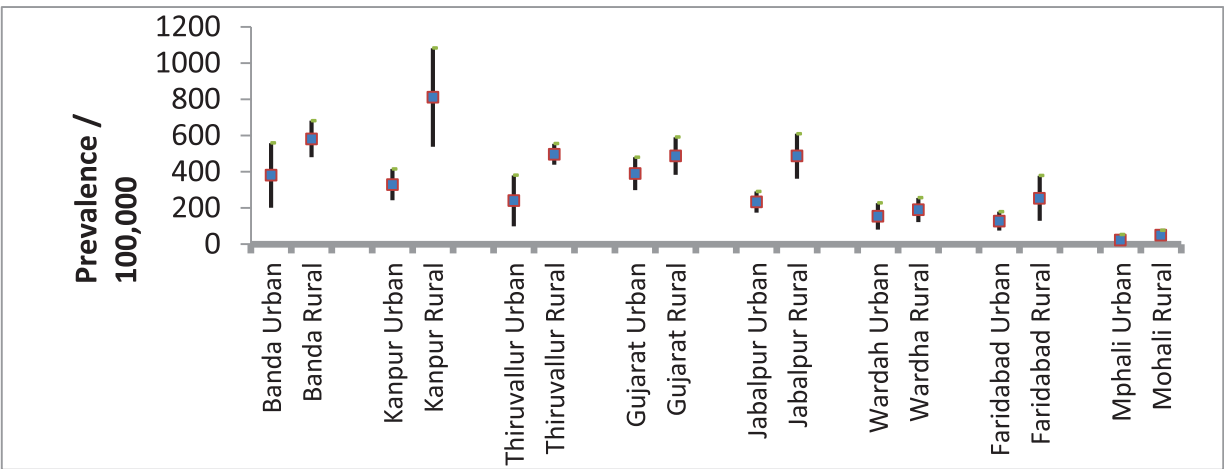
⁴Wells WA, Ge CF, Patel N, Oh T, Gardiner E, et al. Size and Usage Patterns of Private TB Drug Markets in the High Burden Countries. PLoS ONE 6(5). 2011; e18964. doi:10.1371/journal.pone.0018964.

Fig. 6. Prevalence per 100 000 population of bacteriologically positive pulmonary TB across different survey sites in India during 2008–2011



Source: Analysis of Tuberculosis Prevalence Surveys in India (2008–2011), National Tuberculosis Institute, Bangalore

Fig. 7. Prevalence of bacteriologically positive pulmonary TB by sex across different survey sites in India during 2008–2011



Source: Analysis of Tuberculosis Prevalence Surveys in India (2008–2011), National Tuberculosis Institute, Bangalore

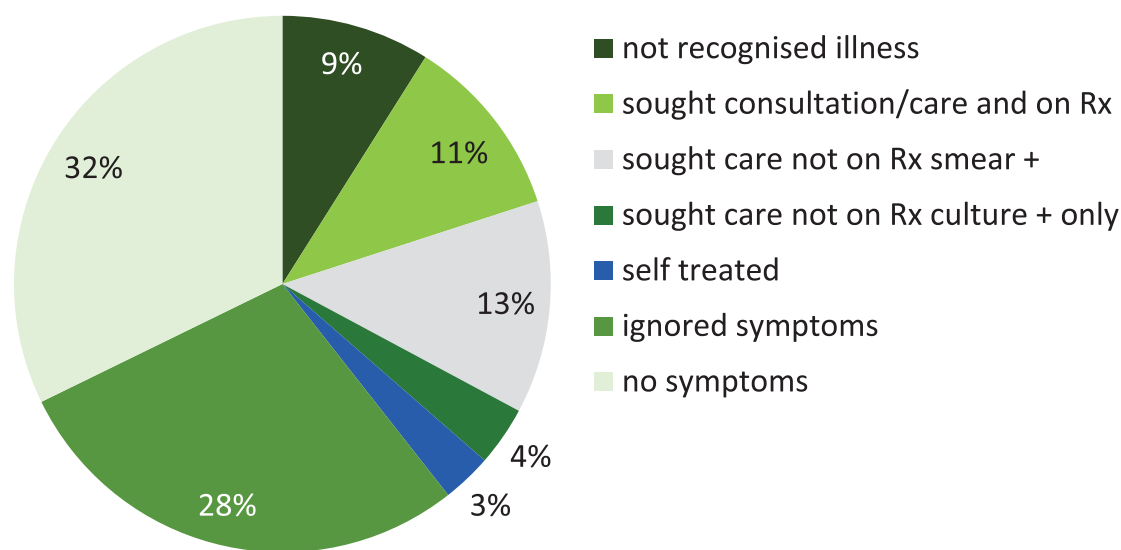
In the only statewide prevalence survey in Gujarat, only 17% of bacteriologically positive cases were currently receiving TB treatment, but 31% had received treatment in the past, mostly within a few years of the time of survey. A third of the cases admitted to less symptoms than those used to define a symptomatic case, i.e. any of the following: cough of 2 weeks or more; chest pain of 1 month or longer; haemoptysis during the preceding 6 months; and fever of 1 month or more. Of the symptomatics, 40% had ignored the symptoms or not recognized these as an illness (Fig. 8). These findings raise a number of concerns:

Given the large proportion of bacteriologically positive prevalent cases with a history of recent treatment, the majority of whom reported getting treatment from the public sector, the cure and success rates reported by the RNTCP may be overstated. One possible explanation is that the treatment outcome is largely based on sputum smear microscopy at the end of treatment, which has poor sensitivity, compared to culture.

Large numbers of people are infectious and are transmitting disease in the community and thus maintain a steady stream of new cases, as observed from the constant rates of new smear positive pulmonary TB cases seen in the notification data.

The majority of prevalent bacteriologically positive people in the community either had fewer symptoms than those used to define a case or did not recognize their symptoms as indicative of a serious illness requiring treatment. This suggests that the criteria used to define a case may be insensitive or that 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. There may even be many cases that never start treatment.

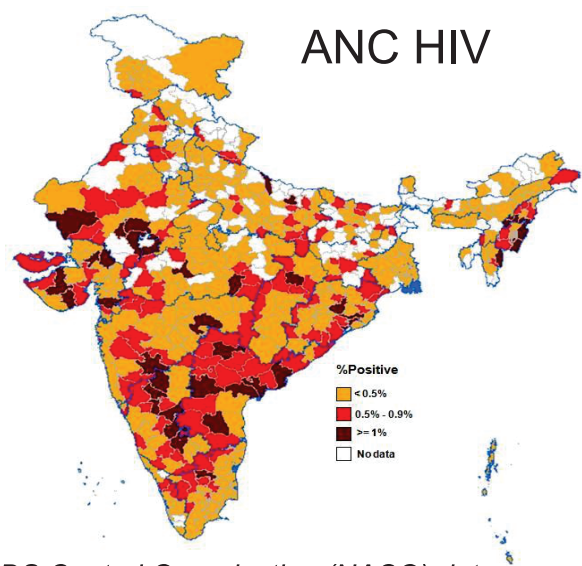
Fig. 8. Bacteriologically positive cases by treatment seeking behaviour, Gujarat 2011 (n=335)



Source: Analysis of Tuberculosis prevalence survey data 2011–12, Gujarat

TB and HIV
There is large variation in the prevalence of HIV seropositivity in the general population according to HIV testing among antenatal patients (Fig. 9).

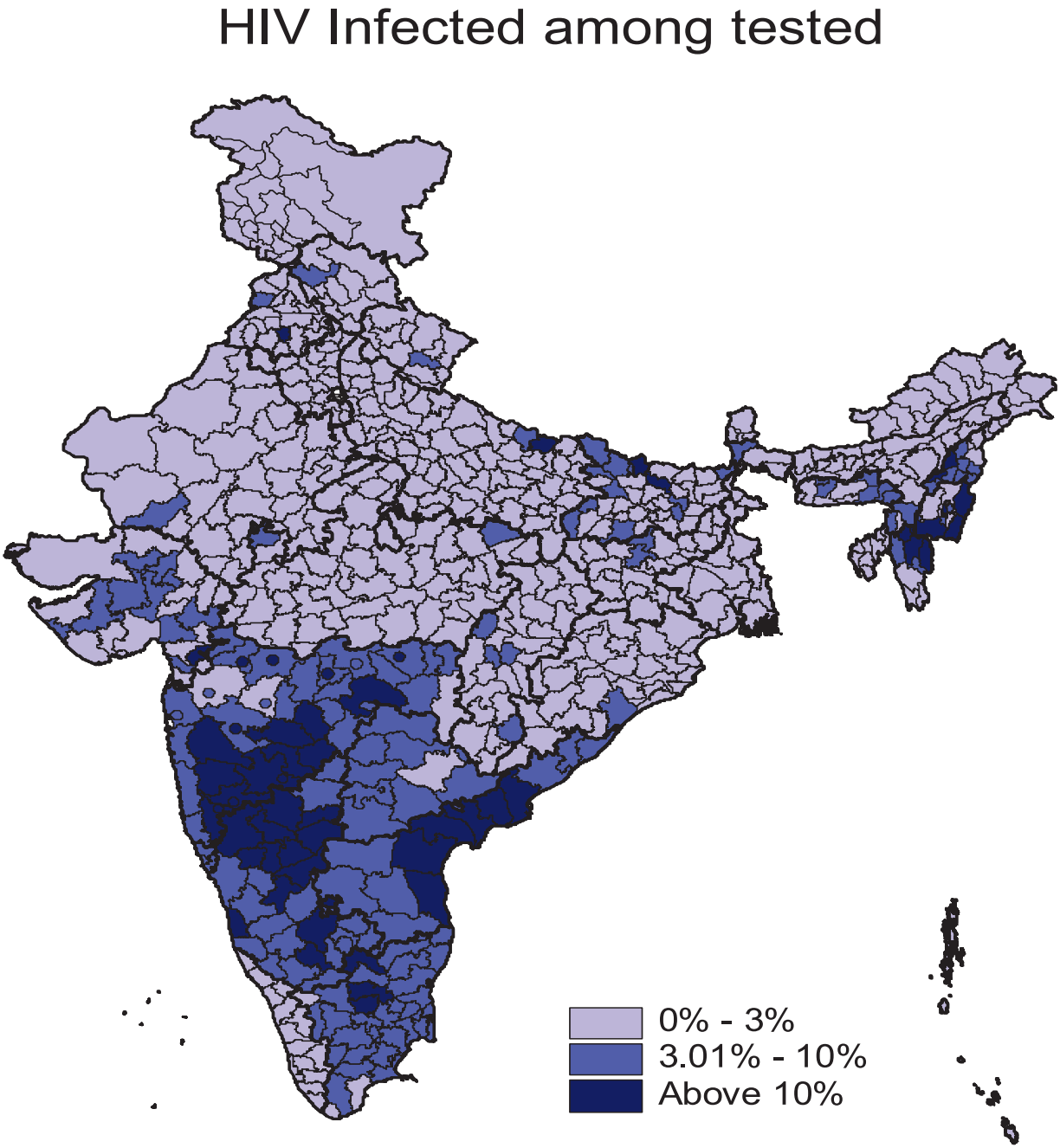
Fig. 9. Map of HIV seropositivity rates among antenatal patients by district in 2010–11



Source: National AIDS Control Organization (NACO) data

The proportion of notified TB patients tested for HIV varies widely in different parts of the country. Among the cases tested in 2014, HIV seropositivity rates varied between 0 and 45% across different districts (Fig. 10). The districts of Bagalkot, Bijapur and 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.

Fig. 10. Map of HIV sero-positivity rates among tested TB patients by district in 2013



Source: Created based on RNTCP data of 2013 from Central TB Division, Directorate General Health Services, Ministry of Health and Family Welfare, GoI, TB India 2014, RNTCP Annual Status Report (<http://tbcindia.gov.in/showfile.php?lid=3142>)

MDR-TB

The WHO Global TB Report 2014 estimated that 62 000 MDR-TB cases emerged in India amongst the notified pulmonary tuberculosis (PTB) cases in 2013. This estimate is based on sub-national drug resistance surveys (DRS) from 3 states (Andhra Pradesh, Gujarat and Maharashtra), from which WHO derived figures of 2.2% of new PTB cases and 15% of previously treated PTB cases in India having MDR-TB. In Gujarat, in 2005–6, the rate of fluoroquinolone (FQ) resistance in MDR-TB cases was 24–31%, suggesting many are at risk of developing XDR-TB, and extensively drug-resistant TB (XDR-TB) was actually found in 4% of the MDR-TB isolates. Across India, a minimum of 2000 XDR-TB cases is thought to occur annually.

Pooled results from previously treated patients gave isoniazid (H) resistance at 60–80%. H resistance is a proxy for poly-resistance⁵ to first-line drugs (FLDs) in previously treated cases.

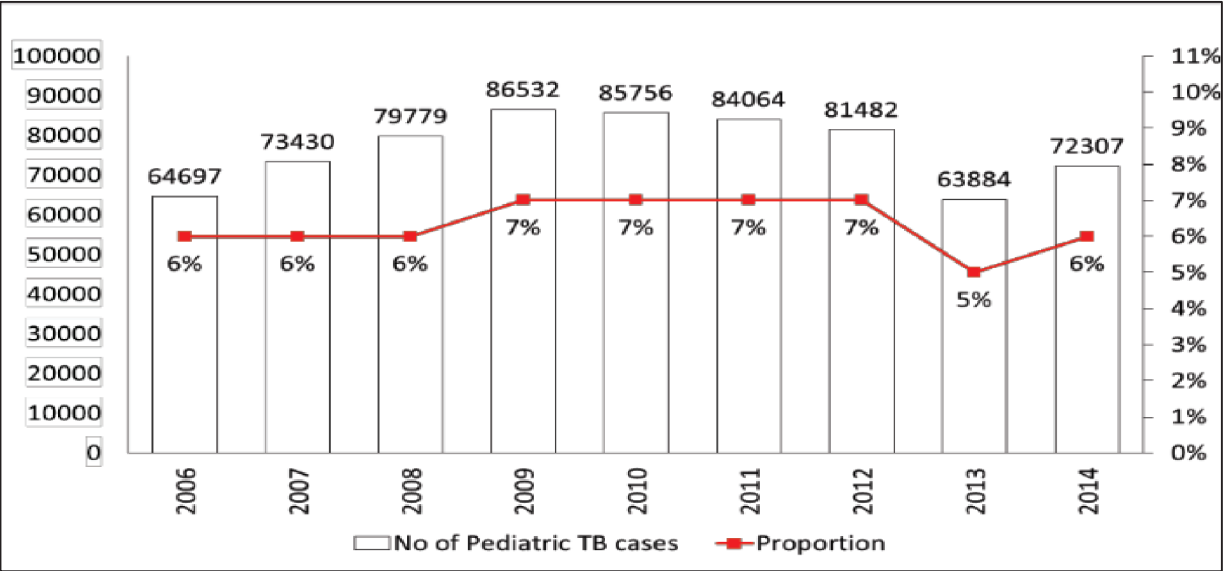
MDR-TB notification rates are very high in some areas, including Sikkim (340 per million), Mumbai (220 per million), Arunachal Pradesh (94 per million) and Delhi (84 per million) compared to the national average of 27 per million population. On the other hand, MDR-TB notification rates are very low in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

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, excluding those children with HIV and TB.⁶ 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%² of the total adult incidence, but only 6% of the total cases reported to the RNTCP are children. This low level of case finding has remained essentially flat for the last 9 years (Fig. 11). The percentage of cases found in the private sector is closer to the expected proportion of child TB cases (Fig. 12). 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 programme.

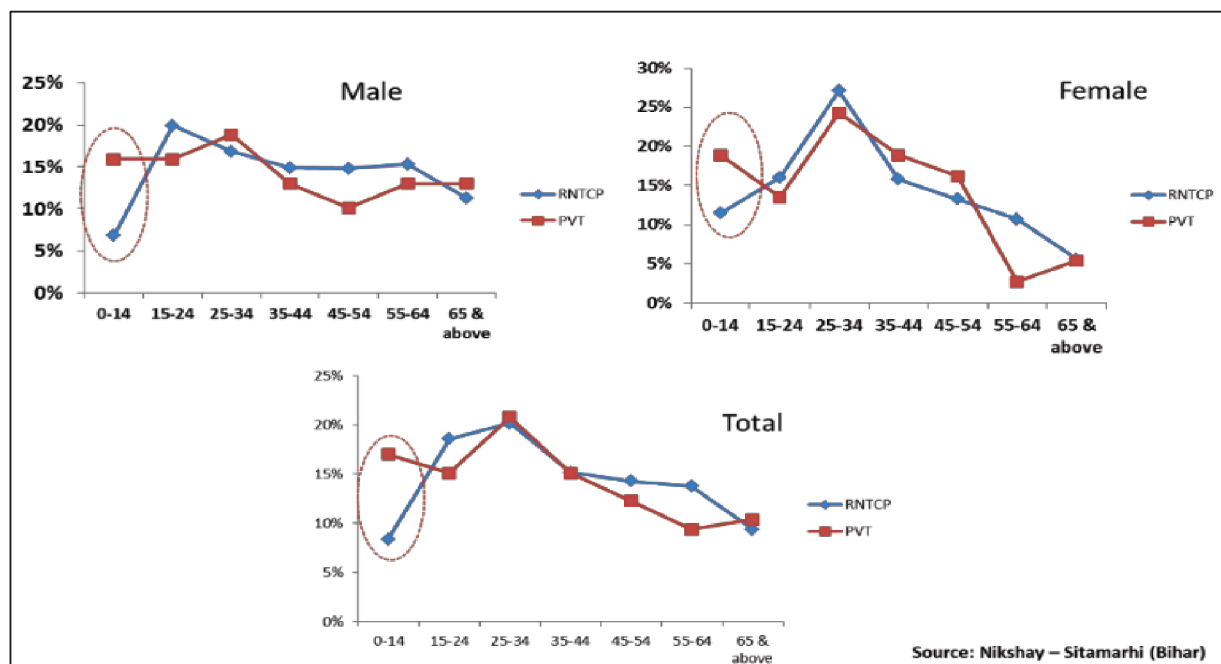
Fig. 11. Number and proportion of childhood cases of TB, 2006–2014



Source: RNTCP data

⁵Defined as resistance to more than one drug, excluding rifampicin (R). H and R resistance is MDR-TB, by definition
⁶WHO. Global Tuberculosis Report. Geneva: World Health Organization; 2014.
²Nelson LJ, Wells CD. Global epidemiology of childhood tuberculosis. Int J Tuberc Lung Dis. 2004;8:636–47.

Fig. 12. Disparity in the number of children notified as cases of TB by the private sector compared to the public sector – September 2014



Source: NIKSHAY

Risk factors for TB

Poverty and other socioeconomic 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. One 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 that has quantified the contribution of tobacco, alcohol and high fasting plasma glucose (essentially the combined risk of diabetes and pre-diabetes) to the TB burden in India. The results were 8.0%, 12.1% and 22.8%, respectively for the year 2013. According to one report,⁷ under nutrition could, however, be responsible for nearly a half of TB incidence in India (Population Attributable Risk Fraction-50%). Similarly, occupational lung disease, indoor and outdoor air pollution may all contribute, but they have been less studied.

2.2.4 Recommendations

Better estimates of disease burden and its trends in different parts of the country are urgently needed. Strengthening of routine surveillance data with a focus on greater inclusion of cases from the private sector, using the newly introduced case-based electronic surveillance system, is highly desirable. Enhancing the coverage of the medical certification of cause of death in the vital registration system, conduct and timely release of verbal autopsy studies, community-based inventory studies and prevalence surveys will be needed for a better understanding of the TB burden. The specific recommendations are discussed in succeeding paragraphs.

Urgently improve routine TB surveillance and monitoring

Historically, the RNTCP 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 NSP articulates a need to transition to notification at diagnosis, from public and private providers alike. Accelerated development of the user-friendly e-NIKSHAY system, which has been inexplicably underfunded and hence underdeveloped, is critical to improving surveillance. 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.

⁷Bhargava A BA, Oxlade O, Pai , Menzies D. Undernutrition and the incidence of tuberculosis in India: National and subnational estimates of the population attributable fraction related to undernutrition. NMJI. 2014;e4–e9(27).

Deployment of strengthened surveillance systems should be accompanied by capacity building in the states for timely performance reviews, identification of hotspots for TB, DR-TB and TB–HIV. Efficient use of the information for patient management will enhance TB control. The JMM also recommends setting a firm timetable and action plan to phase out the paper-based recording and EPICentre-based aggregated reporting.

Deployment of portable digital devices to field staff working with the TB programme will enable real-time data entry and data access, facilitate patient tracking when dropouts and patient transitions inevitably occur, and lead to better programme and patient management. When linked with geographic information for each patient, it will enable identification of transmission hot spots and vulnerable populations, and also enable interventions targeted to disrupt transmission chains and protect the most affected communities.

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 for private patients to access quality diagnosis, counselling, HIV testing, treatment adherence support and needed 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 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 (in 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.

Improve TB burden estimates

Robust estimates of TB incidence, prevalence and mortality trends at the state level are 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 JMM recommends the formation of an India TB Estimation Group, consisting of national and international experts. This group should facilitate development of a comprehensive information system framework for TB. It should also develop modelling techniques for consensus estimates of incidence, prevalence and mortality, nationally and sub-nationally, that take into account the limitations of each data source. This work 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 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 initially for major states. 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 better used. This would help in the estimation of TB deaths nationally and by state, and also help in an improved estimation of incidence and prevalence by modelling the most consistent fit

between data from prevalence surveys, notifications and mortality registrations. Regular coordination between the National TB Programme and Civil Registration needs to be established. In addition, further strategic verbal autopsy studies using modern methods are needed to get a better estimation of mortality due to TB at the state level.

Quantifying risk factors for TB

The JMM recommends that reporting of the proportion of the TB burden that is caused by major risk factors become a routine monitoring activity of the RNTCP.

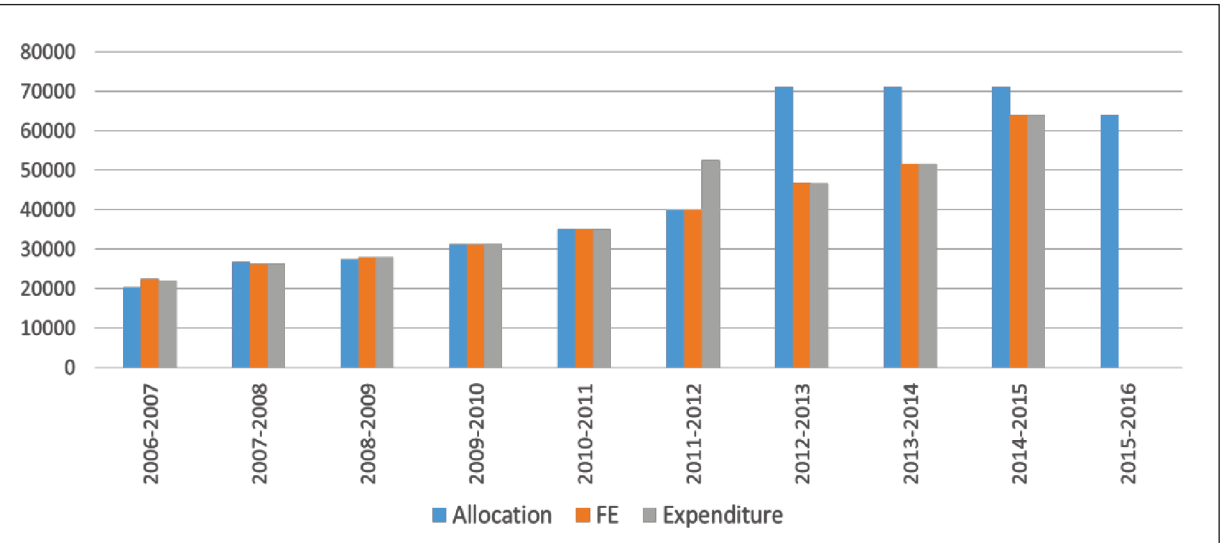
2.3 Financing

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

2.3.1 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 INR 16240 million (1624 crores) received (Fig. 13).

Fig. 13. Funds allocated to the RNTCP, funds actually received as per final estimates (FE) and funds spent by financial year, 2006–7 to 2014–15 (INR in 100 000)



Source: RNTCP accounting data

Integration of RNTCP with the NHM has presented two major advantages. On the one hand, states are now required to contribute 25% of the required RNTCP budget; in some states like Gujarat this has gone up to 31%. On the other hand, 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.

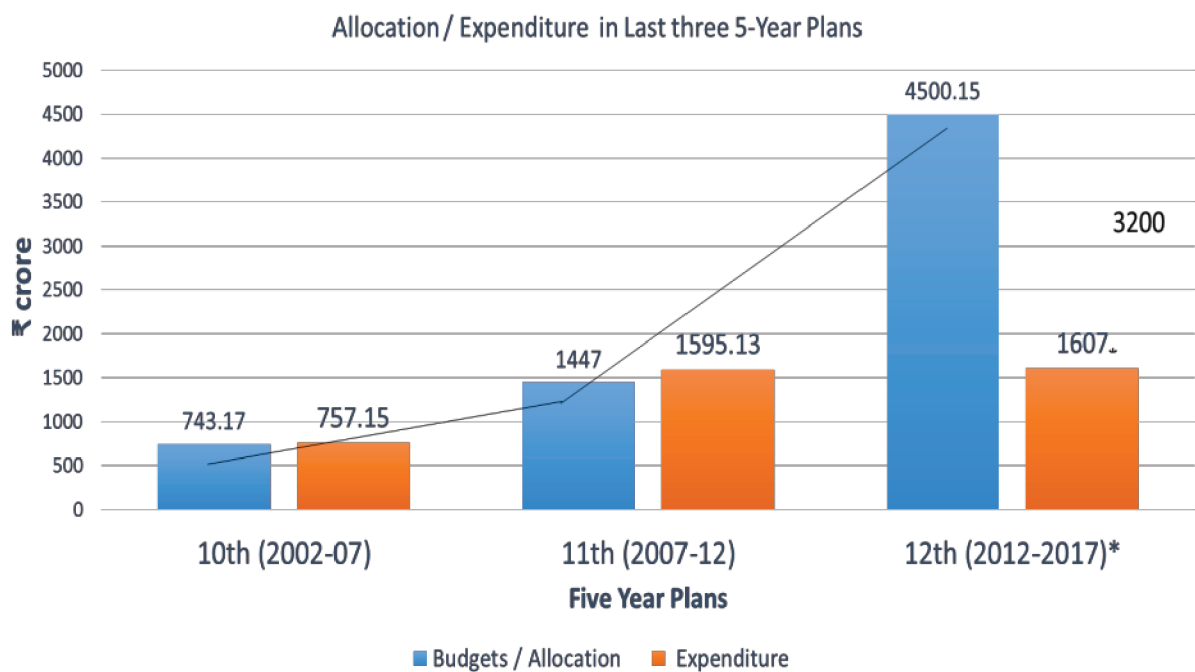
In at least one estimation, every rupee invested in TB control has a one-hundred-fold economic return on investment.⁸

⁸Goodchild, M, et al. A cost-benefit analysis of scaling up tuberculosis control in India. The International Journal of Tuberculosis and Lung Disease. 2011;15.3:358-362.

2.3.2 Challenges

The allocation of funds has not matched the ambitious expenditure increase in the NSP. While RNTCP expenditure has increased by 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 INR 30 000 million (3000 crores), or two thirds of the INR 45 000 million (4500 crores) that the NSP established as the minimum required (Fig. 14). 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.

Fig. 14. Allocation and expenditure for the three five-year plans for TB control since 2002



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 statement of expenditures (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 states' 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 the 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 proactive and manage all the programmatic, administrative, M&E 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/district TB officers (DTOs) for proper and timely implementation of the Programme. Of late, a few of the states have withdrawn those powers on their own, 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 does not possess accounting qualifications or experience in accounting.

2.3.3 Recommendations

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 INR 15 000 million (1500 crores) per year to achieve the goals of the Plan and thus save a further 250 000 lives annually. The MoHFW should also streamline the procurement and decision-making processes to ensure it spends the external grants and credits on time, enabling additional international funding in the future.

Mobilize additional funding to meet the goals of End TB Strategy

Additional Investment of at least INR 7500 million (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.

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. States, in consultation with their finance departments, should draw up a plan with clear timelines for release of grants from the treasury to societies.

Develop e-accounting through 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 release of funds and verification of accounting actions at any time.

Make full use of e-payments and transfers

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

States should transfer the approved share for TB activities to the NHM societies

This should preferably be done in two installments, one in the first quarter and the second immediately after audit of accounts. This should also serve to fill the gaps wherever Central funding is delayed.

Strengthen finance units

Finance units in states and districts should be strengthened by immediate training of finance functionaries and filling of vacant posts.

2.4 Social protection⁹ and support for patients and families affected by TB

2.4.1 Achievements

At the World Health Assembly in May 2014, India endorsed WHO's End TB Strategy that sets the target of zero catastrophic costs for TB-affected families by 2020. Falling ill with TB and accessing health services can impose such severe costs on patients and their families that access to care is inhibited, treatment outcomes worsen, transmission is aggravated and social and economic impacts can be devastating.

India's Constitution recognizes the right to social well-being, health and social assistance. The Gol 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 Gol on 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 the GDP in 1995–96 to 1.75% of the GDP in 2010–11. Some of the social security and welfare schemes that could have a direct effect of reducing the social and economic impact of TB are listed in Table 2. The agencies that operate these schemes at the Central level are the Ministry of Social Justice and Empowerment, Ministry of Labour, Ministry of Health and Family Welfare (MoHFW), Ministry of Consumer Affairs, Food and Public Distribution, Ministry of Women and Child development, Ministry of Rural Development and Ministry of Textiles.

⁹Social 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.

Table 2. Illustrative list of social schemes and benefits relevant or potentially relevant for TB patients

a) Nutritional support (not solely for TB patients)	General: Antyodaya Anna Yojana (AAY); Food Security Act 2013 implemented in 11 states, Integrated Child Development Services Scheme, Mid-Day Meal Scheme
b) Financial support	Departments of social welfare in certain states provide financial assistance to TB patients
c) Income generation activity (including microfinance)	Swarnajayanti Gram Swarozgar Yojana (SGSY), Mahatma Gandhi National Rural Employment Guarantee Scheme (MGNREGS)
d) Health insurance schemes	Rashtriya Swasthya Bima Yojana (RSBY) Employees State Insurance Corporation
e) Benefits in case of death	National Family Benefit Scheme: applicable to TB/HIV patients Compensation to silicosis/silico-tuberculosis patients (e.g. National Human Rights Commission fixed INR 300 000 as compensation in Rajasthan) Group Life Insurance scheme for low-income groups: Jan Shree Bima Yojana
f) Benefits in case of disability	In case of certified disability of >40%, persons are eligible for low-interest loans under National Handicapped Finance Development Corporation
g) Schemes for specific occupational groups	Handloom Weavers Comprehensive Welfare Scheme, etc.
h) Educational Support	Sarva Siksha Abhiyan (SSA) Indira Gandhi Matritva Sahyog Yojana

The JMM found that awareness of these schemes by service providers and patients is very limited and they are usually not exploited for those affected.

The Government's current focus on improving e-governance provides a powerful opportunity. The focus includes transmission of data and sharing data across elements of government via rapid, secure online platforms, the rollout 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. 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 NSP prioritised equity and universal access in the delivery of TB services and articulated a vision of supporting socially and clinically vulnerable populations through its social action plan (SAP). The SAP included access to financial assistance, benefits and support 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 Charter¹⁰ that

¹⁰Patients' Charter for Tuberculosis Care. San Francisco. World Care Council/Conseil Mondial de Soins (www.worldcarecouncil.org/).

outlines right 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 now include support for transport for patients with drug-resistance and HIV infection, though in practice this is inconsistently provided.

The JMM observed that the provision of social assistance (food, cash, referral for social welfare and other forms of support) either through the RNTCP itself or via local societies, NGOs and community members to those affected by TB does happen for some patients. However, there is wide variability of what is provided, how much and to whom, and a large proportion of patients in need are missed. Nevertheless, the JMM documented some impressive experiences, including provision of social welfare payments in New Delhi, Gujarat and Kerala, and different schemes in Tamil Nadu.

The RNTCP has initiated discussions with the Rashtriya Suraksha Bima Yojana (RSBY), a national health insurance mechanism targeting the poor and principally focused to date on defraying hospital-related costs. The aim is to develop a package to support coverage of MDR-TB services. A recent experience in Chattisgarh yielded successful results for reimbursement of treatment costs for MDR-TB patients treated in public and private sectors. The concept note from India to the Global Fund was under review at the time of writing and includes funding to NGOs to facilitate access to social support by TB patients and affected families.

Provision of patient education and counselling is already Programme policy and training modules and materials have already been developed to assist this process. Treatment support is increasingly decentralised to the community via ASHAs, auxiliary nurse midwives (ANMs) and anganwadi workers (AWWs).

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

2.4.2 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% of India's population remains without access to adequate social protection.¹¹ 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 TB 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.¹²

There is a lack of programmatic documentation 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. Specifically, information is lacking on 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 programme officers and others that outline the social support available to all TB patients (not just those with DR-TB), or on nutritional assessment and support, despite the availability of policy recommendations from WHO.¹³ 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.

¹¹Srivastava RS. A social protection floor for India. New Delhi: International Labour Office, ILO DWT for South Asia and ILO Country Office for India; 2013.

¹²Lonnroth K et al A consistent log-linear relationship between tuberculosis incidence and body mass index. *Int J Epidemiol.* 2010 Feb;39(1):149-55. doi: 10.1093/ije/dyp308. Epub 2009 Oct 9

¹³WHO. Guideline: Nutritional care and support for patients with tuberculosis. Geneva: WHO; 2013.

Programme officers, health-care providers, TB patients and communities are generally not aware of the many existing schemes and benefits of the GoI that patients and families can gain access to (Table 2). Ministries and sectors managing these schemes and benefits are also not aware that TB patients and families are eligible for them.

Access to such schemes is often cumbersome, requiring TB patients, affected families and vulnerable communities to prove their eligibility with valid documentation, which often translates into delays or failure 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 TB 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 -Section 3.6.

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 necessary support supervision to learn and improve their technique. TB programme staff is too dependent on contractual staff for performance of core functions, and regular health staff do not take responsibility for counselling of TB patients.

2.4.3 Recommendations

Systematically link all TB patients for economic and social support

In line with the RNTCP's NSP, and the WHO End TB Strategy, the MoHFW must rapidly ensure eligibility, expansion, and systematically link with social welfare schemes for economic and social support to TB patients and affected families. To achieve this, the JMM recommends that the RNTCP take 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.

Develop dedicated capacity to coordinate across all relevant departments and agencies

The RNTCP must develop dedicated capacity to coordinate across all relevant departments and agencies¹⁴ to identify already existing benefits and schemes provided by the GoI and ensure eligibility of TB patients, affected families and their communities to these benefits and schemes.

Social support through a single window

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 e-NIKSHAY to ensure rigorous monitoring of the process, and to link to the larger initiatives of the GoI including the Prime Minister's Jan Dhan Yojana, e-governance, Swach Bharat, National Health Assurance Mission and RSBY to ensure patient support and patient-centred care for all TB patients in the country.

¹⁴MoHFW 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

Develop a national policy for TB and nutrition

The RNTCP should develop a 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 TB, the severity of under-nutrition documented in Indian patients, and recent WHO recommendations on nutrition care and support for TB patients.

Pursue a baseline review and consultation process

The RNTCP should pursue a baseline review and consultation process in the coming year, which should include the following:

- Comprehensive mapping of social support schemes and benefits currently available Centrally, in states, NGOs, municipalities, Panchayati Raj institutions, through taxation, corporate social responsibility (CSR), etc; include lessons learned from the HIV/AIDS programme and other programmes;
- Contract legal and administrative review of available entitlements for, and eligibility of, TB patients and their families including procedures to access them;
- Map current roles and responsibilities within and across ministries and beyond Government in providing social support benefits or facilitating access to them;
- Initiate a representative survey on TB patient costs in pilot states;¹⁵
- Develop potential approaches to cross-review beneficiary databases across TB and social benefit programmes to determine any overlapping coverage and the volume of clients missed;
- Subsequent to the baseline review, and in addition to recommendations above, the JMM also recommends that the RNTCP:
 - o initiate discussions with NITI Aayog and ministries responsible for specific benefits to highlight the unmet needs of TB patients and affected families. Make the case for their eligibility for these benefits and schemes, and cater for necessary budgetary allocations;
 - o organize expert consultations to guide the development of a policy on nutrition and TB;
 - o initiate coordinated efforts to help TB patients and affected families systematically access social support and benefits; track and monitor patient-centred care for all TB patients in the country;
 - o develop approaches for social support to specific vulnerable groups (e.g. 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);
 - o prepare a compendium of best counselling guidance and materials for general health workers and for DOTS providers.

2.5 Procurement and supply chain management

2.5.1 Achievements

Ensuring a reliable and uninterrupted supply of good quality anti-TB drugs and other commodities is the main objective of supply chain management. The Procurement and Supply Chain Management Unit in CTD carries out procurement planning and monitoring, policy formulations, coordination with procurement agents, reporting and coordination with the donors, implementation of procurement risk mitigation plans, handling day-to-day supply related issues and monitoring of the contracts. An independent procurement agency is currently carrying out procurement, but this was recently entrusted to the Central Medical Services Society (CMSS), an autonomous entity under the MoHFW, with a mandate to take independent decisions related to their procurement functions.

¹⁵WHO is piloting a protocol with other countries that may be useful.

First- and second-line drugs were available in all states visited, except for some loose drugs, which are the responsibility of the local government to provide as and when needed. Rifabutin was available for treatment of HIV-infected TB patients who were also receiving certain protease inhibitors, and this was being issued to states. Supplies of rifampicin 150 mg had arrived at government medical supply depots (GMSDs) and was being issued to all the states. Notifications of award for isoniazid 100 mg and 300 mg had been issued and supplies were expected from May onwards.

The RNTCP were procuring 2500 LED and 1500 binocular microscopes (BM). The first tranche of LED (755) and BM (500) microscopes had been issued. CBNAAT machines had been installed in 120 centres.

The Programme had completed training of trainers in all states on supply chain management during 2014.

Hiring of an independent agency for ensuring quality assurance (QA) of anti-TB drugs is in the final stages. Similarly, the processes for hiring a logistics and supply chain management agency, a media agency and organising the Technical Support Group had been initiated by the Programme and were under consideration by the Ministry.

2.5.2 Challenges

Storage conditions are suboptimal at various levels and drugs are not stored according to their required storage conditions. In one state, cycloserine, which needs to be stored in a cool temperature, was outside the store due to inadequate space. Likewise, some injections that need to be stored under controlled conditions were not stored accordingly.

There are communication gaps still persisting at various levels. Districts reported shortages of streptomycin, rifampicin 150 mg, the paediatric drugs for specific weight bands, PC-13 and PC-14, and isoniazid 100 mg and 300 mg. However, rifampicin, for example, was available at state drug stores (SDS), but neither supplied to districts, nor were district tuberculosis centres (DTCs) aware of its availability.

Some key positions, especially DTOs and pharmacists, were vacant at various levels, adversely affecting the supply chain mechanism and drug logistics of the states. Transportation of drugs, especially from districts to sub-districts, is inefficient. In some cases, drugs are being transported on motorbikes from districts to sub-levels and the rider has to do three or four trips to collect all the sub-district's needs from the stores.

With the increase in MDR/XDR patients, preparation of MDR/XDR boxes at SDS seems to be a big challenge within the available work force and infrastructure at SDS. As a result, MDR/XDR boxes are not being prepared at some SDSs and loose drugs are issued to districts.

There were major delays in the procurement of an order for 300 CBNAAT machines and 780 000 cartridges with Global Fund support. These appeared to be at a level above CTD and had been persisting for about 2 years.

The Programme was planning to introduce the daily first-line regimen in five states, which will pose challenges for procurement and supply chain management. Procedural delays at state level hamper supply chains due to delays; for example, in issuing road permits to suppliers, and delays in executing drug transfer advices issued by Central TB Division, which reduces the shelf-life of drugs.

The states, whenever entrusted with procurement of drugs, find it quite challenging. Procurement of high quality anti-TB drugs at the state level, therefore, needs to be restricted to emergency situations only.

Central Medical Services Society (CMSS) has been selected as the new procurement agency, but the transition from RITES to CMSS may be a challenge considering this to be the maiden attempt of CMSS. An alternative mechanism needs to be kept as a standby arrangement if CMSS procurements are delayed, to avoid any shortages or stock-outs of drugs.

2.5.3 Recommendations

- The JMM recommends that the RNTCP should introduce any policy changes in diagnosis or treatment only with due consideration of the available stock of current products, the supplies in the pipeline and the procurement lead time required.
- In order to maintain QA, cost-effectiveness and rational use of TB medicines, the RNTCP should maintain procurement at the Central level as the standard practice for TB medicines. States should procure in emergencies only. States should prepare the MDR/XDR patient boxes, rather than delegating this to districts.
- CTD should take the lead to smoothen the flow of products down to the lowest levels of the supply chain by strengthening communication about available stock between the different levels, improving transportation mechanisms from state level downwards and resolving the issue of road permits through issue of a general waiver by the GoI for all anti-TB drugs.
- The RNTCP should activate the logistic management information system (LMIS) module of NIKSHAY and roll it out; introduce bar coding as soon as possible and real-time monitoring of all supply chain management including stock levels at different points.
- In order to address the impact on supply chain management as a result of planned changes in diagnosis and treatment approaches, the RNTCP should strengthen procurement and supply chain management human resources PSM-HR at CTD and state level and below by filling vacant positions (e.g. state level technical officers, procurement and logistics officials) and refocusing or retooling existing staff and contractors.
- The RNTCP should develop guidelines for QA for drugs being urgently procured locally by states or districts.
- The RNTCP should prepare an action plan for the upgradation of state and district drugs stores following an external evaluation of supply chain management and incorporating good storage practices (GSP) and good distribution practices (GDP) with training provided to all key officials.
- THE JMM strongly recommends that procurement processes, such as those for CBNAAT procurement, be completed speedily. Benchmarks should be established for each step of the process; and if they are exceeded, a clear reason should be provided by the level causing the delay.
- The RNTCP should review all the notifications for the exemption of payment of excise and customs duty for anti-TB drugs and commodities issued by the Department of Economic Affairs (Revenue) and extend them into the future.

2.6 Community engagement

2.6.1 Achievements

The recent campaign with Mr. Amitabh Bachchan as brand ambassador launched initially in Mumbai and then nationally on World TB Day 2015 has, anecdotally at least, raised awareness of TB and helped reduce stigma.

An operational handbook on advocacy, communication and social mobilization (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 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 treatment successfully.

2.6.2 Constraints

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 have 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. An operational handbook on ACSM with NGO schemes is one of these. 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 at 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 on the part of staff in the RNTCP 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 process in place and the capacity in terms of both staff and skills is low at the state and the district levels. Engaging the community is something that is neither understood nor valued. There is no mechanism to implement community engagement; and in the absence of guidelines for it and a clear recommendation for implementation, it is not a priority at any level. The already overburdened staff tends to do things that need to be reported on and budgeted for – community engagement is neither and falls very low on the priority list.

There is therefore minimal involvement of NGOs, community-based organizations (CBOs), faith based organizations (FBOs), civil society organizations (CSOs) and panchayati raj institutions (PRIs). Patient and community voices were absent. The JMM found that 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. Some of the PHC/sub-centre (SC) staff had taken the initiative to reach out to the MDR patients on treatment and encouraged them to support other patients who were newly initiated on treatment. Though this is being done very informally, it was definitely encouraging and was supporting patients to complete treatment. For example, at Rajpur PHC, the in-charge is a regular visitor to the home of a 35-year-old MDR patient from the same village. He supported him during the most difficult time of the treatment, ensuring adherence, and now encourages him to share his story with other patients by either visiting them or talking to them on the phone. This has proven to be very beneficial in helping new patients in starting treatment.

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 Axshaya is 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 marginalized populations to TB services through advocacy, communication and community engagement. However, only the Andhra Pradesh (AP) team mentioned Project Axshaya in its field report. The teams that visited Odisha, Madhya Pradesh (MP) and Tripura, where the Project is also present, made no mention of it at all, which scarcely supports a high visibility. Some members of the JMM asserted that it falls short in increasing access through advocacy and community engagement in the districts visited and remains a missed opportunity.

2.6.3 Recommendations

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, CBOs, 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, maternal and child health (MCH), primary health care (PHC) and noncommunicable diseases (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. 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.

Strategy for community engagement with explicit sub-strategies for engaging civil society, communication and advocacy

Each state should develop and implement a formal strategy for community engagement in the state that has separate and explicit sub-strategies for engaging civil society, communication and advocacy.

The community engagement sub-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 water, sanitation and hygiene (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, e.g. 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 by school children on walls of school buildings, community halls, ration shops, 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, self-help groups (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.

Formation of patient groups and patient forums in every district for treatment adherence support

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.

High level sustained national campaign on TB: “TB free India/TB mukt Bharat”

The MoH should establish a high level sustained national campaign on TB: “TB free India/TB mukt Bharat” with active leadership of national, state and local governments in coordination with corporate and private sectors, NGOs, media and others that will aim to reach, treat and cure every TB patient in the next decade. 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 programme 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 baat to the nation.

2.7 Human Resources for Health

2.7.1 Achievements

The health workforce is a key element for the success of the TB programme. It is hence encouraging that the NSP 2012–2017 has ambitious targets in terms of health workforce development. The health workforce will be more crucial than ever to successfully achieve the objectives of the End TB strategy.

A review of the actions taken following the JMM 2012 indicated that out of several recommendations related to the health workforce, two were satisfactorily met.¹⁶ These were recommendations 9.2a (To revise the terms of reference or develop new job descriptions to address the changing roles of the staff) and 9.3 (To develop a comprehensive training plan to guide the expansion of training required over the next three to five years).

2.7.2 Challenges

Among the recommendations of the JMM 2012, two recommendations were only partially met. These were recommendation 9.4 (To take steps to ensure parity in the service rules of the NHRM and RNTCP contractual staff. Contracts should be renewed in a timely manner. Delink payment of salaries and honoraria from the release of funds for the NHM/RNTCP by the Centre and promote electronic payment of salaries); and 9.5 (To establish strategies to improve retention and performance of staff). One recommendation (9.1) has not been implemented (To strengthen HRD planning and coordination). A national HRD plan is yet to be finalized.

Moreover, a key recommendation of the NSP 2012–2017, regarding key RNTCP positions, has not been achieved. While the aim was to fill 90% or more of key RNTCP positions, the national average is significantly lower (see Table 3). Among the seven states visited during the JMM 2015, only Gujarat has successfully reached this target.

Table 3: Human resource summary data at 4Q14 for the states visited

State	RNTCP Districts	Number of Key Staff in Position								Staff in Place and trained in RNTCP	
		TB Units	DMCs	DTO	2nd MO	MOTC	STS	STLS	LT	MO	Para med staff
Andhra pradesh	24	236	993	17	20	185	200	166	934	85%	88%
Gujarat	36	203	850	28	17	200	202	141	803	92%	92%
Himachal Pradesh	12	49	196	12	1	41	49	46	167	77%	72%
Madhya Pradesh	50	177	759	47	7	125	139	141	787	81%	79%
Meghalaya	7	12	61	6	0	10	11	12	61	82%	69%
Odisha	31	120	523	28	5	95	102	74	433	72%	81%
Tripura	6	15	71	7	2	13	13	7	52	83%	91%
All India total	732	3394	13583	654	330	2847	3066	2548	13630	77%	78%

Source: Central TB Division

¹⁶MoHFW and WHO. Joint Monitoring Mission: Revised national tuberculosis control programme (RNTCP), India. New Delhi; 2012.

In addition, the JMM 2015 also highlighted the following key issues:

- Heavy reliance on contractual staff to meet human resources (HR) needs with precarious employment conditions, no defined career paths, lack of insurance coverage;
- Cumbersome recruitment processes (including financing and clearance/approvals at various levels);
- Lack of uniformity in the monitoring and application of staff service rules by states.

2.7.3 Recommendations

The working group adopted a health system approach to this issue, as it is evident that focusing only on the RNCTP health workforce would not be sufficient to successfully tackle health workforce issues related to TB care in India.¹⁷ Hence, in addition, to reiterating the importance of completing the implementation of the JMM 2012 recommendations, recommendations were made in the areas of governance, health workforce (RNCTP workforce, as well as all HR involved in TB), finance and information systems.

- The MoHFW should speed up the full implementation of the JMM 2012 recommendations, in particular finalizing the development of an HRD plan which would also include specific mention of research roles and potential contributions by private and NGO sectors.
- In the area of governance, the MoHFW should develop and implement indicators of transparency and accountability.
- Specifically for RNTCP human resources, the RNTCP should develop and enhance a national HR policy for contractual staff that would include:
 - o recruitment and retention rules
 - o capacity development
 - o performance appraisal and benefits package
 - o transfer guidelines.
- The RNTCP should seek a sustainable balance between regular and contractual staff by defining benchmarks and implementing an HR audit based on benchmarking and staff service rules (recruitment, retention and transfer and benefits package). Specifically for the recruitment process, the RNTCP should develop benchmarks such as a maximum of 120 days to be taken from approval to getting the person in place.
- The RNTCP should develop mechanisms for training, incentives and performance policies for RNTCP and non-RNTCP staff engaged in TB activities to ensure proper implementation of TB programme policies and activities. Conversely, the RNTCP should develop mechanisms and opportunities for RNTCP staff to contribute to health systems strengthening (HSS).
- The RNTCP should ensure parallel, consistent, performance-based appraisal mechanisms of RNTCP and other staff.
- The RNTCP should articulate justifiable criteria for staff re-training and re-purposing to meet evolving and newly identified RNTCP and health systems strengthening (HSS) needs and priorities.
- The RNTCP should develop a systematic state policy for community-based workers to include multipurpose health workers (MPHWs), ASHAs and community volunteers, focusing on incentives and payment.
- The RNTCP should ensure timely payment of salary and expenses of staff by expanding use of e-payment mechanisms.
- With respect to health information and management, the RNTCP should reinforce the HR module of NIKSHAY.

¹⁷ The working group did not discuss the role of private practitioners as the issues related to the private sector were discussed in another working group.

2.8 Engaging all care providers

2.8.1 Achievements

TB care in India is provided by diverse public, private, voluntary and corporate providers. About 70% of people with TB first approach a private practitioner and a large proportion (about 50%) remain under treatment in the private sector. More TB drugs are sold in the private sector than the amounts used by the RNTCP. The wide range of private practitioners includes those trained in Western medicine and various Indian systems of medicines (AYUSH) as well as informal and traditional providers who practice without any formal training. Engaging all care providers is critical to ensure that all those who need TB care receive it in line with the STCI.

With respect to progress in implementing the recommendations of JMM 2012 and NSP 2012–17, perhaps the most important has been the publication of the STCI. The Indian Medical Association (IMA) and the Catholic Bishops' Conference of India (CBCI) have disseminated the Standards to private practitioners (PPs) and NGOs. Sensitization of PPs by IMA has continued. Medical colleges continue to contribute substantially to case notification. The public–private mix (PPM) schemes (The National Guidelines for Partnership) have been revised and tailored for PPs of all kinds.

New and innovative models of PPM using a public-private interface agency (PPIA) with appropriate application of information and communications technology (ICT) are piloting in three districts – Mumbai, Patna and Mehsana. The early results are very encouraging, with doubling of TB notification. In some states, e.g. Chhattisgarh and Tamil Nadu, DR-TB patients are considered eligible for compensation under the RSBY. More than 85 000 private health facilities had registered under the NIKSHAY surveillance system by December 2014. The National Technical Working Group (NTWG) on PPM has reviewed and advised on strategies to increase private health sector involvement. Although the Technical Support Group (TSG) is not yet formally in place, the Ministry has approved the TOR and the request for proposal (RFP) for TSG and PPIAs.

2.8.2 Challenges

Governance and stewardship

The general health system is weak, coupled with a public–private disconnect. Weak commitment on either side to collaborate further complicates matters because of mutual distrust. In the absence of an agreed policy document to outline a clear process for collaborating with the private sector and an institutional structure not being in place, it is difficult to map the expectations and opportunities in the private sector. Though the NTWG is two years old, there is still much to do to steer the PPM component in the RNTCP.

Finance

There is inadequate funding for implementing the PPM component; and when funds are short, it is often the PPM component that is hit. Out of the total RNTCP budget, 12% is for PPM. Frequently, the PPM budget is used for paying salaries of TB health visitors, leaving little for any field activities, even though they could potentially be used for active case finding and supervising the treatment of private patients. Getting the disbursements sanctioned by the district authorities for PPM schemes is often an obstacle, leading to delayed payments.

Human resources

The capacity and skills of the RNTCP staff to collaborate effectively with the private sector are weak. There is no formal training for staff on PPM. Recruitment of PPM coordinators has begun in many states, but there is no way other than trial and error to build this cadre's capacity in engaging with the private sector. TB care provided by private providers is not standardized and there is much scope for further use of the STCI.

Monitoring and evaluation

Data on PPM activities are not routinely collected. As a result, progress made through diverse activities is not measured. Mapping and identifying potential private providers to link them with the programme are crucial. There have been several JMM recommendations to improve this area, but many of these recommendations are unimplemented.

Regulation

The private sector in India is diverse, disorganized and unregulated. The Clinical Establishment (Registration and Regulation) Act, 2010 requires private providers to register with the district health authorities. However, the states have not been able to implement and enforce the Act to regulate the private sector. Enforcement of regulations such as mandatory case notification and restricting the sale of TB drugs as part of Schedule H1 is weak.

Opportunities

Opportunities exist to redesign a PPM programme systematically. Specific components would include a policy-based approach, appropriate institutional systems and innovative models of financing and collaboration.

- Policy: There is a need for a policy for collaboration with the private sector that clearly articulates the acceptance of private sector engagement as a long-term sustainable option.
- Organization and capacity: In order to implement any partnership strategies in a systematic manner, there is a need to develop institutional structures, systems and capacity with sufficient resources.
- Innovative partnerships: There is potential to explore innovative financing and partnership possibilities with the private sector. These include (i) mobilizing industrial houses and the corporate sector (non-health-care providers) to get involved in the programme through their own health facilities or CSR funds; (ii) explore new models of private-public partnerships such as collocated franchised clinics, demand side financing (vouchers), etc; and (iii) streamlining the release of payments to private practitioners through innovative disbursement mechanisms.
- AYUSH and other providers: AYUSH practitioners offer untapped potential in terms of referring presumptive TB cases, providing treatment supervision and following them up.
- ICT platforms: In order to strengthen the information system and NIKSHAY, private care providers and social entrepreneurs could be encouraged to use ICT platforms such as mHealth applications, as long as they are user-friendly.
- Regulatory compliance and adherence to quality standards: Better enforcement of regulatory policies including ban on serodiagnostics, mandatory TB case notification and rational use of TB drugs
- Establish the referral linkages for treatment of MDR-TB cases.

2.8.3 Recommendations

- The JMM recommends that the MoHFW urgently ensure that patients in the private sector receive early TB detection, appropriate treatment and sustained support for adherence, and that their OOP expenses be minimized. To achieve this, the JMM recommends that the MoHFW:
 - o strengthen 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;
 - o eliminate taxation on TB diagnostics and drugs as a response to this ongoing public health emergency;
 - o extend public health services to privately notified TB patients, including free drug susceptibility testing, provision of free drugs for TB patients managed by providers, contact investigations and co-morbidity screening and care.

- o extend and scale up successful models of adherence support and monitoring to TB patients managed by private providers;
 - o measure the quality of services provided by private providers, and engage with them to improve the quality of care they are providing to TB patients.
- The MoHFW should enunciate a clear policy of engaging the private sector and other care providers that indicates willingness to engage with them as a long-term sustainable option. In the development of guidelines, or their translation into practice or any mid-course corrections, ensure continuous engagement of all stakeholders.
 - The MoHFW and states should develop institutional structures, systems and capacity both at Central and state level with specific focus on technical and managerial capacity of public–private cooperation, including streamlining of payments.
 - RNTCP should engage the Office of the Drugs Controller (ODC) to promote enforcement of schedule H1, restricting prescription of anti-TB drugs to licensed providers. RNTCP should furthermore develop guidelines for districts to periodically collect and use this surveillance information to identify and engage providers who are prescribing anti-TB drugs.
 - The RNTCP should push for improving screening of TB symptomatics in outpatients of large private (and public) hospitals by introducing mechanisms such as the "cough register"; ensure continuity of care for diagnosed TB patients including children; explore engagement of community medicine departments of medical college hospitals to strengthen delivery of TB care and prevention.
 - The RNTCP should expand programmatic management of DR-TB by engaging private laboratories (e.g. IPAQT network), private practitioners and private institutions including medical colleges.
 - The RNTCP should develop and introduce user-friendly ICT applications including mHealth applications through social entrepreneurs as part of e-NIKSHAY to inform private care providers on STCI, facilitate treatment adherence among patients and increase TB awareness in the community.
 - The RNTCP should create, maintain and share a repository of successful PPM initiatives, both from India and outside, for guiding the implementation plan as a menu of options for PPM expansion in the states. It should review the experience from ongoing PPIA projects to identify successful strategies for scale-up.
 - The RNTCP should widely disseminate the STCI to all care providers through various channels, especially to private practitioners through key stakeholders such as the IMA.
 - The RNTCP should engage with the corporate sector, e.g. public sector units, Confederation of Indian Industry (CII), Federation of Indian Chambers of Commerce and Industry (FICCI), etc. and other non-health-care establishments for a CSR funding mechanism to be deployed in the programme.
 - The RNTCP should assess the feasibility of incentivizing and engaging pharmacists and informal providers who identify presumptive TB cases by linking the cases and/or providers directly with digital chest X-ray (CXR) and CBNAAT testing centres.
 - The RNTCP should move faster to set up the Technical Support Group for PPM and ensure regular meetings of the National Technical Working Group on PPM.

2.9 Research to Improve TB care and control

2.9.1 Achievements

The CTD organized two workshops to develop strategies to strengthen the research component in the programme. During these workshops, deliberations were held about the constitution and working of the National Research Cell. This is now under consideration within CTD.

CTD also organized a number of OR workshops in collaboration with WHO/Union/CDC. These involved other stakeholders, departments and organizations like NACP, ICMR, National

Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), National institutes NTI, National Institute of Tuberculosis and Respiratory Diseases (NITRD) and NIRT, NGOs and various developmental agencies. Roughly 200 persons have been trained on OR for TB.^{18,19} Due to active and persistent efforts put in by the division (CTD) and partners (WHO, Union, CDC), nearly 30 publications have been published in peer-reviewed journals since 2012. OR dissemination workshops were held by CTD, WHO, Union and NIRT. The findings from OR conducted by the programme were instrumental in key policy decisions such as reducing the number of follow-up sputum examinations, one sample for culture follow up, revising the diagnostic algorithm, the revised treatment policy, drug susceptibility testing (DST) guided treatment for DR-TB, TB/HIV management, introduction of molecular diagnostics for MDR-TB on a pilot basis, etc. Four National OR Expert Committee meetings have taken place (June 2013, September 2013, March 2014 and February 2015). This committee approved 25 OR proposals. Some states have taken the lead in funding state-specific research projects, e.g. Gujarat.

2.9.2 Challenges

The two major recommendations from the 2012 JMM had not been implemented. The National Research Cell, and the Indian Research Partnership involving the full spectrum of Indian research expertise (including Department of Biotechnology (DBT), ICMR, Council of Scientific and Industrial Research (CSIR) and the private sector) have not been established. In the case of the former, it seems there is lack of clarity in its concept and remit. The latter seems related to the fact that a proactive approach is required at different levels to involve the full spectrum of research expertise and the private sector in India – and this has not been possible so far.

Twenty-five 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. 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. The JMM research group felt that HR capacity built for OR remained insufficient.

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, National JALMA Institute of Leprosy and other Mycobacterial Diseases [JALMA], NITRD, NTI), the network of ICMR institutes, about 350 medical colleges, and the strong basic science institutes under Department of Biotechnology (DBT), CSIR and Department of Science and Technology (DST), India has a unique capacity to be a leader in basic, clinical, translational and operational research. India could advance TB control nationally and globally. In addition, the large burden of disease makes it a high public health priority.

2.9.3 Recommendations

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 its core commitment, the MoHFW should include the ICMR/Department of Health Research, Departments of Science and Technology and Biotechnology, CSIR, other academic/research institutions and the private sector as partners.

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.

¹⁸Kumar AMV, Satyanarayana S, Dar Berger S, Chadha SS, Singh RJ, Lal P, et al. 2015. Promoting operational research through fellowships: a case study from the South-East Asia Union Office. *Pub Health Action*. 2015;5: 6–16.

¹⁹Guillerm N, Tayler-Smith K, Berger SD, et al. What happens after participants complete a Union-MSF structured operational research training course? *PHA*. 2014;4(2):89–95.

This forum requires strong financial and technical commitment from all stakeholders, including representatives from the private sector. It needs to 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. A 5% levy from the annual TB budget could be formally committed for research.

Responsibilities of the Consortium will include creating a nationwide network of scientists, public health and 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, and developing centres of excellence. High-level political advocacy will be solicited for fulfilling this agenda.

The RNTCP should prioritize OR as the best means to improve TB control activities and this 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. Capacity building should be expanded through workshops, mentorship and training at all levels, targeting, in particular, junior faculty and students from medical colleges and RNTCP staff at all levels.

The team stresses the importance of developing a systematic and fully transparent mechanism for research to ensure translation of findings from research into policy and practice. The research consortium should coordinate operational and impact research to assess delivery effectiveness and impact on cost reduction and treatment outcomes.

3

Observations of the JMM on the technical aspects of TB care, prevention and control

3.1 Early diagnosis and case-finding for all types of TB

3.1.1 Achievements

- Serological tests were banned by the GoI in 2012, and their use has dramatically declined since then;
- The STCI were published in 2014, with six 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, extrapulmonary tuberculosis (EPTB) and childhood TB, with CXR and CBNAAT included;
- Laboratory capacity has been enhanced, especially for drug-susceptibility testing, with increase in the number of service delivery points;
- CXRs are very popular among private practitioners (while they under-use and under-value sputum tests). They are widely available in cities and towns, and are affordable, as well as more sensitive than smears. If practitioners can order a CXR early and refer those with abnormal CXR to CBNAAT testing sites, it could shorten the diagnostic delay;
- New diagnostics are being validated in national TB institutes (coordinated by ICMR);
- India committed to the End TB Strategy in 2014, the first pillar of which 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”.

3.1.2 Challenges

Although progress has been made since the last JMM, the RNTCP has struggled to meet the milestones set out in the NSP 2012–17. This is illustrated in Table 4.

Table 4. NSP goals, current status and likelihood of reaching the goal in selected case finding areas

Goal	Goa 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 CBNAAT or equivalent DST is envisioned for the district level by 2017, i.e. are deployed in all districts and medical colleges nationwide	120CBNAATs are currently in the programme as compared to the 500 that were planned for by 2015	Low
By 2017, all confirmed TB cases are to be screened at the outset or early in their course of treatment for drug resistance	Around 25% of all confirmed TB cases are currently getting DST	Low

Source: NSP 2012-2017 and JMM observations

The biggest challenges for TB case detection in India are discussed in succeeding paragraphs.

First, an estimated one million cases are missing (not diagnosed or not notified), and the TB case detection rate has flattened in the past few years.

Studies from India show significant diagnostic delays. Indian TB patients, on average, get diagnosed after a delay of nearly two months, and are seen by 3 different providers before a diagnosis is made.²⁰ Most poor patients begin seeking care in the informal private sector, including chemists and unqualified health providers.²¹ At this base of the health-care 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, and plenty of risk for development of drug resistance.

Diagnosis within the RNTCP is still heavily reliant on direct Ziehl-Neelsen smears (which are insensitive, and cannot detect drug-resistance). Sputum quality is an issue, and external quality assessment (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 CXRs. They rarely seek microbiological confirmation via sputum smear microscopy, culture or CBNAAT.²² Among doctors, awareness about STCI is quite low.

In the public sector, although CBNAAT, which is available, provides both a more sensitive test for TB and a test for drug resistance, it is being used primarily as a DST tool. Both access and uptake are quite limited and even existing capacity is not fully utilized. CBNAAT use for EPTB and childhood TB is low.

Progress towards expanding access to decentralized DST has been slow. Only 60% of persons eligible for DST (under current Programme guidelines) are currently getting tested, and existing culture and DST labs are underutilized. Access to second-line DST is low and a rate limiting step for the selection of appropriate evidence-based individualized treatment. The STCI promote drug sensitivity testing for all presumed cases of MDR-TB (and other groups) but progress is threatened by slow uptake of CBNAAT. It is people with 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 (see section 3.3 and 3.4 on childhood TB and on TB/HIV).

²⁰Sreeramareddy CT, Qin ZZ, Ssatyanarayanan S, Subbaraman R, Pai M. Delays in diagnosis and treatment of pulmonary tuberculosis in India: a systematic review. *Int J Tuberc Lung Dis*. 2014;18(3): 255–266.

²¹Kapoor SK, Raman AV, Sachdeva KS, Satyanarayana S. How Did the TB Patients Reach DOTS Services in Delhi? A Study of Patient Treatment Seeking Behaviour. *PLoS ONE*. 2012. doi: 10.1371/journal.pone.0042458.

²²Satyanarayana S, Subbaraman R, Shete P, Gore G, et al. Quality of tuberculosis care in India: a systematic review. *Int J Tuberc Lung Dis*. 2015;19:751–63.

3.1.3 Recommendations

- The MoHFW should take all necessary steps to increase patient demand for TB testing, including increasing patient demand for sputum testing by running celebrity advertisements on TV, e.g. Amitabh Bachchan's campaign on TB harega, desh jeetega. The Ministry should approach Indian philanthropists and industries (based on their CSR) to fund the publicity campaign, and consult with marketing experts to develop an appropriate communications and dissemination strategy.
- The RNTCP should engage and incentivize informal providers and chemists to refer presumed TB patients for TB testing, since they are usually the first point of care. This could be done by expanding the Private Provider Interface Agency (PPIA), learning from the PPIA ongoing pilots in urban areas. In the public system, ASHAs and community health workers (CHWs) should be offered incentives (or existing incentives should be enhanced) to refer persons with presumed TB, or collect and send sputum samples to DMCs. Sputum collection practises should be improved to enhance quality of samples.
- The RNTCP should expand access to digital CXR as a screening strategy (perhaps with computer-aided diagnostic [CAD] algorithms, after adequate validation) in both public and private sectors, and refer persons with abnormal X-rays for microbiological testing (CBNAAT). The RNTCP should provide vouchers for free CXR in the private sector (with reimbursement scheme) if no public X-ray service is readily available.
- CBNAAT access in both public and private sectors should be massively increased taking into account the lessons of successful experiences from pilot projects.
- The RNTCP should improve the quality of all conventional diagnostic techniques through internal and external quality assessment and by including sputum collection, transportation and patient referral.
- The RNTCP should disseminate the new algorithms for PTB, EPTB, and childhood TB along with a simple, clinical practice guideline, aimed at practising doctors.
- The RNTCP should establish a hotline for telephonic or whatsapp consults, where doctors can get support and link up with pharma companies for free distribution of STCI and educational materials, e.g. mobile apps.
- The GoI should eliminate taxation on all TB diagnostics and thereby increase affordability for patients. It should fully fund and implement the plan for Universal DST by 2019, and in high MDR burden settings (e.g. Mumbai, selected states in the North East), universal DST should be implemented immediately (in 2015). The revised national laboratory scale-up plan 2014–19 should be fully costed and funded.
- The RNTCP should increase capacity for systematic screening among household contacts, with under-5 children as the highest priority, and develop systems for data capture and reporting, so that contact investigations can be electronically tracked and monitored.
- The RNTCP should develop a clear, coordinated strategy for new tool introduction, and prepare the ground for launch of new drug regimens with companion diagnostics. The MoHFW should streamline the regulatory pathway for new drugs and diagnostics, establish minimum standards for regulatory approval of new diagnostics and link national TB Institutes to serve as multicentric validation sites, coordinated by an agency such as ICMR.

3.2 Treatment

3.2.1 Achievements

The most remarkable recent achievement by RNTCP and partners was the development of the STCI through a long, consultative process, and subsequent endorsement by the MoHFW. These standards, 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, TB treatment outcomes remained adequate (Table 5). The RNTCP should be proud of the treatment of over 13.5 million new cases with 87% treatment success, and 3 million re-treatment cases with 75% treatment success.

Table 5. Treatment outcomes of all types of TB cases, 1999–2013 (inclusive)

Patient features	Number of patients evaluated (cumulative)	Cured		Treatment completed		Died		Failed		Lost to follow up		Transferred out	
		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
New													
Smear-positive	6 813 807	5 741 758	84%	173 752	3%	296 947	4%	145 043	2%	412 068	6%	46 219	1%
Smear-negative	4 410 394			3 875 040	88%	155 986	4%	29 057	1%	322 546	7%	29 079	1%
Extra-pulmonary	2 354 372			2 167 769	92%	57 811	2%	3630	0%	100 718	4%	24 148	1%
Total New cases	13 578 573	5 741 758		6 216 561		510 744	4%	177 730	1%	835 332	6%	99 446	1%
Previously treated													
Relapse	1 091 897	747 106	68%	66 072	6%	77 921	7%	52 199	5%	131 246	12%	11 375	1%
Treatment after failure	193 556	106 982	55%	13 272	7%	18 679	10%	29 001	15%	33 495	17%	2449	1%
Treatment after default	826 099	533 500	65%	64 478	8%	70 123	8%	36 234	4%	155 402	19%	17 884	2%
Others	922 890	40 559	4%	712 928	77%	48 681	5%	6855	1%	97 705	11%	15 036	2%
Total Re-treatment	3 034 442	1 428 147		856 750		215 404	7%	124 289	4%	417 848	14%	46 744	2%

Source: RNTCP annual reports

The decentralization of TB treatment supervision and alignment with the block was the most important shift in the NSP, and the JMM noted that about a fifth of the country has undergone this shift. This now brings the Block Medical Officer, in charge of all health staff in his/her block, to be in charge of local TB treatment services. The aim is better involvement of local health systems in TB service provision, improved monitoring of treatment providers, and better follow up.

Decentralization of DOT services to community providers has improved from 46% in 2010 to 54% in 2014. More importantly, DOT providers are diversifying beyond the easy-to-monitor ASHA and Anganwadi networks, to include AYUSH and other community providers. Adherence honoraria were increased four-fold, and now represent a rational honorarium for DOT providers. There has also been remarkable progress in the management of drug resistance (Section 3.5).

The RNTCP has also made substantial progress in tackling discontent with standardized treatment regimens by hosting a meeting in 2014 on treatment guided by drug susceptibility testing (DST). Updates to the diagnostic algorithms had created the opportunity to adjust treatment regimens according to DST results. Key recommendations of that meeting included treatment options for isoniazid (INH) and other forms of non-MDR-TB drug resistance, albeit based on expert opinion.

JMM field teams noted important innovations from field visits. Given widespread challenges in ensuring that DOT providers got the promised honorarium, the system for e-payments for DOT providers, observed in Madhya Pradesh, is a notable advance. Expansion of that approach would be feasible in most states, as the transition to e-payment systems for health workers is nearly complete nationwide. Gujarat has significantly reduced initial loss to follow up by integrating routine initial lost to follow-up tracing into basic programme monitoring. In hard-to-reach areas in Meghalaya, JMM observed an effective, patient-friendly, DOTS delivery service.

Treatment research has also made important progress (Table 6), buoyed by a growing portfolio of clinical research from the National Institute for Research in Tuberculosis (NIRT), Chennai. Much of it raised concern about the suitability of thrice-weekly TB treatment, and its impact in important patient groups, such as HIV-infected TB patients and children. While stable rifampicin resistance was noted from Tamil Nadu relative to a decade earlier, the higher prevalence of ofloxacin (OFX) resistance among new TB patients suggested either substantial misuse in patients with presumptive TB (i.e. TB suspects) and/or high levels of transmitted OFX resistance. Either result is of concern for the use of fluoroquinolones in future treatment regimens.

Table 6. Key Indian TB treatment research reported, 2012 – 2014

Topic	Author, source and date
NIRT-led 2012 repeat DRS for Tamil Nadu, from S+ patients at public sector diagnostic microscopy centres showed stable low RIF resistance, stable high INH resistance (10.4%, 30%), and high baseline OFX resistance (New 10%, RT 14%).	NIRT-led 2012 repeat DRS for Tamil Nadu, from S+ patients at public sector diagnostic microscopy centres showed stable low RIF resistance, stable high INH resistance (10.4%, 30%), and high baseline OFX resistance (New 10%, RT 14%).
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 new smear-positive patients (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 intensive phase 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 JMM was also enthused by the potential of community-driven adherence innovations that offer improved patient support, valid data, and patient empowerment (Fig. 15). These innovations included smarter packaging (99 DOTS, Pharmasecure, smart medication monitors), better counselling (family groups, Photovoice), patient reminders (multiple systems), self-reporting (multiple systems), and ICT applications to help providers contact patients to prevent their loss to follow up.



Source: RNTCP

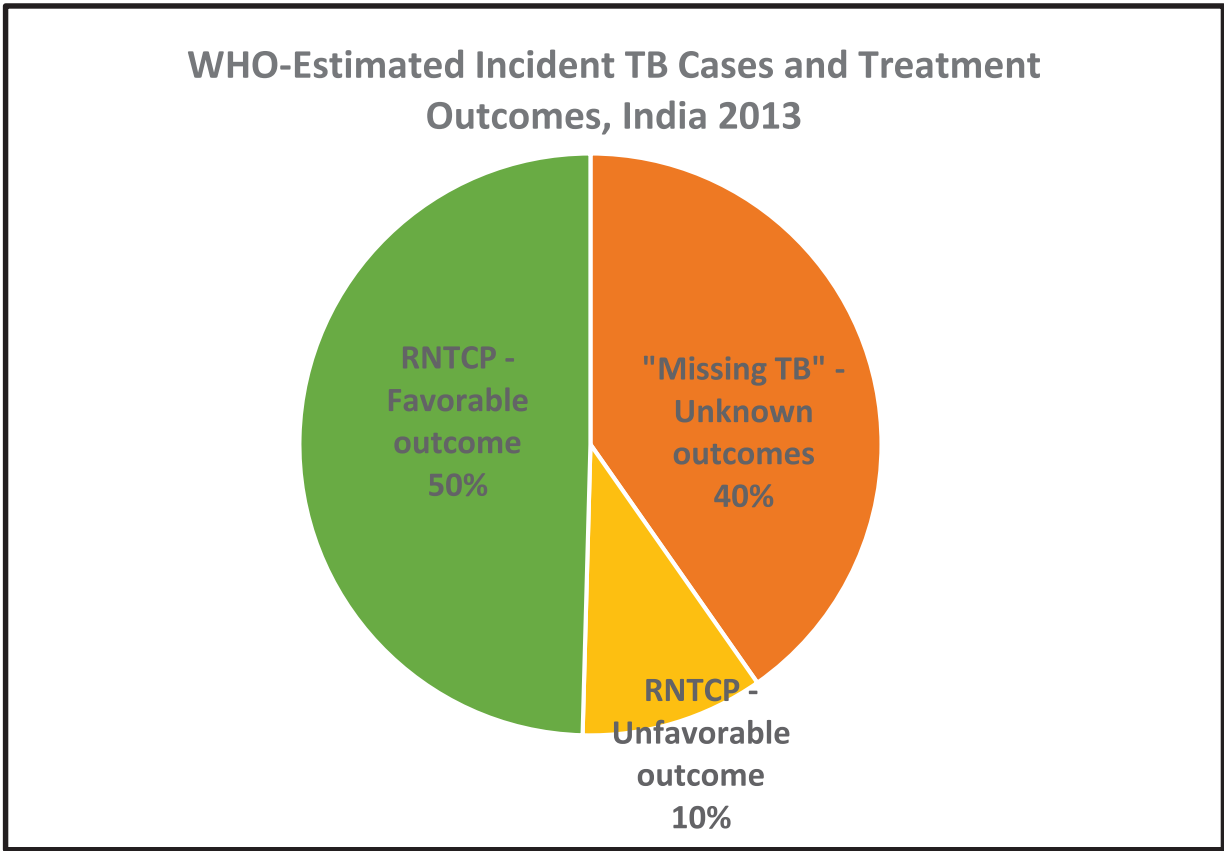
Fig. 15. Examples of innovative products aimed at improving adherence to anti-TB treatment.

Most importantly, several of these innovations are usable by privately treated patients (as long as they are known to the system, i.e. notified) and have interesting potential for development and exportability as “Made in India” products. In light of the interest in social protection mechanisms, the mission was especially encouraged by potential linkages to social support systems, e.g. cash transfers to TB patients as implemented in Kerala for all TB patients, or in socially and economically disadvantaged TB patients in Gujarat.

3.2.2 Challenges

The reported positive treatment outcomes could be falsely reassuring and largely misleading, for two reasons. First, the RNTCP treatment cohort represents only those patients who receive an RNTCP patient-wise box, and does not capture the treatment outcomes of TB treated by private providers, which may constitute a cohort of patients larger than the RNTCP-treated cohort itself (Fig. 16). Second, the reported treatment success outcomes mask unacceptable rates of later relapse and, of even more concern, a high risk of amplification of resistance, to the point of developing resistance to rifampicin during treatment. This was revealed by the RNTCP's own analysis of routine DST results among TB patients with more than one month's treatment, and comparison with follow up, repeat DST with non-MDR drug resistance (Table 7).

Fig. 16. Notional TB treatment outcome cohort, 2013



The details in the figure above are based on WHO-estimated total incident TB figure (2.1 million for 2013), against the number of new and relapse TB cases reported by the RNTCP (1.25 million in 2013), and the proportion of favourable outcomes reported. Note that this estimate for “missing TB” would only account for approximately one third of anti-TB drug sales in the private sector nationwide.

Table 7. Treatment outcomes of mono- and poly-resistant TB cases (other than rifampicin resistant) treated with standard first line anti-TB regimen under RNTCP

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%

Source: Report on National Workshop on Drug Susceptibility Testing (DST) Guided Treatment for Drug Resistant Tuberculosis Patients in India, 26–28 August 2014

Treatment outcomes of HIV-associated TB also remain disappointingly poor, with an unrelentingly high proportion of deaths despite excellent overall coverage of CPT and rising rates of ART during TB treatment (Table 8).

Table 8. Treatment outcomes and rates of initiation of CPT and ART among HIV-infected TB patients, 2011–2013

Year	Cured	Completed	Died	Failed	Lost to follow up	Received CPT	Received 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%	91%
2013	26.9%	49.3%	13.4%	1.2%	6.2%	94%	94%

Source: RNTCP Annual Reports

The JMM also observed a frustrating persistence of poor treatment practices in a few of the visited areas, including selective registration (non-registration of patients perceived likely to be lost to follow up), weak pre-treatment counselling, irregular procurement of ancillary anti-TB drugs and non-standardized care of EPTB. Patients continue to incur high OOP expenditures and loss of wages during DOT, and unsatisfactory reimbursement systems for travel (e.g. as in tribal action plan) are unlikely to be conducive to successful treatment completion.

Opportunities

The JMM observed encouraging movement towards daily anti-TB treatment, although any operational expansion requires an accountable timeline and procurement plan to succeed. 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 intermediate reference laboratories (IRLs) in six states have shown how India can rapidly accelerate implementation when policies, resources, partnerships and administrators are all supportive.

The beginning of TB notification from private providers was welcome. Extending treatment support and monitoring services to patients treated by private providers may be self-reinforcing; with a genuine value proposition for patients and their practices, private providers may be more willing to activate themselves to notify.

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 them. The provisional approval of bedaquiline – with distribution controls – is also a model for how new TB drugs can be rationally introduced, and needs to be met with careful programme planning for rollout. The inclusion of bedaquiline, delamanid and linezolid on the WHO essential medicines list has put pressure on the country to allow access to the few patients who need these drugs. This must be accompanied by controls to prevent irresponsible use, which would otherwise destroy the transformational value of these precious new classes of anti-TB drugs.

3.2.3 Recommendations

Daily dosing

The RNTCP should urgently accelerate implementation of the transition to daily dosing using fixed-dose combinations throughout the country, with a clear timeline addressing the necessary planning and procurements, in line with the STCI.

Daily dosing only reduces the risk of development of resistance, and alone is not a definitive solution, but this is an essential step in averting the potentially ruinous costs of increasing levels of MDR-TB. Furthermore, alignment of the public and preferred private treatment regimens obviates a commonly cited barrier for private providers to refer patients to the public sector for treatment. The Mission recommended avoiding further unnecessary research studies or pilots.

“Test and treat” approach

The RNTCP should introduce the “test and treat” approach with DST as the baseline for all TB patients, and proposed DST-guided regimens.

The End TB strategy advocates DST guidance for treatment and India has developed rational regimens with national experts (daily dosing alone will not eliminate poor treatment outcomes or the development of MDR). The rate-limiting step to implementation of such regimens is the capacity for rapid DST of second line drugs (SLDs), particularly INH and fluoroquinolones, at the district level. The national laboratory scale-up plan will provide interim capacity to proceed with deployment of DST for all TB patients, until the next generation of CBNAAT devices can include SLD testing.

Adherence support and monitoring

The RNTCP should modernize adherence support and monitoring.

The JMM recommends that the RNTCP extend successful models of adherence support and monitoring to TB patients managed by private providers. Including families in treatment supervision is a welcome step. This can be strengthened with standardized counselling tools, including digital platforms for ANMs/AWWs to train patients' families. The existing programme policy of family DOT should be supported by ICT-based systems to monitor DOT providers, such as reminders, e-reporting, and pill-in-hand systems for adherence monitoring. The mission strongly recommends e-payments for honoraria or social support for providers and patients. The Mission recommends the view that DOT is a means to monitor and support adherence, and not an end in itself, and that the RNTCP should move forward with flexibility for new approaches.

Initial risk stratification, management, and follow up

The RNTCP should strengthen initial risk stratification, management and follow up for all TB patients by:

- developing and implementing minimum clinical criteria for hospitalization/specialist consultation (e.g. hypoxic, high respiratory rate, BMI<16, etc.);
- Developing criteria for high-risk patients for encouraging systematic referral to specialist consultants. For example, extensive radiological disease, severe underweight, or comorbidity should indicate early specialist consultation, rather than waiting for clinical failure;
- including therapeutic nutrition for severe undernutrition (BMI less than 16);
- training on pharmacovigilance, and including adverse drug reactions (ADRs) in the recording and reporting (R&R) system;
- developing and implementing simple systematic relapse surveillance, with at least phone calls being made to patient cohorts at 6 and 12 months to ascertain if relapse has occurred. This will be particularly important as a monitoring tool with regimens transition in the programme.

3.3 Childhood tuberculosis

3.3.1 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 STCI published in 2014, and targets within the NSP 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 NTWG on paediatric TB, the National Expert Committee on Paediatric TB etc However, this involvement needs expansion. There has been progress – many activities within the programme are now considering children, as given below:

- **Integration of TB services with the 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 efforts to sensitize childcare providers to the strategies used for TB but the efforts are patchy and inconsistent.
- **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 four 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 with over 95% treatment success rates. However, there are genuine concerns about these weight bands offering low dosages to many children. In order to transition the country to the updated guidelines for paediatric treatment as per the STCI and current WHO dosing guidelines, the Government is planning a pilot in 100 districts of a daily dosing regimen using child-friendly fixed-dose 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 programme 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-16 kg 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.

3.3.2 Challenges

Although the policies required to address TB in children have progressed, implementation 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 programme 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 – a poorly sensitive tool for diagnosis of paucibacillary PTB or EPTB. There is little or no provision for the diagnostic tools children particularly need, e.g. chest radiology, tuberculin skin test (TST) and fine-needle aspiration cytology (FNAC).

Integration of TB Services with the 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 in the states 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 programmes.

Early and intensified case finding. Case finding in children is still low with no improvement for close to a decade (Fig. 11). This is due to several factors including inadequate levels of contact screening, detection of cases being limited 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 programme 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. Included in the programme, the new recommended weight bands and dosages for intermittent therapy are not followed while the programme awaits replacement by the newly recommended daily treatment for which procurement is yet to start. Outside the programme, there are mixed practices for treating and managing children suspected or identified with TB. Quinolones, for example, are often used for drug-sensitive patients.

Drug-resistant TB. Bacteriological confirmation of DR-TB in many childhood forms of TB (particularly EPTB) remains difficult, but even when possible, it is often not performed in young children and in 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. Programme 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 utilization of TB services by childcare providers in both public as well as private sectors as there is little engagement of RNTCP with this sector of health care. There are limited programme schemes to involve private childcare providers. Task forces within medical colleges focus mostly on adult forms of TB, with little or no consideration for 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 to children. There needs to be a specific campaign on preventive therapy for childhood contacts of infectious cases.

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.

3.3.3 Recommendations

If the RNTCP is to successfully address the epidemic of TB in children, they 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 in adult TB that can be used to accelerate the response to childhood TB.

- The RNTCP should leverage other child survival strategies to expand paediatric TB care services, e.g. integrated management of neonatal and childhood illness (IMNCI) packages to cover TB.
- The RNTCP should work out ways to engage with large paediatric institutions, such as in the development of national and state-level model centres 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 protected time to paediatric TB and ensure mandatory representation of paediatricians.
- The RNTCP should take all necessary steps to increase detection and notification of TB in children, including:
 - o capacity building, strengthening of referral services and treatment and linking with molecular diagnostics services;
 - o making use of radiology services in the private sector and setting up the necessary mechanism for reimbursement;
 - o ensuring that a record of contact screening and IPT provision is included in the patient treatment and identity cards and in NIKSHAY.
- The RNTCP should include all care providers in their programme schemes for childhood TB (i.e., X-rays, TST and pathology) and involve school health programmes to help in the identification of children suspected of TB. The RNTCP should ensure that providers receive appropriate training on childhood TB, including DRTB.
- 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 DCGL 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 weekly to daily 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.
- 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 ensure the representation of paediatricians in DR-TB forums.
- RNTCP should specifically address the nutritional gaps for families with children having TB by prioritising and leveraging the existing nutrition supplementation programmes (e.g. mid-day meal) and other social schemes).
- The RNTCP should support the development of a patient's charter for paediatric TB that 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.
- 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 under-reporting.

Research priorities for paediatric TB are given in Table 9.

Table 9. List of research priorities for paediatric tuberculosis

• Health-seeking behaviour of the children (and their caregivers) with presumptive TB and the determinants thereof
• Prospective study of the burden of childhood TB in different parts of India using the new algorithm suggested by the IAP–RNTCP guidelines
• Assessment of trends in case detection of paediatric TB using data available in the RNTCP programme (where and how are they diagnosed, what type of disease?)
• Can pooling of specimens (different days or different specimens) improve yield and efficiency of bacteriological diagnosis among children?
• Is it possible to utilize medical officers (MOs)/multipurpose workers (MPWs) for paediatric respiratory sampling?
• Comparison of pleural fluid characteristics in TB and para-pneumonic effusions
• Understanding nutritional changes prior to and after initiation of ATT among children with TB (weight, BMI, body composition, dietary intake, micronutrient levels)
• Assessment of ADR in children on new drug dosages and combination of drugs
• Assessment of ethambutol toxicity among children on short- and long-term ethambutol-containing ATT regimens
• Study of preventive therapy options for childhood contacts of adults with sputum smear-negative and smear-positive DR-TB
• Evaluation of INH preventive therapy/TB chemoprophylaxis among adolescents with TB infection: safety, adherence, efficacy
• Strategies for identifying TB among childhood contacts (symptom based or investigative)
• Evaluating alternative preventive therapies for childhood asymptomatic contacts
• Evaluation of the immunogenicity of BCG vaccine when given concomitantly with INH among TB-exposed infants
• Evaluation of the tuberculin skin-test response in HIV-infected and non-infected children
• Determination of the rates of adherence to TB treatment, treatment failure, recurrence and relapse in children with and without HIV
• Pharmacokinetic studies for SLDs in children

3.4 TB/HIV and other co-morbidities

3.4.1 Achievements

There has been a slow but steady decline in estimated HIV-related TB incidence and mortality in India since 2004, and the country looks to be on track to achieve the UNGASS and Global Plan targets of halving TB deaths among people living with HIV by 2015. 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 provision.

Concerted efforts to provide a more integrated response have resulted in the co-location of 57% of the country's expanded network of DMCs with HIV care facilities; there are now 7742 co-located integrated counselling and testing centres (ICTCs), 470 ART centres and 960 link-ART centres.

Provider initiated HIV testing and counselling (PITC) among clients presenting with presumptive TB has begun in 194 identified districts. Over a million (72%) registered TB patients knew their HIV status in 2014 – a 25% increase since 2012. The coverage of ART initiation among HIV-positive TB patients has increased by more than 50%, and 91% received ART in 2014. Of these, 70% start ART within 30 days (88% within 2 months). However, some states have lower coverage and 12% of patients start ART after 2 months. CPT coverage increased from 91% to 94% in 2014.

The four-symptom TB screening algorithm was revised and scaled up, mainly in high HIV burden settings. A policy for the provision of IPT among PLHIV identified as eligible by the four-symptom TB screening algorithm was developed in 2012 and is ready for implementation and scale up. The diagnostic algorithm with CBNAAT as the first diagnostic test for PLHIV was revised in 2014 and the national framework for joint HIV/TB collaborative activities was revised in 2013.

The STCI includes a comprehensive package of collaborative TB/HIV activities both within and outside the public sector. A number of good state and NGO initiatives to improve financial and nutritional support for HIV-positive TB patients should soon be taken to scale and be made available for all TB patients. NIKSHAY could provide an excellent opportunity for improved real-time patient follow up and reduce the gaps in the 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. Adoption of the UNAIDS global fast-track 90–90–90 targets for 2020, pushing for 90% of PLHIV knowing their HIV status, 90% of those with known HIV-positive status receiving treatment and 90% of people on treatment with suppressed viral loads will not only prevent HIV-associated TB but will also speed up access to services offering TB prevention, screening, diagnosis and treatment. The Global Fund new financing model and India's joint TB and HIV Concept Note create a framework for expanding TB/HIV activities.

3.4.2 Challenges

An estimated 14% of all TB deaths and a quarter of all HIV-related deaths in India 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 a 15% fatality rate among new cases in 2014.

Whilst joint monitoring and joint supervision is 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 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 total estimated HIV-positive incident TB cases were reported by the RNTCP in 2013; in part, due to low TB case-finding. Recording and reporting of TB screening is not routine in all states.

The algorithm prioritising CBNAAT as the initial TB diagnostic tool for use for PLHIV has not yet been implemented. Stockouts of CBNAAT cartridges lasting 10 months were reported in Andhra Pradesh.

Daily anti-tuberculosis treatment is not yet freely available for PLHIV, despite evidence to show increased relapse, failure and increased rates of acquired rifampicin resistance associated with intermittent TB therapy. Rifabutin is also not yet available throughout the country for PLHIV on ART regimens that include a boosted protease inhibitor. PLHIV attending care facilities for TB and HIV, and PLHIV working in ART centres are exposed to high levels of TB infection due to suboptimal infection control measures. IPT is not yet available for PLHIV in any facility in the country – this is a huge missed opportunity to prevent TB.

Despite efforts to ensure co-location of services, patients still endure lengthy queues to receive more than one service. Patient follow up can be poor, and are without tracking mechanisms between HIV and TB facilities which are not co-located when patients go missing in search of HIV testing or TB investigations. Not all private practitioners are aware of, or carry out, HIV testing and counselling among TB patients.

3.4.3 Recommendations

A much bigger 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 if India is to make significant progress in reducing this dual epidemic – never mind meeting the goals of the NSP Plan or the targets set out in the End TB Strategy.

- The RNTCP and NACP should strengthen coordination at state and district levels and implement regular joint supervisory visits and periodic reviews in all states, districts and sub-district levels, including those with low prevalence of HIV. They should identify areas of linkage loss and set up mechanisms to address the gaps.
- The RNTCP and NACP should intensify the TB/HIV response in line with the shifting dynamics of the HIV epidemic. This includes efforts to increase the proportion of PLHIV diagnosed, as early as possible, through the expansion of community-based HIV testing services, including the use of trained lay providers and use of rapid diagnostic tests accompanied by TB screening, in districts and hotspots with high or increasing HIV incidence/prevalence, as well as among key populations affected by HIV.
- The RNTCP and NACP should conduct operational research and data analysis to:
 - o determine the reasons for higher TB case fatality rates among HIV-positive patients compared with HIV-negative patients;
 - o assess the burden of HIV-associated TB and ways of improving access to services for key populations at risk of TB and HIV, especially prisoners, people who inject drugs, and sex workers;
 - o consider integrating TB services into the Adolescent, Reproductive and Sexual Health (ARSH) programme under NHM.
- The RNTCP and NACP should ensure that the systematic screening for TB, and the recording and reporting of this screening, are carried out among PLHIV in HIV facilities, including in MCH facilities.
- As stated elsewhere in this report, the MoHFW should expedite, without further delay, the procurement and placement of CBNAAT as the first test for TB diagnosis for PLHIV. It should also ensure a sustained supply of cartridges and the procurement of daily anti-tuberculosis treatment for nationwide implementation, to reduce the development of drug resistant TB in PLHIV, and according to the STCI. The NACP should roll out the prescription of daily anti-tuberculosis treatment by ART MOs nationwide, beyond just the 30 ART pilot sites, and improve procurement and distribution of rifabutin for use on all patients taking boosted protease inhibitor (PI)-based ART.

- The RNTCP and NACP should expedite, without further delay, the procurement and distribution of IPT for nationwide implementation, ensuring a sustained supply and monitoring and evaluating uptake and adherence to IPT by PLHIV, according to the National TB/HIV framework.
- The RNTCP and NACP should coordinate exchange of data more, and consider the inclusion of referral, TB screening and IPT in PLHIV within the new electronic recording and reporting system (NIKSHAY) for use by the HIV services.
- The RNTCP and NACP should implement the Guidelines on Airborne Infection Control in Healthcare and Other Settings.²³ They should also expand training to all cadres of staff in facilities providing HIV and TB care, and monitor TB infection control (TBIC) and HIV infection control (HIVIC) practices in facilities providing HIV and TB care during supervisory visits, including regular reporting of TB cases among health-care workers in any health facility.
- The RNTCP and NACP should build on ongoing initiatives for co-location and decentralization of HIV testing and counseling and ART services with DMCs, and move towards more patient-centred care that offers HIV testing (all three tests) as well as ART initiation at sub-district level in high-prevalence HIV districts (category A and B).
- The NACP and RNTCP should ensure the scale-up of provider-initiated HIV testing and counselling in 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. They should also develop and implement a strategy to ensure HIV testing of TB patients by private practitioners and linkage to care and support services.
- The NACP and RNTCP should initiate ART on time in all HIV-positive TB patients along with systematic recording and reporting, and adopt the WHO recommendation to start ART in the first 2 weeks of TB treatment in HIV-positive TB patients with CD4 count < 50 cells/mm³.
- The RNTCP and NACP should 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 practices.

3.4.4 Other comorbidities

Diabetes mellitus

An estimated 63.1 million persons are affected by diabetes mellitus (DM) in India, the second highest burden in the world. In 2013, the India Tuberculosis–Diabetes Study Group found a DM prevalence rate of 13% among TB cases – 10% in North India and 20% in South India. This compares with a 2007 study that estimated 15% of pulmonary TB and 20% of smear-positive TB as attributable to DM among adults in 2000.²⁴ Another study in 2013 found the TB prevalence²⁵ rate among DM patients less than 1%. Newly diagnosed TB patients were much fewer at 0.17%. Diabetics 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 use tobacco, compared with 35% of the general population. Smoking is strongly associated with increased rates of TB infection and with more rapid TB disease progression and poorer prognosis. Experience from Gujarat has provided evidence that “brief advice” for tobacco cessation can be easily and successfully incorporated into RNTCP activities.

²³Directorate General of Health Services. Guidelines on Airborne Infection Control in Healthcare and Other Settings. New Delhi:MoHFW;2010 (http://www.tbcindia.nic.in/pdfs/Guidelines_on_Airborne_Infection_Control_April2010Provisional.pdf).

²⁴Stevenson CR, Forouhi NG, Roglic G, Williams BG, Lauer JA, Dye C, Et al. Diabetes and tuberculosis: the impact of the diabetes epidemic on tuberculosis incidence. BMC Public Health. 2007;7:234 (<http://www.biomedcentral.com/1471-2458/7/234>).

²⁵India Diabetes Mellitus – Tuberculosis Study Group. Screening of patients with diabetes mellitus for tuberculosis in India. Tropical Medicine & International Health. 2013;18:646–54 (<http://onlinelibrary.wiley.com/doi/10.1111/tmi.12083/full>).

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 is up to 39 times more common among silicosis patients than the general population and occurs in 29–39% of silicosis patients in Indian studies.²⁶ The major industries placing workers at risk of silicosis in India are 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 study in 2012 at eight tertiary care centres showed the feasibility of bidirectional screening of DM and TB. As a result of findings from the pilot study:

- directives were sent from the CTD to the NPCDCS to screen all TB patients for DM in 142 districts where NPCDCS operates. No directives have yet been issued for the screening of four symptoms of TB among DM patients, but discussions have started at the Central level to work out how to screen for the symptoms of TB among DM patients and cross refer them for further investigation, if required;
- the RNTCP in collaboration with NPCDCS initiated the development (nearly finalized) of a collaborative DM/TB framework, and diagnostic, training and monitoring guidelines;
- routine DM screening among MDR-TB patients is conducted nationwide;
- the National Action Plan and Monitoring Framework for prevention and control of NCDs aims to reduce the prevalence of tobacco use by 25% and alcohol use by 10% by 2025. This provides a good opportunity to collaborate and mainstream TB into efforts to reduce alcohol and tobacco use;
- silicosis is a notifiable disease under the Mines Act 1952 and the Factories Act 1948, although not yet in the 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 by 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 the notification system is weak.
- 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

- The RNTCP and NPCDCS should finalize and implement the national TB/DM framework nationwide, set targets to promote uptake of activities, finalize the TB/DM monitoring and evaluation guidelines and make the recording and reporting of DM and TB coinfection routine.
- The RNTCP is encouraged to scale up the inclusion of tobacco use screening and cessation counselling nationwide as an integral component of TB care in India.
- The RNTCP should develop and implement a multisectoral 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 TB among silicosis patients and workers in silicosis-risk industries.

²⁶Silicosis - An Uncommonly Diagnosed Common Occupational Disease. ICMR Bulletin. 1999; 29(9) (<http://icmr.nic.in/busep99.htm>). Sikand BK, Parma SP. Preliminary report on the occurrence of silicosis amongst stone masons. Proceedings of the seventh Tuberculosis Worker's Conference, Bombay 1949.

Tiwari RR, Sharma YK, Saiyed HN. Tuberculosis among workers exposed to free silica dust. Indian Journal of Occupational and Environmental Medicine. 2007;11(2):61-64. doi:10.4103/0019-5278.34530.

Detection of silicosis among stone mine workers from Dholpur district, February 2014. <http://www.indianet.nl/pdf/DetectionOfSilicosisAmongStoneMineWorkersFromDholpurDistrict.pdf>

- The RNTCP should assess the burden, and yield and impact of screening for, and addressing TB, among other clinical risk groups e.g. those on immunosuppressive therapy, with alcohol dependence, viral hepatitis, and/or vice versa, and develop and implement strategies accordingly.

3.5 Programmatic management of drug-resistant TB (PMDT)

3.5.1 Achievements

An understanding of the epidemiology of drug resistance is beginning to emerge in India (see Epidemiology section 2.6). The RNTCP started implementing PMDT in 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 laid. They aimed to develop 43 line-probe assay (LPA) laboratories (with 33 liquid culture DST systems) and 120 DR-TB treatment centres, and place at least 40 000 MDR-TB patients on treatment annually by 2014. After a modest start, the expansion of PMDT services has accelerated since 2011, and achieved complete geographical coverage in March 2013 (Table 10). Presumptive MDR/rifampicin resistant TB (RR-TB) cases (Criteria C) in 2015 are:

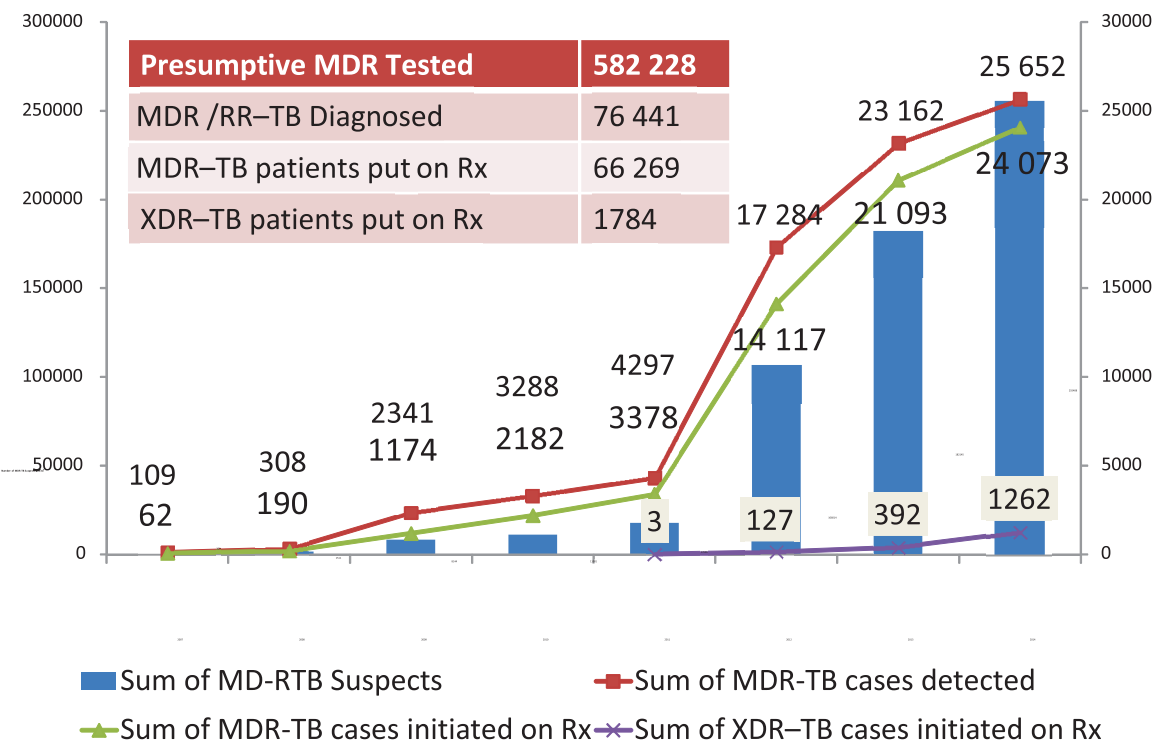
- all pulmonary retreatment TB case at the time of diagnosis
- any pulmonary TB case that is positive by direct smear on follow-up
- all HIV–TB co-infected cases at the time of diagnosis
- contacts of known MDR/RR–TB cases.

Table 10. Expansion of drug resistance service components, 2011–2015

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

Improved access to laboratory diagnosis has enabled initial diagnosis of MDR-TB or rifampicin-resistant TB (RR-TB) by rapid molecular test (CBNAAT or LPA), and a baseline second-line (SL) DST was introduced in six states (Delhi, Gujarat, Karnataka, Kerala, Maharashtra, Tamil Nadu), with a strengthened MDR-TB treatment regimen if ofloxacin or kanamycin resistance was detected. Treatment is largely ambulatory with standardized regimens for MDR-TB through 127 DR-TB centres and 50 linked DR-TB centres. The number of MDR/RR-TB cases detected and started on treatment has increased from 3378 in 2011 to 25 335 in 2014 (Fig. 17).

Figure 17. Presumed and identified cases of MDR/RR-TB, with numbers started on treatment, 2007–2014 (graph and bar chart) and cumulative numbers of cases diagnosed and started on treatment (table)



Source: RNTCP data

Thirteen private and 80 IPAQT laboratories have been engaged, and around two thirds of the DR–TB centres are located in medical colleges. Support systems for MDR–TB patients are available through various state specific initiatives and National Health Insurance Policy (RSBY) in Chhattisgarh. National policy is based on evidence. Field studies are planned on:

- the use of CBNAAT and its positioning in the diagnostic algorithm (prioritized for diagnosis of TB among PLHIV, children, suspected EPTB and smear negative PTB);
- DST-guided treatment to address variants of DR–TB to improve outcomes.

Further scale up was planned in the NSP 2012–17 and the RNTCP expects to treat about 160 000 MDR–TB and 4100 XDR–TB cases between 2012 and 2017. The RNTCP recently updated and revised the National Laboratory and PMDT scale-up plans 2015–2019, which now aim for universal DST and DST guided treatment to at least 90% of all forms of TB cases and building management capacity to enable the treatment of at least 60 000 MDR–TB cases annually.

Of the PMDT related recommendations from the JMM 2012, three have been achieved, three have only partially been achieved, seven are ongoing and one was not done.²⁷ On infection control (IC), one recommendation has been achieved and two were not done.²⁸

²⁷ 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; one culture examination only 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. Not done (1): WHO 2011 recommendations on MDR–TB treatment duration not considered. 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.

²⁸ 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. 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 is complete, but no research on this area has yet been conducted. Not done (2): AIC guidelines not yet updated since 2012 edition; and AIC guidelines not integrated into the Indian Public Health Standards and MCI requisitions for the recognition of medical colleges.

3.5.2 Challenges

The drivers of the DR-TB epidemic are still not well understood. PMDT activities at the state level and DR-TB centres at the district level are irregularly reviewed. The expansion of laboratory capacity and the diagnosis and treatment of MDR/RR cases has not gone as far or as fast as originally planned (25 335 M/XDR-TB cases started treatment in 2014, against the NSP target of 30 000); and the diagnosis/treatment gap is about 5000 cases each year.

Presumptive MDR-TB case identification is insufficient (only 60% of those eligible were tested in 2014), in spite of the existing laboratory capacity for molecular DST (LPA and CBNAAT) remaining underutilized in many sites. Time to treatment initiation varies and can take up to 3 months in some districts, although in most districts times have 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 initial phase (IP) and/or non-switching of patient on to an XDR-TB regimen in some cases. In the cohorts up to 2012, when rapid diagnostics were unavailable, half the patients had unfavourable outcomes (about 20% died, 20% were lost from treatment and 8% failed treatment). The unfavourable outcomes were associated with the following factors: prior treatment episode, initial ofloxacin resistance among MDR/RR-TB cases at the time of diagnosis, under-nutrition (BMI<18), cavitating disease and poor adherence (>7 days missed doses).

Studies have shown high levels of H mono-resistance in new (11%) and previously treated cases (30%), and 30% of MDR-TB cases had baseline FQ resistance. The JMM heard allegations of weak patient counselling, pre-treatment evaluation, ADR management and declining supervision and monitoring at all levels under the programme. As others have noted, surveillance and entry of the MDR-TB data under NIKSHAY is incomplete, which greatly limits its utility.

The JMM observed interrupted supplies of some SLDs (levofloxacin, kanamycin). FLDs and SLDs were available over the counter while drug controllers were not enforcing Schedule H/H1. There was limited implementation of airborne infection control (AIC) measures at all levels of the health services.

Medical college engagement is suboptimal; not all medical colleges have a DR-TB centre and laboratory, and they were conducting minimal TB related research. Irrational prescription practices for TB and DR-TB continue in the private sector and the STCI and partnership guidelines were not widely disseminated.

Enablers and incentives for patients, families and health-care workers were few, and there was limited awareness of, and linkages to, social support systems for patients and families. The funding required to carry out the scale-up plans (2014–19) was not fully estimated, much less secured.

3.5.3 Recommendations

- The JMM recommends that the RNTCP carry out a study to understand the drivers of the DR-TB epidemic, including whole genome sequencing where appropriate. In addition, they should explore how the burden of DR-TB in the private sector can be assessed (by end of 2015).
- The RNTCP should strengthen the e-health management information system (e-HMIS) 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 the end of 2015.

- The RNTCP should address the factors associated with unfavourable treatment outcomes and should:
 - continue building capacity to offer DST at diagnosis in all TB patients, with prompt initiation of appropriate treatment;
 - promote and monitor STCI in the private sector;
 - modify treatment according to DST results, keeping in mind the variable reliability of the DST against some drugs, notably the bacteriostatic agents;
 - ensure timely payments of enablers and incentives as per existing policy, and offer nutritional interventions to patients and their families where appropriate;
 - strengthen adherence monitoring and support via counselling, pharmacovigilance 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 towards universal DST as per the NSP 2012–2017 to cover the following:
 - o priority groups (PLHIV, paediatric age group, EP-TB and smear negative PTB) to be tested with rapid molecular diagnostic methods (CBNAAT) as part of the diagnostic algorithm, with strengthened supervision and monitoring of PMDT services across the whole of the country by the end of 2016;
 - o baseline DST plus initial second-line DST for all detected MDR/RR-TB cases (by the end of 2016);
 - o DST for isoniazid (H) and rifampicin (R) in all registered TB patients using rapid molecular tests (CBNAAT/LPA) by the end of 2017; and
 - o any detected H-/RR-/MDR-TB cases to have DST guided treatment using rapid molecular tests and liquid culture (to be guided by results of the five district pilot).
 - consider revisiting treatment duration as per the WHO 2011 PMDT guidelines; and
 - introduce new drugs as per WHO recommendations (bedaquiline and delamanid).
- The RNTCP should continue to procure SLDs at the Central level for the entire country to achieve economies of scale and ensure an uninterrupted supply of quality assured SLDs.
- The MoHFW should strengthen the mechanisms for engagement of all uninvolved medical colleges in RNTCP's PMDT activities, and enable private providers to have access to RNTCP's network of rapid diagnostic laboratories. Similarly, laboratory services may be outsourced to RNTCP certified private laboratories as per the partnership guidelines wherever necessary.
- The MoHFW should support better linkages for MDR-TB patients and families to social support schemes such as the RSBY, additional nutrition through public distribution systems, etc.
- The RNTCP and the TB research network should consider the following research topics:
 - A rapid validation of SLD LPA susceptibility tests
 - Implementation research on shorter DR-TB regimens
 - Assembling the evidence for the treatment of H mono-, and poly, non-MDR resistance
 - Pre- and post-treatment DST for cases receiving daily FDC treatment to study 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
 - The frequency and severity of post-treatment sequelae
 - The impact of molecular TB diagnostics on patients' outcomes, in addition to access to diagnosis and treatment
 - Document and disseminate the PMDT related experiences of RNTCP on the global stage.

3.6 Target interventions for special groups

3.6.1 Achievements

Diversity in India extends to the epidemiology and impact of TB. The NSP 2012–2017 recognized such diversity and identified special populations that need greater attention and targeted interventions in order to reach the goal of universal access. The NSP focused on enhanced outreach, increased coverage and effective monitoring of services, all for special populations. However, these populations continue to face increased risk to TB, have barriers in accessing care and require more attention, especially for purposes of equity, social justice and human rights.

The NSP and other policy documents articulate well the need for targeting special groups. Relatively good plans have been drafted for selected special groups, although they have not yet been fully implemented. A special tribal action plan has been part of the policy and implementation for a number of years. This JMM noted and appreciated special efforts and projects, such as in urban slums in Mumbai, the Saharia population, Tibetan refugees, district level support programmes in partnership with NGOs and a number of other local level initiatives.

3.6.2 Challenges

There are groups facing increased risk due to biological or behavioural factors which compromise immune function, groups that face increased risk due to where they live or work, and groups that face risk due to limited access to health services. Studies have highlighted a very high burden of TB among certain population groups in the country. For example, the Saharia tribe has a TB prevalence of 1.5%,²⁹ the Tibetan population has high rates of TB and five times higher rates of MDR-TB.^{30,31}

The scale of the implementation to date has matched neither the plans, nor the need. There are three main reasons for this. Firstly, there is a lack of systematic mapping and identification of special groups that results in reactive and ad hoc actions. Secondly, although there are good intentions to do more for these special groups, there is lack of clarity on what additional efforts are required and how to implement them. Thirdly, the shortage of funding and late arrival of funds leads to plans not being implemented; when money is scarce, these activities (together with community engagement) get the lowest priority.

3.6.3 Recommendations

- The RNTCP should fund and implement planned activities for special groups as described in the NSP and other policy documents.
- Each state and district should map and define its special groups, identify interventions and budget them.
 - o Review information available within other health and social welfare programmes and consider studies to better estimate impact and determinants of TB in priority groups.
 - o The JMM 2015 thematic group has suggested an approach for identification of special groups in Table 11.

²⁹Rao VG, Gopi PG, Bhat J, Selvakumar N, Yadav R, Tiwari B, et al. (2010) Pulmonary tuberculosis: a public health problem amongst the Saharia, a primitive tribe of Madhya Pradesh, Central India. *International Journal of Infectious Diseases*. 2010;14(8):e713–6 ([http://www.ijidonline.com/article/S1201-9712\(10\)02347-7/abstract](http://www.ijidonline.com/article/S1201-9712(10)02347-7/abstract)).

³⁰Bhatia S, Dranyi T, Rowley D. Tuberculosis among Tibetan refugees in India. *SocSci Med*. 2002;54 (3):423–32.

³¹Salvo, F. et. al., (2014) 'Survey of tuberculosis drug resistance among Tibetan refugees in India', *The International Journal of Tuberculosis and Lung Disease*, 18:6, 1 June 2014, p. 655-662.

Table 11. Risk group categories and descriptions

Risk group categories	Detailed examples of those within risk group categories
People at increased risk of TB because of biological or behavioural factors that compromise immune function	People living with HIV, diabetes, some forms of malignant disease (even without cytotoxic treatment), or silicosis; people undergoing immunosuppressive therapy, people who are undernourished, smokers, alcohol abusers, or people who use drugs
People who have increased exposure to TB bacilli due to where they live or work	People living in urban slums, contacts of TB patients, or prisoners; workplaces that are overcrowded, without ventilation; health-care professionals, hospital staff and hospital visitors
People who have limited access to health services	People from tribal populations, migrant workers, people who are homeless, women in some rural areas, children, refugees, hard-to-reach areas, fishermen, old peoples' homes, homes for people with mental or physical disabilities or people facing legal barriers to access care

- The RNTCP should identify and work with other government agencies (in health and beyond the health sector) and NGOs that serve special groups, at national, state and district levels, and act on opportunities for integrating TB services within other health and social welfare programmes.
- The RNTCP should use different models to reach the special groups and diagnose TB. The mission thematic group suggests four models (Table 12). It is recommended that these be quickly finalized and used.

Table 12. Models for ways to reach special population groups at risk for tuberculosis

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> House-to-house information and identification of presumptive cases Referral of presumptive cases or specimens to diagnostic facilities Either ongoing throughout the year, e.g. by integrating into MCH outreach services/or 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 Ongoing 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.
<u>Model 4: Managing co-morbidities</u> Bidirectional screening Treatment for both conditions	PLHIV, diabetes, undernourished population, smokers

- Recognizing that some of these groups face different challenges in adhering to, and completing treatment, the RNTCP should consider improving treatment adherence by the following actions:
 - o Systematic counselling and psychosocial support
 - o Training of health staff on counselling, use of call centres and radio
 - o Treatment at home or in the community with flexible treatment support mechanisms
 - o Implement new rates of incentives approved by the Ministry
 - o Better payment mechanisms for treatment supporters and patients.
- The RNTCP should address the socioeconomic issues that constrain the ability of special populations to get good care for TB:
 - o Awareness generation customized to the needs of the group with a focus on stigma reduction
 - o Provide travel allowance for accessing TB care
 - o Reimbursement of OOP expenses of patients
 - o Make all TB patients and their families (and community) eligible for nutritional schemes and actively facilitate access
 - o Work with NGOs and other government agencies for social and economic rehabilitation of patients.
- The RNTCP should implement tools and enablers that are needed to target interventions for special groups:
 - o Use of best diagnostics and most efficient diagnostic algorithms
 - o Notification should include information on special sub-groups
 - o Important programme indicators to be disaggregated by special groups – NIKSHAY should facilitate this
 - o Implement e-payment for incentives
 - o Link TB information with Aadhar card/UID.
- To ensure long-term impact, the RNTCP should empower communities and build their capacity to own and lead the fight against TB in their own community.

4

Reports from the field visits to the states

4.1 Andhra Pradesh

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

4.1.1 Case finding

There was a slight increase in total presumptive cases examined annually (2.8%), with a big dip in 2013 due to civil disturbances, but it rebounded in 2014. Total case notification rate fell gradually from 2012 to 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 their use for diagnosing smear-negative and paediatric TB in the public sector. There are two CBNAAT machines functioning (five are in the process of being set up) and the full procurement of NSP amounts are likely to be close to 15 machines. A cartridge stockout from May 2014 to 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 the 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: There are 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 need 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.

4.1.2 Drug-resistant tuberculosis

The district TB officers (DTOs) are trained in PMDT at the national Level. The district drug store was upgraded for temperature control. The DR-TB services are well integrated with the general health system where ANMs, ASHAs, AWWs, and the Deputy DM&HO are directly supervising and monitoring the programme.

Challenges: Local NGOs are not optimally utilized, and contact screening is not always happening unless the patient is symptomatic, and that too only when an additional provider is involved.

Recommendations: To engage NGOs as per National Guidelines for Partnership for Integrated Services for TB, DR-TB and HIV and carry out systematic contact tracing for early diagnosis of DR-TB.

4.1.3 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 groups. 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 the NSP for case detection. The transportation of specimens to the labs is not optimal.

Recommendations: Engage additional labs in the NGO sector which have capacity to provide services under various partnership options (LPA, liquid and CBNAAT available). 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 transportation system to the labs needs to be strengthened.

4.1.4 Paediatric TB

Paediatric TB in Hyderabad ranged from 10% to 12% in two Qs of 2014 and then fell; in AP it fell from 4.2% to 3.8% between 2012 and 2014. Partnership is encouraged with private paediatricians in Hyderabad who are given access to the public sector CBNAAT machine.

Challenges: Paediatric case finding is not optimal (below NSP target of 9%). Paediatricians are available at area hospitals but are constrained due to lack of X-rays. Sporadic linkages exist with private paediatricians for improving notifications. Not all are aware that TB is a notifiable disease. There are shortages of paediatric TB formulations and lack of state institutions for research.

Recommendations: Improve case finding through newer molecular tools and linkages with PHCs, e.g. induced sputum and gastric aspirate. Ensure access to X-ray machines either by the public or private sector. Systematic engagement and rollout should be done using the Hyderabad example. Raise awareness of mandatory notifications. Ensure buffer stocks are in place and develop centres of excellence for research in paediatric TB.

4.1.5 TB/HIV and other comorbidities

- HIV testing among TB patients was scaled up from 88% in 2012 to 98% in 2014;
- ART coverage among HIV positive TB patients: 83%, though no increase since 2012;
- Sustained universal coverage of CPT over 3 years;
- Ninety-four per cent colocation for designated microscopy centres and integrated counselling and testing centres;
- OR 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 testing of presumptive cases across the state 88%;
- Diagnostic algorithm with CBNAAT as the first diagnostic test for PLHIV not being used;
- IPT and daily anti-tuberculous treatment (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 needed;
- 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.

4.1.6 Involving all care providers

Provision of continuing medical education (CME) to private providers increases engagement, referrals, notification and care. A total 8938 cases were notified of NIKSHAY by private practitioners for the entire State.

Challenges

Involvement of the private sector at a scale commensurate with their presence in AP is not evident. The private sector has limited incentive for TB care and control, and the capacity of the programme to engage with private providers is limited. There is a lack of involvement of the AYUSH doctors.

Recommendations

There is a need to involve the private sector throughout the cascade of care. Strengthen HR and technical capacity within the Programme to engage with private practitioners. Expedite rollout of daily FDC and develop a strategy for broader engagement of other public sector bodies. AYUSH doctors as well as community pharmacists should also be more involved.

4.1.7 Procurement and logistics

All anti-TB drugs (first line, second line and XDR drugs) with the exception of PC-13 are available at all stocking points. There is good documentation. Physical verification following good storage and distribution practices was in place. Temperature and 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 FLDs in Vizianagaram. The current space for the district stores is not always adequate. There is no state drug store in new Andhra Pradesh. The adverse drug reaction (ADR) data is not recorded.

Recommendations

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

4.1.8 Human resources for health

A high sense of motivation and devotion of the staff and the medical officers met by the teams was observed among ASHAs, ANMs, AWWs, senior TB laboratory supervisors (STLSs), senior TB treatment supervisors (STs), etc. ASHA workers are more involved in TB and more accountable under the incentive scheme.

Challenges

- Objectives for HR in NSP are not met; on average vacancies are at 60%, increasing 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

- Review vacancies at state and district levels (especially STSs of TB units);
- Concerned authorities to speed up the recruitment process;
- Establish a state training and demonstration centre for TB with a suitable drug store;
- 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 are available to facilitate a sustained and motivated workforce;
- Provide enhanced training and career opportunities for ASHAs.

4.1.9 Financial support for TB control

The programme conducted essential activities within limited available resources due to bifurcation formalities and new system of release through the treasury route. Presently, the state and districts have funds for the next 6–9 months.

Challenges

There is 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 was not well aware of financial management guidelines and procurement procedures.

Recommendations

Eliminate delays in making funds available for TB control to the district TB societies. The state should provide the DTO with an imprest account so that urgent day-to-day expenditures can be incurred. Working group at state level should address administrative problems and bottlenecks.

4.1.10 Support systems for patients and families

Integrated Tribal Development Agency offered protein-rich food worth INR 500 for every tribal patient going up to 220 patients by December 2014; financial assistance of INR 300 per month per patient was offered to 20 patients by TB association of Andhra Pradesh; ICT enabled Aadhar card (unique personal ID) linked tool is being piloted for the poor to instantly list out all social benefit schemes for which TB patients are eligible; HIV-positive TB patients receive INR 1000 per month; and 50% bus pass compensation and nutritional support is given to ART centres.

Challenges

- The initiatives offering financial, nutritional and systematic support are not to scale as per the 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;
- Post diagnosis, there is some evidence of discrimination by both family and community.

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.

4.1.11 Targeted interventions for special groups

All ASHAs and AWWs in tribal areas have been trained and were providing services, despite the remote rural locations. The tribal patients approach the ASHAs rather than traditional healers when experiencing persistent cough. The Integrated Tribal Development Agency offered protein rich food worth INR 500 for every tribal patient. NGO support was provided for people in urban slums for completion of treatment in Chittoor (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, the elderly, tribals, migrants, industrial workers, etc. to inform focussed response and community-involved interventions for early case detection and treatment support. Develop a strategy for NGO engagement to address TB in identified key populations and NACO-targeted interventions for key populations affected by HIV.

4.1.12 Community engagement, ACSM

There is involvement of Panchayat Raj through community meetings in some areas visited, as well as sensitization and involvement of community leaders in DOT (for follow up) in some of the areas visited. There are limited advocacy programmes with district agencies, industry and priority government departments. Print and electronic media advocacy is visible.

Challenges

- Most NGO involvement is in TB/HIV activities and on MDR-TB but there is 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;
- SHGs identified as an outlet for advocacy dissemination. Not all SHGs were well informed about TB and the programme.

Recommendations

- Develop a strategy and framework for sustained and systematic NGO engagement and systematic sensitization of all panchayats and community leaders;
- Implement extensive promotion of services in the regional language;
- 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 programmes.

4.1.13 Research

The following OR were conducted in Vizianagaram district: a) Linking HIV-infected TB patients to co-trimoxazole prophylaxis and ART; b) Feasibility and effectiveness of provider-initiated HIV testing and counselling of TB suspects; c) Screening of patients with TB for DM. These OR led to policies at the National level in the programme. They are being implemented and are current practice across the country.

Challenges: Currently, research is not part of the programme core.

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

4.1.14 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;
- 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 HR 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.

4.1.15 State level briefing

Increase case finding

There is a need to increase case finding by the following measures:

- Expand the radiological services available in the districts to ensure CXRs for the diagnosis of smear negative TB;
- Work more closely with the private sector to support mandatory notification and ensure all cases diagnosed in the private sector are notified;
- Develop and implement a plan that recognizes the primacy of NGOs in outreach and prevention and works closely 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;
- Increase contact tracing and IPT for under-5 contacts;
- 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 senior TB supervisors; establish state training and demonstration centre for TB plus drug store.

Ensure adequate funding is available for TB control: Eliminate 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 among poor people as well as MDR-TB cases.

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

4.2 Gujarat

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

Jamnagar, Mehsana and Banaskantha Districts were visited. The team visited two district TB Centres, seven TB units, one medical college, TB Culture and Drug Susceptibility Testing (C&DST) laboratory and DR-TB Centre, one sub-district hospital, five CHCs, six PHCs, six designated microscopy centres, two ICTCs, three FICTCs, four drug stores, two NGOs, one corporate hospital (DMC), 15 private practitioners, 12 chemists and 20 TB patients at district and sub-district level.

4.2.1 Achievements

The state has the highest level of administrative commitment which is reflected in budgeting, expenditure, procurements, HR under RNTCP, reviews and process measures undertaken to ensure programme quality. All TB units are aligned with blocks/talukas and optimum numbers of TB units are established in urban areas. The State has proactively implemented OR, pilot interventions such as Universal Access to TB Care (UATBC) in Mehsana and conducted state-funded TB prevalence surveys.

Case finding in public health facilities is strong. The State has made proactive efforts to increase access to microscopy services by expanding its DMC network from 765 in 3Q14 to 850 in 4Q14. A proactive approach for TB case finding has been initiated in 2014. Enhanced case finding activities with house-to-house visits by health workers was conducted in high case load TUs. Systematic active TB screening activities are carried out in a few districts. There has been enthusiastic early response on private notification as reflected with increase in trend to more than 5000 patients notified in 1Q15. 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 an 8-month period with stable notification from the private sector.

The State has an 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. The 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 are effectively utilized in cold chain for diagnosis and follow up of DR-TB patients to cover all districts at six laboratories.

Treatment offered to TB patients is of high quality. The State has been able to establish excellent and diverse decentralization of DOT services. Intensive efforts are put in to control initial loss to follow up. The State has efficient implementation and statewide expansion of PMDT. Facilities for TB-HIV collaborative services are well implemented and services for TB-DM are gaining momentum.

The programme has 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. A much appreciated social welfare scheme stands implemented across the board in the State. Through this, TB patients from SC, ST or OBC castes are given INR 500 per month. There is a movement in many districts to mobilize local resources to extend nutrition support to TB patients. The state has good absorption capacity and expenditure in TB control has grown 38% in real terms during the period 2012–2015, with efficient fund disbursement.

4.2.2 Constraints

The NSP recommendation on HR has been implemented, but HR needs are not yet fully met. The number of patients that have to be handled by one STS range from as low as 19 to as high as 170 in visited districts. Moreover, in areas of high caseload, comorbidities, drug resistance and 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 the state-conducted TB prevalence survey. Patients are missed from surveillance, as 30% of bacteriological positive cases have not yet sought care for their symptoms (TB Prevalence Survey- Gujarat). There is a huge private sector, which includes allopathic and non-allopathic health providers. On preliminary analysis of anti-TB drugs sales in Gujarat, it was estimated that at a given time approximately 60% of TB patients 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 in 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. There is little use of NIKSHAY as periodic reports are not generated and interface is not user-friendly, requires repeated downloads into separate files and lacks flexibility.

ACSM is restricted to conventional activities like community meetings, patient provider meetings, wall paintings, etc. In the visited district, 26% patients were given benefit of the social welfare schemes. However, nearly every TB patient interviewed claimed eligibility. Moreover, the process to avail social welfare scheme support is cumbersome. Nutrition support to TB patients is a welcome move but RNTCP cannot become another public distribution system.

There is a growing gap between needs and budget allocated as against planned and approved. Pressure is on the State to finance the gap. The State's share has gone up from 0 to 32% in the last 3 years. There has been gradual slowing down of flow of funds. Funds releases have shifted towards the last month of the year, presenting challenges to timely expenditure. This is partly due to delay in funds flowing to the State Health Society from an average of 1.5 weeks in 2012–2013 to 10 weeks in 2014–2015.

4.2.3 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 programme 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 anti-TB drug sales in Gujarat has suggested that on any given day, for every two TB patients treated by RNTCP Gujarat, three 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 universal access to TB care (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 increase in the budget. In addition, targeted screening in high-risk groups should be conducted, leveraging health staff for active case finding in slums and other high-risk groups, along with systematic

contact screening using sensitive tools like CXR/LED/CBNAAT. We recommend tracking metrics of the percentage of targeted providers who notify in the last quarter, and the percentage of estimated privately treated patients notified (using models or private drug sales surveillance).

The JMM further recommends strengthening social support services. Gujarat has laudable, country-leading social support initiatives. However, 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, both public and private. Lastly, the JMM recommends intensifying community awareness, engagement and empowerment, in particular to deploy a 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 state commitment and resource requirement.

4.2.4 Specific recommendations

Health system and HR

- 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 and extend public health services to patients diagnosed and treated in the private sector. Flexibly reallocate 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 should be supported by initiatives to strengthen health systems. Use laboratory services as platforms to increase attendance (and utilization) of public health facilities. An enhanced and assured package of lab services is likely to attract more beneficiaries and provide the opportunity to detect additional TB cases.
- Strengthen district level capacity in OR – increased funding, research on why people select a type of provider, care pathways and patient behaviour.

Case finding

- Pursue immediate opportunities for case finding in the public sector like use of high sensitive diagnostic tools (LED microscope, CBNAAT) at high workload settings to begin with. For this, scale up rapid diagnostics.
- Augment systematic contact screening with use of CXR or LED microscopes or CBNAAT for evaluation of TB.
- Scale up systematic active TB screening in vulnerable and marginalized populations. Consider use of mobile medical unit with digital CXR and rapid diagnosis to enhance the existing process of active TB screening. Use existing listing and mapping of marginalized populations and notified slum areas prepared for intensified pulse polio immunization (IPPI) to target the coverage for active case finding activities.
- Accelerate, expand and pursue private sector engagement on 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 the 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, such as the percentage of targeted providers who notify in the last quarter and the percentage of estimated privately treated patients who have been notified (estimated based on model or sales based state-wise denominator).
- Once engaged, encourage and monitor use of standard treatment practices.
- Strengthen the UATBC model with feedback to private providers for adhering to STCI for diagnostic practices, emphasizing microbiological confirmation and prescribing rational anti-TB regimens.
- Implement schedule H1 for surveillance and targeting providers prescribing anti-TB drugs.

Laboratory services

- Expand laboratories with high sensitivity diagnostic tools to give benefit of early diagnosis of TB patients among those for whom microscopy examination has its limitations in detection. Priority should be given to EPTB, paediatric TB and smear-negative TB to begin with.
- Strengthen and sustain HR capacity at C&DST labs. There is need of a second microbiologist in each TB C&DST laboratory.
- Start the process of accreditation for C&DST laboratories in line with ISO 15189.
- Increase the volume of slide rechecking and frequency of supervisory visits in laboratories with low sputum positivity rates. Ensure that the sputum collection process is observed on site by health workers and earmark designated space for collection of sputum samples at health facilities with display of visual aid materials adopted for the needs of patients.
- Give the 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 centres in private health facilities.

Treatment services

- With a reasonably strong foundation of existing strategies of RNTCP for TB care services, the State has the potential and should move to “test and treat” all public or private TB patients. Plan, budget, and implement universal DST for TB patients, i.e. include new smear-positive and smear-negative TB cases for DST and initiate appropriate treatment.
- Assess feasibility of long-term follow up of cured TB patients as per STCI and offer symptom screening, sputum culture, DST and ancillary treatment. Assess cost effectiveness of such activities to guide the programme.
- Experience of tracking initial loss to follow up gives an edge, and the State should move to notification and registration at diagnosis from public sector, and capture patient loss from death/loss to follow up in treatment outcomes.
- Enhance intersectoral 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 second-line DST is crucial; expand the scope of DST.

Avoid unnecessary extension of the intensive phase. Use the liquid culture results for switching to the continuation phase rather than waiting for the solid culture result. Take 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 and provide socioeconomic support for all TB patients to cut down catastrophic expenditure.

Paediatric TB

- Strengthen contact tracing and INH chemoprophylaxis for children <6 years of age.
- Engage paediatricians to improve quality of diagnosis. Capacity of public health facilities should be enhanced to collect bronchoalveolar lavage (BAL), induced sputum and 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 and empowerment.
- Deploy demand generation campaigns, 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 that is more patient friendly and attention catching.
- Build capacity on planning and implementing ACSM activities. Undertake need-based and contextual activities and measure their impact.
- Disseminate information about schemes for patients and community. Engage more actively and meaningfully with cured patients and their families.
- Empower ASHAs with inputs and knowledge about TB and comorbidities. Improve communication tools for ASHAs.

Patient support

- Availability of social welfare scheme is recognized as a 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 schemes.
- Pursue large-scale support from well-resourced and aligned charities. Develop innovative links to nutrition for all TB patients. .

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 the annual allocation in totality by the end of the first quarter to compensate for longer time for fund flow from treasury to State Health Society.
- Make expectations for the State's share clear in advance. Consider giving cash instead of drugs for states that want to change to daily regimen.

4.3 Himachal Pradesh

The State of Himachal Pradesh has a population of 7.1 million, with 89% being rural area. As the name suggests, most of the terrain is hilly and many areas are difficult to reach. There are 497 PHCs, 80 CHCs and 2068 sub-centres providing TB services through RNTCP. Most of the patients access government health facilities. There are three medical colleges including a private medical college.

The team visited two districts, Shimla and Solan. Sites visited include district TB centres, CHCs, PHCs, medical colleges, sub-centres, ESI hospitals and AYUSH hospitals. Persons interviewed were various stakeholders including patients and community workers.

4.3.1 Local epidemiology, application of ICT and programme monitoring

Achievements

The state has shown a steady rate of presumptive TB examination and case notification. Total case notification remains about 210 per 100 000 population per year for the past 8 years; this declined to 196–199 in the past 3 years and increased again to 211 in 2014. NSP case notification also shows a similar trend and is now 78 per 100 000 population per year. Innovations include fortnightly SMSs sent to AYUSH clinics to refer the presumptive cases for TB diagnosis.

Gaps/constraints

The STO and DTOs do not have a full-time responsibility for the TB programme; having additional charges is hampering monitoring and supervision. There is a gap between smear-positive cases diagnosed and those put on treatment. Usage of ICT is suboptimal with many pending entries in NIKSHAY.

4.3.2 Universal health coverage, health system functions, integration of TB services, general health system and equity in access

Achievements

There is a high degree of faith within the community in the established general health system as most of the population seeks care in these establishments. RNTCP services are well aligned with the general health system. The programme has the plan to align all TB units with Block PHC. Funds of Rogi Kalyan Samiti (RKS) are being utilized for patient support activities. Guidelines for STCI have been shared with all stakeholders and programme managers and training on STCI has been initiated.

Constraints and gaps

There are vacancies under RNTCP at State and district level for both old and new positions. Block level MOs are untrained and give little time for monitoring TB programmes. There are non-functional DMCs in somehilly and far-flung areas due to vacant laboratory technician (LT) positions. Sputum collection and transport mechanism is lacking in many difficult areas.

4.3.3 TB services

Achievements

TB diagnostic and management services are provided free of cost. It was good to notice that INH prophylaxis is being provided to eligible paediatric contacts. Also, intensified case finding approach in select areas (such as jails, slums, industrial areas and nomadic populations) has been practiced. Examples are the Model Central Jails in Nahan, Solan, Shimla, Mandi, Kullu, Una and Kangra; activity in slum areas in TU Bhawarna in District Kangra in December 2014; regular IEC activities in the hydropower projects areas in Districts Kullu, Chamba and Kinnour; and sensitization of weavers in the 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, etc. Involvement of AYUSH clinics for referral of presumptive cases and DOT services are good initiatives.

Constraints and gaps

The state continues to have a very low smear-negative case detection rate. There are many non-functional DMCs due to vacancy of Lts. Most DMCs have low referral of TB symptomatics. The CBNAAT at IGMCI, Shimla is underutilized. CBNAAT facility is not utilized for PLHIV, EPTB and children.

Treatment initiation and DOTS is centralized. Less than 10% of patients are receiving DOT through a community provider. There are few “transfer out” patients in spite of large migrant populations.

Recommendations (for 4.3.1, 4.3.2 and 4.3.3)

JMM recommends completing the recruitment of necessary staff at the earliest and training them. In order for the services to reach the population at the earliest, there is an urgent need to develop community-level sputum collection centres and decentralized DOT centres. Intensified case finding (ICF) activity in high-risk populations like DM patients, paediatric patients, slums, industry workers, etc. can help diagnose TB cases early in these high-risk populations.

In order to further strengthen the programme at the field level, block MOs need to be trained and the programme needs to be intensely reviewed monthly by the CMO.

Health-care providers need to be trained on the updated diagnostic algorithm, including use of CBNAAT testing algorithms for its optimum utilization.

The Programme consistently reports a high percentage of EPTB cases. There is a need to evaluate the reasons for the same.

Systematic implementation of “referral for treatment”, “transfer out” and “defaulter tracing” mechanisms need to be ensured so that all patients are followed-up properly.

4.3.4 Drug resistant TB

Achievements/observations

DR-TB diagnostic and management services are provided free of cost. The districts are linked with two DR-TB centres at Tanda and Dharampur.

The pre-treatment evaluations are done in DR-TB centres/district hospitals. The district drugs stores have been upgraded for storage of SLDs. Ambulance services (108) are utilized effectively to transport needy patients to DR-TB centres.

Pharmacovigilance programme has been initiated for DRTB patients in the State.

Constraints and gaps

The number of presumptive DR-TB referrals is low and there are wide variations in the number of diagnosed DR-TB cases among districts. The knowledge level of staff in identifying presumptive DR TB cases is low.

Sputum specimen transportation from districts to IRL is through human carriers due to absence of courier agencies.

There is significant gap between DRTB patients being diagnosed and being put on treatment. Diagnosed RIF-resistant cases are referred to the DRTB Centre for treatment (about 75 km away) from IGMC.

Accreditation of C&DST lab at RPGMC, Tanda is still pending.

There are no two-wheelers for DR TB Supervisors, hampering their supervisory capacity. Vacancies of key positions at DRTB Centre is another major constraint.

Recommendations

Update training on identification of presumptive DRTB patients. Their line listing and prompt referrals need to be given to concerned staff. Regular monitoring of the identification and referral of presumptive DR-TB patients are necessary for early diagnosis of all DR-TB patients in the State.

Systems need to be put in place for tracing of all diagnosed cases and for initiating treatment. Indira Gandhi Medical College (IGMC) Shimla needs to do pre-treatment evaluation and initiation of treatment of all DR-TB patients diagnosed there with intimation to DR-TB Centre. This will avoid delay in treatment initiation and lost to initial follow up.

Develop a proper courier mechanism of sputum transport instead of relying on STS/STLS to carry the sample. Procurement of two-wheeler for DR TB Supervisor should help better supervision by them.

Consider having ICTC/F-ICTC at DRTB Centre to facilitate better TB/HIV coordination.

Accreditation of C&DST lab at RPGMC Tanda needs to be expedited.

4.3.5 Paediatric TB

Achievements

Systematic contact tracing is conducted in parts of the district, including for children, which is commendable. INH prophylaxis is also being offered to paediatric contacts.

Constraints and gaps

The proportion of paediatric TB cases among all notified TB cases in the State is very low (around 5%). The revised paediatric guidelines have not yet been disseminated. The capacity on gastric aspiration/BAL is limited at state level and purified protein derivative (PPD) vials are not available. There are varied practices for paediatric case management at IGMC with regard to regimen and notification.

There is no systematic monitoring of chemoprophylaxis given to paediatric contacts.

Recommendations

CBNAAT should be used preferentially for TB diagnosis in children and necessary guidance and training needs to be imparted to all paediatricians. Capacity development needs to be prioritized in paediatric TB diagnosis, including gastric aspiration/BAL/sputum induction.

Contact-tracing/INH prophylaxis data collection tools need to be formalized. Proper documentation of the experiences and outcomes of this innovative intervention would be very useful.

New guidelines on paediatric TB need to be practiced after necessary training and sensitization. Need-based procurement of PPD vials and uninterrupted supply of INH need to be ensured. Ensure TB/DR-TB counselling at all levels of care for children/care givers and ensure trained staff is delivering such service.

4.3.6 TB/HIV and other co-morbidities

Achievements

There is an increasing trend of known HIV status of registered TB patients (64% in 2014) but with wide variations among DMCs/blocks. Excellent uptake of HIV testing among TB/DR-TB patients (>90%) is seen in specific districts. In Solan, Sirmour and Kangra Districts, blood sugar examination of all TB patients is being carried out from 1Q2015. The programme has initiated recording of smoking history on treatment cards.

Constraints and gaps

Establishment of district coordination committees is pending in eight of 12 districts. DCC meetings are infrequent. There are less numbers of co-located facilities. ICF, infection control (IC), IPT, CPT and ART are not at all streamlined – IPT for TB/HIV co-infected patients is not available.

The CBNAAT facility is seriously underutilized for HIV patients and EPTB patients. Staff at ICTC was not aware of use of CBNAAT in TB symptomatics among PLHIV.

TB/DR-TB treatment outcomes are not segregated for HIV patients and the overall TB/HIV reporting is poor.

Recommendations

State level directions and follow up are required for regular DCC meetings with adequate action on the minutes. All TB patients should be offered ICTC/HIV testing with establishment of more co-located facilities. ICTC/FICTs should be started in DMCs without such facilities as a priority.

Diagnostic algorithm for TB diagnosis among PLHIV needs to be disseminated. Intensified supervision and monitoring for both programmes are required.

All the TB/HIV co-infected must be screened for DR-TB. Implementation of the “3 Is” strategy for HIV patients (ICF/IC/IPT) and co-ordination with HIV services for the whole cascade of care for co-infected patients need to be accelerated. 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. Improvement in recording and reporting for co-infected patients is needed including disaggregated outcome reporting for HIV/TB/DR-TB co-infected patients.

4.3.7 Engagement of all care providers

Achievements

Notification of TB cases from private hospitals has increased in 2014. There is good engagement of AYUSH clinics.

Constraints and gaps

Private practitioner and NGO involvement are sub-optimal. Linkage with NHM concepts of CBM, Rogi Kalyan Samiti and VHSNC committees, etc. are inadequate.

PPM contractual HR positions (PPM Coordinator, TBHVs) are vacant at State and district levels. Systems are inadequate for private hospitals to report treatment outcomes of notified cases.

Recommendations

The Programme needs to proactively engage all private practitioners and private health facilities by promoting mandatory notification of TB cases and STCI. Community DOTS should be promoted with more involvement of ASHAs as they are now placed adequately by the health system.

4.3.8 Role of medical colleges, research and technical assistance

Achievements

All three medical colleges are involved and providing advanced medical care to TB patients. State task force (STF) and core committee mechanism are in place. There is research capacity at the medical colleges, which has the potential to help the programme.

Constraints/gaps

There is no operational/implementation research at the State level and research seems a low priority. The state OR committee seems to be inactive. There are fragmented OR ideas at different levels but no OR agenda at the State level.

Interdepartmental coordination seems to be inadequate. Many TB patients diagnosed in the medical colleges are missed from notification.

Recommendations

Medical college core committee and STF meetings need to be conducted regularly. Community medicine department of MCs need to be involved more actively for coordination, training, monitoring, supervision and research in RNTCP.

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 need to be prioritized. In order to do so, the State OR committee needs to be activated and responsibilities and ownership need to be decentralized to the State level.

Involve medical colleges in capacity building/training, in collaborative OR projects, ethics committees, and for scientific advise/technical support. Document best practices already existing in the State (contact-tracing, INH prophylaxis, gate pass/TB services at the workplace).

MDR-TB cases need to be treated at medical colleges itself.

Strengthen the referral and feedback mechanism with support from district TB centres.

Involve UG and PG students in research studies and community mobilization. Medical college faculty should be trained as trainers in various components of RNTCP. Participation of MC in state internal evaluation needs to be ensured.

4.3.9 Support systems for patients and families

Achievements

There is high political commitment by the State to support TB patients – the new proposal to provide MDR-TB patients with food packages is an example. Nutritional support is provided to all inpatients. An ambulance service is available free of cost on a simple telephone call (108). There is a patient welfare fund at all health facilities.

Constraints and gaps

Many patients have fear of loss of income/jobs. TB is not included in RSBY in the State. There are no established linkages with different social schemes for TB patients. Varied practices of reimbursement of travel cost to DR-TB patients and old rates of honorarium for community DOT providers still persist. Workplace restrictions are hampering access to DOT at some places.

Recommendations

TB needs to be included in the RSBY and State programmes to initiate necessary proposals. Interdepartmental coordination for linkages with different social schemes needs to be established.

The existing nutritional support is to be expanded to all TB patients in the State. Consider food packages for families with TB patients who are BPL and not just for MDR-TB patients, with support from other departments like PDS.

Revised rates of honorarium to community providers should be implemented immediately.

Reimburse transport costs for TB patients. Consider direct financial support to TB patients, especially DR-TB patients, to address the loss of wages and subsequent financial burden on the family.

There should be necessary directives from appropriate authority (DG-FASLI) enabling workers to access DOTS at their workplaces (workplace DOTS).

4.3.10 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 and printed material). The JMM team observed one active ACSM activity in slum/migrant-populated areas.

Constraints and gaps

There is only a limited range of activities in communication and even less in advocacy. Community as well as patient provider interaction meetings are suboptimal. There is a paucity of ideas and mechanisms to deliver effective IEC. The expenditure on advocacy and communication by RNTCP is very low.

Recommendations

A specific need-based strategy for advocacy and communications for TB needs to be developed for the State and adequate resources need to be allocated. Partnerships with NGOs and other community organizations are crucial for the success of the Programme.

4.3.11 Community engagement

Achievements

A sensitization workshop on the Programme was conducted for NGOs.

Constraints and gaps

In 2014, only four NGOs were engaged in the TB programme, that too not formally under any signed schemes. 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 adequate funding for community NGOs to participate in TB activities by the inclusion of necessary activities in the annual action plan and meticulous follow up on their implementation.

Support NGO participation at all levels of care from community awareness, to diagnosis, to treatment.

4.3.12 Targeted interventions for special groups

Best practices/achievements/innovations

The state/district is sensitized on TB in special groups (especially migrants, slums and factory workers). The attitude of the health staff (DMC, OPD, DOTS centres, private DOT providers) towards special groups was excellent (especially towards migrants who constitute two thirds 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 centres during working hours without risking their jobs. DMC/DOTS centres are opened in large factories, bringing TB services to the workplace.

Challenges/constraints

There are no targeted activities among special populations in the areas visited (in Solan district, only ACSM activities were there, no ICF)

The working hours (09:00–16:00) of TB services (especially DOTS centres) are not convenient for workers.

Possible solutions/recommended actions

“Open a DOTS centre or issue gate passes” should be a clear message to all employers in high-TB burden pockets and hotspots. Introduce legislation to protect patients with TB/DR-TB and facilitate the use of services.

Conduct systematic ICF activities in slums, large factories, etc. Ensure TB/DR-TB counselling is held at all levels of care for special groups and ensure that trained staff is delivering such services.

There is a need to think out of the box and pilot non-DOT adherence support practices in special groups who cannot practice DOT.

4.3.13 Drugs and supplies

Achievements

Procurement of INH and few SLDs at the State level.

Constraints and gaps

Pharmacist and store assistant positions at SDS are vacant. There is inadequate space at SDS. No established mechanism of drug transport exists to districts and TU. District Drug Store at Shimla is not maintained by a pharmacist.

Recommendations

Appointment of two posts under RNTCP for SDS needs to be done on priority. DDS Shimla needs to be maintained by a pharmacist. Logistics management of drugs needs improvement.

4.3.14 Programme financing

Achievements

NHM releases funds from its pool to STC irrespective of fund receipts from Gol for RNTCP (after receipt of ROP from Central NHM). There was no delay in release of funds from STC to districts. Mechanism for loans from NHM to RNTCP exists at district level as well.

Constraints and gaps

Districts were not updated on approved activities. Revised rates of remuneration to contractual staff and incentives to beneficiaries have not been implemented. TA/DA of STS/STLS have not been paid for the past few months, affecting mobility for field supervision. The funds required for training are provided through the districts to STDC and expenditure is booked by respective districts. This mechanism creates delay in organizing training activities.

Recommendations

The new financial norms of RNTCP need to be implemented immediately.

STDC should provide the training calendar and budget to STC and STC should release necessary funds directly to STDC so that training, supervision and monitoring activities of STDC can be carried out smoothly.

4.3.15 Human resources for health

Achievements

Appointments of staff are either through outsourcing and/or deployment from the general health system. Laboratory technicians are provided from RKS at a few high-load facilities.

Constraints and gaps

Many DTOs, medical officers tuberculosis control (MO-TCs) and other key staff in the State are untrained. Approved HR positions in the ROP of 2014–15 are yet to be filled. Majority of contractual positions at State and district levels are vacant. At State level, three key positions – assistant programme officer (APO), MO-STC and DRTB coordinator are vacant. Position of microbiologist is lying vacant for the past one year. Vacant positions are there at SDS and DRTB centre.

All training is done at State level and there is no mechanism of district level training.

Recommendations

Fast tracking of HR recruitment process at State and district level is needed.

Following training aspects need attention:

- 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 were trained 3–5 years back, should be given refresher training;
- District level training is to be decentralized to the district level;
- District level sensitization for all the doctors (comprehensive including PMDT, paediatric TB, TBHIV) to be undertaken.

4.3.16 Governance and health information system

Achievements

State and district health administration is very supportive of the Programme and conduct regular programme reviews in NRHM meetings. State has increased RSBY limit to INR 175 000 from INR 30 000.

Constraints and gaps

Manpower at the State TB Cell is inadequate. State-level monitoring and evaluation activities and DTO review meetings are irregular and suboptimal. There was only one SIE and one DTO's quarterly review meeting in the past year.

There were no State IRL Team visits to districts for EQA for the last two years due to non-availability of microbiologist. District level on-site evaluation (OSE) visit report, feedback and action taken report are not properly documented. A crucial component of mobility support with provision of two-wheeler vehicles along with POL support is lacking in the field. Most of the patients are not being visited at home. Non-alignment of TUs with block programme management unit (BPMU) is another lost opportunity as with more TUs, the Programme could utilise the services of more STSs. Municipal corporation's involvement in the Programme is suboptimal.

Recommendations

Municipal councils should be involved fully under the Programme. Proper communication from State level followed by coordination meetings with the Municipal Commissioner need to be proactively done by the Programme.

Strategy to involve other sectors needs to be planned.

For strengthening of monitoring and evaluation (M&E) mechanism, the state programme should:

- conduct regular State-level DTOs review meeting, supervisory visits at all levels and State level internal evaluation to be undertaken as per the norms;
- facilitate district level review meeting of block medical officers by CMO on monthly basis to improve TB control. Review by DM on quarterly basis will help the programme;
- STDC Dharampur to ensure supervisory visits to each district at least twice a year. The required mobility support (vehicle and POL) for field visit to be provided from State resources;
- properly document district-level OSE visit and monitor the activities at State level
- procure two-wheelers as per guidelines.

4.4 Madhya Pradesh

The JMM visited the State headquarters at Bhopal and districts of Ujjain and Jabalpur.

4.4.1 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 a tribal population of 1.65 million with four districts that have the majority of the tribal population and 19 districts with scattered tribal population. There are 51 revenue districts and 50 RNTCP districts.

4.4.2 TB services

There are 202 functioning TUs and 313 revenue blocks. 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 with NGOs/private sector. There are 34 631 DOT centres.

For PMDT, there are six DR-TB centres including one in a private medical college. Three more are under development. For diagnosis of MDR-TB patients there are six gen Xpert labs and 2 LPA labs. One more LPA lab is coming up at Gwalior Medical College. For follow-up cultures, four solid culture labs and one liquid culture facility are available. One more liquid culture lab is under accreditation process at BMHRC Bhopal.

For TB/HIV services, there are 186 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.

4.4.3 Epidemiology

Of the 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 41 7171, implying 2.7% of the 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 among this tribe.

4.4.4 Case finding and TB notification

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

External QA system is in place in all designated microscopy centres. The 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. Symptomatics examined per 100 000 population has increased from 158 to 186 in the last year, the rate of change being 18%.

Major challenges/constraints

Considering the higher prevalence of TB in MP, especially in rural and tribal areas, the case finding efforts need further augmentation. Case notification is not uniform – there are many districts where the symptomatics 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

Some recommendations are 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 needs to be facilitated along with provision of personal digital assistants (PDAs) 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 is needed.

4.4.5 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 the TB programme. Online portal for recruitment of staff, e-transfer of payments of salary to staff and honorarium for DOT providers, local procurement of drugs online through Government Medical Stores Depot (GMSD) or TNMSC and good infrastructure development in the general health system are other good examples.

Major challenges/constraints

Due to insufficient fund flow to state and districts, only 60% of PIP submitted gets allocation. This leads to the delay in initiating new activities envisaged as per NSP in the State. Delay in release of funds in 2014 resulted in delay in payment of salaries to the contractual staff. The NHM management structure's involvement in TB care is suboptimal. There are many staff recruited under NHM including the staff at district programme management units (DPMUs), block programme management units (BPMUs), etc. However, the focus is mainly on reproductive and child health (RCH) services. There is no coordination between TB programme staff and NHM staff as both find their jobs are different. This silo approach is not advantageous to anyone. 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 a few poor MDR-TB patients in Indore.

Possible solutions/recommended actions

NHM staff needs to be sensitized and proactively involved in TB care activities. In order to strengthen integration of TB care with the general health system and NHM, there needs to be a structure for collaboration at State and district levels similar to the TB/HIV coordination committee. There are different types of counsellors in the district; every programme has put in one more counsellor and now the 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 the possibility of e-transfer of honorarium through linking with NIKSHAY.

4.4.6 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 ASHAs and community volunteers.

Major challenges/constraints

These include delay in treatment initiation owing to practices of service provision by concerned geographically located service delivery points; sub-optimal treatment monitoring and lack of adjunct services to improve quality of life and treatment outcomes. ADR 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 was noted in some districts and local procurement of drugs are delayed due to system issues.

Recommendations

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. There is a need for enforcement of schedule H1 by drug regulatory authorities.

4.4.7 TB/HIV

Main achievements

These include formation of TB/HIV coordination committees; State Coordination Committee meeting held in 1Q15 and TWG in 3Q14; co-location of services has increased substantially in the last two years and now 73% of facilities are co-located as compared to 42% two years ago. Of the TB patients, 66% know their HIV status, which is a leap of 50% compared to last year. Of the tested TB patients, 1% are HIV positive. Among coinfecting patients, 85% are on CPT and 94% are on ART.

Major challenges/constraints

One third of TB patients do not know their HIV status; intensified case finding for TB among PLHIV was found to be deficient; no IPT to PLHIV without TB; there is a knowledge gap on use of CBNAAT for PLHIV among MOs; district-level coordination meetings are infrequent and there is a shortage of HIV second and third test kits with zero stock at State level. Linkages are not available for other comorbidities, i.e., TB–diabetes, TB–tobacco.

Recommendations

Streamlining of procurement and distribution of both HIV test kits and all necessary drugs should be prioritized along with expansion of co-located facilities for effective TB and HIV care. CBNAAT should be preferentially used for TB diagnosis in PLHIV presumptive TB; necessary communications and training for intensified TB case finding among PLHIV needs to be imparted to MOs; and IPT to non-TB PLHIV needs to be implemented to reduce incidence of TB in PLHIV.

4.4.8 Paediatric TB

Main achievements

These 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

Diagnosis of paediatric TB is mostly limited to speciality health-care settings; diagnosis is mostly dependent on clinical judgement and radiological evidence. There are stockouts of INH and shortages of paediatric drug formulations in the Programme, especially for children weighing less than 6 kg. Additional tools for bringing out sputum such as BAL/induced sputum, etc. are not used.

Recommendations

Revised algorithm for childhood TB should be practiced by proper dissemination/training of paediatricians and medical officers; equip manpower and provide facilities for microbiological confirmation of paediatric TB; CBNAAT to be utilized for diagnosis of paediatric TB; INH to be procured and made available for prophylaxis; training of staff administering the Mantoux test is needed for better utility of TST; recommend and use other tools like aspiration and nebulisation for sputum extraction; and use of CBNAAT for diagnosis.

4.4.9 Drug-resistant TB services

Main achievements

PMDT services have been scaled up to include the entire State with availability of rapid diagnostics for all presumptive DR TB cases.

Major challenges/constraints

These include suboptimal sputum collection and transport mechanisms and lack of decentralized treatment services. The initial clinical work up of 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 were 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 the medical college, effective linkages are not in place. Delayed or no second-line DST was observed.

Recommendations

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

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

4.4.10 Engaging all care providers

Main achievements

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

Major challenges

Mechanisms for complete TB notification from all departments of medical college have not been established. Medical college faculty is untrained in basic TB as well as PMDT services. There is suboptimal utilization of partnership provisions in the Programme to increase reach and improve service delivery. No active measures have been taken to engage the private sector in a big way. There is no IMA engagement in the State. Awareness on STCI 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 colleges should be a priority.

4.4.11 Finance and human resource management

Main achievements

The State has taken advantage by utilizing NHM funds for funding deficit, e-transfer of salary to staff and honorarium to DOT providers.

Major constraints

Long standing vacancies at State and district level are adversely affecting the programme. The powers of reallocation of funds lie with the state health society and hence districts do not have the flexibility of reallocations as per need. STDC Bhopal does not have adequate infrastructure/HR to conduct state level training/supervisory visits.

Recommendations

Fill vacant positions on priority. Carry out 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 should be made functional with all components (training, bacteriology, programme monitoring, review and analysis, ACSM, etc).

4.4.12 Governance and HMS

Main achievements

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

Major constraints

There is a gap in realignment 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 the general health system for TB control services was found to 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 suboptimal.

Recommendations

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

4.4.13 Procurement and logistics

TB drug stores are established at various levels including second-line drug stores (with temperature control), and drugs stocks are being monitored for utilization within shelf life.

Major constraints

The existing State Drug Store is space constrained for both FLDs and SLDs. Nil stock of prolongation pouches, PC 13, INH 100 mg, INH 300 mg was observed at the State level and at facilities visited in the district. No mechanisms were in place for procurement of drugs as and when directed by Central TB Division, leading to nonavailability of loose drugs and Inj. streptomycin. There is no proactive mechanism of drug transportation from State to district drug stores for SLDs. The CBNAAT cartridges were in short supply and required relocation of cartridges from various sites and projects to keep the machines running.

Recommendations

Urgently establish two more additional state drug stores. Streamline the mechanism for procurement of drugs as and when directed by the Centre. Ensure adequate availability of CBNAAT cartridges for seamless services. The resources available at the State TB cell to be utilized for proper supply chain management. Capacity building is needed in drug management at all levels, including e-learning and blended learning solutions.

4.4.14 Patient support systems

There are no established patient support systems except some NGO-supported nutritional support for a few patients.

Recommendations

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

4.4.15 Advocacy, communication and social mobilization

Major achievements

These include TB awareness creation efforts at the State level including advertisements in electricity bills. “Gain and gap study” was done to analyse knowledge, awareness and community issues pertaining to TB. RNTCP IEC activities are closely linked to State health IEC activities.

Major constraints

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

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 are needed, as also structured measures to assess the outcome of ACSM activities being conducted by different players.

4.5 Meghalaya

The state of Meghalaya in north-east India caters to a population of 3.3 million covering an area of approximately 22 430 sq km and is predominantly inhabited by the tribal population (95%). About 70% of the state is forested. There are 11 districts. The male–female ratio is 1000 : 1011 with an adult literacy rate of 75%. The State's per capita income (INR 29 000) is lower than the national average (INR 38 000). The proportion of the child population is 40% and infant mortality rate is 49 per 1000 live births.

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

The JMM 2015 team members have strategically reviewed the programme implementation status by analysing the outcome of the field visits and interactions held at East Khasi Hills as listed below:

State:

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

District (East Khasi hills):

- District TB Centre, District Drug Store, three TB units (Shillong, Mawphlang, Sorah), six 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 Akshaya Project
- Debriefing meeting with the Additional Chief Secretary, Secretary Health, Mission Director NHM, Commissioner Health, Director General Health services, State and district RNTCP teams.

The key points and observations are discussed below.

4.5.1 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 programme data of 2014:

- Total TB case notification rate is 154/100 000/year
- New sputum positive case notification rate is 54/100 000/year
- Amongst all diagnosed TB cases, 37% were extra pulmonary cases
- A total of 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
- Of the new sputum positive cases, 82% are getting cured with 54% success rate in previously treated TB cases. High failure rates (up to 18% in previously treated cases in East Khasi hills) have been noted in the State.

4.5.2 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 PIP under NHM annually to achieve universal access to quality TB diagnosis and care.

RNTCP has reorganized its structure along the health block lines, aligning and integrating sub-district programme management and supervision with NRHM. The pending re-engineering of four new districts and four TB units had been approved in the budget for FY 2014–2015 but has not been established, and has thus now been planned for FY 2015–2016. 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 human resource development (HRD) plan to update and develop the skills of both programme 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. The issue of accessibility to 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.

Challenges/constraints in achieving universal health coverage

State TB training and Demonstration Centre (STDC) has not been established. No IRL is available in the State. The culture facility is being utilized from IRL Guwahati. X-ray facilities are not available in the entire East Khasi Hills District except at Civil Hospital Shillong. There is minimal involvement of general health system staff in TB care services.

There are many vacant positions – second MO at DTC, pharmacist and store assistant at SDS for SLDs, specialists at CHCs, ANMs, tuberculosis health visitor (TBHV), LTs, etc. None of the DTOs are trained in TB/HIV. Last MOTC training was held in 2013. MOs of peripheral health institutions (PHIs) are again mostly untrained, including in PMDT. There is high turnover of staff, 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 needs to be done. Their civil works should be completed so that they become functional during this financial year. The state-of-the-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 training, culture and 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 SLD management. All health staff require urgent training/retraining in all components of TB control (EQA, PMDT, TB-HIV and STCI). The districts 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 need to be established in districts for improving treatment accessibility of DRTB patients.

4.5.3 Diagnosis and case finding (including paediatric TB, key vulnerable populations and comorbidities)

The majority of the population in the State of Meghalaya is tribal, which resides in hard-to-reach areas. The paediatric population under 6 years of age is 560 000, which constitutes 25% of the total population. The key vulnerable group includes the tobacco users (smoking and tobacco chewing), which constitute 54% of the over-15 years population. Current tobacco users are 73% of the male and 36% of the female population. 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 the international border of Bangladesh are accounting for nearly 6% of the initial defaulters in the Programme.

Best practices/achievements

The MOs are generally aware of diagnostic algorithms but not intensified case finding guidelines. Presumptive TB sputum examination rate is satisfactory. The proportion of TB cases amongst children was 8% in 2014 in the State which is higher than the national data of 6%. In East Khasi Hills, 9.7% of all TB cases were reported as paediatric TB in the year 2014. The health staff has been oriented on the revised paediatric guidelines. PPD vials are being used for diagnosis of TB in children. Paediatricians with PG qualification are following the 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 is unsatisfactory at some places and key vulnerable populations. Contact tracing is not happening. Low sputum positivity rate was noted at few DMCs. Diagnostic facilities for smear-negative pulmonary TB, EPTB and paediatric TB are not available in peripheral areas. Functional binocular microscopes are not available in many DMCs. The external QA system for TB diagnosis is not in place. Presumptive paediatric TB cases are referred to the Government Childrens Hospital in Shillong. However, many fail to reach the hospital.

Newer technology (LPA, CBNAAT, etc.) is not frequently used by general physicians. Most of the practitioners are unaware of STCI.

Recommendations

EQA training for all key staff needs to be conducted on priority. Accessibility to sputum diagnostic services needs to be improved by establishing sputum collection centres. Availability of X-ray facilities at CHCs to facilitate diagnosis of sputum negative cases needs to be ensured. Necessary infrastructure for paediatric TB and EPTB diagnosis at CHCs is needed. 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 Mos.

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. Sensitization of cement and coal mining companies on TB and establishment of DMC or sputum collection centres for coal miners and cement workers are required. Enhanced and regular screening, including staff at entry and periodic screening and isolation of diagnosed TB patients are required in prisons.

On discharge from prison, TB patients need to be referred to RNTCP DOT centre under intimation of DTO. Contact tracing mechanism and tracking/transferring migrant population needs to be strengthened. Blood sugar testing facility for TB patients needs to be scaled up as per the national programme for NCDs.

4.5.4 Treatment of drug-sensitive TB

Best practices/achievements

FLDs were available except Inj. Streptomycin. Community DOT providers are available near patient homes. Mobile DOT services were available.

Challenges/constraints

Treatment success rate is 85% with 5% death rate and 6% default rate in new sputum positive cases.

Treatment outcome in re-treatment cases is poor with 54% success rate, 10% failure rate, 16% lost to follow up rate and 7% death rate. Patients have to travel long distances for injections incurring high OOP expenditure and loss of wages. Many patients who are smear positives at follow up are subjected to DST.

INH prophylaxis is not initiated in the majority of child contacts. Some paediatricians are adding quinolones for serious TB cases. MDR-TB treatment is being done using non-standardized regimens in some cases.

Recommendations

Ensure initial home visits by health staff and reduce treatment delays and initial loss to follow up. Involve community DOT providers in urban areas and strengthen patient counselling. Strengthen mobile/flexible DOT services including workplace DOT for factory workers. Develop a mechanism for monitoring IPT in individual child contacts.

4.5.5 Programmatic management of drug resistant TB (PMDT)

Complete geographical coverage of PMDT services was achieved by the State by the 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 is being done 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. SLDs are available and most MDR-TB cases including some from the private sector are being treated in designated DR-TB centres. 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 analyse the reasons for variation in the data of the two DR-TB centres.

MDR-TB among presumptive MDR-TB cases			
	2012	2013	2014
Meghalaya State	57%	32%	30%
DR-TB Centre Shillong	75%	52%	47%
DR-TB Centre Tura	24%	7%	5%
Shillong District			56%

No IRL or CBNAAT lab is available in the public sector. New cases are being diagnosed based on a single LPA report; thus, MDR-TB treatment is being given against guidelines. At the same time, LPA is not done in some presumptive MDR cases, resulting in possible MDR-TB cases being missed. Similarly, second-line DST is not done in some presumptive XDR cases leading to missing of XDR-TB cases.

The collection of sputum samples is centralized at the DTC. Delay in initiation of treatment up to 1–4 months was noticed. Patients have to travel long distances for injections, and sometimes have to be hospitalized for receiving injections. Follow-up cultures are not done as per schedule, and there are delays in receiving reports, resulting in most MDR-TB patients getting 8–9 months of intensive phase of treatment.

There are an inadequate number of beds in MDR wards. N-95 masks are not available at DR-TB centre. Airborne infection control (AIC) measures are not adequate. Though sufficient windows are present, they remain closed leading to insufficient air exchange.

Treatment cards at the DR-TB Centre is not updated for months, which raises the question of authenticity of quarterly reported data from these centres. One CBNAAT facility available at H. Gordon Robert Hospital in the private sector is not utilized by RNTCP. Poor contact tracing is happening although there is evidence that in 2014, 36% MDR-TB cases were detected among the contacts.

Recommendations

Laboratory capacity needs to be strengthened. IRL for the State needs to be established. CBNAAT facility can be utilized from H Gordon Hospital under partnership schemes. Decentralization of sputum collection and transportation at TU level need to be done. NGOs can be involved under the partnership schemes to increase accessibility to diagnostic services. Counselling of DR-TB patients and proper support systems need to be provided.

There is a need to streamline transportation of follow-up sputum specimens to IRL Guwahati and timely receipt of results.

Cross checking of quarterly reports from DR-TB centre needs to be done to ensure that only authentic data is reported.

4.5.6 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, one ART centre, two linked ART centres and three mobile ICTCs. There are 18 co-located DMCs at ICTCs. State TB–HIV Coordination

Committee and State Technical Working Group are in place. Intensified TB case finding is being conducted for HIV patients at ART centres. No shortage of ART kits was reported in the recent past.

Challenges

The last State TB-HIV Coordination Committee meeting was held in March 2014. Only one third of TB patients were tested for HIV in 2014. ART centres are congested, which emerges as a challenge for AIC. Uninterrupted supply of HIV testing kits is a challenge as shortage of kits had been noted a few months ago.

Recommendations

State TB-HIV Coordination Committee meetings need to be held quarterly. ICTCs counsellors should participate in RNTCP monthly review meetings at district level. State AIDS Control Society (SACS) should provide HIV testing facility at all DMCs.

AIC measures at ART centre need to be strengthened. Training of key health staff in TB-HIV intensified package needs to be done.

4.5.7 Engagement of all care providers (including medical colleges)

Best practices

There are 61 private health facilities including nursing homes, laboratories and private clinics supporting the programme and notifying TB cases being treated by them. Till date, there are 1828 TB cases notified to the programme from the private sector, which is appreciable. Good support and collaboration with Nazareth Hospital has helped the DR-TB diagnosis in TB patients. One medical college (NEIGRIHMS) is involved in the programme and has a DMC and DOT Centre. The Medical College Core Committee, State OR Committee and State Task Force are all in place and are meeting regularly. In 2014, of the total cases registered for treatment, the Medical College has contributed to 21% of the cases.

Challenges/constraints

Not all private practitioners are sensitized in STCI. Culture and DST facility are not available at Medical College although it is running a PG course in microbiology.

Recommendations

Training/CME of all private health-care providers on STCI is needed. Sensitize informal providers as well. Notification needs strengthening. Expedite C&DST facilities in the Medical College on priority.

4.5.8 Operational research

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

- How to decrease the 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 levels of drug resistance in presumptive MDR-TB ?
- How is it that about 35% of new EPTB cases have MDR?

4.5.9 Drugs and logistics management

Achievements

The upgradation of the State Drug Store and district drug stores for stacking of SLD is as per RNTCP guidelines. Records at the State Drug Store are well maintained for FLDs and SLDs, but the index should be included as the first folio of the drug stock register. District drug stores

have well maintained records for FLDs. Reconstitution of MDR-TB drugs of default/dead patients is being done, but only in one district. There is a good practice for packaging of SLDs, including recycling boxes.

Challenges/constraints

A stockout of Inj. Streptomycin was observed at State and district drug stores as on 10 April 2015.

The post of contractual pharmacist and store assistant for SLD management is vacant since the rollout of PMDT services. The drug stock is being maintained by a BCG technician and public radiographer at the district drug store. The drug store register for SLDs is not available at the district drug store. Transportation mechanism for distribution of drugs from State to districts and within the districts is not mainstreamed; transportation of drugs is being done by the supervisory staff of RNTCP.

Demand and supply of drugs is not as per the Quarterly Report on Programme Management and Logistics (QRPML) and 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 FLDs and SLDs are not adequate either at State or at 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 of Inj. Streptomycin and do emergency procurement, if necessary, as per instructions of the CTD. The State is also requested that in future, CTD should be informed sufficiently early prior to expected stockout of any drug. Appointment of a pharmacist and store assistants should be done on a priority basis (within a 3 months' period). The district authorities are advised to ensure that all drug stores at district and periphery levels are manned by pharmacists. Drug stock register for maintaining SLDs 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 MDR-TB drugs be issued to 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 whether 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 six 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 for FY 2015–16.

4.5.10 Patient support systems

No strongly established patient support systems are in place in the State except some nutritional support being provided to selected TB patients under Project AXSHYA. Project AXSHYA workers are also providing counselling services to MDR-TB patients.

TB-HIV coinfecting patients registered in the Meghalaya State network of PLHIV get nutritional support from the State Social Welfare Department.

Recommendations

The State should develop and strengthen the patient support system by developing linkages between RNTCP and social assistance programmes (social welfare, nutrition, counselling, etc.). Counselling of TB patients, especially MDR-TB patients, needs to be strengthened and

standardized at the level of MOs, health staff and DOTS providers. Comprehensive training needs to be provided to DOTS providers, especially for identification of ADRs for early and prompt management. Travel costs to the MDR-TB patients and one attendant for treatment initiation and follow-up examination has to be reimbursed as per the RNTCP guidelines on a priority basis.

4.5.11 Finance

The status of fund utilization for FY 2014–15 in the State is 67%. Only one instalment of INR 43.3 million was released by MoHFW to the State Treasury of Meghalaya, of which INR 23.6 million was released to the districts.

The fund flow mechanism is smooth within the State with strong support from NHM. In a majority of districts, fund utilization on civil works was zero. There are substantial unspent balances in training in EK, WKH, Ribhoi and EGH districts which suggests that regular training is not being conducted, as also observed during interaction with the health staff. There are substantial unspent funds in honorariums, patient support and transportation charges, NGO support and ACSM/IEC. These are sensitive issues and if taken care of, can give a good boost to the outcomes.

4.5.12 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 fit for condemnation and should be replaced.

The State should ensure that all emergency procurement of drugs follows QA protocol.

4.5.13 Advocacy, communication and social mobilization

Best practices

IEC material was displayed in local languages at the health facilities visited. ACSM activities under AXSHYA includes sensitization of local political leaders and opinion leaders through the publication Axshya Samwad.

Challenges

Low motivation of volunteers under Axshya project was observed due to payment issues. Reach of Axshya workers is limited.

Recommendations

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

4.5.14 ICT application for surveillance

All seven districts are reporting in NIKSHAY. No data analysis is being conducted at State or district level for performance review. There is a backlog of data entries pending in the State. For 4Q14, 78% of the data entry has been completed. Sixty-one private health facilities have been registered under NIKSHAY.

4.5.15 Overall recommendations

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 the Secretary Health at least once a quarter for the next 6 months. District reviews should be held monthly under the chairmanship of the district medical and 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. The State should build its HRD and special population coverage plan in consultation with the Central TB Division at the national level.

4.6 Odisha

4.6.1 Organization of TB services

Findings

Core components of TB services are in place in the State and the general health services are also partially engaged. There are gaps in leadership, supervision, HR and quality of services. The STO's position is at a level between CMOs and DTOs and therefore lacks authority. Only two of the 31 DTOs are employed on a full-time basis and the DTOs demonstrate suboptimal involvement in the programme. Of a total of 549 DMCs, 82 lab technician positions are vacant. Many contract MO positions are vacant. ACSM officer and PPM coordinator positions at the State level are also vacant. Many MO positions in the general health services are also vacant. While the State is eligible to have 314 TUs by virtue of its 314 blocks, only 159 TUs are functional. Funds for civil work upgradation of 75 additional TUs has been provided in the current year but there is no allocation for HR and two-wheelers. Collaboration between TB and HIV programmes is good.

Recommendations

The STO's position needs to be upgraded to bring it at least at par with other programmes like malaria. The 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.

4.6.2 Programme monitoring

Findings

Monitoring, reviews and evaluations are conducted regularly. However, TB programme reviews get low priority at the district level. The Programme at all levels in the State still follows the old 70/85 targets while the NSP 2012–17 targets are 90/90. The State is using NIKSHAY, the case-based web-based software for entering data of TB patients, both in the public as well as the private sector. Only the patient registration module is being used and there is a backlog of entries across the State on the status of HIV, follow-up examination and results 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 – STSSs, STLSSs, etc. All the payments in the State from the public sector to ASHAs 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

The Programme should get priority for review, especially at the district level. The State should follow NSP's target of 90/90 at all levels of the Programme. Districts should explore the possibility of doing data entry at block/TU level for timely registration of TB patients in NIKSHAY through the data entry operators (DEOs)/pharmacists/HAs, 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 programme should also line list all health-care providers, register in NIKSHAY, sensitize, share the notification format, follow up with each facility and then subsequently the patients can be diagnosed and treated by private health facilities. Usefulness and ethical issues of ICT models may be considered.

4.6.3 Case finding

Findings

Total presumptive TB patients screened by the RNTCP shows 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 TB 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 are not being initiated on treatment over the last 6 years. Paediatric TB diagnosis is restricted to DTC and the patients registered are dependent on availability of paediatric drugs. Only two of the 31 DTOs are full-time, who are not assigned any responsibility other than TB control.

Recommendations

TB referrals for testing need to be monitored from the programme management report and shared with the Chief District Medical Officer (CDMO). As per the programme needs, diagnosis facility should be provided in PHCs that have an LT and a microscope. Case detection should not be confined to sputum positive cases only and should encompass detection of new smear-negative (NSN) and extrapulmonary (EP) cases as well. Wherever available, X-ray facilities should be encouraged and utilized for diagnosis of smear-negative cases. Efforts for community awareness need to be prioritized by village-wise mapping of TB suspects, using laboratory registers. The State needs to intensify efforts to address the low case detection in coastal areas and focus on intensified case finding activities involving HWs, health supervisors and ASHAs. There is a need to practice infection control measures at all microscopy centres, district hospitals and DR-TB centres by ensuring implementation of various components of RNTCP in line with the NSP. There is a need to ensure better coordination and linkages with NHM. The large number of vacancies of lab technicians in designated microscopic centres needs to be addressed and filled up on 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, intersectoral convergence with other programmes and departments other than Health has to be initiated by the district TB officers at the block level.

4.6.4 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 HR shortages. As a result, the TB programme as well as the broader health system is also not able to perform fully. The State authorities are cognizant of the general issues but there is no clear timeline by when issues are likely to be resolved. Issues like degree of reliance on contractual staff and related salary aspects should be considered in this context.

Some additional performance issues arise from low engagement with private sector providers. Existing platforms such as the IMA 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 geographical areas. With regard to the RNTCP, there is in fact a financial incentive provided for notification, 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 rethinking. There are shortages of some types of staff like LTs. In some districts, existing LTs across the health system are underutilized because of restrictions from the RNTCP 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 programmes 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 ASHAs are weak and there is often unnecessary task shifting to them, which causes inefficiency (e.g. transport of sputum samples from ASHAs all the way to CHCs). These issues need to be urgently addressed. Additionally, the remuneration of ASHAs is low as compared to their workload which is extensive, and further funding is needed to ensure that ASHAs' 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 RNTCP 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 programme and NHM. These issues also need to be addressed in a streamlined computerized financial management system across all levels and programmes 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 PHCs, CHCs and higher levels will be the key to monitoring and improving quality of services. This computerized system should of course be interoperable with NIKSHAY. Additionally, QA 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.

4.6.5 Procurement and supply chain management

Findings

There was no stockout of adult or paediatric medicine boxes at the peripheral level. Due to short supply of medicines (Inj. SM and INH), some of the districts had to procure loose anti-TB drugs. There has been no QA for local procurement as this is done only in emergencies, where the district cannot wait for the QA 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 concerned person has to make two or three trips to collect the complete stock. Further, storage conditions are

suboptimal. 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 not kept inside the refrigerator. System gaps were visible in drug management, e.g. low buffers, shortage of SM, RIF 150, PC-13, PC-14, INH 100 mg/300 mg. Also, Rifampicin was available in the State Drug Store but DTOs were not aware of it.

Recommendations

QA of locally procured drugs needs to be done at State/National Accreditation Board for Testing and Calibration Laboratories (NABL)-accredited labs. Block management units have to assume responsibility for transportation of drugs. The State may also consider annual contracts 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 need to be done routinely. Storage conditions need to be improved. Information regarding drugs availability at SDS may also be shared with districts, so that they can request for the same accordingly.

4.6.6 Treatment and treatment support

Findings

Overall treatment outcomes under RNTCP are good. Community DOT providers were engaged in 80% of cases treated. However, supervision of community DOT providers' work is suboptimal. A large number of TB patients are managed with inadequate standards in the private and public sector and they remain unnotified. Only 1158 were cases notified in NIKSHAY from the private sector in the past year.

Recommendations

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

4.6.7 Drug-resistant TB

Findings

PMDT services are available in all districts of Odisha with rapid molecular diagnostics through RNTCP certified labs (two LPA, three CBNAAT) and treatment with SLDs (three DR-TB Centers – Cuttack, Behrampur, Burla) free of cost. IRL Cuttack is certified for all DST technologies (solid culture, liquid culture and LPA) for FLDs. It advanced to DST for SLDs in March 2015. A National Reference Laboratory for east India is located at RMRC Bhubaneswar and is certified for LPA and solid culture while advancing for liquid culture for first-line and second-line drug susceptibility testing (SL-DST). Till 2014, around 7200 presumptive MDR-TB patients were tested and 668 MDR-TB patients and 20 XDR-TB patients were put on treatment. Around 80% of enrolments in national drug resistance survey from four selected TB unit clusters of Odisha have been completed. MDR-TB drugs are adequately supplied. XDR-TB drug is procured locally.

There are many unresolved issues affecting access and quality of PMDT services due to limited monitoring at the State and district levels. Key staff positions sanctioned for PMDT services like one senior MO for DR-TB Centre Cuttack, three counsellors for DR-TB Centres and five district PMDT TB–HIV coordinators need to be filled.

At IRL Cuttack, the following challenges had remained unaddressed for nearly 6 months: (i) Maintenance and repairs of six critical lab equipment including the air-handling unit of bio-safety level BSL III facility compromising bio-safety of lab staff; (ii) National training of lab staff appointed by FIND India was pending due to issues of travel allowances from RNTCP; (iii) Stocks of lab consumables for LPA and liquid culture last for only a month; (iv) CBNAAT sites

are not monitored by IRL Cuttack; (v) CBNAAT site at Koraput is suboptimally utilized. Only 150 tests were done in 2014 against an optimal capacity of 3000. This led to expiry of 59 cartridges; (vi) Around 50% of eligible patients were offered MDR-TB diagnosis in 2014. Access to sample collection is available only at district level in most districts; and (vii) Existing laboratory capacity of five labs suboptimally utilized.

Issues with MDR-TB treatment services were as follows. The total 25-bed capacity was saturated at the three existing DR-TB centres 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 the DR-TB Centre at Cuttack has been sanctioned but is held up since a year due to administrative reasons. Three more DR-TB centres stand sanctioned in the budget 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 patients have to pay for this test and are reimbursed later; however, many poor patients cannot pay and do not get the test. Only 76% lab confirmed MDR-TB patients were initiated on treatment. Only seven of 31 districts initiated >95% diagnosed MDR-TB patients on treatment, the lowest ones being Rayagada 29%, Sonepur 57% and Bhubaneswar 66%. Coordination and information exchange between DR-TB centres and district staff monitoring patients' 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 and DR-TB centres in NIKSHAY was minimal. Second-line anti-TB drugs like Levofloxacin and AmoxyClav were found being sold over the counter at pharmacies without prescription.

Recommendations

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

At IRL Cuttack, repairs of laboratory equipment need to be urgently addressed, particularly air handling unit of BSL III; bottlenecks for lab staff training need to be removed; CBNAAT site utilization needs to be optimized and monitored.

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

Resolve bottlenecks in expansion of DR-TB centre Cuttack; expedite initiating of services at three new DR-TB centres; plan district DR-TB centres in district hospitals (train specialists, reserve 4–6 beds) in a phased manner.

Decentralize sample collection and transportation to block level and involve ASHAs/ANMs/MPWs in transportation; engage PHC staff in patient tracking and care to improve treatment initiation of MDR-TB patients.

Contract out thyroid function test from the State level to relieve patients of financial burden.

Instruct DR-TB and TB–HIV coordinators of all districts to regularly meet the concerned DR-TB centre staff each month for updating patients' progress on treatment to improve care.

Extend social welfare schemes to MDR-TB patients irrespective of BPL 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 centres in NIKSHAY.

Strengthen stringent implementation and monitoring of Schedule H1 drugs at all pharmacies in the State through the State Drug Controller and drug inspectors.

4.6.8 Engaging all care providers

Findings

Large numbers of presumptive TB cases are accessing care from the non-public health-care facilities of the State. In the districts visited, patients and community members told that when they have a 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 then 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 of 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 far, only 19 cases have been notified since January 2013 from the private sector in Cuttack.

Despite the above situation, there were very limited efforts by the RNTCP, especially at district level, to engage all care providers with the RNTCP. 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 programme. The State commented that they were unaware of any such mandate given by CTD for the training modules and also that 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 PPIAs for the urban areas' private sector coordination. The PPIAs were to be assigned in 2013. The PPM coordinator's position at the State level 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 programme needs to engage with the 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 from 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 Schedule H1. The chemists and rural health-care providers (RHCPs), who are less qualified 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 Odisha State AIDS-control Society (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 key populations. They should be invited to participate in the Programme and partnership guidelines should be used to engage them. PPIAs should be engaged to play a crucial role in the engagement of private providers in the urban centres and help find the missed

cases and increase awareness of STCI and TB notification. Strong efforts are essential also in the perspective of occupational health issues in the State.

4.6.9 TB–HIV and other co-morbidities

Findings

The State has good TB–HIV coordination. Sixty-eight per cent of TB patients know their HIV status. The death rate of TB–HIV patients is high (17% new, 19% PT) mainly due to access issues and delayed diagnosis and ART initiation. The intensified package was started in 2009 and State-level SCC and SWG meetings are conducted regularly. DCC meetings are conducted in most of the districts. In Cuttack, two meetings are held per month. Integrated HIV/TB services exist in the CHCs and the Medical College visited. ICTs and DMCs are co-located. Identified TB patients are sent across for HIV testing. HIV patients tested at ICTs/ART centres are sent for TB testing. Good numbers of TB patients know their HIV status as per shared reports. Good numbers of coinfecting patients are receiving CPT and ART as per the extract of the coordination meeting held in February 2015. Good record-keeping on HIV/TB co-infected patients has been seen.

On the other hand, there are very limited infection control measures applied in co-located facilities, DMCs, ICTs and ART centres visited. For example, in ITCs, ARTs and DMCs visited, waiting rooms are shared by both HIV and TB patients and are not properly ventilated; providers for both HIV and TB patients are not taking adequate infection control measures (no masks, gloves for LTs; and no masks were provided to MDR patients). The death rate of HIV/TB patients is high, though no clear reason was given for this. There is no easy access to the diagnosis centres; patients have to travel more than 30 km to get access to CHCs and ICTs. There is no early initiation of treatment due to stockouts and shortages of drugs. IPT was not available. There was stockout of HIV test kits at ICT centres. Counsellors were not available for co-infected TB–HIV patients.

Recommendations

The State should implement infection control guidelines and monitor TBIC practices in HIV and TB care facilities. There is a need to ensure measures such as designated AIC focal points in each HIV and TB facility, facility AIC plan, AIC checklists, patient education and AIC in local languages on cough etiquette, availability of masks, cough monitoring and fast tracking and training of staff on TB and HIV infection control. Research to find out the reasons for the high death rate among TB–HIV patients should be encouraged. The State should ensure that it receives IPT procurement from CTD, and implements and monitors the uptake of IPT among PLHIV according to the National TB/HIV framework. Odisha SACS should request NACO to supply HIV test kits to ICTs and ART centres.

4.6.10 Paediatric TB

Findings

The State has made significant efforts to address TB in children, especially in 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% paediatric cases of the total TB cases, which is below the current national average of 6% and far below the 10–20% of new paediatric cases that are estimated to occur in India. In relation to contact screening, initial visits to households 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 stockouts 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 were no records to indicate that the children had completed IPT.

There are many reasons for the low identification of children through diagnosis. These are a combination of issues related to poor use or lack of use of available tools and 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 diagnose a child. Within the programme, facilities are not only poorly equipped but many also have inexperienced and poorly trained technicians; and hence children suspected of having TB are not adequately investigated.

In addition to these weaknesses within the programme, it is apparent that many cases of paediatric TB are identified and diagnosed outside of the RNTCP within the public and private sectors. Even given this reality, the Programme has little to no interaction with these providers (both public and private) and these providers are not notifying their patients to the Programme. A prime example of this is the lack of involvement with Shishu Bhawan, the largest paediatric health-care institution in the State. The diagnostic practices among doctors involved in childcare 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, DR-TB. Currently, there is improper investigation and treatment, e.g. Cat. I treatment is given without any efforts for a bacteriological diagnosis throughout the 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 are available.

Recommendations

There is an opportunity through NIKSHAY to gain a better understanding of paediatric TB in the State to better address the issues; but NIKSHAY must be expanded to include large paediatric institutions, as well as its data analysed 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 have been 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 TBHVs 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 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), linkages 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 paediatric-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 deficiencies 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.

4.6.11 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). Regional Medical Research Centre (RMRC), a research institute, is estimating the TB burden among the tribal population and diabetics. There is evidence to say that there is a significant burden of undetected TB among the tribal population. A survey among children in a tribal school showed that the prevalence is four times as compared to the rest of the State. Prisons are engaged in RNTCP but systematic screening of inmates and infection control are not in place.

Recommendations

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

4.6.12 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.

4.6.13 Community engagement and advocacy, communication and social mobilization

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. They have networked with the State and the arrangement is mutually beneficial. The school health programme is used to good effect to disseminate the 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 RNTCP in the State. The ACSM Officer's position at the State level is vacant for the last few years, with important implications for implementation of the ACSM strategies. The ACSM budget is only 2–3% of the RNTCP budget and expenditure is about 45% to 50% of this amount. Involvement of AYUSH doctors in RNTCP is inadequate. Though they work in PHCs, they are not given proper orientation to identify and refer presumptive TB cases to RNTCP. 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 and groups in villages. The 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 the district level, and forums for these organizations 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.

4.6.14 Research and technical assistance

Findings

Technical assistance to RNTCP is provided by WHO, FIND, IMA and other partners. Awareness drives and community-based active case finding is done in 10 coastal districts and has resulted in 11% incremental increase in case notification. Intensified case detection in Jagatsinghpur led to incremental increase of 8/100 000 cases. The 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. The State should take measures to strengthen the OR capacity by recruiting a focal point or by collaborating with research institutions or medical colleagues.

4.7 Tripura

Tripura has a population of 3.67 million, with 88% literacy. It has eight districts, (only six RNTCP districts), 11 TB Units and 56 DMCs. Full coverage by RNTCP was achieved in October 2005. PMDT coverage was completed in 2012. The State has one Culture and DST lab, but it is not yet accredited. There are no LPA or CBNAAT labs. There is one DR-TB Centre.

The JMM team visit included the following:

Unokoti District: District Hospital and RGM Hospital, Kailasahar; DTC and TU, Panisagar CHC; Irani PHC; Kanika Memorial PHC sub-centre; District Jail and one tea garden. Five TB patients and tea garden workers were interviewed at health facilities and at their homes.

North Tripura: District Hospital, Dharmanagar; Kadamtala PHC; Kanchanpur Sub-Divisional Hospital/PHC– TU; Jampui PHC (tribal area, >3000 ft above sea level) and pharmacies in Dharmanagar market. Four TB patients including one MDR-TB patient were interviewed, and six non-TB patients in general wards at health facilities and at their homes.

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. Three MDR-TB patients were interviewed at health facilities and at their homes.

4.7.1 Key observations

Political and administrative commitment for universal access of TB Care

TB is a State health priority, as evidenced by a large advances (INR 10 million) to TB work from the common flexi pool of NHM funds and 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.

Numbers of TUs have been increased with decentralization and use of norms for hilly districts in Tripura. TB–HIV and PMDT services are in place.

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

A high level of treatment success amongst the new smear-positive PTB cases has been maintained. There has also been a relatively high level of treatment success amongst smear-positive PTB re-treatment cases, with a slight decline in lost from treatment, but mirrored by a slight increase in death (small numbers of patients). There has been a significant increase in identification and examination of presumptive MDR-TB cases from 2014 onwards. However, annual (2014) new smear-positive PTB case notification rate is 36 per 100 000, which is below the national average of 50.

NIKSHAY has been 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 doing well;
- Minimal initial lost to follow up observed.

TB Care: treatment of TB

- 878 DOT centres are 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 the 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.

There has been a rapid increase in the number of presumptive MDR-TB cases examined from 2014 onwards, mainly due to resolution of sputa transportation and logistics issues. One hundred per cent of detected MDR-TB cases were placed on treatment, most within 1 week of the sample being sent for DST, and virtually all within 2 weeks. All investigations are provided free to patients, as are all ancillary drugs for ADRs (including reimbursements of any prescribed purchase from a private pharmacy). AIC measures in DR-TB Treatment Centre were found to be 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 health-care facilities are already registered in NIKSHAY. There are a large number of tea gardens in the State, most of which 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

Eighteen DMCs have a co-located ICTC, and 37 are co-located with a FICTC. Across the State, around 70% of TB patients know their HIV status, which has been steadily increasing annually since 2011. Eighty-five per cent 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 is collecting alternate specimens (GA, induced sputum, etc.) for the diagnosis of TB in children.

TB care: targeted interventions for special groups

DOT centre has been set up in the Central Jail of the State.

TB care: support systems for patients and families, social protection, UHC

All TB patients under RNTCP who successfully complete treatment are entitled to INR 900 from the State Government. Reimbursement of transportation cost as per actuals 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 rates.

Programme financing and health system strengthening

High percentage expenditure of disbursed funds was seen in 2011–12. Additional funds from NHM supported RNTCP in many activities.

Advocacy and communication

Some IEC materials are available in the local language. There is good knowledge of available services in the community. Patient provider and ASHA meetings are held by NGOs in North Tripura District.

Daily health camps and monthly village health nutrition day (VHND) are held.

Others

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

4.7.2 Constraints

Political and administrative commitment for universal access of TB care

STO also has other functions apart from TB care. 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 exist, which impacts on both financing and activities (e.g. quantum of training conducted). Across the State, 15 STS and STLS posts are vacant out of 22.

Many sub-centres have one MPW instead of two, with majority of their time being spent on MCH. There is no DTC in North Tripura district. Some rigidity in financing structures hamper smooth fund flow.

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

Estimated caseload of TB and MDR-TB has been extrapolated from national level estimates. There is a slow decline in both presumptive TB examination and notification rates across the State and most districts. Monitoring and supervision was 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 observed were 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 a resultant drop in symptomatics tested and an observed decreasing case detection. Many LT vacancies are there in Unokoti district. Non-DMCs are doing RNCTP smear microscopy work in North

Tripura district. A number of binocular microscopes need replacing. No rapid diagnostic technology is available anywhere in the State. Monitoring and supervisory activities were observed to be variable across the State and districts.

TB care: treatment of TB

There is virtually no buffer stock of PWBs in place in North Tripura District at Kanchanpur TU drug stores. INH 100 mg and 300 mg are not available and there were shortages of R150 mg as well. State Drug Store (SDS) has no electricity supply. SLDs are kept in a separate AC room. DOT providers' list is not available; duplicate Rx cards are not seen with DOT Providers and there are some delays in payment of honorarium to DOT providers.

TB care: drug-resistant TB

Sputum samples from presumptive MDR-TB cases need to go to Guwahati IRL for DST, and are transported by the Tripura State Bus Service, creating unnecessary delays. 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. Awareness of staff on provisions for patients and families is not adequate. Clinical monthly FU of patients once on treatment is not followed. Management of ADRs is not being handled well. There is inadequate personal protection for staff in the 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 government 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 were 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 is INR 80–100). There is only one ART centre at AGMC, and three link ART centres across the whole State. Whole blood testing for HIV is 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 HIV positive clients for TB. There is 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 100 mg and 300 mg are unavailable.

TB care: targeted interventions for special groups

There are no formal linkages between RNTCP and the medical services in the prisons and tea gardens. There is minimal emphasis on TB at the NACP Targeted Intervention (TI) sites. There is little documentation on the TB situation among the 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 the approved amount.

Advocacy and communication

TB and RNTCP not included in health camp and VHND activities.

Others

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

4.7.3 Key recommendations

While the basic components of the RNTCP are in place, the focus and importance given to TB at the State level is not translated to 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 coinfecting patients and DR-TB patients are available in the State, they require strengthening, both by decentralization 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 ensure that the patients are treated as the VIPs of the programme. Fully separate and equip the two undivided districts for optimal functioning of the TB programme. Fill key vacancies urgently, and consider decentralization of recruitment of key district-level HR to the district level in future. As an interim measure, use existing LTs in more than one DMC on a rotational basis, particularly for 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.)

Importance of timely general reporting and registration under NIKSHAY needs to be reinforced to the appropriate officers and staff. Capacity needs to be developed for analysis of programme data at district level from NIKSHAY and to use the information for further improvement.

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 need to be filled urgently. Non-DMCs doing RNTCP smear microscopy work in North Tripura should be stopped; instead, establish effective sputum collection and transportation mechanisms. The current siting of the DMCs needs to be reviewed and DMCs may be moved depending on workloads. Replace binocular microscopes as required with LED microscopes where appropriate. CBNAAT and LPA should be made available to the State.

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. Consider sending SDS storekeepers for retraining.

Easier and timely system such as e-payment needs to be established for disbursement of DOT providers' honorarium.

TB care: drug-resistant TB

The practice of sending the sputum samples to Guwahati IRL by the Tripura State Bus Service should be stopped and alternative transportation arranged, e.g. via individual vehicle hiring. All State and RNTCP policies and norms need 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 second DR-TB Treatment Centre in the northern part of the 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 advice on treatment. Awareness of patients and families of MDR-TB, transmission, treatment, etc. needs improvement.

Strengthen training to DPs in regard to ADR management. N95 masks need 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 first introducing LPA and CBNAAT at the AGMC Microbiology Department laboratory, whilst continuing to build capacity to do culture and DST. Second CBNAAT needs to be installed in Dharmanagar Hospital, North Tripura District.

Review staffing needs at AGMC laboratory as the plan for laboratory strengthening is finalized.

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, e.g. 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 decentralized 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 among HIV positive clients at the ICTCs is needed, as is 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). CTD should resolve the issues of non-availability of paediatric PWDs, INH and PPD urgently. Implement RNTCP 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 need to be sensitized 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 districts.

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 OR study to assess whether RNTCP policy on the said area needs reviewing.

Waste disposal and management needs strengthening. As an interim measure, it should be promoted that waste should be soaked overnight in phenol solution and buried in a deep pit.

Annexure

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