Revised National Tuberculosis Control Programme

NATIONAL STRATEGIC PLAN FOR TUBERCULOSIS ELIMINATION 2017–2025

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Central TB Division, Directorate General of Health Services,
Ministry of Health with Family Welfare, Nirman Bhavan, New Delhi – 110 108

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ACRONYMS

AIDS	Acquired Immuno- Deficiency Syndrome
ACSM	Advocacy Communication with Social Mobilisation
ANM	Auxiliary Nurse Midwife
ART	Anti-Retroviral Therapy
ARTI	Annual Risk of Tuberculosis Infection
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
BPHC	Block Primary Health Centre
BPL	Below Poverty Line
CCC	Community Care Centres
CDHO	Chief District Health Officer
CDMO	Chief District Medical Health Officer
CFR	Case Finding Report
CSO	Civil Society Organisation
CGHS	Central Government Health Scheme
CHC	Community Health Centre
CIDA	Canadian International Development Agency
CMO	Chief Medical Officer
CTD	Central TB Division
CPT	Cotriamoxazole Preventive Therapy
DR	Drug resistant
DS	**Drug sensitive**
DCC	District Coordinating Committee
DDG	Deputy Director General, TB
DEO	Data Entry Operator
DFID	Department for International Development, of the United Kingdom
DGHS	Directorate General of Health Services
DLN	District Level Network of PLHIV
DM	District Magistrate
DMC	Designated Microscopy Centre
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment, Short-Course
DPM	Deputy Programmer Manager
DRS	Drug Resistance Surveillances
DST	Drug Sensitivity Testing
DR-TB	Drug resistant tuberculosis
DS-TB	Drug Sensitive Tuberculosis
DTC	District Tuberculosis Centre
DTCS	District TB Control Society
DTO	District Tuberculosis Officer
EPTB	Extra pulmonary Tuberculosis
EQA	External Quality Assessment
ESI	Employees State Insurance
ESR	Erythrocyte Sedimentation Rate
FBO	Faith Based Organisation
FICTC	Facility Integrated Counselling and Testing Centre
FNAC	Fine Needle Aspiration Cytology
GDF	Global Drug Facility
GFATM	Global Fund for AIDS, TB and Malaria

HA	Health Assistant
HIV	Human Immune- Deficiency Virus
HRD	Human Resource Development
IEC	Information, Education and Communication
ICF	Intensive Case Finding
ICTC	Integrated Counselling and Testing Centre
ILFS	Infrastructure Leasing and Financial Services
IPT	Isoniazid Preventive Therapy
IRLs	Intermediate Reference Laboratories
LAC	Link ART Centres
LQAS	Lot Quality Assurance Sampling
LRS	Lala Ram Swarup Institute of Tuberculosis and Respiratory Diseases. New Delhi
LT	Laboratory Technician
LWS	Link Worker Scheme
MBPH	Market Based Partnerships for Health
MDG	Millennium Development Goal
MDR-TB	Multi Drug Resistant Tuberculosis
MO	Medical Officer
MOHFW	Ministry of Health with Family Welfare
MO-TC	Medical Officer –Tuberculosis Control
MPHS	Multi –Purpose Health Supervisors
MPW	Multi-Purpose Workers
NACP	National AIDS Control Programme
NAICC	National Airborne Infection Control Committee
NARI	National AIDS Research Institute
NCRL	National Commission on Rural Labour
NGO	Non-Governmental Organization
NRLs	National Reference Laboratories
NHM	National Health Mission
NTRI	National Tuberculosis Research Institute, Chennai
NSP	New smear positive
NSP-RNTCP	National Strategic Plan for Tuberculosis Control
NTF	National Task Force
NTI	National Tuberculosis Institute Bangalore
NTP	National Tuberculosis Programme
NUHM	National Urban Health Mission
OPD	Out Patient Department
OR	Operational Research
ORW	Out Reach Worker
OSE	On-Site Evaluation
INTERPHASE AGENCIES	Private Provider Interface agency
PHC	Primary Health Centre
PHI	Peripheral Health Institution
PHW	Peripheral Health Worker
PLHIV	People Living with HIV/AIDS
PPM	Public Private Mix/ Partnership
PMR	Programme Management Report
PP	Private Practitioner
PRI	Panchayati Raj Institution
PT	Preventive Therapy
PTB	Pulmonary Tuberculosis
PVPI	Pharmacovigilance programme of India
PWB	Patient Wise Box
QA	Quality Assurance
QC	Quality Control

QI	Quality Improvement
RBRC	Random Blinded Rechecking
RKS	Rogi Kalyan Samity
RNTCP	Revised National Tuberculosis Control Programme
RTR	Results of Treatment Report
SA	Statistical Assistant
SACS	State AIDS Control Society
SC	Sub Centre
SCC	State Coordinating Committee
SC/ST	Scheduled Caste/ Scheduled Tribe
SCR	Sputum Conversion Report
SOE	Statement of Expenditure
SPCB	State Pollution Control board
STCS	State Tuberculosis Control Society
STDC	State Tuberculosis Training and Demonstration Centres
STF	State Task Force
STLS	Senior Tuberculosis Laboratory Supervisor
STO	State Tuberculosis Officer
STS	Senior Treatment Supervisor
TB	Tuberculosis
TBHV	Tuberculosis Health Visitor
TH	Taluk Hospital
TI	Targeted Intervention
TO	Treatment organization
TSG	Technical Support Group
TU	Tuberculosis Unit
NTGW	National Technical Working Group
USAID	United States Agency for International Development
VCTC	Voluntary Testing and Counselling Centre
VHND	Village Health and Nutrition Day
VHSC	Village Health and Sanitation Committee
WHO	World Health Organization
XDR	Extensively Drug Resistant
ZTF	Zonal Task Force

EXECUTIVE SUMMARY

India has been engaged in Tuberculosis (TB control activities for more than 50 years). Yet TB continues to be India's severest health crisis. TB kills an estimated 480,000 Indians every year and more than 1,400 every day. India also has more than a million 'missing' cases every year that are not notified and most remain either undiagnosed or unaccountably and inadequately diagnosed and treated in the private sector. This tragic loss of life, continued suffering, poverty need to end with concerted efforts from all of us.

India is now better prepared to address TB better than ever before. It possesses advanced and effective interventions and technologies for diagnosis, treatment and care of TB. This NSP for 2017–25 for TB elimination in India (NSP) embraces these opportunities to leverage its full potential and proposes transformational changes to TB care service delivery.

Over the last NS period, we made significant gains in strengthening the support structures, programme architecture and implementation environment for TB control. This includes mandatory notification of all TB cases, integration of the programme with the general health services (National Health Mission), expansion of diagnostics services, programmatic management of drug resistant TB (PMDT) service expansion, single window service for TB-HIV cases, national drug resistance surveillance and revision of partnership guidelines. However, we have to recognize that more needs to be done to drastically reduce the TB incidence in India. We need aspirational objectives, a thoughtful and structured approach and a supportive environment. The NSP 2017-2025 builds on the success and learnings of the last NSP and encapsulates the bold and innovative steps required to eliminate TB in India by 2030. It is crafted in line with other health sector strategies and global efforts, such as the draft National Health Policy 2015, World Health Organization's (WHO) End TB Strategy, and the Sustainable Development Goals (SDGs) of the United Nations (UN).

The NSP for TB elimination 2017 -2025

The NSP for TB elimination 2017–25 is a framework to guide the activities of all stakeholders including the national and state governments, development partners, civil society organizations, international agencies, research institutions, private sector, and many others whose work is relevant to TB elimination in India. The NSP 2017-2025 which builds on the success and learnings of the last NSP, and articulates the bold and innovative steps required to move towards TB elimination, is a 3 year costed plan and a 8 year strategy document. It provides goals and strategies for the country's response to the disease during the period 2017 to 2025 and aims to direct the attention of all stakeholders on the most important interventions or activities that the RNTCP believes will bring about significant changes in the incidence, prevalence and mortality of TB. These strategies and interventions are in addition to the processes and activities already ongoing in the country.

As a strategic document, the subsequent operational plans will necessarily follow. The NSP will guide the development of the national project implementation plan (PIP) and state PIPs, as well as district health action plans (DHAP) under the national health mission (NHM). This NSP replaces previous strategies, and will inform and guide the technical and operational guidelines refresh and associated programme tools modifications.

The development of this NSP has been a collaborative effort between all the stakeholders including national and state governments, development partners, civil society organizations, and private sector in India which was led by the Central TB Division, Ministry of Health and Family Welfare. Knowledge and insights generated from a series of workshops and consultations with the

stakeholders, learnings from the implementation of the past NSP and experiences from the pilots, models and approaches tested over the last NSP period informed the strategies proposed in the current NSP.

Vision, Goals and Targets of NSP

The NSP proposes bold strategies with commensurate resources to rapidly decline TB in the country by 2030 in line with the global End TB targets and Sustainable Development Goal's to attain the vision of a TB-free India.

VISION: TB-Free India with zero deaths, disease and poverty due to tuberculosis
GOAL: To achieve a rapid decline in burden of TB, morbidity and mortality while working towards elimination of TB in India by 2025.

The results framework below highlights the core impact, outcome indicators and targets of the NSP that highlight the four thrust areas that include private sector engagement, plugging the leak from the TB care cascade, active TB case-finding among key populations (socially vulnerable and clinically high risk) and specific protection for prevention from development of active TB in high risk groups.

Table 1: Results Framework (impact and outcome indicators and targets)

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

Achieving the goals of NSP

TB control faces daunting challenges in India. Decades of unrestrained transmission has left hundreds of millions of Indians with latent TB infection, which may re-activate at any time. A significant proportion of the population[1] is undernourished, which weakens immunity and drives TB reactivation. A considerable number more suffer from risk factors for tuberculosis, including diabetes, indoor air pollution from cook stoves, or smoking. Tens of millions with previous, inadequately treated TB may recur at any time. The dense, growing urban environment facilitates the transmission of the disease cutting across all economic strata. Infectious TB cases spread disease to their family and community, perpetuating the age-old cycle of transmission and risk.

Despite these odds, countries have repeatedly demonstrated that TB can be controlled in the modern era, as long as TB is diagnosed early and treated properly and transmission thus interrupted. The overwhelming challenge facing TB control in India remains delayed diagnosis and inadequate treatment, particularly among patients seeking care from private providers, who alone are ill-equipped to sustain their patients on prolonged, costly treatment. Patients seeking care in the public sector have a better chance of treatment but still 1/3rd are lost between care-seeking and successful cure. India also has a large burden of multi-drug resistant (MDR-)TB and extensively drug resistant (XDR-)TB most of whom are undetected and continue to transmit disease; even those who are detected endure long toxic and costly treatments only to have poor odds of treatment success, along with a high loss to follow up.

Although India has managed to scale up basic TB services in the public health system, treating more than 10 million TB patients under RNTCP, the rate of decline is too slow to meet the 2030 Sustainable Development Goals (SDG) and 2035 End TB targets. Although sufficient insight and expertise exists to inform TB program decision-making, these resources have often been underutilized in terms of meeting the needs of policy makers for quantitative analysis and improvements in TB control policy and implementation.

Continuation of prior efforts have yielded inadequate declines, and will not accelerate the progress towards ending TB. New, comprehensively-deployed interventions are required to hasten the rate of decline of incidence of TB many fold, to more than 10-15% annually. The requirements for moving towards TB elimination have been integrated into the four strategic pillars of "**Detect – Treat – Prevent – Build**" (**DTPB**).

Explaining the DTPB approach of NSP 2017 -2025

D E T E C T	HOW DO WE DO IT?
Find all DS-TB and DR-TB cases with an emphasis on reaching TB patients seeking care from private providers and undiagnosed TB in high-risk populations.	• Scale-up free, high sensitivity diagnostic tests and algorithms • Scale-up effective private provider engagement approaches • Universal testing for drug-resistant TB • Systematic screening of high risk populations
T R E A T	**HOW DO WE DO IT?**
Initiate and sustain all patients on appropriate anti-TB treatment wherever they seek care, with patient	• Prevent the loss of TB cases in the cascade of care with support systems • Free TB drugs for all TB cases • Universal daily regimen for TB cases and rapid scale-up of short-course regimens for drug-resistant TB and DST guided

[1] 35% of adults and almost half of children in India are undernourished. NFHS-3

friendly systems and social support.	treatment approaches. • Patient-friendly adherence monitoring and social support to sustain TB treatment • Elimination of catastrophic costs by linkages of eligible TB patients with social welfare schemes including nutritional support
P R E V E N T	**HOW DO WE DO IT?**
Prevent the emergence of TB in susceptible populations	• Scale up air-borne infection control measures at health care facilities • Treatment for latent TB infection in contacts of bacteriologically-confirmed cases • Address social determinants of TB through intersectoral approach
B U I L D	**HOW DO WE DO IT?**
Build and strengthen enabling policies, empowered institutions and human resources with enhanced capacities.	• Translate high level political commitment to action through supportive policy and institutional structures: •National TB Elimination Board with 4 divisions instead of the current administrative set up at the national level - TB Elimination efforts to be implemented in a "Mission mode" •National TB Policy and Act • Restructure RNTCP management structure and institutional arrangement: •HR reforms to include unified state level contractual supervisory cadre (merger of STS/STLS) and dedicated staff for TB surveillance network in the country • Build supportive structures for surveillance, research and innovations, and a cafeteria approach of interventions based on local epidemiological situation •Reforming STDCs and expanding the role of the Medical Colleges to include surveillance and as centers of excellence (COEs) •Redefining the role of National institutes (NTI, NRTI, to encompass the burgeoning need for evidence to support policy advice • Scale up Technical Assistance at national and state levels. • Align and harmonize partners' activities with programme needs to prevent duplication

Throughout the NSP period, concerted attempts will be made to sharpen the programmes focus on increasing the yield and results from its strategies. This will be defined by the following:

- Nature of partnerships with private sector –RNTCP's role will be both enabling service provision, stewardship and monitoring.
- Collaborations and linkages between national programmes, departments and ministries
- Research, innovations and knowledge management - integral and critical for progress
- Strategic resource mobilization – explore mechanisms of raising resources for TB control beyond the Government's allocation
- Accountability to TB patients – especially women and other key populations
- Enhanced voice of the leadership role of India in the global TB arena

The next set of actions

The implementation of this NSP will be a combined effort of all stakeholders working towards the same goals. A restructured Central TB Department (CTD) at the MoHFW will oversee the implementation of the plan by coordinating the work of the National TB Control Board at the national level. State TB Cells will continue to oversee the work at state and district levels. Implementation of the NSP will begin on 1st April 2017.

Significant increase in the budget allocations for financial years (FY) 2017-2018 and beyond will be required to implement the NSP. It is also known that the resource requirements for implementing the NSP will be a function of the pace of implementation of the strategy, the demand from states, and the availability of resources in an environment of significant (% over the last 2 NSP periods) growth in the overall programme budget. Hence advocacy with national government and resource generation strategies will be aggressively pursued. It is expected that the cost of implementing the new NSP at Rs 16,649 Crores (USD 2485 Million) will involve a significant increase over the last NSP budget.

For achieving the goals of the NSP 2017 – 2025, the following critical components of the programme will be addressed on priority. The next set of actions include:

1. MoHFW will evolve a scheme to address the patients seeking care in private sector. The scheme will have suitable incentives for the private doctors and patients to report TB cases coupled with another scheme to provide free of cost medicines to TB patients going to a private doctor/institute.
2. A robust, modern MIS system will be developed to monitor the newly diagnosed as well as existing cases of TB on delivery of the drug kit to the patient, compliance to treatment regimen etc. The MIS system will have suitable linkages with the private pharmacy on sale of anti-TB drugs thereby integrating those patients into the MIS.
3. The availability of rapid molecular tests will be suitably augmented so that these diagnostic facilities are also made available for patients referred by any private doctor or institute.
4. To improve the compliance of the TB patients to the treatment regimen, MoHFW will start customized SMS services to the individual patients on regular basis reminding them about the time to consume the drugs.
5. The MoHFW will establish mechanisms for facilitating nutritional support to the TB patients, including financial support through DBT mode.
6. The MoHFW will work on a scheme to provide suitable incentives to the States doing well in RNTCP. The incentives will also be linked with performance in “Swachh Bharat Mission”.
7. TB Corpus Fund: To improve financial sustainability in the TB sector the programme will mobilise additional resources to accelerate TB control efforts, for which the ‘Bharat Kshay Niyantran Pratishtan’ (India TB Control Foundation) is proposed. Activities like nutrition support for TB patients, active case finding in prisons, slums, tribal area, sputum collection and transport in difficult areas will be carried out.

All these priority activities will be supported by a high visibility advocacy and communication programme, “TB Mukt Bharat” (the national “sweep out TB”) campaigns, which are massive, repetitive, intensive and persuasive, for case-finding and community commitment at panchayat, district and state level.

Tracking the progress

A national level annual review of the programme will be undertaken by the TB elimination board chaired by the Prime Minister’s Office (PMO). Apart from the SDG related indicators the review will also track programme performance and provide directives to enhance the ease of programme implementation at all levels.

Annual district TB control mission plans and report cards will incorporate the NSP priorities and evaluate its roll out in the districts and sub district level. Community accountability score-cards will be introduced in the current plan period which will ensure community ownership and early identification of system challenges.

A detailed plan to monitor and evaluate progress towards NSP goals is drawn up with input from all the stakeholders. Implementation and measurement will be 'bottom-up'. The CTD Monitoring and Evaluation unit will produce reports based on regular input from the states and all sectors represented in TB control efforts. Regular central and state programme evaluation will continue as is being done now with necessary changes in the TOR based on new interventions and strategies. As is being done over the past two decades, there will be an annual report highlighting the programme performance, a comprehensive evaluation report at the midpoint of the NSP and a final evaluation report at the end of the NSP. All reports will be posted on the national programmes website: www.tbcindia.org.

The NSP period 2017 – 2025 is a time of immense potential with the hopes of seeing new drugs, regimens and diagnostics. Wider application of ICT tools and health financing methodologies carry with it a promise for a stronger and rapid response to the TB epidemic. The national programme is alive to these possibilities and will suitably modify the NSP to incorporate these new tools.

To summarize, the ultimate impact of this NSP will be transformational improvements in the End TB efforts of India thereby contributing to the health and wellbeing of its population. The programme expects quality improvements as well as efficiency benefits contributing to significant cost savings. By taking a **Detect – Treat – Prevent – Build** approach the national programme can achieve significant positive change and make a real difference in the lives of the many people it serves. The impact of this NSP will be seen with commensurate investments, proposed as Rs 16500 crores in the national TB programme, especially in view of the required massive increase in notification from the private sector and building patient support mechanisms for all TB patients.

CHAPTER 1
INTRODUCTION

The journey so far

The National Tuberculosis Programme of India (NTP) was initiated in 1962 and was originally designed for domiciliary treatment, using self- administered standard drug regimens. A combined review of the programme in 1992 concluded that the NTP could not achieve its objectives of TB control and hence, on the recommendations of an expert committee, a revised strategy to control TB was pilot-tested in 1993. A full-fledged programme was started in 1997 and rapidly expanded with excellent results. This Revised National Tuberculosis Control Programme (RNTCP) that uses the DOTS (Directly Observed Treatment, Short-course chemotherapy) strategy achieved country coverage on World TB Day, 24th March, 2006. The programme has achieved several milestones related to diagnosis and treatment services of TB since 2006. Since inception in 1997 and up to December 2015, more than 19 million patients were initiated on treatment and more than 3.5 million additional lives have been saved.

National AIDS Control Programme and RNTCP have developed a "National framework of joint TB/HIV Collaborative activities". Nationwide coverage of services for programmatic management of drug resistant TB, which began in 2007, has been achieved in March 2013. The Government is also proactively engaging with private practitioners, number of private organizations, NGOs, Professional bodies like Indian Medical Association, to enhance notification of TB cases. Central TB Division, in collaboration with National Informatics Centre, has developed a case-based web-based platform- 'Nikshay' in 2012, which has now been scaled up nationally.

The Standards for TB Care in India (STCI) have been published jointly by RNTCP and World Health Organization in 2014, which lays down uniform standards for TB care for all stakeholders in the country.

NSP 2012-17 Key Achievements

India's achievements in TB control over the past decade are remarkable. More than 90 million people have been tested, more than 19 million TB patients detected and treated, and millions of lives saved by the RNTCP's efforts. India's ambitious National Strategic Plan (NSP) to achieve Universal Access to quality TB diagnosis and treatment has guided activities and created accountability against results. India achieved complete geographical coverage for diagnostic and treatment services for multi-drug resistant TB (MDR-TB) in 2013, with a remarkable 93,000 persons with MDR-TB diagnosed and put on treatment till 2015. The nation's first national anti-TB drug resistance survey is being conducted by NTI, Bangalore. The RNTCP and the National AIDS Control Organization (NACO) have made HIV-TB collaboration efficient and effective; most TB patients registered by RNTCP receive HIV screening, and now 90% of HIV-infected TB patients receive anti-retroviral treatment (ART).

In a landmark move, the Government of India, Ministry of Health and Family Welfare has notified for prohibiting the import of sero-diagnostic test kits for tuberculosis and also the manufacture, sale, distribution and use of such kits for tuberculosis, on 7th June 2012. Another government order issued by the Government of India in May 2012 mandates all healthcare providers to notify every TB case diagnosed and/or treated, to local authorities. The banning of serological tests for diagnosis of active TB, saved countless persons from inaccurate test results and unnecessary expense. Since TB became a notifiable disease in 2012, private providers nationwide have notified more than 0.7

million TB patients. This also benefited from the Government's adoption of a unifying 'Standards for TB Care in India', applicable for public and private sector alike.

The year 2014 saw large strides being made with many new initiatives and policy changes in RNTCP. From the launch of first nationwide anti-TB drug resistance survey of India, guidelines being formulated on DST guided treatment for drug resistant TB patients, molecular techniques like CBNAAT being deployed at ART sites in 5 high TB/HIV burden states to detect MTB in presumptive TB cases among people living with HIV, screening all TB patients for diabetes under programme settings and the release of Standards for TB Care in India, a comprehensive handbook facilitating patient centric standards for TB care for all stakeholders.

The national programme also rolled out an innovative and visionary electronic recording and reporting system (Nikshay) across the country in 2012, 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 with India's leading actor, Amitabh Bachchan's campaign, "TB Harega, Desh Jeetega", with commendable investments by the Ministry and corporations to broadcast these messages.

Throughout, RNTCP has demonstrated unprecedented financial absorption capacity. While allocations have been lower than requested, it has been spent fully. During the last NSP a sum of Rs. 3003.76 crores were received out of which Rs 2754.33 crore was spent (information as of 14th Feb 2017). 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 TB Burden in India

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 the absolute numbers of incidence cases each year. Mortality due to TB is the third leading cause of years of life lost (YLLs) lost, in the country. The estimated incidence (new TB cases per year) is 2.8 million cases in 2015 (217(CI: 112 to 355) per 100000 population) with a confidence interval of 1.47 to 4.65 million. The estimated mortality due to TB is 480,000 (CI: 380000-590,000). Approximately 5% of the incident TB cases have co-morbidity with HIV, though this proportion varies depending on the HIV prevalence of the population.

However India has a wide spectrum of TB epidemiology. Data from the 7 subnational prevalence surveys, sub national and district level prevalence of infection surveys and analysis of programme notification data on TB, MDR TB and TB HIV reveals that the country has varied epidemiology from very high TB prevalence to very low TB prevalence, high and low TB/HIV coinfection and DR-TB depending on state/regions. There is general epidemiological difference between urban and rural areas, urban areas typically characterized by lower prevalence with higher Annual Risk of TB infection (ARTI), which rural areas characterized by higher prevalence and lower ARTI. The diversity of TB epidemiology in the country necessitates different approaches to be adopted for addressing the problem.

But challenges remain

The JMM 2015 observed that the implementation of the NSP for 2012-2017 did not achieve the projected increase in case detection by the RNTCP. In addition, the ambitious expansion of resources planned under the NSP, 2012-2017 will have tripled the expenditure of the prior plan, but has not been matched by allocations. While RNTCP expenditure has increased 27% since 2012, there is a growing gap between the allocation of funds and the minimum investment required to reach the goals of the Plan.

The private sector is massive, heterogeneous, and growing with more than half the TB patients in the country being cared for in this sector. In spite of mandatory notification, many patients are still not notified to the RNTCP. Two decades of attempts to improve collaboration between the public and private sectors, have not yet worked except in a few innovative pilots. The existing TB surveillance system lacks the capacity to count the large pool of privately diagnosed and treated TB cases, and what is not measured is unlikely to be improved.

Within the public sector, there is heavy dependence on an insensitive diagnostic test, microscopy of sputum, which, in addition, cannot diagnose drug resistance. The NSP, in line with the STCI, promote drug sensitivity testing for all presumed cases of MDR TB and other groups.

While the expansion of treatment of MDR TB cases is a major achievement, the cost of providing services is approaching 40% of total RNTCP expenditure. This threatens the future of TB control in India and underscores the necessity to prevent drug resistance. Universal drug susceptibility testing and switching to a daily regimen with adherence support will address this problem.

The enormous diversity between states, and even districts, in terms of the population, terrain, level of development, health systems, and epidemiologic variety pose problems for a uniform centralized approach to TB control. TB patients, civil society leaders, and community-based organizations need to be meaningfully and intensively engaged in the TB response at all levels. The draft national health policy 2015 recognizes the diversity in India and very well articulates the need for special efforts to reach and address TB in vulnerable and disadvantaged groups. These key affected population groups are vulnerable, face barriers in accessing care and deserve more attention for reasons of equity, social justice and human rights. There has been limited 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 matched the scale of the need.

In the rural areas, the RNTCP has been able to develop a structure for programme implementation because of the established rural health infrastructure under the general health system. In the urban areas, however, there is no established health structure owing to the slow progress of the National Health Mission in the urban areas. The lack of effective partnerships with the private sector too adversely impacts the control efforts in the urban areas. Tracking patients put on treatment, especially the migrant urban slum dwellers, has also remained a challenge.

The integration between the health systems and the programme has been achieved in the provision of services. However it is limited in other operational areas such as administration, financial management and monitoring and supervision. This has affected the quality of implementation because of the multiple administrative, financial and operational functions to be carried out by the field level staff. The numerous vacancies within the health system adds to the weak implementation capacity of the programme.

TB PROBLEM

India has the highest burden of Tuberculosis and multi-drug-resistant TB (MDR-TB) in the world, disproportionately high even for India's population.

Recent evidences indicate that India's TB burden may be reducing, but only very slowly.

There is wide geographical variation in the epidemic and its trends. Severe local epidemics are hidden behind inadequate data and surveillance systems, which miss most privately-treated patients.

Delay in diagnosis, inadequate treatment, high rates of recurrent TB, drug

Analysis of the environment in which the TB programme operates

An analysis of the economic, political and social context in which TB programme operates has given insight and knowledge of the need to respond rapidly to the many challenges required to address the unrelenting TB epidemic. The continued resource crunch, increased demands of a weak public health system and an indifferent private sector add to the challenges faced. However, research has demonstrated that the programme has huge strengths to draw on as it takes the opportunities

presented by new diagnostics and drugs, emphasis on digital technologies and radical strategies for making the required epidemiological impact.

	Strengths	Weakness
Internal factors	1. High level political and administrative commitment providing fresh impetus to TB combat efforts in the country. 2. Deliberate efforts to move away from the routine and set aspirational goals, targets with strategies and actions to match. 3. Availability of new drugs, regimens, diagnostics, approaches and strategies to end TB.	1. TB epidemiology in India is diverse, and many communities have been poorly served by one-size policy prescription. 2. TB programme structure unable to cope with the growing demands for ending TB 3. Limited human resource at the central TB division which severely limits programme management at the National level. 4. Private sector involvement in public health actions related to TB control is not commensurate to its size and dominance in TB care.
	Opportunities	**Threats**
External factors	1. Aggressive research agenda driven by the research consortium including clinical trials for new drugs, vaccines and genomic studies provides unheralded potential for TB control. 2. In-country innovations and pilots with potential for replication and scale up. 3. SDGs and End TB strategy provide ambitious targets to aim for by the national efforts.	1. Amplification of drug resistance. 2. Insufficient budgetary outlay for health in the national budgets compromising the allocation to TB. 3. Variable implementation capacity, capability and ownership of the states. 4. Loss of independent, third party, technical assistance from development partners

Crafting strategies for the current NSP involved the analysis above, inputs from the working groups set up for specific thematic areas (Annex M) and also included TB impact modelling.

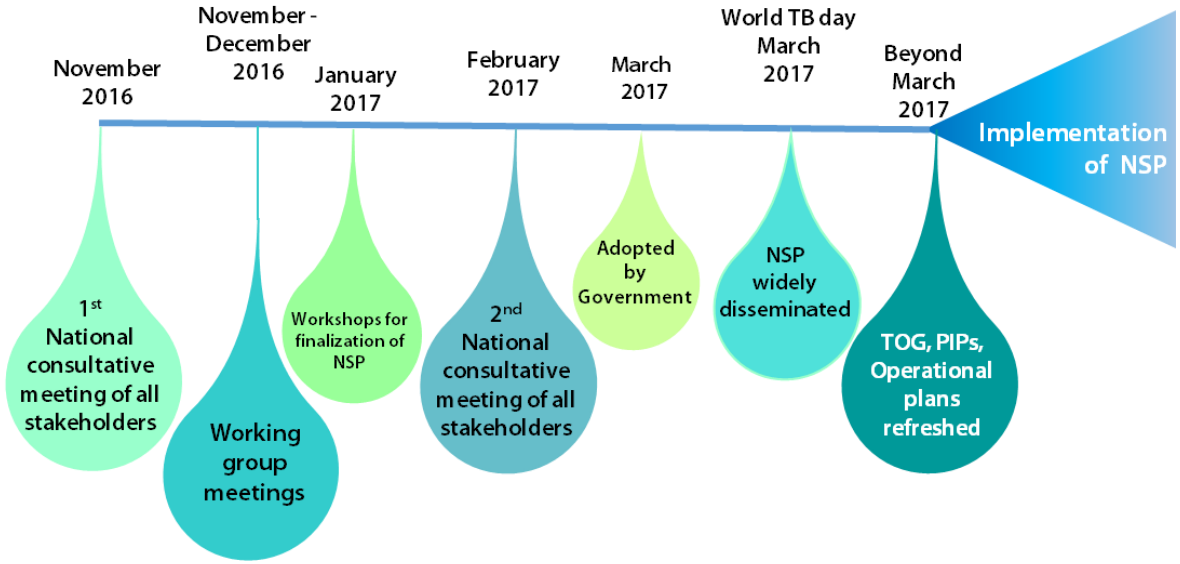
TB impact modelling

Early modelling exercises shows that increased coverage of care both in public and private sector will result in a decline by roughly half the TB incidence in the country over a decade. Activities to address determinants of TB such as urbanization, housing, malnutrition, and interventions such as active case finding in high risk population, are expected to further reduce the incidence. Ongoing analysis is incorporating these interventions to understand the additional reduction in incidence that may be possible and commensurate activities to achieve the ambitious goals of this NSP.

CHAPTER 2
DEVELOPING THE NSP

The Ministry of health and family welfare in consultation with over 150 national and international experts working in the field of public health, program managers, donor agencies, technical partners, civil societies, affected community representatives and other stakeholders of TB control both from public as well as private sector finalized the new National Strategic Plan for TB 2017-2025 (NSP).

This new NSP was prepared in two phases. The first phase of preparation was completed at a National consultative meeting for the development of NSP in October 2016. That consultation attended by all the major stakeholders in the country, culminated in a process of extensive consultations and confirmed the proposed strategic directions. The second phase coalesced and finalized necessary technical work to address the main comments from the working group discussions and comments received from partners and experts. The new strategy benefits from the comments and suggestions given to the team during these enriching consultations. This NSP is intended to contribute to the decisions of the policy makers at the national and state levels, development partners, and other stakeholders supporting the RNTCP efforts to end TB in India.



This NSP outlines a new strategic vision for tuberculosis control that places emphasis on bold and innovative strategies supported by an enabling structural and policy environment to roll out the interventions nationally. These have been informed by the periodic programme reviews and programmatic gap analysis. Although this NSP does not include every intervention that must happen in India to manage TB, its preparation has been informed by abundant in-depth policy work, conducted at the central level, setting forth analysis on direct benefit transfers to patients, on nutrition support, on extensive use of ICT in the programme, and a renewed commitment to universalize diagnosis and treatment for TB, particularly in the private sector. It provides the vision of the national programme on the need to strengthen health systems and also address key challenges in the near future that include managing the disease in diabetics, cancer patients, elderly and children. Through the implementation of this new NSP, RNTCP plans to further strengthen its analytical and operational work in these important areas.

The new NSP 2017 - 2025 identifies a path of action and internal functional modifications for its implementation to bring about essential improvements in the programme performance. It identifies necessary changes that will allow better support for the programme as well as stakeholder's efforts to achieve results.

DETECT

What does it mean in the context of this NSP for TB elimination in India?

Early identification of presumptive TB cases, at the first point of care be it private or public sectors, and prompt diagnosis using high sensitivity diagnostic tests to provide universal access to quality TB diagnosis including drug resistant TB in the country.

What does it entail?

1. To use high efficiency diagnostic tools for early and accurate diagnosis linked treatment across the country
2. To strengthen surveillance systems including introduction and scale up of next generation sequencing platforms
3. Purchasing services and ensuring notification through laboratories from the private sector and link to laboratory surveillance
4. To promote and foster research for new diagnostic tools
5. To build capacity for diagnosis of LTBI

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- **CHAPTER 6: PATIENTS IN PRIVATE SECTOR**

Programme Indicators

Strategy	Indicators	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Detect	Total TB patients notified	1607983	1745000	2350000	3000000	3350000	3600000	3600000	3100000	2700000	2300000	2000000
	Range			1900000 – 2700000	2400000 – 3200000	2600000 – 3650000	2800000 – 3900000	2700000 – 3900000	2450000 – 3650000	2000000 – 3400000	1600000 – 3100000	1200000 – 2600000
	No of TB patients registered under RNTCP	1423181	1420000	1450000	1500000	1550000	1600000	1600000	1350000	1200000	1100000	1000000
	Range			1400000 – 1500000	1400000 – 1600000	1400000 – 1650000	1400000 – 1700000	1300000 – 1700000	1250000 – 1650000	1000000 – 1600000	800000 – 1500000	600000 – 1300000
	No of TB patients notified by private sector	184802	325000	900000	1500000	1800000	2000000	2000000	1750000	1500000	1200000	1000000
	Range			500000 – 1200000	1000000 – 1600000	1200000 – 2000000	1400000 – 2200000	1400000 – 2200000	1200000 – 2000000	1000000 – 1800000	800000 – 1600000	600000 – 1300000
	No of presumptive TB pts to be offered bacteriological test (Sputum microscopy)	9132306	9200000	8235000	8100000	8085000	6300000	6550000	5800000	5175000	4650000	4125000
	No of presumptive TB pts to be offered rapid molecular test	40000	156600	2063000	3670000	5670000	8670000	11670000	13420000	14770000	15870000	16620000
	No of presumptive MDRTB pts to be offered rapid molecular test	170698	365400	420000	560000	810000	990000	1080000	1170000	1260000	750000	750000
	Total of presumptive and diagnosed TB pts to be offered rapid molecular test	210698	522000	2483000	4230000	6480000	9660000	12750000	14590000	16030000	16620000	17370000
	Proportion of identified targeted key affected population screened annually	0	0	80%	90%	100%	100%	100%	100%	100%	100%	100%
	Proportion of TB patients notified by the private sector	11%	19%	38%	50%	54%	56%	56%	56%	56%	52%	50%
	Proportion of microbilogiclly confirmed TB patients out of those notified by private sector	2%	3%	10%	15%	25%	30%	35%	40%	42%	45%	45%
	Proportion of notified pulmonary TB patients offered DST	25%	30%	50%	60%	70%	80%	90%	95%	98%	99%	100%
	No of presumptive MDRTB patients to be examined	341395	444933	600000	700000	900000	1100000	1200000	1300000	1400000	1500000	1500000
	MDR TB notified			70500	90000	100500	108000	108000	93000	81000	69000	60000
	No of MDR/RR TB patients notified	29057	36000	53460	66000	78975	92000	92000	78250	69000	61500	55000
	No of MDR/RR TB patients initiated on treatment	27104	33000	48114	59400	71078	82800	82800	70425	62100	55350	49500
	No of H mono-poly resistant TB patients notified	11802	13144	32076	79200	189540	276000	276000	234750	207000	184500	165000
	No of H mono-poly resistant TB patients initiated on treatment	100	200	28868	71280	170586	248400	248400	211275	186300	166050	148500
	No of Pre XDR TB patients notified	1837	1785	13365	22500	25125	27000	27000	23250	20250	17250	15000
	No of Pre XDR TB patients intiated on treatment	1670	1550	12029	20250	22613	24300	24300	20925	18225	15525	13500
	No of NTM patients notified	580	720	1974	2520	2814	3024	3024	2604	2268	1932	1680
	No of NTM Patient initiated on treatment	NA	NA	200	500	1500	2419	2419	2344	2041	1739	1512
	No of XDR TB patients notified	2340	1340	2406	2970	3554	4140	4140	3521	3105	2768	2475
	No of XDR TB patients initiated on treatment	2127	1197	2165	2673	3198	3726	3726	3169	2795	2491	2228

Strategy	Indicators	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Treat	Proportion of notified patients initiated on treatment (public & private sector)	88%	89%	90%	92%	95%	99%	99%	99%	99%	99%	99%
	Proportion of pateints from private sector who are provisioned or reimbursed by the program for anti TB drugs	1%	3%	25%	50%	80%	80%	90%	90%	90%	90%	90%
	Treatment success rate of TB Pts in the pvt sector	13%	15%	50%	70%	80%	90%	90%	90%	90%	90%	90%
	Treatment success rate for DS TB	75%	75%	78%	80%	85%	90%	90%	92%	92%	92%	92%
	Treatment success rate for RR TB	46%	46%	48%	48%	56%	65%	70%	72%	73%	74%	75%
	Proportion of notified TB patients using ICT supported adherance systems	1%	2%	10%	30%	50%	80%	90%	90%	90%	90%	90%
	Proportion of notified TB patients receiving financial support through DBT	0%	0%	2%	50%	70%	80%	90%	90%	90%	90%	90%
Prevent	Proportion of tertiary and secondary facilities with budgeted action plan for AIC in TB facilities	0	0	0	40%	60%	80%	100%	100%	100%	100%	100%
	Proportion of district hospitals and medical colleges with installed environmental control using UVGI in the DR TB Centers/ TB wards in RNTCP	0	0	0	40%	60%	80%	100%	100%	100%	100%	100%
	Proportion of identified/eligible individuals for preventive therapy / LTBI s – initiated on treatment	10%	10%	15%	25%	40%	60%	80%	90%	90%	95%	95%
Build	No of rapid molecular laboratories established	123	628	1235	2235	3235	5235	6235	6985	7585	8085	8335
	No of first-line DST (Phenotypic) laboratories established	62	66	81	96	101	101	101	101	101	101	101
	No of first-line DST (Genotypic) laboratories established	44	46	54	54	54	54	54	54	54	54	54
	No of second-line DST (Genotypic) laboratories established	0	0	54	54	54	54	54	54	54	54	54
	No of second-line DST (Phenotypic) laboratories established	18	26	40	55	70	85	100	101	101	101	101
	No of districts covered for call center support for tretament adherence (including 99 DOTS districts)	4%	4%	18%	50%	80%	100%	100%	100%	100%	100%	100%
	Proportion of sanctioned positions (newly created positions in this NSP) filled	NA	NA	30%	80%	100%	100%	100%	100%	100%	100%	100%
	No of TB surveillance unit (CTD & NTI) established at the national level	NA	NA	1	2	2	2	2	2	2	2	2
	No of TB surveillance units established at the State / UT level	NA	NA	5	20	42	42	42	42	42	42	42
	Proportion of TB surveillance units established at the district level	NA	NA	30%	80%	100%	100%	100%	100%	100%	100%	100%
	Proportion of treatmemnt supporters paid incentives/honorarium using DBT/PFMS	NA	NA	30%	80%	100%	100%	100%	100%	100%	100%	100%
	Proportion of private providers paid incentives/honorarium using DBT/PFMS	NA	NA	25%	50%	80%	80%	90%	90%	90%	90%	90%
	Proportion of Contractual staff salaries paid through DBT	NA	NA	50%	100%	100%	100%	100%	100%	100%	100%	100%
	Proportion of patient provider support agency units established at the state level	NA	NA	30%	80%	100%	100%	100%	100%	100%	100%	100%
	Proportion of patient provider support agency / units established at the district level	NA	NA	30%	80%	100%	100%	100%	100%	100%	100%	100%
	Proportion of Electronic drugs and supply chain management systems deployed in the districts	NA	NA	30%	100%	100%	100%	100%	100%	100%	100%	100%
	Porportion of districts with capability for identification local and focal epidemic using GIS based ICT tools	NA	NA	30%	80%	100%	100%	100%	100%	100%	100%	100%
	Porprotion of notified TB pts receiving social support from CBOs, NGOs, FBOs	NA	NA	5%	25%	50%	70%	80%	90%	90%	90%	90%

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CHAPTER 4
LAB SYSTEMS AND DIAGNOSIS

Introduction

To achieve universal access to early accurate diagnosis of TB and enhancing case finding efficiency, identification of presumptive TB cases at the first point of care and linking them to the best available diagnostic tests is of paramount importance. Early case detection is vital to interrupt the transmission of TB disease.

RNTCP screens around 20 million TB symptomatics by microscopy and initiates around 1.5 million cases of TB on treatment annually since 2007-08. Rapid molecular diagnostics introduced since 2009 and scaled up from 2012 onwards has ensured that Line Probe Assay and CBNAAT testing is available throughout the country. In 2016, 520,000 patients have been tested and 35,000 Rifampicin resistant/MDR-TB patients have been diagnosed. Second line DST using Liquid culture systems are in place and are being scaled up to cover the entire country by December 2017.

RNTCP has a three tier laboratory network system for the diagnosis of Tuberculosis. The NRL, IRL, and DMCs, all the laboratories under RNTCP follows the quality assurance protocol for all technologies as per the WHO guidelines. RNTCP uses sputum smear microscopy for primary diagnosis of drug sensitive TB and rapid molecular test for the diagnosis of drug resistant TB.

The integrated diagnostic algorithm as described in the TOG prioritizes the use of high sensitivity tools like Chest X-Ray as a screening method to improve the sensitivity of detecting pulmonary TB followed by a high sensitivity diagnostic test like CBNAAT as tool for universal DST.

Routine Surveillance for TB and DR TB is rudimentary in the country is mostly derived from prevalence surveys for disease burden, ARTI surveys for new infection and State and district level drug resistance surveys. The recently concluded first National Drug Resistance Survey has provided new insights on various drug resistance patterns and is the first step to build capacity for setting up continuous surveillance system in the country.

TB Research has been conducted in India through various specialized institutions like ICMR, DBT etc. RNTCP has made special efforts to promote research especially operational research in medical colleges and other national institutes. This is now being further refined through a national mechanism of setting a TB Research Consortium to promote and foster research. However RNTCP will continue to support ORs and also liaise with the consortium for field evaluations and implementation research for new improved tools in the area of diagnostics.

Hitherto the programme did not have an articulated policy for LTBI management except for children less than 6 years of age who are contacts of smear positive pulmonary TB or PLHIV. It is envisaged that with the country adopting the end TB strategy, LTBI diagnosis and treatment will be initially used as a strategy only in low prevalence settings as notified by the programme.

Achievements

RNTCP has scaled up the use of rapid molecular diagnostic tools like LPA and CBNAAT and has over 735 CBANNAT facilities for decentralized DRTB testing. This expansion resulted in significant increase in the number of MDR TB diagnosed in the year 2015-16. In addition, baseline second line DST using the MGIT system was scaled up with 25 labs throughout the country providing complete geographical coverage. RNTCP has made available more than 1800 LED FM (LED based fluorescent microscopes) for the high workload DMCs to improve efficiency of smear microscopy services. RNTCP has established two additional NRLs to improve supervision and monitoring of state level

laboratories, in conjunction with adaptation of newer technologies and increase in number of state level laboratories to ensure even distribution of the increasing work load. RNCTP has engaged private sector laboratories under the revised NGO-PP schemes for service delivery. In addition a novel private sector approach for ensuring affordable diagnostics for patients seeking care in the private sector which is an innovative business model developed with private engagement through a mechanism called Initiative for Promoting Affordable and Quality TB Tests. This is a platform to bring RNTCP or WHO-approved tests like CBNAAT, LPA, liquid culture DST (MGIT) etc.
As stated in the NSP 2012 to 2017, RNTCP has achieved DMC which includes more than 1800 LED FM DMC in the high workload DMCs.

Unit	2012	2017
DMC_LED	15	>1800
IRL/ Solid	7	44
FLD-LC	3	33
SLD-LC	3	25
LPA	15	54
CB NAAT	18	628
Private Sector	3	14

Another key achievement is the strengthening of sputum collection and transport for laboratory testing by building capacity for decentralized collection. This has resulted in rapid turnaround times for receipt of results for patients to be initiated on MDR TB regimen as soon as possible. The programme has a very well established quality assurance (QA) mechanism which follows the WHO system of hierarchal control from the highest level of National Reference laboratories to State Intermediate Reference labs (both IRL and CDST), to CBNAAT at the district/sub district level and then designated microscopy centres at the most peripheral level. The QA has all elements of internal quality control, on-site evaluation and external quality control. The EQA for DST is through structured panel testing and retesting exercises. The proficiency testing schedule is annual in nature with biennial certification process for all technologies (both DST and molecular). RNCTP has a WHO supranational reference laboratory (SRL) for the South East Asia region located at Chennai (NIRT, ICMR) which also serves as a NRL. Quality assurance panel for both first and second line drugs to the SRL and two other NRLs (NTI Bangalore and NITRD Delhi) is provided by the WHO coordinating lab (Antwerp) of SRL network.

Challenges

RNCTP has multiple challenges in relation to laboratory services. These include the following.

- Collection of appropriate specimens from children and EPTB. The capacity for specimen collection (children and EPTB) at district level is also deficient. Transportation of specimens from hard to reach areas (hilly, tribal, deserts, etc.) continues to be challenging despite local efforts to improve the sputum collection and transport system.
- Establishment of TB containment labs at state level.
- Procurement of equipments with original manufacturers from outside the country having no or restricted post sales services in the country threatens unhindered lab operations. With only a limited number of firms in country with capacity to provide AMC services in select locations, the cost of AMC is high. AMC for equipments is an issue due to limited technical knowledge and availability of funds
- Supervision is sub-optimal mainly driven by limited resources for OSE and excessive workload due to expanding PMDT services. The paper based system of monitoring (recording and reporting) is tedious leading to delayed reporting, limited analysis and troubleshooting of errors of lab data. There's limited capacity of the programme to take timely corrective actions.

- Retention of trained staff and compensation packages is a barrier for sustainability for ensuring consistent performance.

Expanding and strengthening the capacity of laboratories

The goal of diagnosis and lab services is to further expand and strengthen capacity of laboratories in conducting mycobacterium tuberculosis culture and drug sensitivity tests (C and DST) towards achieving universal access to quality TB diagnosis including drug resistant TB in the Country.

Strategies for attainment of the goal.

1. Use high efficiency diagnostic tools for early and accurate diagnosis linked treatment across the country
2. Strengthen surveillance systems including introduction and scale up of NGS platforms
3. Purchasing services and ensuring notification through laboratories from the private sector and link to laboratory surveillance
4. Promote and foster research in conjunction with the TB Research Consortium for new diagnostic tools
5. Build capacity for diagnosis of LTBI

Activities

1. Scale up of rapid molecular tests for TB diagnosis. Facilitate research in the development of POC tests. Details are described in the chapter on research.
2. Provision of Digital X-Ray preferably enabled with Computer Aided Diagnosis (CAD) and tele-radiology services across the health sector: Most of the district hospitals have an X-Ray facility and these will be utilized for screening. For those districts which might not have an X-Ray machine the programme will facilitate access to radiology services. For patients seeking care in the private sector the services will be made available free either by free tests in the government facilities or through mechanisms for reimbursement of costs.
3. Universal DST to at least Rifampicin for all diagnosed TB patients through offer of CBNAAT will be rolled out in a phased manner starting 2017. DBT will be utilized for purchase of services from private/non-health sectors
4. Diagnostics for NTM detection and DST will be introduced and scaled up. The guidelines to diagnose and manage NTMs has been added to the updated PMDT guidelines and will be rolled out in a phased manner throughout the country starting 2017. This will also include the building of capacity of the labs to hasten the roll out.
5. A sentinel surveillance system as per the lab scale up plan will be established in the country with National TB Institute, Bangalore as the nodal Centre. Initially it will involve setting up sentinel centres at 10 sites with additional human resource and sequencing equipments and reagents. The sentinel surveillance, initially will be through these select sites which will progressively be transitioned to routine surveillance in private labs and linked to RNTCP surveillance.
6. Scale up effective mechanisms of affordable diagnostics for TB in private sector will be done including provision of services by the programme, giving diagnostics to the private sector or reimbursement of the cost.
7. In order to address the higher requirement of TB culture tests for follow ups and outcomes, programme will use its own laboratory capacity to its optimum and will opt for using private sector with reimbursement of costs.
8. Additional required human resources deployment for laboratories including biomedical engineer/biotechnologist.
9. Establishment of 2 Additional NRLs (West and North-East).

10. Health Insurance for healthcare workers including laboratory personnel will be extended by the programme. Efforts will be made to link these personnel with the existing government insurance schemes. Further details are available in the chapter on Surveillance.
11. The programme will empanel accredited labs for diagnostics. NABL accreditation for public sector labs will be undertaken per the lab scale up plan. MoU with NABL for providing proficiency panels to private and corporate sector labs for quality assured diagnostics and DST will expand the capacity and accessibility which will be further augmented by training NRL representatives to be NABL assessors for TB labs.
12. Implementation of laboratory information management system and linking it to e-Nikshay will also be hastened during this plan period.

CHAPTER 5
CASE FINDING

Introduction

Early identification of people with a high probability of having active TB (presumptive TB) is the most important activity of the case finding strategy. Screening and diagnosing patients with appropriate tests and strategies will largely determine the response to appropriate treatment.

Presumptive TB patients will be promptly identified and are to be referred to diagnostic facility for appropriate investigation. Patients attending health institutions both in the government and private need to be systematically screened for symptoms of TB by the health care provider.

Passive case finding alone leads to missed cases or delayed diagnosis. Enhanced outreach activities to detect more TB cases are critical to universal access. Screening for TB has also to be undertaken at every point of contact with health care among key population including clinically and socially vulnerable group of people.

RNTCP achieved complete geographic coverage in March 2006 and since then case notification rates increased till it reached a plateau and remained stationary. The case notification rates have started decreasing in many parts of the country despite increasing efforts of symptomatic examination in public sector. Efforts for ensuring TB notification from private sector has contributed to an increase in overall notification; but it still is only incremental. Prevalence surveys also suggest that not all chest symptomatics seek care and many ignore the symptoms. This necessitates that the programme and health services need to make special efforts for reaching the unreached. Active case finding (ACF) is one way to do it, in a campaign mode.

ACF is basically a provider initiated activity with the primary objective of detecting TB cases early by active case finding in targeted groups and to initiate treatment promptly. It can target people who anyway have sought health care with or without symptoms or signs of TB and also people who do not seek care. Increased coverage can be achieved by focusing on clinically, socially and occupationally vulnerable populations. It must be remembered that 'screening' is a dynamic process and the prioritization of vulnerable groups, choice of screening approach and screening interval will be regularly reassessed by the programme. Decisions on when and how to screen for TB, which vulnerable groups to prioritize and which screening tool to use depend on the vulnerable group, the capacity of the health system, and the availability of resources.

Considering the above, it is highly imperative to shift from the passive to active in addition to passive case finding. While, more vulnerable target groups have been well defined by other national programmes, it is being done for Tuberculosis and reaching such vulnerable population in a campaign mode is proposed hereby. This will create mass awareness about the signs and symptoms in general population. Also, while programme will be able to increase symptomatic examination by 50-60%; it will also result in substantial additional case finding, those that would have remained undiagnosed and unreached by the programme.

Achievements:

To improve the integration with general health system 5082 TUs were aligned and reporting as on March 2016. Sputum collection and transport system was developed but only for presumptive MDR TB. With CBNAAT available in almost all district level facilities, the collection and transport of specimen from the PHI/DMC will be relooked into. During the last NSP period limited success was achieved with Intensive case finding limited to a few sites.

Challenges:

- Lack of awareness in the community on TB diagnostic facilities in the programme (patient pathway- largely multiple consultations leading to delays)
- Case finding is largely passive
- New diagnostic algorithm will require additional resources for CXR, and molecular tests.
- Ensuring active case finding in at risk groups and repeating the activity periodically.
- Engaging with private sector and opening RNTCP diagnostic facilities in the private sector.

Activities:

1. Implementation of the revised diagnostic algorithm characterized by use of expanded definitions of TB symptomatics, using CXR as a screening test and use of rapid molecular test upfront.
2. For early diagnosis of drug resistance, DST will offered upfront to all diagnosed TB patients.
3. Large scale engagement of the private sector for early and quality diagnosed as highlighted in the next chapter on private sector.
4. A high visibility campaign – 'TB mukt bharat' campaign for awareness generation to ensure early case finding
5. For better diagnosis of EPTB, the use of EPTB guidelines will be promoted and necessary tools will be provided.
6. Sputum collection and transport schemes will be promoted.
7. Active case finding activity and screening

Active case finding activity (ACF) in vulnerable groups is a focus over the next 5 years and considerable efforts are made to reach these populations. The pprioritization of vulnerable groups for screening and ACF is as follows:

Priority	Urban area	Rural area	Tribal area
1	Slum	Difficult to reach villages	Difficult to reach villages and hamlets
2	Prisons inmates	Mine workers	Villages with known higher case load
3	Old Age homes	Stone crusher workers	Tribal school hostels
4	Construction site workers	Populations groups with known high malnutrition	Areas with known high malnutrition
5	Refugee camps	Populations known to drink raw milk	Villages seeking care from traditional healers
6	Night shelters	Populations **known** to eat uncooked meat	Populations known to drink raw milk
7	NACO/SACS identified HRG for HIV	NACO/SACS identified HRG for HIV	Populations known to eat uncooked meat
8	Homeless	Weaving and Glass industrial workers	Tribal areas with little ventilated huts
9	Street children	Cotton mill workers	
10	Orphanages	Unorganized labour	
11	Homes for destitute	Tea garden workers	
12	Asylums	Villages largely seeking care from traditional healers	

Systematic active TB screening in high risk groups through house visits or target population/area visit is the key strategy for active case finding.

The key strategies of active case finding will include:

1. Screening at every visit with the most sensitive screening tool. The screening test is not intended to be diagnostic and people with positive results on the screening test will undergo diagnostic evaluation.
    a. Screening strategies
        i. Community screening can be done by:
            1. Inviting people to attend screening at a mobile facility or a fixed facility. Invitations may target specifically people within a given vulnerable group, those who have had recent close contact with someone who has TB and people with symptoms of TB
            2. Going door to door to screen households
        ii. Institutional screening:
            1. In Health care facilities : Systematically perform active screening of vulnerable individuals attending hospitals and other health care institution
            2. In congregate settings: Systematically perform active screening of vulnerable individuals in shelters, old age homes, refugee camps, correctional facilities and other specific locations such as workplaces.
2. Linking to nearest TB diagnostic facilities will ensure confirmation of diagnosis thereby ensuring early detection.

A well designed ACSM strategy will be adopted and integrated with the planning process for ACF which will result in a multiplier effect in case finding efforts. Partnerships will also play a key role in ACF primarily for optimum utilization of resources and skills which exist in the health care system outside the government including partner agencies, private sector and also in the community.

The programme will utilize manpower in RNTCP and its partner organization working for TB control; and support of manpower in General health services.

Activities for ACF

1. Sensitization of the political and administrative leadership in the states.
2. Active case finding in a campaign mode conducted in 3 rounds during the year.
3. Large scale IEC through print and electronic mass media and local channels about the campaign
4. Stringent planning and monitoring at the national, state, district and block level by the programme leadership.
5. Identify and map high risk / vulnerable population in local area. If additional information is available locally, it can be used for prioritization of target groups. Symptom screening will be done in identified and mapped target groups only (not in general population).
6. Use high sensitive tool like CXR upfront followed by specific tool like rapid molecular tests to optimize yield.

CHAPTER 6
PATIENTS IN PRIVATE SECTOR

Over 80% of people with TB first attend the private sector[2], yet substantial diagnostic delays occur, and diagnosis and treatment are of variable quality[3]. This, combined with the absence of drug quality controls, leads to drug resistance. This urgently necessitates enhanced engagement with the largely unorganized and unregulated private sector which accounts for at least half of those treated for TB in India. Studies conducted since the 1990s have documented the extent to which TB is diagnosed and treated in the private sector, as well as the prevalence of largely inappropriate diagnostic and treatment practices.[4] [5] Patients from low-income households lose several months of their income in the process of paying for inappropriate diagnostics and treatments before starting approved therapy[6]. As a result, there are delays in diagnosis, out-of-pocket expenditure, and irrational or unsupported treatment. Patient treated by private providers are uncommonly notified to the RNTCP, despite existing government orders to that effect [Annex K]. Patients cared for by private providers rarely receive sputum testing, and DST. Similarly, public health services such as surveillance, adherence monitoring, contact investigation, and outcome recording rarely reach privately-treated TB patients. Thus, diagnosis and treatment of TB in the private sector is both a problem and an opportunity.

The NITI Ayog[7] has recognized that social security framework in the health sector cannot be realized without engaging the private sector and recommended the Government to take stewardship role. Effective engagement of the private sector on a scale commensurate with their dominant presence in Indian healthcare is crucial to achieve Universal Access to TB Care.

Achievements

RNTCP has long acknowledged the need to engage providers outside the public sector. Partnership guidelines have been in place in some form since 2002, and some notable progress has been achieved with medical colleges. Recent efforts, supported by GF-supported project 'Axshya', have improved participation of civil society NGOs. Private providers, however, remain a critical and elusive gap in partnership efforts.

Major gains have been made in garnering support for engaging the private sector from the highest quarters in the Country which has led to significant achievements. This includes the ground breaking executive order by the Government of India mandating the notification of all TB patients from the private sector (Annex K). To facilitate TB notification, the programme has developed a case-based-web-based TB surveillance system – NIKSHAY. This provides a platform for notification of TB patients from both public and private sector providers. Since a mandatory TB notification order was issued in

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[2] *Private sector referred to in this section is everything outside the ambit of the government run public health initiatives*

[3] *Satyanarayana S, Nair SA, Chadha SS, et al. From where are tuberculosis patients accessing treatment in India? Results from a cross-sectional community based survey of 30 districts. PLoS One 2011; 6: e24160.*

[4] *Sachdeva KS, Kumar A, Dewan P, Satyanarayana S. New Vision for Revised National Tuberculosis Control Programme (RNTCP): Universal access – "Reaching the un-reached". Indian J Med Res 2012; 135: 690–4.*

[5] *Uplekar MW, Shepard DS. Treatment of tuberculosis by private general practitioners in India. Tubercle 1991; 72: 284–90*

[6] *Pantoja A, Floyd K, Unnikrishnan KP, et al. Economic evaluation of public–private mix for tuberculosis care and control, India. Part I. Socio-economic profile and costs among tuberculosis patients. Int J Tuberc Lung Dis 2009; 13: 698–704.*

7 National Institution for Transforming India (NITI ayog) is a Government of India policy think-tank established in 2015 to replace the Planning Commission.

2012 through 201, more than 0.7 million TB patients had been notified from the private sector. Especially notable was the effort and contribution from States of Maharashtra and Gujarat, which implemented 80% of signed 'partnership schemes' nationwide, and contributed more than 25% of all private notifications.

Innovative approaches for attracting TB notification from private sector by linking access to services and ICT support have been implemented. This includes "Universal Access to TB care" a PPM intervention implemented in Patna, Mehsana, Mumbai and Nagpur demonstrated what is required to reach TB patients seeking care in private sector at large. In 2015, only three of the districts contributed 18% of national TB patient notifications from private sector.

The need of additional human resources for PPM was addressed with the sanctioning of 764 PPM coordinator positons, one for each state and district. Programme guidelines for engagement of NGO and Private Providers were updated in 2014, expanding number of partnership options to 22.

Pediatricians were engaged for improving TB detection in children and accelerating access to quality TB care interventions. The interventions offered CBNAAT, specimen transport, advocacy and engagement with pediatricians, resulting in more than 20,000 presumptive pediatric TB patients tested from four cities since 2014. The Indian Association of Pediatricians (IAP) is collaborating with the programme for comprehensive training of pediatricians on TB management

Achievements

1. Executive order by the Government of India mandating notification of all TB patients
2. More than 0.4 million TB patients notified from the private sector till 2015
3. "Universal Access to TB care" PPM intervention projects implemented in 4 cities, Patna, Mehsana, and Mumbai contributed to 18% TB patient notification from private sector reinforcing the role of private sector in TB elimination in India.
4. A case based, web based TB surveillance system – "NIKSHAY" developed to facilitate notifications
5. Additional human resource provided to enhance support for PPM activities upto district and sub-district level
6. Significant cost reduction of select diagnostics achieved by Initiative for Promoting Affordable and Quality TB Tests (IPAQT). 131 private sector labs networked to provide four quality tests for TB at or below the 'ceiling prices

A reduced cost to patients of 33-66% of select TB diagnostics offered by accredited private laboratories was achieved by the Initiative for Promoting Affordable and Quality TB Tests (IPAQT), which has provided a platform to bring WHO-approved tests at affordable prices to patients in the private sector. Under the Initiative, 131 private sector labs have been networked to provide four quality tests for TB at or below the ceiling prices. From 2013-2016, more than 300,000 patients accessed reduced cost TB diagnostics via this initiative. The programme also collaborated with the Indian Pharmaceutical Association to engage with community pharmacies systematically in select states.

Medical colleges contributed an impressive 2,90,470, 20% of all forms of TB cases diagnosed by RNTCP in 2015, and stepped up support to drug resistant TB services by establishing 15 (of 65) culture and DST laboratories and 65 (of 141) DR-TB centers.

Corporate sector engagement is largely made through collaborative efforts with the UNION's Call to Action initiative. The initiative has encouraged large corporates like Gas Authority of India Limited (GAIL), Travel Corporation of India (TCI), National Thermal Power Corporation (NTPC) and DLF to

support TB control efforts. The UNION led AXSHYA project supported by GFATM, has sensitized 25,000 rural health care practitioners and expanded to facilitate TB notification from private providers.

In recent years, our understanding of the role of private providers has increased considerably as a result of patient pathway surveys, Standardized Patient studies, and analyses of private drug sales.

Challenges

The biggest challenge has been the scale of private sector engagement which considering the size of India's private sector is meagre. The paradigm shift in approach envisioned in NSP 2012-17 could only be implemented at demonstration sites.

Challenges

1. Scale of private sector engagement is meagre relative to the size and contribution to TB care, by the sector.
2. Up take of RNTCP PPM schemes remain very low
3. Absence of a policy for private sector engagement
4. Funds earmarked for private sector are used for other activities at the state/district level
5. Enhanced human resources support to states not utilized fully and uniformly
6. Use of inappropriate tools, uncertain quality standards and out of pocket expenditure continues

Funding for implementing the PPM initiatives remains inadequate especially when funds for programme interventions are less or limited, it is one of the most vulnerable to cuts. Though the budget for PPM was increased to 12% in the last NSP, it has been mainly used for salaries for TB Health Visitors, leaving little for new field activities or ongoing NGO engagement. Multiple administrative hurdles to disbursements for services contracted under existing partnership schemes often resulted in delayed or non-payments to partners. Despite updating the National Guidelines for partnership, uptake of schemes remained stagnant. Delays in payment, lack of clarity on performance expectations and poor partnership management capacity are some of the barriers to uptake of the schemes. There is a fundamental lack of trust for financial partnerships outside the public system. In addition, there is neither a systematic needs assessment for partnership nor adequate capacity at the local level to identify areas of partnership in TB care.

Many of the PPM interventions are partner or donor driven. Funding partners and donors are increasingly investing and focusing on private sector engagement. However, their targets, goals, and approaches are not aligned with (current or proposed) national strategies and priorities. In the absence of a policy for private sector engagement it causes friction and tension between the agencies. There is also a challenge of synergizing locally tailored interventions with a uniform central PPM results framework. This results in innovations not supported which leaves innovators dis-incentivized.

Only 295 of the 764 PPM coordinator positions have been filled, and limited efforts have been made to build their capacity.. Budgetary flexibility given under PPM head to support engagement of NGO/PP and for innovation has not been utilized at all, by any states in the country in the last NSP period. Diagnostics and drugs are often in limited supply and reserved for public provision which therefore usually are not extended to the private sector patients. While the Programme has made certain services such as CBNAAT available which attract private providers to avail access for their patients, the services are not marketed or made accessible to private providers, hence patients do not receive them unless they attend public health facilities. Advocacy with the private sector too has remained ineffective. There are some efforts to disseminate STCI but with very moderate success. In

addition, collaboration with Indian Medical Association (IMA) and CBCI could not move in NFM grant support of the GFATM. There is still lack of clarity on roles of AYUSH in TB patient care and hence, engagement with AYUSH practitioners is currently guarded.
Utilization of amendment in Schedule H1[8] was restricted to dissemination of information. There are a few sporadic efforts from the states of Chhattisgarh, Punjab and UATBC intervention sites to use H1 schedule benefits to support surveillance, but there are no systematic large scale efforts.

Guiding principle for reaching out to patients in the private sector

The NSP period 2017-2025 will see services are established as per Standards for TB Care in India to privately-managed patients. Standards for TB care in India, mandatory TB notification, NIKSHAY, ban on sero-diagnostics and amendments in H1 schedule are among the existing tools to improve TB care services in private sector. Regulatory tools, however, are limited, and partnership is the preferred way to move forward. Programme staff must understand that RNTCP needs private providers more than private providers need the RNTCP.

The learnings that guide the efforts to invoke support from the private sector and provide public services to its patients include the following:

1. The government will be an enabler and not see itself as the sole provider of TB care.
2. "Go where the patients go" and currently around half of the TB patients go to the private sector. This should be true of investments to address this fact as well.
3. The cost of involving the private sector is not high. It is almost the same or marginally higher than the cost in the public sector[1].
4. Investments in involving the private sector yields significant returns in case detection, with doubling or even trebling of the case notification rates.
5. Public health actions to support the private sector provides for better outcomes related to access, notifications, adherence, treatment outcomes and cost savings.

Collaboration with and participation of the private sector in TB services will increase by the acceptance of the following by RNTCP:

1. Internationally approved diagnostic and treatment protocols,
2. Reliance on market forces rather than normative exhortation,
3. Increased use of accreditation and contracting,
4. Further outreach to private laboratories,
5. Increased control over TB drugs, and
6. Innovative use of information and communication technologies for TB notification and treatment adherence monitoring.

Objectives

This strategy is designed to systematically engage private providers on a scale commensurate with their role in the India health system. The annual number of TB cases notified by private providers needs to increase ten-fold, from 0.2 to 2 million annually, or 56% of total case notification, by 2020. The programme will take responsibility to monitor and improve quality of care, with indicators including the proportion of privately-notified cases that are micro-bacteriologically confirmed (50% by 2020) and the treatment success rate amongst privately notified cases (90% by 2020). Program subsidies for diagnosis and treatment, as well as access to patient financial support, will ensure that no TB patients face catastrophic financial expenses, where ever they seek care.

Strategy

[8] The notification specifies, "The Chemist, while selling Schedule H1 drug, would, however, be required to comply with the requirements for the sale of drugs covered under the said notification in respect of requirements of sale of these drugs against the prescription of an RMP and maintenance of sale records as specified therein." This prohibits OTC sale of all anti TB drugs.

The proposed strategy amounts to a total transformation of the way in which the programme has engaged private providers heretofore. It will be systematic and large-scale, rather than ad hoc and insignificant. It will capitalize on advances in information and communications technology and on India's drive towards digital financial inclusion. Mistrust will be replaced by constructive partnership. Rather than compete with private providers, the programme will work with them to deliver quality STCI services to the entire population. Rather than additionally burdening existing under trained and over-stretched staff, the programme will contract professional agencies with the skills and capacity to engage with thousands of providers. For the first time, budgetary resources commensurate with both the problem and the opportunity of private sector care will be allocated to address the challenge.

The overall strategy is to provide an ecosystem with an explicit framework that outlines interventions for collaborating with the private sector, and earmark resources to support its execution. The broad pathway to reach TB patients seeking care in private sector is depicted in the figure below:

Path way to reach patients seeking care in private sector:

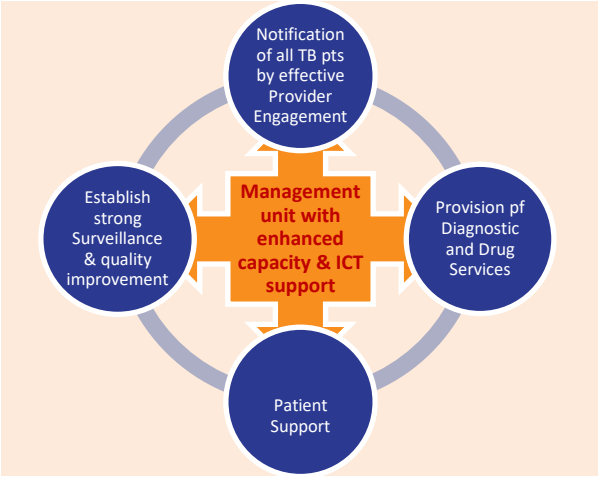
The first step will be to get notification of all TB patients diagnosed or treated in private sector through effective engagement of private providers.

Provision of diagnostics and drug services is expected to attract private providers and would benefit TB patients in terms of cost and quality.

Patient support is the key to ensure completion of treatment and monitoring of care for private sector.

Establishment of a strong surveillance and quality improvement systems will ensure coverage and effectiveness of interventions.

Enhance management capacity of the system to engage private providers at a scale commensurate to their presence and to extend services to almost double the patients than those managed at present; and effective use of ICT support as a force multiplier.



1. Increase Private Health Provider Engagement

Private providers will be considered as assets in government's efforts for reaching all TB patients for TB care and control. The programme will establish systems of engagement which give value proposition to private health care providers and ensure quality of patient care. The approach will be to first capture all TB patients by attracting TB notification from private providers and then work to improve the quality of care.

The value proposition for private providers to attract/sustain TB notifications, and to monitor/improve quality of care would include (1) access to free drugs and diagnostic tests as per STCI, (2) patient-centric adherence support to their patients for retention in care, (3) incentives and/or enablers to providers to take care of their business interests, and (4) respect for providers' autonomy within the ambit of STCI.

The first step to provider engagement will be complete census/mapping of providers. All key providers including private doctors (both allopath and AYUSH), chemists and laboratories will be mapped. Existing list of health facilities registered with NIKSHAY, professional associations or Government agencies will be used to prepare a comprehensive census of providers. A universal

census will provide platform for identification and prioritization of key providers for engagement to achieve better efficiency in terms of patient coverage. Engagement of professional agency (like those supporting drug marketing) for conducting mapping and prioritization of providers should be considered, especially when private providers are in large numbers like in urban area.

Sensitization and motivation of private providers either through CMEs, personal communication, peer pressure or professional associations needs to be reformed. It is critical to highlight the importance of unique processes followed while motivating the providers. Operationalization of this process requires appropriate capacity building. Enhancement of capacity of staff (like that of medical representatives) has a very big role to play in sustaining the relationship with providers. Informational presentations and discussions should provide healthcare providers with valuable scientific and clinical information about TB management that may lead to improved patient care. The Programme, by itself or in association with recognized institutes will develop various training courses for self-learning or certification of providers as a part of capacity building and recognition of providers.
Once engaged, continued interaction and coordination are needed with providers to sustain the rapport. A 'customer service' approach and procedures for that like feedback system, grievance redressal system, and recognition system for following good clinical practices will be established.

An option of contracting a patient provider support agency (PPSA) will be considered. In such cases, the agency will conduct mapping of private health care providers and will be responsible for their end-to-end engagement.

Considering the large number of AYUSH providers (3,598 hospitals and 25,723 dispensaries) in India, efficient symptom identification and referral system will be established to enable early diagnosis. Existing referral linkages will be strengthened and some new linkages will be established based on provider mapping. This will result in early and accurate diagnosis of TB and timely initiation of treatment, improved access to TB care, less number of patient drop-outs and increased patient satisfaction. They will also be involved in expanding the patient support system.

Private Providers will be provided incentives to promote TB case notification, ensure treatment adherence and treatment completion. The incentives will be provided upon notification in the TB reporting software i.e. Nikshay through a smooth and programme integrated direct beneficiary transfer.

The incentives to the Private Sector TB Care Provider are as follows:

a. Rs 250/- on notification of a TB case diagnosed as per Standards for TB Care in India
b. Rs 250/- on completion of every month of treatment

Rs 500/- on completion of entire course of TB treatment. For notification and management of a drug-sensitive patient over 6-9 months as per STCI, a private provider will be eligible to receive Rs 2750/-. For notification and correct management of a drug-resistant case over 24 months as per STCI, a private provider will be eligible to receive Rs 6750/-

2. Free drugs and diagnostic tests to TB patients in private sector

Provision of free drugs and diagnostic tests to TB patients in the private sector will reduce cost, attract private providers and their patients and ensure quality of care. There are two approaches for ensuring access to these services to patients in private sector – access to programme- provided drugs and diagnostics through attractive linkages; and reimbursement of market- available drugs and diagnostics
Programme-provided rapid diagnostics (like CBNAAT) and daily FDC drugs will be available for diagnosis and treatment of TB patients in private sector, respectively. The programme will ensure

forecasting and procurement of adequate diagnostics and drugs to provide for patients in private sector. Effective provider and patient friendly linkages to support delivery of these services to meet the need of private health care providers will increase uptake of free services provided by the programme.

There will be instances when the programme need to purchase diagnostic services, such as when demand for rapid diagnostic tests or chest X-Ray exceeds availability in public facilities or when patients and their providers exhibit string preference for private channels. In such cases, services provided by the private sector will be reimbursed considering market rates of diagnostic tests and drugs. A system of smooth reimbursement to providers for validated services will be established. Purchasing of these services will be integrated into RNTCP e-payments for timely and reliable reimbursements. Empanelment and validation mechanisms will be established to ensure transparency and quality. Financial norms for purchasing various diagnostic services are revised and accounted for in the costing of this NSP.

For access to diagnostic services like CBNAAT under the Programme, the scope of existing system of specimen collection and transport used for patients in tribal and difficult areas and for DR-TB patients, will be expanded to establish linkages for giving diagnostic access to patients in private sector. Private providers/NGOs/Volunteers will be engaged and incentives/honorarium would be integrated in the programme e-payment system.

For access to daily FDC from programme, the drugs will be provided to the doctor, chemist, stockist or distributor, depending on the local context. Incentives will be provided to cover their cost of stocking, distributing and dispensing the FDC.

3. Increasing support for patients seeking care in the private sector

Public health response to all TB patients notified from private sector will be the responsibility of public health system. Patients support services i.e. adherence support, drug susceptibility testing, comorbidity detection, ensure treatment outcomes, infection prevention measures would be extended to patients in private sector. To ensure equitable care the programme will need additional manpower capacity enhanced by ICT tools.

Benefit given to TB patients in public sector will be extended to patients in private sector including social welfare support. These benefits would empower patients to demand notification if integrated / triggered patient honorarium and social welfare payments are linked to notification and adherence. A system will be put in place to provide incentive/enablers to patients for validated services via Aadhar-enabled direct benefit transfer (DBT).

All patients, irrespective of their place of treatment, will be linked to applicable social support schemes (Annex I) for ensuring adherence and successful completion of treatment.

To address financial & nutritional hardship the patient and family undergoes due to TB and to reduce catastrophic cost to patient due to TB, cash incentive of Rs. 2000 will be provided for every TB patient through Direct Beneficiary Transfer.

To extend public health services to the large number of TB patients in private sector, programme needs to have availability of human resource as per the norms of the programme. Wherever required, programme should use NGOs to expand these services. These services should be purchases using e-payment services with validation system in place.

4. Enhance Surveillance and Quality improvement

A comprehensive surveillance system for TB patients and their providers will be built into eNikshay. This will be supported by a call centre for user-friendly private reporting and patient monitoring. Quality improvement program will look at care provider-wise, and guide feedback and engagement efforts by program managers and staff. To improve the quality of care, surveillance will be

strengthened by patient feedback systems, periodic prescription audits, drug sales surveys, chemist surveillance through Schedule H1 and laboratory surveillance including private laboratories.

Drug sales monitoring will be used as baseline indicator. The approach of tracking drug sales provides an important guidance to the programme as to the extent of coverage and the need for additional efforts. The drug sales information will be incorporated at least state-wise or district-wise or in major cities where possible, into the routine programme monitoring and evaluation (M&E) framework.

In order to improve surveillance across all sectors and geographies and for more accuracy of information, the MIS system will be unified. Routine collection of Aadhar number, geo coding, contact numbers and bank details will maximize scope of surveillance.

The drug voucher system will open up the opportunity to bring prescriptions on anti-TB drugs given by private practitioners, under the surveillance. The system can identify practitioners to work upon for improving prescription practices. Systematic use of the information gained from voucher analysis will be used to influence practices of private practitioners

A similar opportunity is currently available if Gazette notification of Schedule H1 drugs is effectively executed and information of prescription details is utilized. To monitor quality of prescription, TB patients will be monitored from Schedule H1 surveillance. In addition, prescription audit will be carried out with support of Drug Controller of the State.

A system of regular feedback to the providers for quality of care aspects will be part of the engagement process.

The following audits will be conducted on an annual basis –

1. Prescription Audit
2. Data audit
3. Financial audit
4. Standardized patients studies
5. Patient feedback survey

5. Expand ICT support

Effective ICT support will be the cornerstone for facilitating engagement, user-friendly patient reporting, patient centric adherence monitoring, and for smooth financial transactions. The eNIKSHAY platform, supported with efficient call centres and provision of sufficient digital tools to field staff and providers, will be key to reaching patients in private sector.

An ICT based, web-based TB case management and surveillance system of the programme will be enhanced to eNIKSHAY. All the patients will be registered in this system by their certified providers as beneficiaries based on their demographic details, mobile number and a bank account number. An alpha-numeric Beneficiary ID will be generated for patients which will be used by him/her to avail the services at every point. TB diagnostic test reports (Digital X-ray and GeneXpert test) and monthly prescriptions will be updated in this MIS, which will assist TB case management system in maintaining an end-to-end diagnostic and treatment trail of the patient.

All the TB drugs will be bar coded or QR coded. At the time of dispensing drugs, pharmacy will verify the prescription for regimen as per Standards for TB Care in India and capture information as mandated under H1 schedule. Pharmacy will also access patient case details in web-based TB case management system based on beneficiary ID assigned to the patient and will scan bar codes/ QR codes for capturing information of drugs refills in the system. After six continuous drug refills, the treatment outcome will be generated as ‘Treatment Completed’. In case of failure of drug refill, the

system will generate an alert. Health workers will establish contact with such patients and will provide support for resuming their treatment.

Adherence system using ICT platform will be strengthened with the use of additional emerging tools such as 99 DOTS, Pill box etc.

6. Build management capacity

Based on the estimates, the programme will be dealing with more TB patients in the private than in public sector in most of the states. The programme will need additional manpower to carry out field operations, as well as enhanced managerial capacity and ICT tools for large-scale engagement. Within the programme, three layered differentiated capacity building requirements need to be met. These are for planning and contracting at the national level, management and monitoring at the state level, and engagement and sustainable relationship with private providers at the district level.

Capacity building will be done of district TB officers, PPM coordinators and sub-district level staff for relationship management with private health care providers. Addition of sub-district level HR with appropriate TOR of STS/STLS will increase partnership capacity. In Urban areas, additional HR such as TB-HV with focused job responsibility to engage private providers will be ensured.

In addition, to reach out to huge number of practitioners, a 'patient provider support scheme' will be developed, for NGOs/agencies, to augment programme capacity to monitor and manage patients seeking care in private sector; wherever required, expected to be in most large urban corporations, or wherever public health system is particularly weak. Targeted approach would be adopted to identify districts which would require such support of external agency. Broadly, this will include districts in which the number of patients exceeds the public health sector capacity to reach them and districts which need additional support from RNTCP due to gaps in basic health care delivery systems. Under the scheme based approach, a package of managerial services which will include provider engagement, linkages, patient support and monitoring will be purchased through a scheme awarded to an external agency.

7. Strengthen regulatory approaches

To ensure sustainable and long-term success, regulatory measures will be taken into consideration. TB notification regulation will be strengthened with sufficient legal backing on violation of not notifying a TB patient. To ensure the quality of anti-TB drugs, its combinations, standardized dosages and treatment regimens for the patient is treated in public sector or private sector, regulation of drug sales and distribution in public or private sector in the country will be established.

Effective use of Gazette notification of H1 schedule will help to ensure quality of treatment regimen and also help to capture information of practitioners who prescribe anti-TB medicines. This may help to identify practitioners for prioritizing or targeting to encourage TB notification from them.

8. Involvement of Medical Colleges

Scope of activities of medical colleges is going to be expanded with increasing diagnostic and treatment services in newer areas of TB control efforts. This will include following:

a) **Decentralized drug resistant TB services**: DR-TB wards will be expanded to more number of medical colleges to support district level DR-TB treatment services. These DR-TB centres in medical colleges will be useful for management of not only MDR-TB but, for DST-guided treatment, use of newer regimen and management of complicated cases of drug resistant TB. Existing staff of medical college i.e. medical officer and TB-HV will be utilized for these DR-TB wards for coordination with the programme and DTC data entry operator will support e-communications and for MIS operations.

b) **Culture service support:** With follow up of drug sensitive TB patients with culture at the end of treatment and post treatment follow up with culture for all TB patients, additional capacity of laboratories with culture facilities would be needed. To support this strategy, the programme will engage medical colleges to expand its microbiology laboratory for RNTCP. The programme will identify and support these microbiology laboratories through existing HR and infrastructural norms for culture laboratories.

c) **Air borne infection control measures in health care facilities in districts:** Under the air borne infection control committee of the districts, medical college faculties will be involved to execute AIC measure in all health care settings in the district. The faculties from medical colleges will be trained at the state level and then support in assessment, recommendations and monitoring of AIC implementation in all health facilities in the districts.

d) **Planning, surveillance and quality improvement support to districts:** Faculties of medical colleges will be involved in planning of RNTCP services and subsequent monitoring and evaluation. The department of community medicine will be involved to in monitoring and surveillance of disease including carrying out local surveys. For quality assurance of laboratory services, the department of microbiology will be involved and appropriate capacity enhancement will be done.

e) **Private provider engagement:** Support of medical colleges will be sought for peer education, dissemination of diagnostic and treatment practices and advocacy with professional associations.

f) **Research:** Operational Research mechanisms will be strengthened. Uniform systems of protocol development and capacity building wokshop will be implemented. An online system of protocol submission, protocol review, approvals and quick release of funds will be established.

9. Health care providers within public sectors (Outside Ministry of Health & Family Welfare)

There are large numbers of health facilities run by public sector other than Ministry of Health & Family Welfare under different ministries of Centre/State Governments. There are corporate sector companies in the public sector like Coal India, SAIL etc. which run their own healthcare set ups. Usually these facilities cater to a "captive population" who receive subsidized or free services from said facilities. Additionally ministries like defence, railways, home ministry etc. have their own medical services set up. The program will have a mechanism to regularly communicate update in TB services to these facilities and a communication channels will be established at all levels. There will be regular meetings with these organizations to ensure smooth implementation of uniform TB care services by all health care providers. Efforts will be continued to set up RNTCP services in all these health facilities. At the same time, those facilities which do not opt to have RNTCP set up, will be engaged for reporting of TB patients and their treatment outcomes. All patient support services will be extended to their patients in equate to public health facilities.

10. Involvement of corporate hospitals

32% of the national bed strength is in the 150 plus private corporate hospitals. Current, strategy through partnership option provides HR at par with medical colleges and reimbursement for reporting and for diagnostic and treatment services. Incentive mechanism and diagnostic and

treatment services will be extended to these corporate hospital as mentioned below. In addition, ICT advances and interface will be used to facilitate reporting from these corporate hospitals which have their own MIS. Additional capacity enhancements of patient management will be used to ensure treatment adherence and patient retention as value addition to these corporate hospitals. A coordination mechanism will be established at the Centre to regular communications with central corporate units to ensure uniformity in implementation of TB care services across all its units.

TREAT

What does it mean in the context of this NSP for TB elimination in India?
Provide sustained, equitable access to high quality TB treatment, care and support services responsive to the community needs without financial loss thereby protecting the population especially the poor and vulnerable from TB related morbidity, mortality and poverty..

What does it entail?

1. Providing daily regimen using FDCs to all TB patients.
2. DST guided treatment for DR TB.
3. Patient centric approach to treatment.
4. Prevent loss at cascade of TB care

- **CHAPTER 7: TREATMENT SERVICES**
- **CHAPTER 8: KEY AFFRECTED POPULATION**
- **CHAPTER 9: PATIENT SUPPORT SYSTEMS**

CHAPTER 7
TREATMENT SERVICE

Introduction

Universal access to free, standard treatment services for all TB patients in the country encompasses an ambit of services in and around each patient's care cascade. Strengthening of these patient centered treatment services in RNTCP with enhanced capacity to rapidly accommodate new drugs and treatment modalities will be the cornerstone of the current NSP.

The revised technical and operational guidelines for TB control in India, defines the major groups of TB patients who are offered standard treatment regimens. Patients are classified based on drug sensitive and drug resistant patterns like mono, poly, multi and extensive drug resistance. For drug sensitive TB patients, thrice weekly regimen being followed since program inception has been switched to daily regimen for treatment of all TB patients.

The principles of treatment for TB is:

1. Screen all patients for rifampicin resistance and additional drugs wherever indicated.
2. For drug sensitive TB, administer daily fixed dose combinations of first-line anti-tuberculosis drugs in appropriate weight bands for all forms of TB and in all ages, including four drug FDC in the intensive phase and three drug FDCs in the continuation phase.
3. All Rifampicin Resistant /Multi Drug Resistant TB patients are subjected to baseline Kanamycin and Levofloxacin all across the country. In addition country has introduced extended DST to all second line drugs in a phased manner.
4. RR/MDR-TB patients without additional drug resistance are treated with standard short course treatment regimen for MDR TB. And in those with mixed patterns of resistance, standard MDR TB regimens were modified as per revised guidelines.
5. Where DST patterns for extended DST are available, the management protocol will follow essential optimized regimen for patients diagnosed with drug resistance other than MDR and XDR TB.
6. Minimize leakage across the care cascade and maximize adherence through innovative patient support strategies and real time monitoring.

As part of new drug and treatment services introduction, the programme plans to introduce shorter MDR TB regimen as per WHO treatment guidelines.With extended DST for second line drugs being available upfront, the NSP 2017-2025 also envisages country wide scale up of new drugs like Bedaquiline (being currently provided in six sites across the country) and Delamanid.

Holistic approach to patient centered care encompasses appropriate TB treatment strategies coupled with adequate support structures for treatment adherence. This NSP articulates innovative implementation strategies to address the twin objective of treatment support and adherence services for its patients by adoption of ICT tools and partnerships. The use of support structures to empower patients and their families' is crucial to achieve the goals of NSP 2017-2025.

Achievements

The NSP 2012-2017 made bold advances in treatment strategies with introduction of new drugs and modifications in the existing drug regimes. The core of treatment delivery system has been direct observation. In order to make the services more patient friendly, the last NSP rolled out strategies such as the concept of family DOT, counsellors for MDR TB and adoption of ICT tools for monitoring the swallowed doses while the patient is at home. Implementation of flexible NGO schemes (revised version released in 2014) and adoption of standards of TB care in India across the country is also ongoing.

The achievements of NSP 2012-2017 in providing patient friendly treatment services includes the following.

1. In the past five years, more than 7 million TB patients have been detected and initiated on treatment with 1.2 million additional lives saved in the country.
2. Among all cases registered under the RNTCP, treatment success rates are consistently about 85% in new cases and 75% among retreatment cases.
3. NSP 2012-2017 took significant strides in acceleration of MDR TB management country wide. Exponential scale up of Programmatic Management of Drug Resistant TB (PMDT) was completed to achieve country wide coverage in March 2013. In the past 5 years, 120,299 DRTB patients have been detected and put 110,808 on treatment (data up to Q3 2016).
   While thousands of lives were saved with the standard MDR/XDR TB treatment protocols, the changing trends in global MDR treatment strategies forced the program to review its data and introduce individualized treatment regimens based on DST patterns. Further, there was a constant demand from the clinicians and program managers to expedite possibilities to deploy DST guided treatment for DRTB other than MDR and XDR that may not be optimally managed with standard first and second line treatment currently available within the program. In March 2016, the Revised Technical and Operational Guidelines were rolled out with detailed regimen build up for early treatment stratification guided by DST results.
4. All HIV infected patients showing the four symptom complex are offered **rapid molecular tests along with daily treatment regimen with FDCs** for improved treatment outcomes in the high risk group.
5. **Newer weight bands** for adult and pediatric dosages are created
6. **Bedaquiline CAP roll out** in six sites across the country. The conditional access program (CAP) has been rolled out in 2016 across six sites in the country with a country wide scale up planned in 2017-2020.
7. Standards of TB care for India (STCI) to guide all health care providers on expected standards / quality of care across all sectors
8. Guidelines for management of extra pulmonary TB (Index TB) was

Challenges

1. No information on treatment practices, adherence and treatment outcomes from the private sector, amounting to a majority of the TB patients in the country.
2. The lost to follow up and death rates among treatment experienced are unacceptably high. For the cohort of treatment experienced patients registered under the programme in the entire country during 2015, 12% were lost to follow up and 8% died during the course of treatment.
3. No availability of information on the long term outcomes of treatments. With an absence of long term outcomes in TB patients, information on treatment efficacy cannot be established. The high rate of recurrence from limited studies is another cause of concern.
4. The current approach to treatment monitoring is health system centric instead of being patient centric; prioritizing programme comfort instead of patient needs.
5. Although treatment success rates among new cases are satisfactory at the national level, many districts report lower than expected success rates.

6. Accessibility to drug regimens containing injections in the rural areas is currently a concern owing to the guidelines limiting the use of injections by trained health provider.
7. Delay in initiation of treatment of DRTB owing to non availability of pretreatment evaluation services at the district and sub district level. Insufficient coordination between the district and sub district levels in communicating the test results and the treatment plan

Strategies

1. **Initiation of appropriate treatment for all diagnosed TB patients.**
    a. Provision of daily regimen for all TB patients
    b. Introduction of shorter regimen for MDR TB
    c. Incorporation of new treatment strategies with newer drugs
    d. Effective strategy to ensure STCI for patients treated by private providers – *discussed in details in the chapter on private sector (Chapter 6)*
2. **Implementation of TB treatment services in health facilities and communities.**
    a. Decentralisation of treatment services through ICT support.
    b. Promote appropriate treatment adherence mechanism including provision of mobility support to workers, patient enablers and insurance to TB patients, social support systems, nutrition support, ICT mechanisms, pharmacovigilance etc. *Discussed in details in the chapter on patient support system (Chapter 9)*
    c. Extend patient support services for patients in private sector which are the same as for patients in the public sector mentioned above - *Discussed in details in the chapter on private sector (Chapter 6)*
    d. Roll out of DST guided ITR in a phased manner for DRTB
3. **Regular and long term follow up and rehabilitation of all treated TB patients**

Activities:

1. **Treatment of pts in the private sector:** Once the patient is notified the responsibility of these will also be on the public sector to provide patient support that will ensure successful completion of treatment. This will include patient friendly adherence support, screening for co-morbidities and drug resistance. Mechanisms will be developed to ensure treatment regimens as per the STCI and quality assured drugs in the private sector. The mechanisms to ensure treatment regimens as per the STCI will include
    a. Effective use of Schedule 1 provisions
    b. Use of reimbursement mechanisms

2. **Treatment of DSTB:** The priorities of the current plan include change of regimen for DSTB using daily FDCs as per patient's weight band with augmented continuation phase and intensified treatment support systems using ICT. This will be scaled up across India by the end of 2017 and also extended to the private sector in a phased manner over the next 5 years.

3. **Treating drug resistant TB:** RNTCP will embark upon addressing all forms of drug resistant TB. The thrust areas in the treatment for DR-TB over the NSP period will include the following.
    a) Management of H Mono Poly resistance: H mono-poly resistance is known to be around thrice as prevalent as RR-TB. It has been observed from programmatic data that nearly half of such patients treated with standard first line treatment failed and further half of them amplified to MDR-TB. Thus, a specific 9-12 month treatment regimen to manage H mono-poly resistance with available first line drugs substantiated with a fluoroquinolone and a second line injectable. This regimen will be scaled up across the country by end of 2017.

b) Shorter MDR-TB regimen: Since inception of PMDT services, RNTCP has witnessed a treatment success rate of just under 50% with the standard 24-27 months regimen. In 2016, WHO endorsed and recommended a shorter MDR-TB regimen for 9-11 months duration based on growing evidences of its effectiveness to improve treatment success particularly in RR-TB patients with additional resistance to fluoroquinolones and second line injectable. WHO also recommends prompt triaging of RR-TB patients with a simultaneously endorsed second line – line probe assay (SL-LPA) test to rapidly separate patients susceptible to fluoroquinolone and second-line injectables. Shorter MDR-TB regimen will be scaled up across the country by end of 2017 for all RR-TB patients.

c) Newer drugs containing regimen: In 2016, RNTCP introduced Bedaquiline with an optimized background regimen for management of RR-TB patients with additional resistance to fluoroquinolones and or second line injectables. Based on the early experiences of treating ~300 patients with Bedaquiline containing regimen, RNTCP will expand the access to Bedaquiline across India by the end of 2017. Simultaneously, RNTCP will also introduce another new drug Delamanid within 2017 after conditional approval from DCGI and undertake research with support of ICMR to evaluate the use of these newer drugs in combination therapy to reduce the duration of DR TB regimen to 4-6 months.

d) DST Guided DR-TB Regimen: RR-TB patients with additional resistance to fluoroquinolones and second-line injectable with or without resistance to any other first or second line drugs, but either not eligible or unfit or not consenting for newer drugs will be managed by appropriate regimen designed based on the DST results. This approach will also be scaled up along with Bedaquiline expansion across India by end of 2017.

e) NTM treatment: Non-tuberculous Mycobacterium are environmental opportunistic microorganisms that can cause human disease with signs and symptoms similar to MTB. These organisms can affect the lungs or any other extra-pulmonary sites. The diagnostic approach will require a mix of various diagnostic technologies like smear microscopy, rapid molecular tests, conventional culture and species identification while the treatment may vary with species. RNTCP will initiate addressing NTM and will be scaled up across India by end of 2018.

f) Decentralization of DR-TB treatment: As RNTCP intends to move to universal DST with CB-NAAT at every district, second line rapid molecular DST, Shorter MDR-TB treatment and DST guided treatment with or without newer drugs, the volumes of patients to be managed at centralized DR-TB centers will delay treatment initiation as well as loss to follow up. To mitigate this anticipated loss and promote DR-TB treatment initiation within 24-48 hours, RNTCP will decentralize district DR-TB centers to initiate standard H mono-poly or Shorter MDR-TB regimen at every district level that will be established within close proximity of the CB-NAAT site while patients with additional resistance to second line drugs or drug intolerance or seriously ill patients needing regimen modification will be managed at the nodal DR-TB centers.

g) Palliative care and rehabilitation – Patients with extensive drug resistance in whom an appropriate regimen could not be formed as per the WHO recommended regimen, even with addition of newer drugs and who need care beyond cure will be offered palliative care through the nodal DR-TB centers or at the community level under guidance of nodal DR-TB center. Necessary rehabilitative services including pain relief, surgery, prosthesis, psycho-social support, respiratory physiotherapy etc. Integration with existing network of Pallium India for knowledge and skill transfer to nodal DR-TB center will be explored. Any additional cost required for palliative care and rehabilitation will be covered under existing insurance scheme like NHPS.

h) Prevention of relapse and development of DR in presumably pan sensitive first line treatment

i) Extension of CP in cavitary and bilaterally/ extensive disease
ii) Nutrition support
iii) Role of immunomodulators and vaccines both preventive and therapeutic
iv) PKPD studies
v) Exploration of targeted drug delivery
vi) Exploration of nano- aerosol technology

4. **Making care cascade monitoring a management priority:** Activities for ensuring care cascade monitoring for enhanced outcomes include the following:
    a. Incorporation of local care cascade information into the district plans
        i. Identification of active groups/local structures in villages/taluk/cities for supporting the care cascade.
        ii. Uptake of available RNTCP partnership options / partnership guidelines
        iii. Collaboration with ongoing public health programs in the district for TB advocacy, ICF, care and management and subsequent rehabilitation of TB patients.
        iv. All stakeholders participating in the care cascade to be notified on Nikshay platform for direct benefit transfers, monitoring and notification of TB patients.
    b. Sensitization of state and district officers on the need to budget supplementary activities required for care cascade support. These include administrative and health functionaries at all levels.
    c. Regular monitoring to be undertaken through review meetings and onsite checklists at district and state level. Incorporation of "Care Cascade Check" indicators in the program management reports of the state and districts.
    d. Trainings of program staff, partners, and volunteers on the reporting formats used for monitoring the care cascade. As the "e-gurukul"[9] system becomes operational, these trainings will be shifted on the electronic interface.
    e. Patient feedback of service provided will be taken through the helpline "Call centre" support. The information obtained will be shared with individual treatment supporter via "e-Nikshay" for remedial actions, if any.
    f. Direct beneficiary transfer to all notified health facilities and patients will be done through e-Nikshay interface.
    g. All the required logistics and coordination required for quality uptake of the patient Care Cascade will be provided by the District.

5. **Empower patients** with information, support structures and enablers/honorariums to initiate and sustain treatment
    a. Sensitization of communities through ACSM
    b. Each patient notified under the Nikshay platform starting from diagnosis, need to be enrolled for ICT enabled treatment adherence support and direct benefit transfers as per norms.
    c. Patient support services will be linked with individual patient registry in e-Nikshay. Once the patient gets diagnosed by a public or private partner, the patient gets registered in e-Nikshay. Treatment information is further updated regarding the regimens, dosages, adherence mechanism and benefit schemes chosen. Accordingly timely alerts and feedback mechanism will get initiated through e-Nikshay.

[9] E-gurukul app is a platform of GOI for e learning under development

d. The facility for ICT enabled benefit transfer through smart cards will be made available from the district TB office. In situations where the patient gets tested and treatment initiated somewhere else, support for patient enablers will get started based on the need for the same.
e. Through the e-Nikshay platform, automated reminders on treatment initiation, interruption and follow up will be sent to treatment provider and patients. In addition, SMS support services will also be made available for awareness, counselling and reminder alerts.
f. An offline app for patient education will be available for free download. Information regarding TB diagnostic and treatment services, enablers, grievance through call center support will be linked on the app through e-Nikshay.
g. Nutritional support/enabler honorarium linked to continuation on treatment through e-Nikshay.
h. Each District has been provided with a counsellor for providing necessary counselling. In addition, the Treatment supervisor and district accountant will monitor the availability of ICT enabled treatment adherence support and fund movement, respectively.
i. Several innovative models of involvement of patient support groups in rural areas has been found to be successful in providing a holistic approach to TB care. Such models will be replicated based on the availability of applicable norms

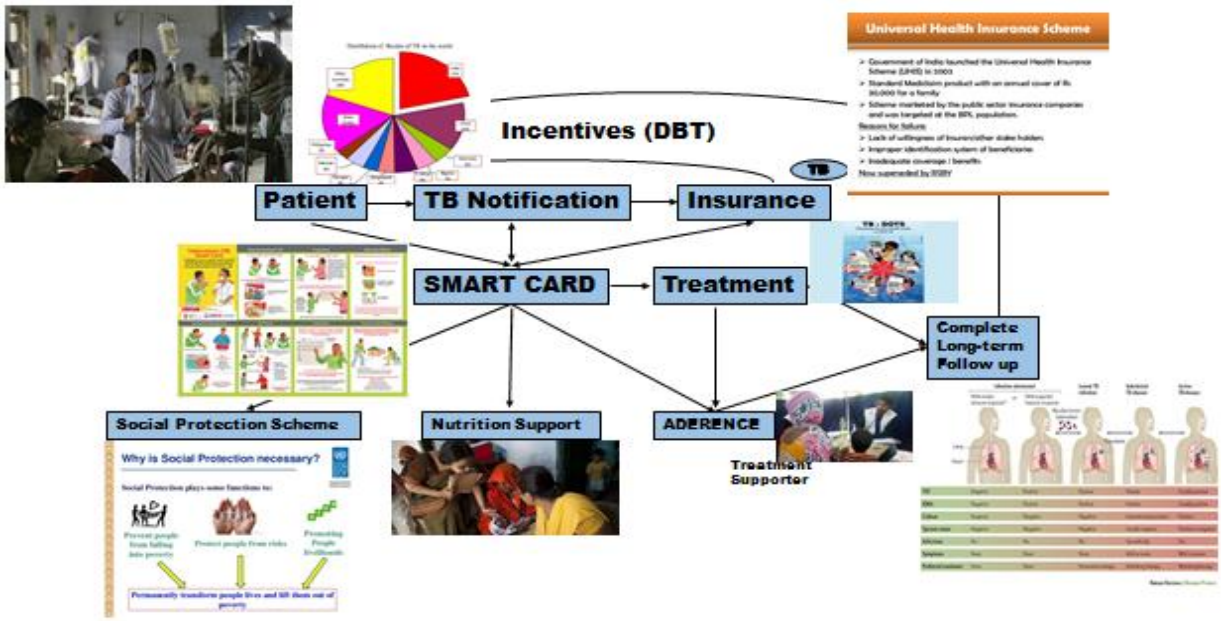
6. **Expanding options for adherence monitoring**

Different choices for ICT based treatment adherence support mechanisms are as below

a. **Mobile based "Pill-in-Hand" adherence monitoring tool** In this mechanism, each time a patient takes a dose of medication, a hidden number appears which is printed on the strip behind the drug. The patient need to send a missed call to a particular contact number with the digits appeared on drug package. This will be documented at a centralized ICT unit. And thus, an electronic treatment record of each patient will be maintained to monitor the treatment adherence.
b. S/he can also be providing the option of where in the patients treatment will be remotely followed up with help of Interactive Voice Response (**IVR**), **SMS** reminders. A call center has been established for care cascade and adherence monitoring
c. Specially designed **electronic pill boxes** or strips with GSM connection and pressure sensor can be used to monitor the pill consumption by tracking the weight of the remaining pills.
d. The treatment provider can use the **Patient Compliance toolkit;** a mobile app for patients to report treatment compliance using video, audio or text message.
e. **Automated pill loading system**, which will load the dosage as per the pre-programmed settings. Medication dispenser: a color-coded reminder system built in the dispenser that will hold drugs.
f. Treating doctors can be provided with **innovatively designed ICT enabled smart cards** to educate them on correct TB prescription methods. Doctors will then give these cards to TB patients, instructing them to SMS the server/ customer care centre (CCC) the unique code on the card which will register them on the network and also SMS the unique codes printed on their TB drugs as they take them. The CCC will then deliver phone interventions like reminders to take medicines, financial incentives, follow up calls, and TB health tips via SMS and phone balance recharge, mobile APP for scheduled dose reminders and alerts.
g. A Short Messaging service **(SMS) gateway** to be made available by which the patient can report day to day events like pill consumption, minor side effects or his need for help through simple and shortcut SMS templates. The gateway can allow incoming services in

pre-recorded or Interactive Voice Response (IVR) mode to inform patients about their test results, as follow up reminders and as periodic counselling messages.

7. **Direct Benefits Transfer (via Smart Cards) :** *Discussed in more details in the chapter on patient support systems*



Since the very inception of the TB control programme in India, it has tried to adopt a holistic approach to treatment and patient care. Providing treatment enablers in the form of financial incentives and nutritional support can provide for increased adherence and treatment success rates. To meet these twin objectives of adherence and treatment support, the programme has launched a "Direct Benefits Transfer (DBT)" scheme to financially aid TB patients.

There has been an increase in rural access to banking facilities over the years especially with the recent push through PM "Jan-Dhan Yojana". Subsequently DBT initiatives in social welfare schemes have also shown promise, making it prudent that the program too adopts a similar approach towards treatment enablers.

By using an ICT based benefits transfer system, the programme aims to prevent leakages and delays in transfer of benefits with effective targeting so that the benefits only flow to the intended beneficiary. The DBT is implemented via a smart card linked to AADHAR[10]. This provides a tamper-proof storage of user and account identity. It allows for a comprehensive multi-sectoral multi-scheme benefit to the treatment care receiver. AADHAR linked smart cards will help streamline treatment when the patient comes in contact with the programme at different locations. This smart card acts as single unique identifier for patients across private and public sector, insurance and across different central and state social welfare schemes that may become available to the treatment receivers over the course of his treatment. A smart card based system can be implemented utilising infrastructure set up for other public healthcare schemes like Rashtriya Swasthya Bima Yojana (RSBY).

A smart card provides improved patient identification, needed in the light of treatment incentives like financial support to be provided to the patients. At the same time from a programmatic point, it ensures increased administrative efficiency by providing medical records

[10] Aadhaar card is a universal identification number for every citizen of India. The Aadhar card is a biometric card that stores an individual's personal details in a government database, and is fast becoming the government's base for public welfare and citizen services.

management. Multiple health programs across the globe are utilizing smart cards in different capacities.

This smart card will have inter-operability with a range of devices including ATM machines for payments, patient information recording devices for programme's recording and reporting and follow-up activities. The level of utilization and utility of the smart card will be scaled up as internet infrastructure develops across India.

8. **Improve clinical support**

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

a. Developing and implementing minimum clinical criteria for hospitalization/specialist consultation (e.g. hypoxic, high respiratory rate, BMI<16, etc.)
b. Developing criteria for high-risk patients for encouraging systematic referral to specialist consultants. For example, extensive radiological disease, severe underweight, or comorbidity will indicate early specialist consultation, rather than waiting for clinical failure
c. Including therapeutic nutrition for severe undernutrition (BMI less than 16)
d. 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. This will also address the missing millions and decrease the initial loss to follow up. **A major shift proposed is to initiate every TB patient on treatment at the site of diagnosis.**

9. **Pharmacovigilance activities**

Current treatment regimens for TB patients are long and complex and their toxicity when used in certain patient subgroups may not be completely profiled. Several of these patients will also be treated for other co-morbidities, including HIV infection, at the same time. The introduction of new drugs and the repurposing of medicines beyond their primary indication are expected to become more widespread as RNTCP strives to improve outcomes for its patients. With the GOI vision as a long term guide, the programme defined objective for 2017–2025 is to strengthen linkages with the Pharmacovigilance programme of India (PVPI) for monitoring, identification and detection of signals. This will act as a feedback mechanism to regulators and RNTCP at regular intervals. RNTCP will also establish programme wide pharmacovigilance activities at national, state, district level and block levels that will also include the private sector.

CHAPTER 8
KEY AFFECTED POPULATIONS

Introduction

'Key affected populations' is a disadvantaged group of people as compared to others, mainly on account of their reduced access to medical services and the underlying determinants of health. Vulnerable, underserved or populations at risk of TB infection and illness constitute a challenge for TB control. Insofar as TB is concerned, these can be segregated into following broad groups.

Table:

People who have **INCREASED EXPOSURE** to TB **due to where they live or work**	•Prisoners, sex workers, Slum dwellers, miners, hospital visitors, healthcare workers, and community health workers
People who have **LIMITED ACCESS TO QUALITY TB SERVICES**	•Migrant workers, women in settings with gender disparity, children, Physicaly challenged, Tribals and poulations living in hard to reach areas, refugees or internally displaced people, illegal miners, and undocumented migrants
People at **INCREASED RISK** of TB because of **biological or behavioural factors** that compromise immune function	•People who live with HIV ,have diabetes or silicosis, undergo immunosuppressive therapy , are undernourished , use tobacco , suffer from alcohol-use disorders, and inject drugs

Source: Stop TB Partnership, Global Plan to End TB – Paradigm Shift, 2015

Several studies have suggested that the disease burden in these special groups is higher than general population. TB control activities in these special populations are being provided by the government and non-government sector, mostly NGOs, private practitioners and corporates, but, none have been able to produce a perceivable impact. The current NSP acknowledges the significant actions required to address the key populations and elaborates it in the sections below.

Common activities for intensifying TB control activities in key populations:

1. **Mapping and identification of key populations:**
   a. Detailed information using knowledge of front-line staff from the health care agency (MO-PHI/LT/STS/STLS/TBHV) and civil society partners relating to the vulnerability factors will be gathered. These staff will have direct patient/client contact, and will be able to report about threats faced by their patients/clients. Vulnerability factors (threats) will be used to build up assessments of size and locations of vulnerable groups
   b. The health needs assessment will be undertaken within the most vulnerable communities of interest to identify specific health needs relating to identified multiple threats. Communities will be given the opportunity to carry out action research lead by members of their own community.
   c. Mapping of socially and clinically vulnerable groups will be undertaken using available data from the RNTCP (TB laboratory register, TB treatment cards, TB Register and NIKSHAY data) or from data sources other than RNTCP (Municipal/ Block/ Taluka/ Zilla Panchayats records, from other health programmes and sectors, prisons and such similar sources).

2. **Comparative analysis** of vulnerable group-specific case notification rates and success rates against the baseline case notification rates with success rates of the overall population of the district/area.
3. **Priorities** for action will be decided based on the analysis and needs, effectiveness, feasibility and resources.
4. **Training** of health-care providers to recognize the increased risk of TB in these populations and give special attention to surveillance and preventive services.
5. **Screening** of people at high risk/ vulnerable to increased risk of TB infection, disease and death from TB for signs and symptoms suggestive of TB, at regular intervals.
6. **Campaign approach to address TB in key populations**
    a. **National campaign against TB**- widespread awareness using mass media, community engagement, utilizing trained community volunteers in identifying TB symptomatics. Local self-government to spearhead the campaign.
    b. **Active case finding in high risk groups/areas**: Active TB case finding strategies will be prioritized based on risk group so as to maximize yield.
    The tools for active case finding include:-
        a) Community level campaign followed by active case finding with symptom screening. Approaches such as health camp, use of mobile health services etc. will be explored.
        b) Periodic Digital X-ray
        c) Rapid molecular diagnostics tools
7. **Community engagement**: For the above mentioned interventions to succeed, it will require active and extensive community engagement. This will be a local self-government driven community mobilization effort and NGO supported initiatives. Community involvement could help overcome some of the resistance and distrust often encountered in these groups.
8. **Targeted interventions** to improve access and ensure adequate diagnosis, treatment and follow-up of TB cases, building on partnerships with other service providers.
9. **Link** all eligible TB patients with social welfare schemes including nutritional support

Activities:

1. **Designating intensified case finding (ICF) sites** within states/districts. These ICF sites could be pockets within a district or state or institutions qualifying by virtue of the kind of services/ population they cater.
2. **'CBNAAT Lab on Wheels'** to provide a point of care solution to accessibility issues related to quality diagnosis of TB
3. **Analyze health care seeking behaviour** of patients, especially elderly women in areas with low TB case notification in that age group and plan strategies for improving the health care seeking behaviour. Participation of ASHA workers, women self-help groups and NGOs can be useful in these areas.
4. Undertake **detailed review of accessibility issues** at district, TU and DMC levels and find out local accessibly issues and implement solutions. In order to identify issues, hold periodic consultations with the authorities and leaders of different constituencies of the community (e.g. labour authorities, managers of labour intensive industries, authorities dealing with migrants/ prisons/ health care providers in the private sector, tribals, slums, etc.).
5. Workshops with **local practitioners** (qualified/traditional/unqualified) in ICF sites
6. Establish **DMCs as per norm**. Plan and implement need based sputum collection and transportation system. Ensure the designated microscopy centers are functional and accessible to patients. There will be provision for collection of sputum samples, even if the laboratory is closed after the working hours. Ensure binocular microscopes are in good condition, and have AMC in place. A well-established EQA system for sputum smear microscopy is essential.

7. Promoting **uptake of RNTCP schemes** including slum scheme, sputum collection with transport scheme, adherence scheme and DMC Scheme.
8. Adoption of key population groups under **corporate social responsibility** by corporate houses.
9. **Targeted ACSM** as a tool for universal access to TB care:
   a) Wide dissemination of information in the population regarding availability and location of TB care services
   b) Use of local media, cured patients, NGOs, religious, political and other community leaders to spread the message on TB

10. Specific activity to aggressively control TB in High Priority Districts

For the year 2016-17, the programme has categorized and prioritized the districts across the country based on the following criteria:

Categorization	Criteria	Category	Number of districts
High TB	Total TB case notification rate > 180 per lakh population	A	83
High TB-HIV	>10% Proportion of known HIV positives amongst TB patients tested for HIV	B	41
High DR-TB	> 25% Proportion of relapse out of incident smear positive TB cases	C	47
Very low case finding effort	Annual TB suspect examination rate of < 400 per lakh population	D	60
Average	None of above	E	489
High case finding but Low TCNR	Annual suspect examination rate >1200 per lakh population and Total Case notification rate < 80 per lakh population	F	10
Grand Total			730

(TB-HIV: Tuberculosis and HIV co-infected patients, DR-TB: Drug Resistant Tuberculosis,
TCNR: Total Case Notification Rate)
(For RNTCP programmatic purposes strategies / services are based on population and hence due to high population in urban areas especially municipal corporations, additional districts have been created. As a result the total number of districts in the country under RNTCP is 730)

In these prioritized 184 Districts + 4 Metros and 1 State (i.e. Sikkim) active case finding will be implemented using the following broad strategies as below:

Categorization	Number of districts	Broad strategies for implementation
High TB	44	• Village-wise microanalysis to identify high TB pockets • Intensified / active case finding with decentralized diagnosis • Visibly improve IEC activities • 100% contact tracing
High TB-HIV	40	• Complete utilization of rapid diagnostics for early diagnosis of TB among HIV+ • Implementation of Isoniazid Preventive Therapy for all HIV+ • Daily regimen TB treatment
High DR-TB	43	• Testing 100% eligible drug resistant TB suspects within 3 days • Treatment support mechanisms to improve adherence and outcomes including linkages for nutritional support for all TB patients • Implement long-term follow-up policy at 6, 12, 18 and 24 months post treatment

Very low case finding effort	57	• Village-wise microanalysis to identify village with <5 suspect examined per 1000 pop annually to prioritize case finding activities • Focus IEC activities (Panchayati raj institutes members and schools) • Active screening of all health facility attendees for TB suspects and ensure testing
Total	184	
Additional Metro cities and Sikkim State	68	Implement all above strategies

TB-HIV

Introduction

TB-HIV collaborative activities between Revised National Tuberculosis Control Programme (RNTCP) and Department of AIDS Control (DAC)/NACO started initially in the year 2001. Since then, TB-HIV activities have evolved in line with updated scientific evidences. National Framework for joint TB-HIV collaborative activities is developed under which National, State and District level coordinating mechanism were put in place. Components such as dedicated human resources, integration of surveillance, joint training, standard recording with reporting, joint monitoring with evaluation, operational research are strategically implemented .The key approach suggested as per the National Framework Nov 2013 is as below:

Strategic Interventions

1. **Strategies for reducing the burden of TB among People living with HIV/AIDS**
    a. **Intensified case finding activities in HIV care settings:** Program will emphasis on use of a simplified clinical algorithm for TB screening that relies on the absence or presence of four clinical symptoms (current cough, weight loss, fever and night sweats) to identify people eligible for further diagnostic work-up of TB. Also rapid molecular test CBNNAT will be offered to all presumptive TB cases among PLHIV for early diagnosis of TB in settings such as ART centres, Link ART Plus centre (LAC+), Link ART centre (LAC), Integrated Counselling with testing centres (ICTC) and Targeted Intervention Projects (By 2017)
    b. **Airborne infection control in HIV/TB Care settings:** People living with HIV are at higher risk of developing TB and TB is cause of high mortality among PLHIVs. National Airborne infection control guidelines recommend implementation of AIC measures at all HIV/TB Care settings. These measures include:
        i. Developing time bound action plan to implement AIC measures at all Centres.
        ii. Training of MOs and Nursing Staff in AIC guidelines
        iii. Risk assessment at all centres with recommendations of implementing AIC guidelines.
        iv. Health care workers surveillance for TB and appropriate AIC measures at all centres.
    c. **TB prevention among PLHIV:** Isoniazid Preventive Therapy (IPT) Strategy for prevention of TB among PLHIV, to be implemented nationwide by 2017.
    d. **Early initiation of ART**: All PLHIV with less than 500 CD4 count will be eligible for the ART. Considering this PLHIV already registered in Pre- ART care, additional one lakh fifty thousand patients will require to be started on ART. Additionally nearly 50,000 patients will be added annually per year.
2. **Strategies for reducing the impact of HIV among TB patients**

a. **Provider Initiated HIV testing and Counselling (PITC) among presumptive TB cases** is now a policy. The implementation is being done in a phased manner, starting with high prevalent states and then in A and B category districts in rest of the country by 2017.
b. **Early initiation of ART among HIV infected TB patients:** Systematic measures to extend financial support to the HIV-infected TB patient for travel to ART centre for evaluation and treatment initiation. There will be a provision for travel support for HIV-infected TB patients to visit ART centre. Efforts will be made to optimize outreach activity undertaken by different categories of NACP outreach workers.
c. **Nutritional support for TB and HIV patients:** Linking all TB and HIV patients for nutritional support through PDS.
d. **Implementation of daily anti TB regimen with 2 years of post-treatment follow-up**

3. **Strategies for establishing mechanisms of Co-ordination**
   a. **Improved surveillance:** Linking patient-wise database, implement a case-based, web-based electronic surveillance system to enable real time monitoring of inter-programme linkages.
4. **Strategies for high priority 20 selected districts**
   a. Early Diagnosis: Increasing access to rapid diagnostics for PLHIV with clients accessing HIV testing services including strengthening Sputum Collection and transportation.
   b. Innovative strategies for addressing local epidemics esp. in 20 high priority districts
   c. Decentralized TB-HIV treatment delivery services through community led models
   d. Strengthening social support and institutional support for co-infected patients
   e. Private sector engagement in TB HIV Collaborative activities
   f. Newer initiatives Community Based HIV testing, Test and Treat, implementation of Targeted Interventions strategies under NACP

The implementation of TB HIV activities will require CBNAAT to be deployed at all ART/COE s Centres in the country for early diagnosis of TB (by 2015). Department of AIDS control to expand coverage of whole blood finger prick HIV screening test at all PHIs. General health system needs to provide storage facility for HIV testing kits, budget for implementation of AIC measures at HIV TB care settings (600 ART centres, LAC, ICTC), and budget for ART drugs. Availability of adequate stock of Isoniazid is to be ensured. E-Training module to be used for HIV care staff.

Diabetics, Tobacco use and Alcohol dependence

Introduction

India is experiencing an escalating epidemic of diabetes mellitus. Available data suggest that an estimated 11% of urban people and 3% of rural people above the age of 15 years have diabetes mellitus, with about half of those in rural areas and one third in urban areas being unaware of the problem. Most recent estimates put the number of persons with diabetes mellitus at 62 million (10% of the adult population), with a further 77 million having impaired glucose tolerance. Epidemiological surveys and studies have been completed and published or are currently being conducted in India on the association between diabetes and tuberculosis.

Tobacco use is the leading global cause of preventable death (6 million deaths per year). Tobacco-related mortality in India is among the highest in the world. The percentage of Indian women and men aged 15-49 yr. who smoke tobacco is 2.9% and 24.3% respectively. In addition, 18.4% of women and 32.9% of men chew tobacco. Tobacco consumption in India is responsible for half of all cancers in men and a quarter of all cancers in women, in addition to representing a major threat to many other conditions, such as cardiovascular diseases, chronic obstructive pulmonary diseases, and TB.

Strategic Interventions

1. **Development and Implementation of collaborative framework for TB associated with Diabetes, Tobacco use and Alcohol consumption**

This framework will identify the diabetics and tobacco/alcohol users among TB patients and support them to quit tobacco/alcohol use as well as provide screening for TB among this vulnerable group visiting public health facilities across the country. As per NSP 2012-2017, efforts will be made in the next five years to collaborate closely with the National programme for prevention and control of Cancer, Diabetes, Cardiovascular disease and Stroke (NPCDCS) and National Tobacco Control Programme for screening of TB patients.

2. **Linkage with other National Health Programmes:**

In order to reach out to populations with multiple risks / vulnerabilities, RNTCP will also be linked to other development schemes and national programs such as the National Tobacco Control Programme, NGOs working with the International Organization for Migration in the Ministry of Labour, National Programme for Non Communicable Diseases, special programs for those with occupational risk such as silicosis with the Ministry of Labour, rail travel and other support available for special groups. This will be coordinated through NGOs where appropriate and active involvement of civil society will be sought to implement, monitor and track progress on these interventions.

Proposed Interventions:

1. **Bidirectional screening** of TB and DM
2. Identifying current tobacco user and brief routine cessation advice: Ask, Advice, Assess, Assist and Arrange, will be provided by the programme,
3. Smoke free health care facilities
4. Linkage of all current tobacco/alcohol addicts to the cessation/de-addiction clinics
5. Treatment support Counselors to be appointed at each health care facility (by 2017)

Poor, undernourished, economically and socially backward communities

Introduction

It has been observed consistently that poverty is associated with much higher risk of TB infection, prevalence of TB disease, and of adverse outcomes of treatment including mortality.

In India the prevalence of self-reported TB was found to be 5.5 times higher in the lowest income quintile compared to the highest income quintile according to the National Family Health Survey-3. Tuberculosis also worsens poverty, as the poor spend a much higher proportion of their income on the direct and indirect costs associated with TB care. The END TB strategy highlights integrated patient-centered care and prevention as its first pillar.

Strategic Interventions

1. **To make the TB programme pro-poor in its overall orientation**, and respond to the challenges faced by them in a flexible, innovative and sustainable manner. This will involve the following:
    a. Mapping the poor and vulnerable populations in the jurisdiction of each district TB programme.
    b. Identification of the barriers to care and adherence in the district.
    c. Removal of those barriers by appropriate administrative and other actions, and monitoring the results of these actions by indicators which report on case finding, case-holding and treatment outcomes.
    d. Creation of **a grievance reporting and redressal mechanism**, which will empower this socially vulnerable and marginalised population.
    e. To consider a **group life-insurance scheme** for all TB patients to prevent the catastrophic consequences for the family in the event of death during TB treatment.
2. **To evolve a high-quality patient-centred model of TB care for the urban and rural poor**
    a. Launch of new regimens
    b. Universal DST before initiation of treatment.
    c. Comprehensive assessment of patients at diagnosis to identify any red flag features which may indicate higher risk of complications including death.

    d. Patient support at the family and systems level
3. **Provision of nutritional and financial support, and effective treatment of comorbidities**.
    a. Better surveillance of patients with severe disease to enable hospitalisation for management of severe disease, serious adverse events etc.
    b. Counselling and information support to be also provided by previously treated TB patients in the community who will act as DOSTs (Deliverers Of Support during Treatment)
    c. Assessment of TB patients at the end of treatment with regard to symptoms, functional status and degree of disability if any. To enable those affected by sequelae access to social assistance schemes available for the rehabilitation of the handicapped (soft loans, employment quotas).
4. **To engage and mobilise community participation in TB control**:
    a. Long term engagement with ASHAs, and community level health workers.
    b. Utilise the ACSM components of the TB programme to create a community of actors in the government, non-governmental, educational and other social sectors who will be committed to TB control.

TB Control in Hilly and Difficult Terrains

Introduction

Though TB control programme in India has achieved the global targets, yet the TB control activities in India has always faced challenges in the hilly, desert and difficult areas due to issues with accessibility. Some of the states with tribal and hilly terrains in India have been reporting a high incidence of not only drug sensitive but also drug resistant TB cases. Hence it becomes even more important to strengthen the TB control activities in these difficult areas.

Strategic Interventions

1. Constitute a **Task Force at State, district and sub-district level** with members (Administrative and Technical) from all stake holders (Dept of Health, the dept pertaining to that difficult area, Social Welfare, Education, Civil Society) headed by the local parliamentarian to review the TB Control activities. This will generate high level of administrative commitment at district level and will help in overcoming the district and area specific bottlenecks in TB control activities.
2. **Mapping of the vulnerable population** in the difficult areas with regards to accessibility and health needs.
3. **Increase accessibility to TB control activities** for case finding as well as case holding in the hilly and difficult terrains which will involve the following:
    a. Designating all PHIs with a laboratory as a microscopy centre irrespective of the population being catered to.
    b. Establish a **designated sputum collection booth** at every village with dedicated man-power with a monthly minimum remuneration for collecting and transporting sputum to the nearby laboratory.
    c. Incentive may also be considered for government employees in the difficult areas who are involved in TB control activities. Incentive can be on per case basis.
    d. Upfront rapid molecular testing to further reduce the delay in diagnosis.
4. **ACSM and Community Mobilization**
    a. Involvement of the traditional healers/quacks which has got substantial presence in the hilly and difficult areas.
    b. Mobile unit with display of IEC materials along with facility for sputum collection and transportation.

Substance Dependence and Sexual Minorities

Introduction

The key populations with regard to HIV are defined as: men who have sex with men (MSM); Transgender persons (TG) with Hijra, women in sex work (SW) and people who inject drugs (PWID).There is a clear evidence to suggest that socioeconomic and cultural factors lead to barriers in accessing health care including TB care.

Strategic Interventions

Key strategies that perhaps need to be established to facilitate improved case-finding, testing and treatment of TB among KPs are given below:

1. **Detection; Testing and counselling**: stigma free and community sensitive TB testing and counselling, integrated with current HIV testing and treatment facilities.
2. **Peer outreach at TB testing and treatment sites:** HIV-TB peer educators will be linked with TB service providers. These can be peers from targeted intervention or HIV care and support programs. Community or peer-led measures will penetrate better into the intricate layers of KPs and facilitate ICF.
3. Make available safe virtual or physical spaces (for example telephone hotlines, or drop-in centres) for KPs to seek information and referrals for care and support to TB treatment. DIC's for KP's under TI's can have a TB corner and weekly/ fortnightly awareness sessions, testing days and follow-up testing days for TB can be organised in coordination with district TB officers (DTOs).
4. To increase coverage and access to comprehensive HIV- TB prevention, treatment, care, support and related services for KPs, their sexual partners and families and their clients (SWs in particular).
5. **Community led early detection and treatment services:** TB related services can be dispensed through community based organisations (CBOs)/ civil societies, to ensure adherence and side-effects management among KPs.
6. **Health system strengthening:** Strengthening referrals between prevention, care and treatment for TB, in light of needs and issues pertaining to KPs.

TB and Pregnancy

Introduction

TB in pregnancy is special situation wherein woman needs special attention and care. RNTCP and RCH division proposes specific activities to address the special needs of clinically and socially vulnerable populations.

Strategic Intervention

1. Estimating number of women among clinically and vulnerable groups and measuring burden of TB among them
2. Intensive case finding among pregnant and lactating women, women having infertility, women who smoke, women having diabetes, HIV/AIDS, malnutrition; who constitute clinically vulnerable risk groups for TB
3. Increase awareness about high risk and available TB services and support to clinically and socially vulnerable women through specifically targeted national mass media campaign
4. **Establishing linkage with RMNCHA**- Symptom screening, physical examination and necessary investigations for ruling out TB during Ante natal/ post-natal check-ups and noted in ANC/PNC Cards and Maternal with Child Tracking System (MCTS)
5. Development of collaborative framework with RNTCP. Several development partners are working with RMNCH+A and possibilities for collaboration must be explored. There will be recurrent mechanism of joint supervision with monitoring, the expenditure for which must be factored in

6. Offering Universal DST through use of rapid molecular testing for diagnosis of pulmonary and extra-pulmonary TB among pregnant and lactating women
7. Prioritised support for access to transportation, nutrition, counselling and social welfare schemes
8. Explore and advocate for micro-insurance and health covers for management of complications due to TB among pregnant and lactating women and support for assisted reproduction in cases of infertility due to genital TB.

Paediatric Population

Introduction

India has the highest burden of the Tuberculosis in the work and there is substantial morbidity and mortality among TB patients. TB in paediatric age group often go undetected due to nonspecific symptoms and non-uniformity of diagnostic modalities in public and private sector. In year 2015, Paediatric TB contributed (6-7%) of total TB cases while considering the burden of the disease, the paediatric case detection need to exceed 10%. While the provided figure stands for the government sector, the case notification from private paediatrician can actually provide real picture of Paediatric Tuberculosis.

Strategic Interventions

1. Development of Paediatric screening guidelines which can act as easy reference for both public and private doctors and healthcare workers
2. Roll out of paediatric new guideline and review of status for it's rigorous implementation. Adequate and regular supply of paediatric FDC which can be provided to Public as well as Private paediatric TB patient's free of cost
3. Household contacts and other close contacts will be systematically screened for active TB
4. Development of strong IEC material for disseminations of RNTCP extended services for diagnosis and treatment for private diagnosed Paediatric TB patients. Private sector will also need to understand 'Standards for TB care in India' while diagnosing and treating paediatric TB case.
5. Involvement in Indian Association of Paediatricians for notifying all diagnosed TB patients to RNTCP, use STCI as reference manual while managing presumptive paediatric TB case.
6. RNTCP to associate itself with other ministries and department to address the missing cases in the community.
7. Maternal and child health programs can also be targeted for local awareness and symptomatic screening for early diagnosis and referral of samples for rapid molecular tests/ other technologies.
8. Rashtriya Bal Suraksha Karyakarm (RBSK) Program has a reach to millions of paediatric population and RNTCP can benefit from such existing mechanism to reach paediatric population, spread awareness regarding TB and instant referral of symptomatic cases to nearest health facilities.

Prison Inmates and staff of prisons/jails

Introduction

There are, at present 1401 jails in India. On 31 December 2015, there were 4, 19,623 in these jails and the combined Occupancy Rate of all jails was 114.4%[1]. Information on the number of prisoners with tuberculosis is scarce. Prison conditions can fan the spread of Tuberculosis, through overcrowding, poor ventilation, weak nutrition, inadequate or inaccessible medical care, etc. The best strategy for preventing tuberculosis in prisons is early diagnosis combined with effective treatment. Measures to reduce overcrowding and to improve living conditions for all prisoners will be implemented to reduce transmission of TB.

Strategies for case-finding in prisons:

1) through self-referral; 2) through screening at entry to the prison; and 3) active case-finding among prisoners.

Strategic Interventions:

1. Collaborative efforts between the prison and general health services
2. Conduct screening of new inmates and periodic screening of prisoners and penitentiary services staff to detect active TB in a timely manner.
3. Ensure airborne infection control, including protective measures for staff
4. Provide preventive therapy for individuals with LTBI
5. Ensure a continuum of care for released prisoners who are on treatment for TB and for individuals who are on treatment before entering the prisons
6. Provide psychological counselling and support for prisoners to improve TB and HIV treatment adherence
7. Strengthen TB control in prison-based programs by raising awareness about TB among inmates and prison medical and non-medical staff. Avoiding transfer of TB patients, improving communications between prisons to ensure treatment follow-up after transfer and facilitating transfer to community clinics for released prisoners
8. Scientific research, including Operational Research will be linked to the development of specific knowledge about dealing with the problem specific to the prison environment

Women in settings with gender disparity:

CHAPTER 9
PATIENT SUPPORT SYSTEMS

Introduction

TB causes catastrophic economic effects on both the individual suffering the disease and their households. National economies are also affected with estimates suggesting significant impact that will hamper national development. RNTCP provides free diagnosis and treatment to patients registered under the programme but many patients experience associated health care costs, including payment for ancillary drugs and extra diagnostic tests, as well as considerable non-medical costs, including expenditures for transport and accommodation. Furthermore, patients and other household members who care for them may suffer reduced incomes due to lower productivity and/or loss of employment opportunities, and may experience the intangible costs related to social stigma associated with their illness.

Adherence to regular and complete treatment is the key to cure from TB. To assess and foster adherence, a patient-centered approach to administration of drug treatment, based on the patient's needs and mutual respect between the patient and the provider, will be developed for all patients.

A good patient support plan is imperative for treatment success and will be developed at the time of initiation of treatment. This support will include the following:

1. initial and frequent follow-up counselling of the patient and family members,
2. supervision of treatment by a trained treatment supporter (a health worker or community volunteer),
3. locally managed additional nutritional support,
4. retrieval of treatment interrupters,
5. screening for adverse reactions,
6. appropriate social support scheme,
7. psycho-social support,
8. co-morbidity management, and
9. follow-up laboratory investigations.

In addition to addressing the morbidity and mortality due to TB, efforts under this NSP are also geared towards reducing the economic burden of TB on patients and their households. The primary objective of the support systems are to increase treatment adherence and to eliminate catastrophic expenditure by TB patients**.**

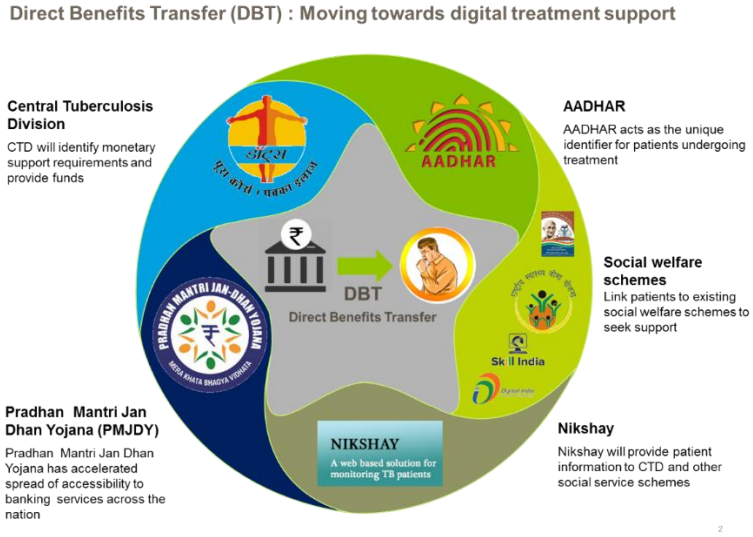
Strategic interventions

Link TB patients and households to the applicable government social schemes and leverage the governments thrust on digital payments to transfer benefits and incentive payments directly to the patient's bank account.

1. **Linking Pradhan Mantri Jan-Dhan Yojana[11], AADHAR and NIKSHAY (JAN) for direct cash benefits to patients:**

[11] PMJDY is India's National Mission for Financial Inclusion to ensure access to financial services, namely Banking Savings and Deposit Accounts, Remittance, Credit, Insurance, Pension in an affordable manner.

The programme will adopt a Direct Benefits Transfer (DBT) mechanism for transfer of monetary support and incentives to patients. This will ensure the funds reach rightful recipients in a timely manner.



The cornerstones of the DBT mechanism will be:

i. **RNTCP** – In addition to providing funds for DBT, CTD/programme will also identify and review incentives and treatment supports to be provided to the patients

ii. **PMJDY** – Pradhan Mantri Jan Dhan Yojana has introduced banking facilities even to the poorest and remotest citizens of our country. PMJDY accounts will allow for quick establishment of DBT linkages for patients irrespective of their economic strata or geographic location.

iii. **NIKSHAY** – As a case based patient identification system, NIKSHAY will keep a real time track of patient eligibility for DBT and ensure quick activation of DBT linkages to patient accounts

iv. **AADHAR** – AADHAR will act as the unique identifier for patients seeking treatment support via DBT mechanism It is also hoped that in the future the TB number will become redundant with the use of AADHAR instead of it.

2. Reducing the out of pocket expenditure for TB patients

The programme strives to limit and eliminate catastrophic out of Pocket Expenditure to the patients. To this effect, the major causes borne by the patient and their redressal mechanism (existing and proposed) are detailed in the figure XX and its remedial measures in Table XX.

Figure XX:

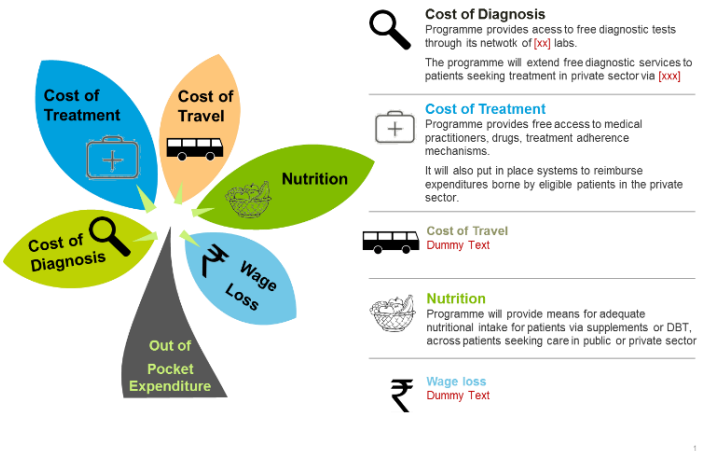


Table :

Type	RNTCP will cover the costs across sectors			
	Public sector		Private Sector	
	Cost	Cost covered by	Cost	Cost covered by
Cost of Diagnosis	Free	RNTCP lab network	Proposed to be free*	Reimbursement to private labs or patients
Cost of Treatment	Free drugs and access to medical practitioners	Public health system	Proposed to be subsidized	Free drugs to be provided to patients seeking care in private sector. Reimbursement of practitioner fees to eligible patients
Nutritional Support	Proposed as nutrition support to every TB pt	RNTCP through DBT	Proposed as nutrition support to every TB pt	RNTCP through DBT
Cost of travel	Provided under existing guidelines	Applicable National programmes and schemes	Provided under existing guidelines	Applicable National programmes and schemes of the government
Wage lost		Linkage with skill development programmes and applicable National programmes and schemes of the government		Linkage with skill development programmes and applicable National programmes and schemes of the government

*Except CXR

Periodic out of pocket surveys will also be undertaken to assess the needs as well as the impact of the interventions to reduce catastrophic costs.

3. Providing financial support for nutritional support to the TB patients.

In tuberculosis as in many other infectious diseases, there is a bidirectional interaction between nutritional status and active disease. Under-nutrition is a risk factor for tuberculosis which in turn worsens the nutritional status, generating a vicious cycle which can lead to adverse outcomes (during and following therapy) for patients with active tuberculosis including those with multi-drug resistant TB. This interaction is particularly important in the Indian context where food insecurity and under-nutrition coexist with a large burden of tuberculosis. To address this issue it is proposed to launch a scheme to provide a monthly cash incentive for every TB patient through DBT. All individuals with active TB will receive:

(1) an assessment of their nutritional status
(2) appropriate counselling based on their nutritional status at diagnosis and throughout their treatment.
(3) If undernutririon is identified, it will be managed according to programme recommendations. Linkages for extra nutritional support for TB patients or of his contacts on IPT will be extended with existing government schemes like public distribution system (PDS) or applicable food security schemes.

(4) Linkages with exisitng intervenitons of manging undernutirion like nutrition rehabilitation centers (NRC's)

4. Patient-centred approach to treatment

Adherence to regular and complete treatment is the key to relapse free cure from TB. To assess and foster adherence, a patient-centred approach to administration of drug treatment, based on the patient's needs and mutual respect between the patient and the provider, will be developed for all patients. A good treatment support plan will be developed at the time of initiation of treatment. This plan will include initial and frequent follow-up counselling of the patient and family members, supervision of treatment by a trained treatment supporter (a health worker or community volunteer), locally managed additional nutritional support, retrieval of treatment interrupters, screening for adverse reactions, psycho-social support, co-morbidity management and follow up laboratory investigations.

A treatment supporter who is acceptable, accessible to the patient and accountable to the health system will be identified and trained. A health worker in the hospital/ health centre may be the best person to provide all the envisaged components of treatment support program. However, access to such a health worker in person, place and time may be limited since the centre may be far away from patient's residence, working hours may be restricted and the worker may be away on field visits. Compelling the patient to travel long distance to avail directly observed treatment is against the principles of patient centric approach. Hence all efforts must be put in to find a treatment supporter close to the patient's residence. Accumulating evidence has pointed to the effectiveness of a wide variety of approaches including community and family-centered , which is more achievable for most developing healthcare systems and produce comparable outcomes to directly observed treatment by healthcare worker.

Wherever appropriate, a family member can also be assigned with the responsibility of observing treatment. Such situations may arise with sick and bed ridden patients, children, long-day workers etc. In such situations, the family member who is assigned with the responsibility to observe treatment will be trained well and supported during the process by a health worker by frequent visits to the house.

Each patient and his/her treatment supporter will be supervised by a health worker. It may be a peripheral health worker in the public health system. If the patient is initiated on treatment by a private health care provider, public health system may offer this supportive role when requested.

While observing treatment is one of the best modalities of promoting treatment, other modalities also may be deployed to further enhance adherence to treatment. Intelligent deployment of information communication technologies (ICT) is an example of such modalities. A patient who is unable to undergo supervised treatment will not be denied treatment. Frequent on-job travellers, truck drivers, sailors etc may require identification of proper treatment supporter. To promote treatment adherence among these patients, ICT modalities like frequent calls, SMS reminders, IVRS etc. may be deployed.

Counselling may be required to quit substance abuse. Nutritional assessment and support, ancillary drugs, co-morbidity management, compensation for lost wages etc. are some other requirements. To avail these, healthcare providers will derive synergies between various social welfare support systems like RSBY, National Family Benefit Scheme, Group Life insurance scheme(Jan Shree Bima Yojana), national rural employment guarantee scheme, corporate social responsibility (CSR) initiatives, counselling centres etc. to mitigate out of pocket expenses such as transport and wage loss incurred by people affected by TB.

Details of the social welfare schemes, applicable to TB patients is provided at Annex I.

PREVENT

What does it mean in the context of this NSP for TB elimination in India?
Prevent the emergence of TB in susceptible populations

What does it entail?

1. Scale up air-borne infection control measures at health care facilities
2. Treatment for latent TB infection in contacts of bacteriologically-confirmed cases
3. Addressing social determinants of TB through intersectoral approach

- **CHAPTER 10: AIR BORNE INFECTION CONTROL**
- **CHAPTER 11: CONTACT TRACING**
- **CHAPTER 12: LTBI TREATMENT**

CHAPTER 10:

AIR BORNE INFECTION CONTROL

Acute respiratory infections (ARIs) are the leading cause of morbidity and mortality from infectious disease worldwide, particularly affecting the youngest and oldest people in low and middle-income nations. These infections, typically caused by viruses or mixed viral– bacterial infections, can be contagious and spread rapidly. Although knowledge of transmission modes is ever-evolving, current evidence indicates that the primary mode of transmission of most acute respiratory diseases is through droplets, but transmission through contact (including hand contamination followed by self-inoculation) or infectious respiratory aerosols at short range can also happen for some pathogens in particular circumstances.

CHALLENGES AT COMMUNITY LEVEL

Social habits

- Cough etiquettes not being followed
- Indiscriminate spitting
- Sneezing without covering face
- Alcoholics and mentally challenged patients
- Delay in reaching health facility for specific diagnosis

Special groups

- Migrant population, back ward areas and tribal pockets
- Old age homes, poor homes, children homes, jails, hard to reach areas
- Delay in diagnosis in co-morbid conditions like Diabetes, HIV, Cancers, etc.

Environmental aspects

- Environmental pollution

In modern medicine, infection prevention and control (IPC) measures in health-care settings are of central importance to the safety of patients, health-care workers and the environment, and to the management of communicable disease threats to the global and local community. Application of basic IPC precautions, such as Standard Precautions, is a cornerstone for providing safe health care. In an era of emerging and re-emerging infectious diseases, IPC in health care is as important now as ever.

CHALLENGES AT INSTITUTIONAL LEVEL

Outpatient facility

- Patients with chest infection at outpatient settings
- Overcrowding - mixing of patients in queues and waiting areas
- Poor ventilation in the facilities

In patient facility

- Cough screening, separation, fast-tracking, mask and counseling provision missing
- Infectious patients getting admitted at General wards
- Cough etiquettes not followed in wards
- Overcrowding in the wards – no restricted entries

TB infection control is a combination of measures aimed at minimizing the risk of TB transmission within populations. The foundation of such infection control is early and rapid diagnosis, and proper management of TB patients. National guidelines on airborne infection control in all health settings including HIV care settings were developed that included a

combination of simple managerial, administrative, environmental and personal protection measures. Operational feasibility and effectiveness of the guidelines have been conducted in the states of West Bengal, Gujarat and Andhra Pradesh.

TB infection control in health care and congregate settings: The National Airborne Infection Control Committee (NAICC) with representations from Medical Colleges, NCDC, NACO, CTD, WHO, Architects and PWD Engineers was established in 2008. National guidelines on airborne infection control in all health settings including HIV care settings were developed that included a combination of simple managerial, administrative, environmental and personal protection measures. Pilot testing of operational feasibility and effectiveness of the guidelines have been conducted in the states of West Bengal, Gujarat and Andhra Pradesh and baseline assessments have been conducted in 35 health facilities.

Integrating airborne control guidelines: The programme envisages integrating the airborne infection control guidelines of the programme with the general health system guidelines. Activities such as advocacy, guideline awareness and capacity building will be initiated at the state level and subsequently overseen by the general health system.

SOLUTIONS AT INSTITUTIONAL LEVEL

1. Certification of Health facility for AIC Compliance
2. Develop cough corners/counters - Cough screening, separation, fast-tracking, mask and counseling
3. Posting of specific staff for fast tracking and providing masks
4. Providing N 95 masks to the Hospital staff in High risk settings
5. ACSM at OPD and other settings like Posters, Clippings etc
6. Implementation of AIC in all settings
7. In house AIC complaint facility for treating nomads, destitutes, homeless patients
8. Separate IP facility for bacteriological positive DS/DR TB patients and other airborne infectious patients in major institutions
9. Proper infection control measures in ART centres.
10. Proper follow up of daily reported cases
11. Proper disposal of sputum and infected materials
12. Early diagnosis and initiation of treatment
13. PPE for concerned staff
14. Wet mopping and disinfection
15. Periodic screening of staff
16. Proper ventilation, renovation if necessary
17. Facility risk assessment and reporting
18. Periodic trainings
19. Ongoing monitoring dashboards/checklist for AIC practices at all levels
    a. Community level - LSG, PHI field staff
    b. Institution level – Nurses, IC focal points, heads of institutes

NAIC guideline will be implemented at high risk centers at DR-TB Centers, ART Centers, C and DST Laboratory. The Implementation of National Airborne Infection Control policy includes following:

- Airborne infection control committee and plan
- Baseline assessment
- Resource planning and budgetary provisions
- Training of health care workers
- Implementation of administrative, environmental and personal protection measures.
- Establishment of health care centres will be in accordance with NAIC policy.

All measures for airborne infection control must be implemented as per the national AIC guidelines while managing all TB patients.
To scale up treatment services PMDT sites have been planned at 1 site per 10 million population for up-gradation for airborne infection control measure for rolling out of services.

Chapter 11
CONTACT TRACING

In RNTCP contact screening has been a clinical function with cursory programmatic monitoring. In this NSP contact tracing will be made more rigorous, expansive and accountable. The end result expected is that most TB pts will have their contacts screened, with secondary cases detected and treated.

Contact investigation

- All close contacts, especially household contacts will be screened for TB using Chest X Rays.
- In case of paediatric TB patients, **reverse contact tracing** for search of any active TB case in the household of the child must be undertaken.
- Particular attention will be paid to contacts with the highest susceptibility to TB infection

Since transmission can happen from index case to the contact any time (before diagnosis or during treatment) all contacts of TB patients must be evaluated.

The highest priority contacts for active screening are:

- Persons with symptoms suggestive of tuberculosis
- Children aged < six years
- Contacts with known or suspected immune-compromised patient, particularly HIV infection
- Contacts with Diabetes Mellitus
- Contacts with other higher risks including pregnancy, smokers and

Use of Chest X Rays upfront for screening of contacts will be prioritized during the NSP period. Setting specific screening approaches (for example in prisons, urban slums, etc.) according to the RNTCP TOG will be undertaken.

All close contacts of DR-TB cases will be identified through contact tracing and evaluated for active TB disease as per RNTCP guidelines. If the contact is found to be suffering from pulmonary TB disease irrespective of the smear results, he will be identified as “Presumptive MDR-TB”. The patient will be initiated on regimen for new or previously treated case based on their history of previous anti-TB treatment. Simultaneously two sputum samples will be transported for culture and DST to a RNTCP-certified C&DST laboratory.

CHAPTER 12
PREVENTIVE THERAPY/ LATENT TB INFECTION TREATMENT

TB infection is the seed bed for developing TB disease and continued transmission. The lifetime risk of reactivation of LTBI in healthy HIV-uninfected individuals is 10%, with 5% developing TB disease during the first 2 to 5 years after infection. The risk of reactivation is greatly increased in the context of immunosuppression, primarily due to HIV infection. ART reduces the risk of TB by approximately two thirds. Child contacts living in TB-affected households are particularly vulnerable populations for progression to TB and severe disease forms such as disseminated and meningeal TB. WHO has included scaling up TB preventive therapy for persons at high risk of developing TB in its End TB Strategy and increasing coverage of contact investigations and TB preventive therapy for PLWHIV and child contacts are important strategies. Scaling up TB preventive therapy is therefore important to meet the goals of ending TB in India.

India, with one-fourth of the global burden of TB, has 40 per cent of the population infected with M.Tb. Treating 40 per cent of the population for LTBI based on Tuberculin Skin Test (TST) positivity or Interferon Gamma Release Assay is neither rational nor practicable, thus emphasizing the need for a focused approach. In clinical situations, the most obvious group for LTBI treatment will include high-risk patients such as those receiving long term corticosteroids, immunosuppressant's, HIV-infected and juvenile contacts of sputum-positive index cases. The selection of the risk group that will be prioritized for screening, investigation to rule out TB and treatment is as follows:

1. People living with HIV
2. Child PTB contacts
3. Patients with silicosis
4. All patients where clinically indicated (high risk) for eg. pts in immunosuppressant's
5. High risk adult contacts

Isoniazid Preventive Therapy

Children are more susceptible to TB infection, more likely to develop active TB disease soon after infection, and more likely to develop severe forms of disseminated TB. Children < 6 years of age, who are close contacts of a TB patient, will be evaluated for active TB by a medical officer/ pediatrician. After excluding active TB he/she will be given INH preventive therapy irrespective of their BCG or nutritional status. The dose of INH for preventive therapy is 10 mg/kg body weight administered daily for a minimum period of six months. The INH tablets will be collected on monthly basis. The contacts will be closely monitored for TB symptoms.

In addition to above, INH preventive therapy will be considered in following situation:-

- For all HIV infected children who either had a known exposure to an infectious TB case or are Tuberculin skin test (TST) positive (>=5mm induration) but have no active TB disease.
- All TST positive children who are receiving immunosuppressive therapy (*e.g.* Children with nephrotic syndrome, acute leukemia, *etc.*).

- A child born to mother who was diagnosed to have TB in pregnancy will receive prophylaxis for 6 months, provided congenital TB has been ruled out. BCG vaccination can be given at birth even if INH preventive therapy is planned.

Close contacts of index cases with proven DR-TB will be monitored closely for signs and symptoms of active TB as isoniazid may not be prophylactic in these cases. Although alternative prophylaxis treatments have been suggested, there is no consensus regarding the choice of the drug(s) and the duration of treatment. Prompt treatment of MDR-TB is the most effective way of preventing the spread of infection to others. The following measures will be taken to prevent spread of DR-TB infection:

1. Early diagnosis and appropriate treatment of MDR-TB cases;
2. Screening of contacts as per RNTCP guidelines

Further research into effective and non-toxic chemoprophylaxis in areas of high MDR-TB prevalence is required.

Isoniazid Preventive Therapy (IPT) For PLHIVs

Children living with HIV who are more than 12 months of age and who are unlikely to have active TB on symptom-based screening, and have no contact with a TB case will receive six months of IPT (10 mg/kg/ day) as part of a comprehensive package of HIV prevention and care services

Systematic recording and reporting:

All events in the cascade of IPT implementation including symptom screening at all contacts, IPT eligibility assessment, investigations, and the compliance with regimen will be systematically recorded and reported.

BUILD

What does it mean in the context of this NSP for TB elimination in India?
Undertake critical management reforms, restructuring of HR and financial norms, pathways for private sector participation, in order to improve efficiency, effectiveness and accountability of the health system for an improved response to the TB epidemic.

What does it entail?

1. Build synergies with existing health service delivery mechanism under Urban Health Mission and plan for integration of services
2. Reform and restructure HR in TB programme to align with the enhanced programme needs for surveillance, participation of private sector and community participation.
3. Strengthen RNTCP's regulatory capacity to control TB drugs through appropriate laws, regulations, and policies.
4. Position TB high on the health and development agenda of the nation to ensure adequate resources, greater demand for and universal access to TB care services.

- **CHAPTER 13: URBAN TB CONTROL SYSTEMS**
- **CHAPTER 14: HEALTH SYSTEM STRENGTHENING**
- **CHAPTER 15: ADVOCACY, COMMUNICATIONS AND SOCIAL MOBILIZATION**
- **CHAPTER 16: SURVEILLANCE, MONITORING AND EVALUATION**
- **CHAPTER 17: RESEARCH**
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Chapter 13
URBAN TB CONTROL SYSTEMS

It is often assumed that marginalized people residing in urban areas in general have better access to health services due to their supposed proximity to urban health facilities. However what is often overlooked is the weak public health infrastructure in urban areas and the crowding out effect together with weak referral and outreach system which severely limits access of poor to urban health services in general and TB services in particular. The social exclusion and lack of information and assistance at the secondary and tertiary hospitals makes them unfamiliar to the modern environment of hospitals, thus restricting their access to services.

The key to TB control services in urban areas will be synergy with existing health service delivery mechanism and proposed mechanism under Urban Health Mission to make optimum use of scare resources and plan for integration of services. TB health service already exists as one of the service delivery indicator in Urban Health Mission and thus the state programme implementation plans (PIPs) when prepared by RNTCP will ensure adequate resourcing for it.

TB problem in Urban Area:

The epidemiology of TB in urban area is characterized by, lower prevalence, high transmission and higher incidence. Patients most commonly seek care in private sector, frequent migration and lack of support structures leads to inability of complete treatment leading to drug resistance. High TB burden in urban slums with generally poor health services make urban TB control really challenging.

The strategic interventions for TB control in urban areas during the NSP period include:

1. **Institutional arrangement**: The State will constitute a separate City/Urban TB Control Mission under the State Health Society headed by the administrative head of the city. This will help ensure better coordination with other health and related departments. The City/Urban TB Control Mission will be implemented after developing the city specific annual PIPs for the cities/towns in a state over the NSP period.
2. **Planning**: Planning process in urban areas is complex as there's a lack of capacity for public health actions in urban local bodies. Most cities are also found lacking in city-specific epidemiological data, inadequate information on the urban poor, illegal clusters, and inadequate information on existing health facilities especially in the private sector. Data collection at the local level, including mapping of slums is therefore necessary to understand the status of urban health and to assess the urban community needs for health care services especially TB. Planning the pathway for diagnosis to completion of treatment will prioritize private providers, labs and referral centres for both TB and MDR TB services.
3. **Private sector engagement:** Detailed in Chapter 6 on private sector involvement.
4. **Social Mobilization Campaign:** Urban TB control will involve a strong element of ACSM with specific focus on women, children and youth. Specific material needs to be developed for promotion of involvement of private medical establishments (including labs and chemists) in general and private medical practitioners in particular. Another key aspect to be highlighted through ACSM campaign will be the aspect of airborne infection control measures. RNTCP will explore to promote availability of TB services in private sector as a separate brand certified by RNTCP and adhering to standards of TB control and treatment in India.

5. **Primary Healthcare Services**: The primary place for getting TB services will be the Urban Primary Health Centre (U-PHC) near a slum where a presumptive TB patient will be diagnosed by a Medical Officer at an OPD which should provide services in tune with the communities need for example open till 8pm.
6. **Referral Services**: Urban Health Mission is in the process of establishing Urban Community Health Centre (U-CHC) as a satellite hospital for every 4-5 U-PHCs. U-CHC will be utilised for providing specialist services in case of complications for TB patients. U-CHC may also be utilised for providing C and DST services and also for DR-TB services. Patients can also be referred to RNTCP certified labs for C and DST services and DR-TB centres in private sector. Referral linkages will also be established with existing state government hospitals and medical colleges for treatment of complicated cases of TB.
7. **Active case finding in urban slums**: RNTCP will undertake targeted interventions for people living in notified and non-notified slums. Active case finding efforts in urban slums utilising the services of Female Health worker will be a key intervention.

   To strengthen the community involvement thrift and saving groups/SHGs/Mahila Arogya Samities (MAS) created at slum will be utilised for process of community mobilisation for TB services. This groups will be utilised for referral of chest symptomatic, DOT provision by MAS members.
8. **Involvement of partners/NGOs**: The presence of active NGOs in several cities presents a unique and powerful opportunity to extend the reach of health services through various ways of outreach and enhancing utilization by raising community demand for the existing services. The support of the NGOs will be encouraged especially in undertaking situational analysis, identification and mapping of slums, identification and capacity building of link Volunteers and IEC/BCC activities. RNTCP will utilize the services of these NGOs for the following:
    a. Development of context specific IEC material for Urban slum
    b. Training and Capacity building of MAS
    c. Training of ASHA on TB control
    d. Training and capacity Development of Ward level Standing Committee on health under urban local body
    e. Baseline survey and slum mapping
    f. Mapping of health care providers in urban areas
    g. Hiring of NGOs/private providers for U-PHC services
    h. Facilitating involvement of private labs and chemists for TB control
    i. Special interventions for vulnerable groups like sex workers, street children, migrant labour, etc.
    j. Innovations in urban TB control
    k. Process documentation
9. **Convergent action with other stakeholders**: RNTCP will utilise the resources and existing schemes from different government departments and ministries for providing quality TB services in urban areas. An example includes utilising the services of mobile medical units and referral transport scheme of MoHFW for provision of TB services in urban slums and transportation of TB patients to higher referral facilities. Convergence of actions will include planning, mapping, coordinated service delivery, addressing gaps in health and health determinants and joint monitoring. This will include convergence with MoWCD, MoHUPA, MoUD, MoHRD and MoLE. Specific areas of convergence will include the following:
    - Under JnNURM at the city level as part of the city development plans, GIS based physical mapping of the slums is being undertaken. The Urban TB Mission for City level planning process will leverage the GIS based mapping wherever completed.

- GIS based physical mapping of the slums and the spatial representation of the socio-economic profile of slums (Slum MIS) is being undertaken under Rajiv Awas Yojana (RAY). This will be utilised for development of city health plans
- The community centers being created under Integrated Housing and Slum Development Programmes (IHSDP) will be used as sites for conducting fixed outreach session
- School Health Programme of Ministry of HRD helps in advocating healthy behavioral practices and imparting awareness about preventive and curative health measures to the school going children. This will be utilised for involving children in TB control activities.
- Information from RSBY of MoLE will be utilised for involving private sector health providers for TB control.
- Information from Ministry of Corporate Affairs will be utilised for using CSR funds for slum development and TB control activities.

10. **IT based Monitoring**: The availability of ITES in the urban areas makes it a useful tool for effective tracking, monitoring and timely intervention for the urban poor for TB control. RNTCP staff will utilize the handheld devices for uploading data and notification and other services like SMS will be utilized for follow-up of TB patients. Mobile telephony will be used for data gathering and follow ups .This will also involve setting up of a helpline for TB patients to have correct information and facilitate decision making by the patients.
    IT based system will also be utilized to facilitate grievance redressal by patients and other stakeholders. A grievance redressal mechanism will be put in place in which a committee, comprising of members from government and reputed community members will be constituted which will help resolve the problems and complaints.
11. **Community Monitoring**: Community based monitoring system will be created with help of civil society partners. Social Audit will be part of the community monitoring process whereby the civil society will facilitate social audit of the services being provided in urban slum.
12. **Research**: Separate fund will be allocated to government Medical Colleges in the urban areas to carry out action research/operational research and special studies on aspects of TB control in urban areas.

Involvement of Medical colleges in RNTCP

To widen access and improving the quality of TB services, involvement of medical colleges and their hospitals is of paramount importance. The current mechanism of their involvement through structured task forces at National, Zonal and State levels will be continued during the NSP period. The role of the task forces will continue to be as it is. The main role of the NTF will be to recommend policy suggestion regarding medical colleges' involvement in the RNTCP and monitor the activities of the ZTF. The ZTF will facilitate the establishment, functioning, and monitoring of State Task Forces (STF), and coordinate between the NTF and STF. The STF will facilitate establishment of DMCs and DOT centres, in all the medical colleges in the respective States.

Scope of activities of medical colleges are going to be expanded with increasing diagnostic and treatment services in newer areas of TB control efforts. This will include following:

a) **Centers of excellence (COEs)**: Select medical colleges will be designated COE for a particular thematic area of the programme on the lines of AIIMS being designated a COE for extra pulmonary TB.
b) **Decentralized drug resistant TB services**: DR-TB wards will be expanded to more number of medical colleges to support district level DR-TB treatment services. These DR-TB centres in medical colleges will be useful for management of not only MDR-TB but, for DST-guided treatment, newer regimen use and management of complicated cases of drug resistant TB. Existing staff of medical college i.e. medical officer and TB-HV will be utilized for these DR-TB

wards for coordination with the programme and DTC data entry operator will support e-communications and for MIS operations.

c) **Culture service support:** With follow up of drug sensitive TB patients with culture at the end of treatment and post treatment follow up with culture for all TB patients, additional capacity of laboratories with culture facilities will be needed. To support this strategy, the programme will engage medical colleges to expand its microbiology laboratory for RNTCP. The programme will support identify and support these microbiology laboratories through existing HR and infrastructural norms for culture laboratories.

d) **Air borne infection control measures in health care facilities in districts:** Under the air borne infection control committee of the districts, medical college faculties will be involved to execute AIC measure in all health care settings in the district. The faculties from medical colleges will be trained at the state level and then support in assessment, recommendations and monitoring of AIC implementation in all health facilities in the districts.

e) **Planning, surveillance and quality improvement support to districts:** Faculties of medical colleges will be involved in planning of RNTCP services and subsequent monitoring and evaluation. The department of community medicine will be involved to in monitoring and surveillance of disease including carrying out local surveys. For quality assurance of laboratory services, the department of microbiology will be involved and appropriate capacity enhancement will be done.

f) **Private provider engagement:** Support of medical colleges will be sought for peer education, dissemination of diagnostic and treatment practices and advocacy with professional associations.

g) **Research:** Operational Research mechanisms will be strengthened. Uniform systems of protocol development and capacity building workshop will be implemented. An online system of protocol submission, protocol review, approvals and quick release of funds will be established.

CHAPTER 14
HEALTH SYSTEM STRENGTHENING

Introduction:

Healthcare is one of India's largest service sectors. Under the Indian constitution, health is a state subject. Each state has its own healthcare delivery system in which both public and private (for profit as well as non-profit) actors operate.

The health systems in India have evolved based on the geographical dispersion of the population and in context of the specific needs of the rural and urban areas. There are separate programmes catering to the rural areas under the national rural health mission (NRHM) and equivalent urban initiatives are within the purview of national urban health mission (NUHM), both of which were merged in 2013 into the national health mission (NHM). The TB control programme will focus on developing strong linkages with NHM to improve access to diagnostic and treatment services. Though in rural areas the tremendous success of the NHM has facilitated the delivery of quality diagnostic and treatment services closer to the community, the urban areas remain a challenge.
The previous NSP (2012-17) envisaged strengthening the health system by developing an integrated approach to TB and leveraging on the existing capacity of the health system to achieve the goal of universal access to TB control services.
The objective and strategies of health system strengthening for TB control in India for the coming years will focus on mechanisms for critical management reforms, restructuring of HR and financial norms, pathways for private sector participation, in order to improve efficiency, effectiveness and accountability of the health system for an improved response to the TB epidemic. With strategies and actions to strengthen the health system the programme envisages that people and institutions, both public and private, will effectively undertake functions to improve TB outcomes. This it believes will protect people from catastrophic financial loss and impoverishment resulting from TB and ensure patient satisfaction in an equitable, efficient and sustainable manner. The NSP also envisages to strengthen the health system by continuing to develop an integrated approach to TB and leveraging on the existing capacity of the health system to further TB control goals.

Achievements

The twelfth five-year plan period saw several notable achievements under RNTCP as envisaged in the previous NSP. Supervisory and management units were aligned with general health system through decentralization of TB units in line with the NRHM blocks with a corresponding increase in STS. Additional dedicated programme staff was provided for RNTCP at state and district levels.
The programme developed a new diagnostic algorithm for early diagnosis of TB and using new rapid diagnostic technology as part of the process. DRTB diagnostic systems were scaled-up to provide country-wide coverage. Structured mechanisms were developed for interventions in clinically vulnerable populations like TB-Diabetes, TB-Tobacco and TB-HIV. Enablers and incentives were incorporated for improving access to services.
RNTCP was also linked to the NHM Public Finance Management System (PFMS) for better streamlining financial operations with NHM.
Various innovative ICT enabled surveillance and treatment adherence systems were either piloted or conceived to support treatment adherence. The NIKSHAY platform was strengthened further with incorporation of modules covering new thematic areas and the concept of enhanced NIKSHAY or e-NIKSHAY was introduced.

Patient support systems such as family DOT provider found a place in the Revised Technical and Operational Guidelines. The National Strategic Plan 2012-17 also addressed the issue of creating social support systems for patients and families from different stakeholders like local self-governments, NGOs, state welfare schemes etc.

Challenges

In spite of the significant achievements, it is realized that the power of existing interventions is not matched by the power of health systems to deliver them to those in greatest need, in a comprehensive way, and on an adequate scale. Although integration between the health systems and RNTCP has been achieved in the provision of services, it is limited in other operational areas such as administration, financial management and monitoring and supervision. This has affected the quality of programme implementation because of the multiple administrative, financial and operational functions to be carried out by field level staff.

Human resource: Following decentralization of especially TB Units (alignment with NHM blocks), recruitment of contractual positons against newly created blocks have been greatly delayed in 12th FYP. Over 20% of the contractual staff positions have been vacant and to even upto 40% in certain states. Payment of salaries to staff in a many states has been delayed due to weak financial management systems. Also, there was little or no scope of opportunities for career progression in the previous HR management system. This, poses a challenge to retain skilled staff at various level.

Trainings: The programme periodically requires trainings but the current training systems is not commensurate with the demand. The training programmes need to cover more than 2 million trainees which will require a multi layered cascade system of training. This is a huge task and hence will be optimized for reach and quality by developing e-modules using different types of ICT system.

Policies: The indifference of the private sector towards public health actions to control TB and the programmes limited success in engaging the private sector has resulted in under par performance of the programme. The weak enforcement of the notification regulation has contributed to lack of information from the sector which if not addressed in the current NSP will deny benefits under social schemes to such patients. This is also compounded by the weak implementation of the “Schedule H” drug regulation thereby ensuring ‘over-the-counter’ availability of TB drugs. Moreover the lack of explicit policies to address the social issues adversely affects equity in programme uptake.

Structure: The central tuberculosis division at the ministry of health and family welfare, which is the nodal department for TB control in India, is under staffed with four full time senior officers providing leadership to the programme considering the size and scope of the programme. The programme management structure at both the state and district levels continue to burden the programme managers with administrative functions leaving them with little or no time for supervisory and monitoring activities. The states capacity for training and research has remained weak with the STDCs not being able to support the programmatic demands for these activities.

System challenges continue to plague TB control efforts and will require a major shift in the regulatory and legal support to effect changes that will complement and accelerate the efforts to end TB.

Health System Strengthening for TB Control under the new National Strategic Plan:

The overall goal of system strengthening is to provide equitable access to high quality TB cares services responsive to the community needs without financial loss thereby protecting the population especially the poor and vulnerable from TB related morbidity, mortality and poverty.

The efforts for the programme will focus on the traditional five pillars of HSS depicted in the table X below. The following chapters explain the NSP related strategic interventions and activities for

financing the TB programme, ensuring medical products and technologies, and efficient service delivery.

Table X

HSS pillar	Strategies
Human resource (HR) in RNTCP	Reform and restructure HR in TB programme to align with the enhanced programme needs for surveillance, participation of private sector and the community.
	Conceive and adapt effective ways for strengthening ongoing capacity building and maintenance of skills/ competence in programme staff.
Governance of RNTCP	Develop policy support for ending TB in India.
	Develop programme planning expertise, leadership and management capabilities for TB elimination.
	Build civil society/ private sector capacity for better advocacy to increase accountability.
Health Information	Create a culture of evidence based decision-making by the use of ICT based applications from grass root level upwards.
	Support integration and improvement in TB information systems, including NIKSHAY for achievement of TB elimination goals. *(covered in chapter on treatment and patient support)*
Medical products and technologies	Strengthen supply chain components to ensure the uninterrupted supply of TB drugs, including creating a supportive environment for a sustainable supply chain.
	Strengthen RNTCP's regulatory capacity to control TB drugs through appropriate laws, regulations, policies, and standard operating procedures.
	Enhance human and institutional capacity to manage drugs and other logistics management systems and services
Service delivery	Scale up quality, and coordinated delivery of TB care services.
	Develop, implement cost effective essential TB care services.
	Improve the knowledge base on links among incentives, productivity, and quality TB services in the private sector.
Financing the TB programme	Increase public and private domestic resources for TB control services
	Catalyze private sector investment in TB control using public private partnerships.

Strategic interventions:

The selection of the strategies for HSS was informed by RNTCP's experience and capacity, emerging evidence and innovations, and the need to ensure that health systems are geared to address the significantly enhanced programme needs and accommodate local epidemiologic situation.

1. **Bold policy initiatives:**
    a. **National TB Policy and TB Bill**

    All efforts will be made to support a comprehensive TB bill placed in the parliament which will promote TB care as a rights issue and hasten the control of TB in the country. The various clauses of the bill will cover all aspects of TB prevention and care to protect, promote and fulfil the rights of persons with Tuberculosis during delivery of TB care and services and for matters connected therewith or incidental thereto and also to accelerate the response from every sector. Various stakeholders including academia, experts, and political establishments (inter-ministerial consultation) need to be consulted while formulating the bill.

The TB policy will be aligned to the National Health Policy. The necessary regulations under the TB policy, inter-alia, will include:

- Mandatory notification of all TB patients
- Assured access to quality diagnosis and treatment as a standard of care through all healthcare providers
- Regulation of use of diagnostic tests
- Regulation/Ban on sale of anti-TB drugs in open market
- Non stigmatization for TB patients and families etc.
- Right to access to public health care
- Compensations
- Occupational screening, workplace interventions
- Enforcement (Immigration/admission to educational institutions)

Market Based Regulation will also be part of the regulatory efforts and will include:

- Certification of C/DST Laboratories
- Establishing linkages with existing health Insurance schemes of the government and at a later date with the Universal Health Coverage (UHC) of the Government.
- Regulate access to anti-TB drugs
- Incentives to the private providers
- Introduction of new anti-TB drugs

The programme also aspires for converting RNTCP into 100% central programme in the long term.

b. National TB Elimination Board

It is proposed to create an apex body to facilitate policy development, co-ordinate multi-sectoral involvement and overview the implementation of the strategy to move towards TB elimination. Proposed constituents include Prime Minister as patron, Union Minister Health and Family Welfare as Chairperson, Secretary Health as member secretary with other members including secretaries of related departments, representatives of affected communities, representatives of technical and donor partners, representatives from NGOs etc. Central TB Division will directly report to National TB Elimination Board (NTEB).

Similar structure at the State level (State TB Elimination Board) also needs to be created, with State specific changes as required. This structure will provide the highest level of political, administrative, social commitment to TB control at the local level where it is required the most. It shall also be the major medium for addressing issues of **health system strengthening**. This will enable local epidemiological features of the epidemic, local problems to be identified and local solutions to be implemented. The Board will **review performance** periodically. This will also enable the **multisectoral response** required for action on the social determinants of TB and its outcomes.

c. Re-structure the TB program management structure (detailed in the organogram below)

i. **Strengthened and empowered CTD:** To provide a multi-stakeholder response for managing TB beyond the public health structure, it is proposed to establish a separate independent organization like NACO.

ii. **Thematic Technical Resource Groups (TRG)/Stakeholders Task force:** To review, optimize and make recommendations for implementation of TB control activities in the country under the broad policy framework of the National Strategic Plan for TB control.

iii. **Institutionalization of surveillance and research and HRD:** The existing STDCs, apart from the current role expected of them, will play a bigger role in planning of interventions related to all services including HRD under the programme.
The Medical College Task Force mechanism will focus more on the clinical aspects related to TB control and also play a greater role in establishment of research and surveillance mechanisms. Medical colleges will evolve as centres of excellence (CoE) for a particular thematic area like paediatric TB, TB-Diabetes, TB-HIV to name a few, as has been done for extra-pulmonary TB (AIIMS-Delhi being the Centre of Excellence).

iv. **TSUs with a focus on patients beyond the public health sector at National/State level:** Based on success of public provider interphase agencies (INTERPHASE AGENCIES) models in the last NSP period and learnings from NACO, intermediary agencies to bridge and link the various players in TB care will be scaled up. These agencies having the capacity to bring together different players especially the private and public sector and enable operations based on RNTCP guidelines, other acceptable practices or through referrals to the public sector is the cornerstone in programme efforts to engage private providers and reach out to patients being treated in the private sector. This will be mandated to engage with mainly two aspects i.e. (1) the private healthcare sector and (2) line ministries to address the social determinants for TB. In addition, it will take the responsibility of contracting with private players. This organization will be capacitated to generate national / international resources to bridge the funding gap in TB Control and will have a replicable structure at State / District levels.

v. Knowledge network of Service providers:
In order to improve access to knowledge, a need has been long felt in the country to establish a TB Knowledge Network (TBKN), inter-connecting all knowledge and research institutions in the country through a virtual network. The overarching role of TBKN will be to establish a backbone connectivity which will enable knowledge and information sharing amongst TBKN connected institutes, enabling collaborative research, development and innovation amongst TBKN connected institutes, facilitating advanced distance education in specialized sub-areas of TB, facilitating connection between different sectoral networks in the field of research.

2. **Re-define multi-sectoral approach to address risk factors and mainstreaming TB into other key ministries that include** Finance, Mines, Food and civil supplies, Social justice and empowerment, Tribal welfare, Rural/Urban development, Women and Child Development, and Environment and forest. Inter-ministerial and departmental coordination for providing comprehensive support for addressing TB is necessary and this includes efficient disbursements, strong policies, effective regulations and strict enforcement.

3. **Human resource (HR) in RNTCP**
Qualified HR is the biggest asset to RNTCP and its becoming more complex and demanding, with multiple new tasks for MDR-TB management and TB-HIV care. An adequately staffed, trained, and motivated health workforce is required to achieve the ambitious TB control objective of ending TB. The goal of RNTCP's HRD strategy is to optimally utilize available health system staff to deliver quality TB services, and to strengthen the supervisory and managerial capacity of programme staff overseeing these services. RNTCP will align more effectively with health system under NHM to leverage field supervisory staff more effectively, and increase capacity building of the staff to equip them to handle multiple tasks of TB care, DR-TB and TB-HIV. The RNTCP has integrated its HRD policy in the NHM HR policy to enable it to function at optimal capacity in the states/districts in an integrated manner with the General health system. The programme has created standardized training modules for each component and customized it for each category of staff. As a consequence, several lakh of health care providers in the general health system

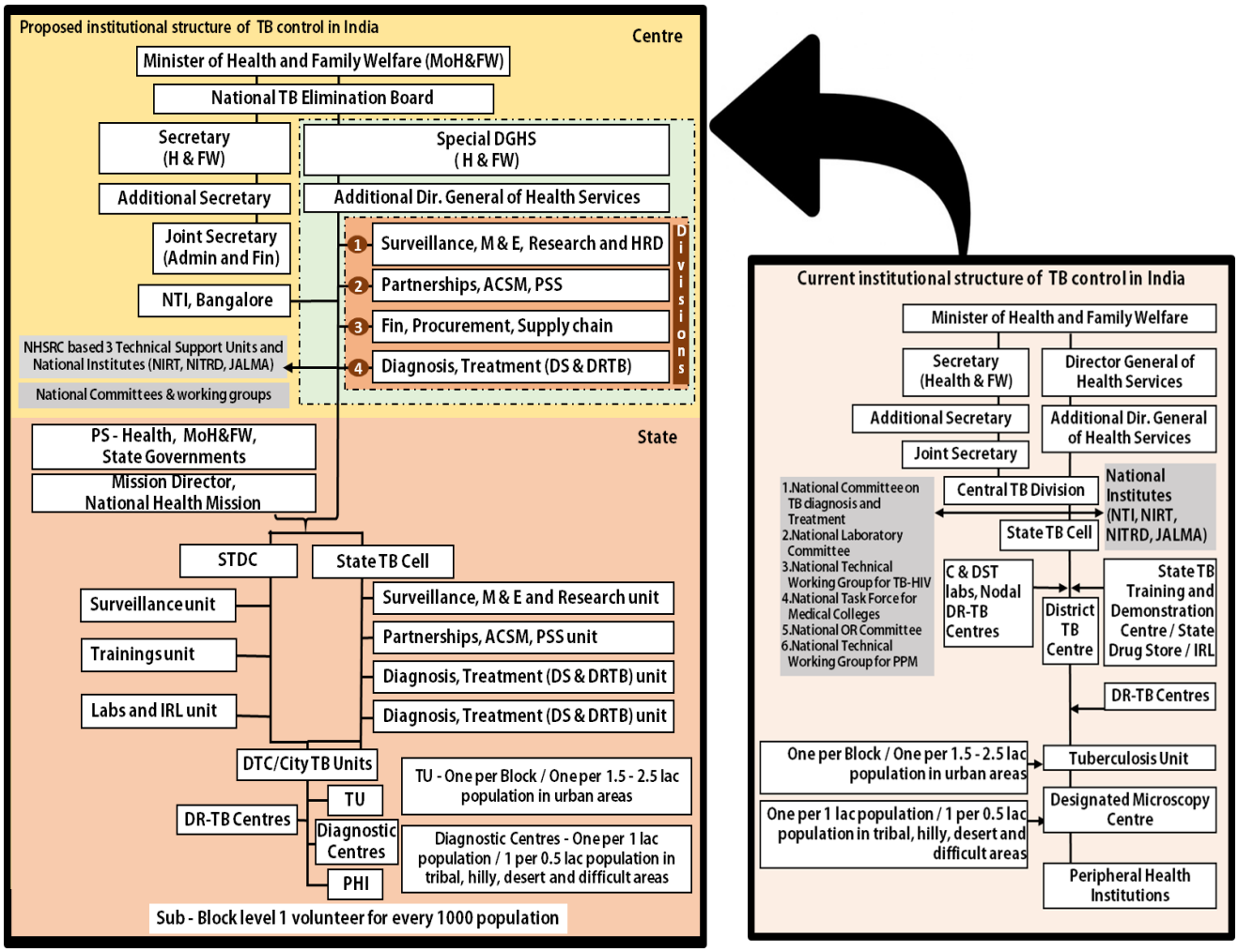
have been trained in various initiatives of the RNTCP. TB case finding, treatment, DR-TB, TB-HIV, PPM, and ASCM activities required to achieve universal access need a better approach to human resource development.

The HR plan of RNTCP prefers posting of regular state staff for senior positions in RNTCP for eg. MO STC, MO STDC, etc. In the event of unavailability of such at the state level, the programme will hire staff on a contractual basis. Budgetary provisions have been made for such hiring's.

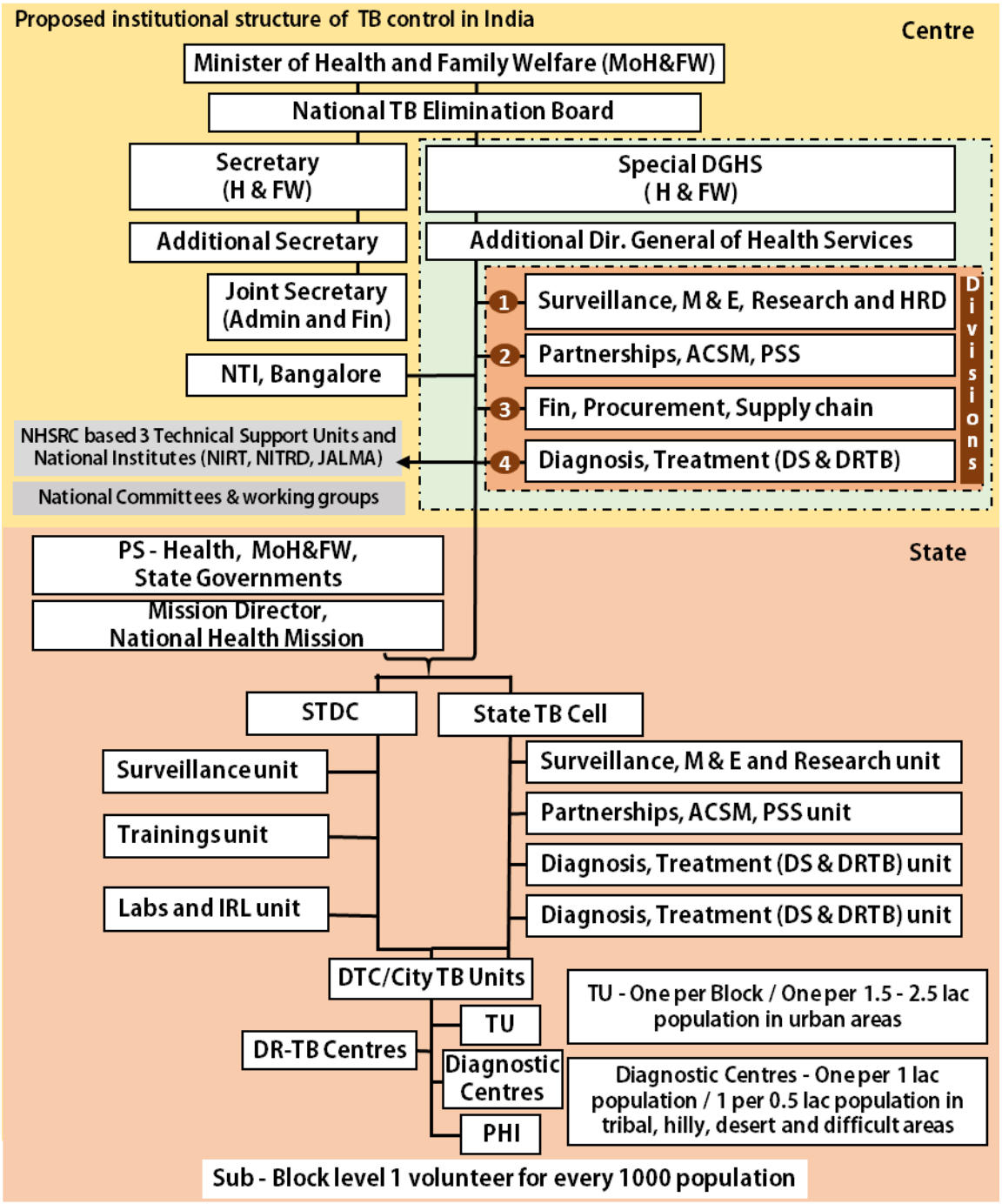
The big ticket changes envisaged in the NSP include the following:

1. **National level:** Creation of 4 divisions each in charge of key programmatic areas instead of the current CTD structure with a commensurate increase in staff strength including technical and operations staff.
2. **State Level:** Creation of 4 divisions to mimic the structure at the National level.
3. **District level:** Unified cadre for supervision to provide one TB supervisor for every block.
4. **Block level:** One community volunteer for communicable disease for every 1000 population to undertake community focused functions like active case finding, treatment support, etc. Programme specific honorarium will be available to these functionaries.

The proposed HR restructuring during the NSP period will ensure increased provider coverage by 10 times and patient coverage by 2.5 times.



A larger image of the proposed institutional structure for TB elimination in India is depicted below.



Trainings

The proposed institutional stricture also entails increased volumes and quality of trainings. Newer and modern methods of learnings are proposed in the NSP.

During the programme expansion in the last five years, RNTCP has developed and updated training material for new initiatives which include PMDT Guidelines, TB-HIV collaborative framework, revised paediatric TB guidelines and various laboratory training modules for newer diagnostics, based on need to reflect revised policies and recommended practices. RNTCP has traditionally adapted the cascading methodology to train its Staff, with National institutes and NRLs being involved as centres for training the trainers (STO, STDC Staff, IRL Staff, DTO, Medical College faculty and STC MO-RNTCP,

etc.) on various components of the programme. These trainers come back and train the relevant cadre. The STDCs have been playing a major role in imparting State level RNTCP trainings. The Block level MOs are presently being trained at the STDCs who are entrusted with the responsibility of training the Medical Officers at district level. The supervisory staff (STS, STLS) are also trained at State level who go on to train DOT providers and lab technicians, respectively, at the district level.
Challenges with trainings: Several new components like Daily regimen, PMDT, TB-HIV and other co-morbidities, Paediatric TB, Nikshay, Notification, Pharmacovigilance, Partnerships, etc. have been added to RNTCP in its course of evolution. Moreover, with the alignment of TB Units with NHM Blocks has resulted in an increase in number of human resource under RNTCP.
Strategy:
The key strategy is to move towards an e-learning mode utilizing the web based and mobile based learning experiences. The programme will be transitioning from conventional stand-alone modular training methodologies to newer composite tools which enable self-learning.

- The training tools will be designed in a way that they can be administered as per specific need and level of use. These can be taken by the participant at his or her own pace.
- The National TB Institute, Bengaluru shall be playing a pivotal role in facilitating this transition and authoring and testing these e-learning tools.
- The STDCs will act as resource centres for translating the content to vernacular and adding relevant content as per local needs at the State level.
- The STDCs will also continue to act as centres for final certification of successful completion of training by interacting with the participants after culmination of e-learning and administering a post-test questionnaire, if needed.

These steps will not only help in rapidly filling the gap of untrained staff but will also prove to be an effective and sustainable way to keep-up with changing policy guidelines and percolating correct knowledge to every level of staff.

Addressing social determinants of TB

The current NSP recognizes the critical role of addressing the social determinants of TB in order to achieve its ambitious goals. Social determinants are a cross cutting issue and has been dealt with in the chapter on case finding, treatment, patient support system and HSS. This includes nutritional support to TB patients and families, financial incentives to patients and providers, health system strengthening, and linking patients with existing social and financial support systems of the government.
Addressing poverty, malnutrition, urbanization, indoor air pollution, etc. require inter departmental/ ministerial coordinated activities and the programme will proactively facilitate this coordination. For example extending subsidized LPG gas connections to BPL households and TB affected community is expected to reduce indoor air pollution in these high risk group. Programme will make active efforts to establish linkage with such services. These interventions at population level are expected to have additional impact on accelerating decline in incidence.
To address gender and other equity issues, special efforts by engaging concerned departments and agencies will be prioritized.

Chapter 15

ADVOCACY, COMMUNICATION AND SOCIAL MOBILIZATION / TB CAMPAIGN

Introduction

Since the inception of the programme, advocacy and communication initiatives in RNTCP are seen to generate demand leading to earlier diagnosis and correct treatment. It creates positive behaviour change amongst patients, influences decision-makers, and engages and empowers communities to change. It is an important component of the TB control strategy to ensure long-term and sustained impact.

ACSM is a cross cutting, supportive strategy that focuses on all aspects of TB care for ensuring quality in diagnosis and treatment interventions, strengthening social support systems for TB care and community interventions to reduce stigma. ACSM activities in the current NSP will focus on improvement in early identification of symptoms of TB and referrals from community aiding in early case detection, support for treatment adherence; combating stigma and discrimination; people's empowerment; mobilizing political commitment and capacity building for decentralized planning.

Although distinct from one another, advocacy, communication and social mobilization (ACSM) are most effective when used together.

1. Advocacy seeks to ensure that there is strong commitment for TB control.
   a. Policy advocacy informs politicians and administrators how an issue will affect the country and outlines actions to take to improve laws and policies
   b. Programme advocacy targets opinion leaders at the community level on the need for local action
   c. Media advocacy validates the relevance of the subject, puts issues on the public agenda, and encourages the media to cover TB-related topics regularly and in a responsible manner so as to raise awareness of problems and possible solutions.
2. Communication aims to favourably change knowledge, attitudes, behaviours, and practices among various groups of people.
3. Social mobilization brings together community members and other stakeholders to strengthen community participation for sustainability and self-reliance.

Achievement

1. The last NSP period saw a significant movement on the ACSM front with a high visibility media campaign involving Amitabh Bacchan, India's biggest film star and an ex-TB patient, as the TB brand ambassador. This has made a big impact on conveying the threat of TB to the public at large.
2. Call to Action for a TB-Free India brought all the key stakeholders together on a high visibility "call to action summit" in March 2016. Wide participation of various stakeholders in TB, especially private health sector, corporate sector, civil society, media, academia and the community committed to the ambitious goals of the End TB strategy. TB Champions from

amongst patients, technical experts, political representatives, public figures, sportsperson, and celebrities added their voice to increase visibility and action on TB.

3. Substantial efforts have been made towards capacity building of programme managers, state IEC officers and communication facilitators in ACSM with dedicated national, regional and state level ACSM trainings and workshops. National ACSM TOT was completed to facilitate the drawing up of ACSM plans at the State level and also reinvigorate the efforts country wide.
4. Establishment of the state ACSM quality support group is completed in all the states. This group has representation from staff with core competencies in capacity building and institutional strengthening, community advocacy and events, mass media production and distribution as well as monitoring and evaluation and has enhanced the ACSM functions in the states. However monitoring and evaluation remains a weak link.
5. Parliamentary forum for tuberculosis

Challenges

1. There has been a lack of involvement in TB ACSM by general health staff dealing with ACSM which is a prime reason for non-alignment with general IEC structure in the health system. Peripheral health staff who deal with all programmes at field level tends to give less attention to TB ACSM due to priority issues. Although coverage by the auxiliary health workers, mainly the female health workers, Anganwadi workers (AWW) and Accredited Social Health Activists (ASHA) is considerable, their involvement in TB ACSM is relatively limited as a result of competing priorities such as maternal and child health, nutrition, malaria and other social issues.
2. Even at the higher levels, there is a lack of coordination between the TB ACSM and IEC management to establish a cohesive and integrated management structure to coordinate programme activities.
3. Coordination with stakeholders to develop formative, evaluative, impact and outcome research methods and tools in ACSM has not progressed. ACSM M&E remains the weak link in ACSM functions of the programme.

Key ACSM priorities:

1. GOI should declare TB as a *public health emergency* and combat it in a *campaign mode*
2. Increase budgetary provisions (it is presently only 3%) and launch a National TB Campaign engaging ambassadors at regional level to increase visibility
3. Rebrand RNTCP (name/logo/ slogan)
4. Engage diverse stakeholders esp. elected representatives, civil society and establish inter-sectoral coordination
5. Empower and engage TB community - Patient reported score cards on TB Care services ; establish a mechanism for real time feedback from civil society and community monitoring groups to key health officials and participation in planning
6. The designated / trained spokesperson of the program should routinely and openly

Strategic interventions

1. Advocacy for administrative and political commitment, and to keep TB control high on health and development agenda and increase the budgetary provisions which currently is 3% of the programme outlay.
2. Political, media and programme advocacy to get the GOI to declare TB as a public health emergency.
3. High visibility, high decibel communication for demand generation and stigma reduction
4. Audience segmentation, targeted behaviour-change interventions and community mobilization for increase demand and accountability of service providers.
5. Community ownership and mobilization for case finding and support of TB patients.
6. Facilitate meaningful and sustained collaboration amongst partners.

Activities

To significantly reduce TB burden by 2020 in India, intensified case finding will be one of the most important interventions. National "sweep out TB" / "TB Mukt Bharat" campaigns, which are massive, repetitive, intensive and persuasive, for case-finding and community commitment from the panchayat, districts and states, will become centre-stage in the program. A major component of this campaign is strategic ACSM. It will have 3 separate components advocacy, communication and community engagement.

1. **Advocacy**
   - Engage diverse stakeholders specifically political and administrative (at national, state , district, panchayat)
   - Empower TB community (affected community, cured patients, caretakers) to speak up/ voice their concerns (through treatment literacy)
   - Ensure civil society partnerships from groups such as Rotary, faith based organizations
   - Engage with the media (print, TV, radio, digital)
   - Establish Inter-sectoral coordination – amongst different ministries
2. **Media Advocacy**
   - Designate and train media spokespersons at national/state/district levels in the program
   - Routinely and openly share information about TB with the media
   - Engage academia / subject experts to share scientific research publications with the media
   - Sensitize media and program staff about language so as to avoid stigmatizing
   - Design effective online and social media strategies for TB to engage with the public (FB/ Twitter handle for program)
3. **Communications**

   As a first step towards the goal of universalizing access to quality TB care, a pan-India communication campaign will be launched which will create awareness about TB symptoms, an urgent need of TB symptomatics to visit a nearby public or certified private TB diagnostic facility, TB diagnostic and treatment services available free of charge to all TB patients seeking care in the private sector and treatment efficacy if help is sought early. A more comprehensive message on symptoms will be disseminated shifting the focus primarily from "cough for more than two weeks" to "any of the four – cough, fever, weight loss and night sweats". Communication campaign will also focus on clinically vulnerable populations such as people living with HIV, household contacts of TB cases, malnourished children, diabetics and tobacco users. This widespread awareness about TB and free services will therefore target bringing 'missing' TB cases in the country under the umbrella of National TB program.
   - Launch and sustain National TB Campaign over next 5 years
   - Engage ambassadors (celebrities/ influencers etc.) at regional level to increase visibility
   - Empower patient advocates and give them necessary platforms (to speak/write/share)
   - Design a campaign to combat stigma/myths
   - Expand Helpline (patients/ providers) to all states, mobile campaign(SMS/Voice SMS)
   - Assess, revise and disseminate patient education literature
   - Simplify messages so they are understood by the community – *avoid program/ medical jargon* – eg. DMC/ ICTC/TU/rapid molecular tests etc.
   - Focus on prevention (cough hygiene/ etiquette)
   - Do not just focus on pulmonary TB – give equal importance to extra pulmonary, pediatric and Tb in women when designing communication
   - Greater thrust on-ground activities such as street plays, video van, group meetings , outdoor communications in high risk areas/vulnerable populations
4. **Community engagement**

- TB patients must not be seen as passive recipients of care. A rights based approach to patient care must be adopted
- Patient reported score cards on TB Care services will enhance accountability of TB services. Ultimately it is expected to enhance the quality of services.
- To evaluate gaps/ effectiveness of programme interventions a mechanism of civil society/key stakeholder feedback will be devised.
- Patient/community networks (such as HIV Positive network/ Caretakers) should be made key stakeholders at all stages of planning, decision making, implementation and monitoring
- Establish peer group support and family support at the community level and make them part of long term sustainable solutions
- Formulate Community Monitoring Groups which will include PRIs, community leaders, religious leaders, cured TB patients, family members of affected TB patients etc.
- Develop and Institutionalize a patient mentorship program through identifying, training, hand holding patients to be patient advocates

5. Planning WTB Day

- Each state to take a different theme as per state data/ requirement during each WTBD
- Planning has to be realistic to augment the limited resources
    - Disseminate patients charter at the Community level

6. M&E of ACSM activities

For long, ACSM M&E has been a neglected function. It is proposed to undertake evaluation of implementation status of the activities which will include:

1. Impact assessment of ACSM activities- baseline, interim and post NSP period to draft further policies
2. Rapid assessment in 2017 to identify bottlenecks and plan ahead
3. Outcome and impact evaluation of ACSM activities at the end of the plan period will be undertaken.

Documentation will support the dissemination of successful interventions in the programme and will consist of publishing quarterly booklets on the ACSM activities.

Chapter 16
SURVEILLANCE, MONITORING AND EVALUATION

Introduction

Transitioning of the ways of working in the TB programme over the next NSP period will require a stringent monitoring of programme interventions especially related to the quality of interventions. This necessitates adherence to the full M&E cycle with follow ups, mentoring and supportive supervision as the key.

Well-performed surveillance is an instrument for informing healthcare workers, public health experts and decision makers in order to guide and prioritize their action. It is a basic component in the control and control of TB and provides information on the epidemiology of the disease, the evolution of trends and the description of those groups in the population at increased risk of TB and unfavorable prognosis. It is an essential element in monitoring the effectiveness of interventions aimed at control and control of the disease.

A good TB surveillance system will require timely notification of all TB cases in the population and will be able to capture necessary variables for demographic, clinical, socio-economic, geographic, spatial characteristics to enable better understanding of the local epidemiology and trend of tuberculosis.

TB surveillance will include data from laboratories as they play a pivotal role in TB diagnostics and case ascertainment; this will help to ensure completeness of reporting. Surveillance of TB will address the current challenges of the disease. In that sense, surveillance of drug resistance and treatment outcome monitoring are essential tools for the evaluation of TB control. Reliable case-based notification systems are vital for a good surveillance system. Surveillance will also be enhanced for vulnerable groups.

Achievements:

- National Case Based web-based surveillance system (Nikshay) has been developed and deployed across the country with more than 7 million TB patients registered including 7 lakh cases notified by private sector since 2012.
- Transition to registration at diagnosis is in process with amendment in recording and reporting system as per technical and operational guidelines and will be completed by December 2016. This will bring accountability for more than 1,00,000 smear positive TB patients which were previously being diagnosed but not treated under RNTCP annually since more than a decade
- National DRS survey has been conducted and final results are awaited in March 2017
- Interim revision of estimation of TB burden proposed by WHO, Geneva and approved by Govt of India is more realistic for measuring progress towards achieving sustainable Development Goals regarding ending TB epidemic. The re-estimated TB incidence including HIV-TB is 2.8 million (217 per 1,00,000) and mortality excluding HIV-TB is 4.8 lakh (36 per 1,00,000). Though these results are interim; pending the results of planned national TB prevalence survey in 2017-18.

Challenges:

- Underfunding of Nikshay and Manpower shortage
- Procurement of tablets and establishment of call center under e-Nikshay
- Use of case based surveillance system for programme planning, monitoring and evaluation

Strategies

1. Establish TB surveillance system at district, state and national level to monitor the epidemiological characteristics of TB in the population over time and geography.
2. Monitor the performance of TB control activities and feed this information into the decision-making cycle to allow for appropriate interventions to upgrade the districts, state and national TB plans.
3. Identify and describe vulnerable populations at increased risk of TB and unfavourable prognosis to which targeted public health activities will be addressed.

Strategic interventions and activities

1. **Case Based Routine Surveillance**
    a. An ICT supported systems to rapidly receive and transmit data up-down with GIS mapping of every patient, and identify hot spots will be crucial for a quick and adequate response. It will capture information on household income, high risk occupation if any, residential status: native/migrant/temporary worker/visitor, and co-morbidities. It will also capture systematic screening of close contacts and neighbourhood: number of contacts eligible and screened for every case.
    b. Strategies to monitor adherence will include proven ones like 99 DOTS, MERM, etc. and also automated dose reminders, prompts for timely actions, etc.
    c. Geo mapping of areas with high risk for TB and those with poor treatment outcomes will also be a part of the routine surveillance.
    d. It will also capture provision of enables and incentives through e-transfers, linkage with social welfare schemes, and nutrition support.
    e. ADR monitoring and death audit in TB patients too will form the part of the case based routine surveillance.
2. **Evaluate the epidemiological characteristics of TB**
    a. Strengthen nationwide surveillance systems and other sources of data collection, and reinforce the use of standard reporting and definitions including DR TB cases in order to gather reliable data that are comparable within and between states, and internationally over time.
    b. Develop the use of enhanced laboratory techniques such as DNA fingerprinting and molecular typing to evaluate the spread of DR TB cases and identify outbreaks.
    c. Integrate laboratory, clinical and epidemiological data on TB cases, at district, state and national levels.
    d. Create algorithms for the detection of local outbreaks and clusters.
3. **Monitor TB control activities**
    a. Expand drug-resistance surveillance activities to monitor and improve case management.
    b. Collect TB cases with laboratory information on co-morbidity status to improve care such as joint management of TB/HIV co-infected patients, TB/DM management etc.

c. Enhance the collection of information on case notification, monitoring treatment adherence, social support and treatment outcomes at all levels in order to monitor and improve patient management.

4. **Identify and describe vulnerable populations for TB**
    a. Analyze routine surveillance data and perform ad hoc surveys to identify vulnerable populations.
    b. Enhance or implement TB surveillance in migrants, prisoners and other vulnerable populations according to the particular situation in the district/state.
5. **Establish TB Surveillance system from district to National levels**
    a. TB Surveillance units at district level in DTC, at State level in STDC and National level at NTI
    b. Sentinel surveillance units at medical colleges
    c. Laboratory surveillance units at all IRLs and NRLs
    d. Use of e-NIKSHAY as the major data source with analytical outputs readily available at all levels
6. **Burden estimation:**
    a. National TB Prevalence Survey planned to be implemented in 2017-2018
    b. Mathematical modelling to be continued under GBD India on periodic basis
    c. Regular programmatic survey conducted by programme staff for district level estimation of disease burden
7. **Monitoring:**
    a. Monthly review of national institutes, NRLs, STOs, STDCs, IRLs, DRTCs at national level and DTOs at state level for monitoring as well as capacity building, using video conferencing in addition to biannual review meetings
8. **Evaluation:**
    a. Central and State internal evaluation to be continued with updated methodology to include all type of patients as per TOG
    b. External evaluation / social audit of at least 4,000 patients eligible for incentives
    c. Death audit of at least 10% of deaths reported by programme
    d. Evaluation conducted by donors will be conducted at a fixed frequency and in synchronisation of all stakeholders/programme

Laboratory surveillance

Initiate sentinel surveillance as per the “building and strengthening surveillance plan” and further scale up to continuous surveillance. Establish Laboratory Surveillance in the country with National TB Institute Bangalore as the nodal institute for building capacity of sentinel surveillance sites at labs in public and private sector.

Healthcare worker surveillance for TB

Successful AIC implementation is important in preventing HCWs from becoming infected with drug-susceptible and drug-resistant TB, and thus preventing occupationally acquired TB disease. Screening HCWs at high risk of TB is likely to reduce transmission and with earlier diagnosis and treatment, prevent serious illness and disability. Screening of HCWs for TB is a high priority of the programme. Necessary guidelines are already available and implemented during this NSP period.

All HCW are classified as key affected populations due to their higher risk of acquiring TB and those who are symptomatic or/and with any signs of TB or chest X Ray abnormality will be offered an upfront rapid molecular testing upfront to rule in or rule out TB at the first instance and during periodic screening also. Necessary health insurance schemes will be made available to the HCWs as per the State government policy.

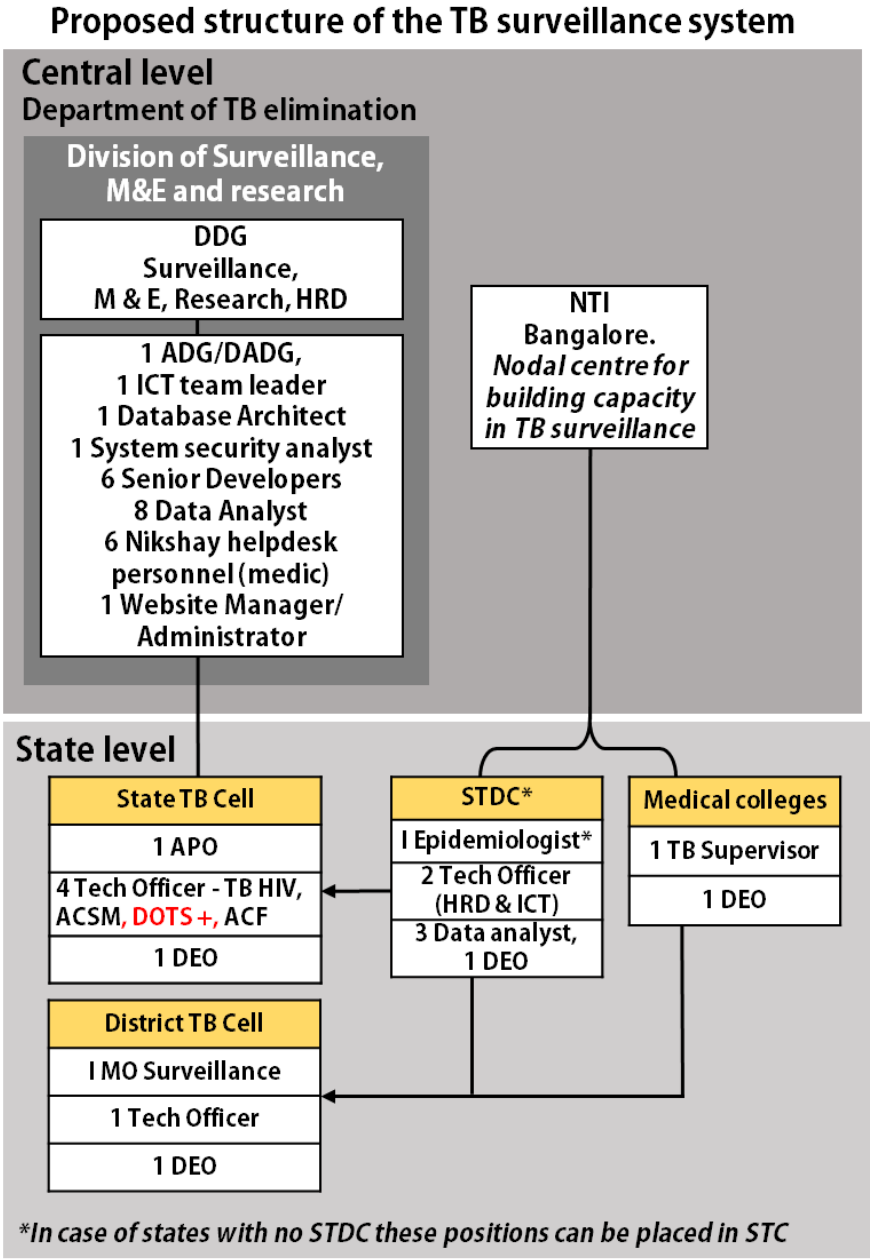
Surveillance of Airborne Infection Control (AIC)

a. Map and categorize high transmission settings: health facilities, congregate settings, workplace, public places-schools, colleges
b. Monitoring AIC as per the national guideline.

Migrant Surveillance

a. Strengthen existing mechanism of registration of TB patients
b. Enlist migrant camps and locations
c. Capture data on systematic screening in such risk groups
d. Ensure continuity of treatment

National TB Surveillance system structure



Chapter 17
RESEARCH

The National TB Control Programme is based on global scientific and operational guidelines and evidence. As new evidence became available, RNTCP made necessary changes in its policies and programme management practices. In addition, with the changing global scenario, RNTCP is incorporating newer and more comprehensive approaches to TB control. To generate the evidence needed to guide policy makers and programme managers, the programme implemented measures to encourage operational research (OR).

The program requires additional knowledge and evidence of the effectiveness of interventions to optimize policies, improve service quality and increase operational efficiency. This has led to the realization of the need for a more proactive approach to promoting OR for the benefit of the TB control efforts. Furthermore, the program seeks to better leverage the enormous technical expertise and resources existing within India both within the Program, and across the many medical colleges, institutions and agencies.

Operational research aims to improve the quality, effectiveness, efficiency and accessibility (coverage) of the control efforts. To promote and support OR, a Research Cell has been constituted at CTD to Coordinate the **National Standing Committee on Operational Research** comprising of 14 individual and institutional members. This Committee mainly provides technical guidance to CTD on OR and expertise to identify OR priority areas for commissioned research. Apart from it there are Zonal and State Operational Research Committees which identify priority areas for research as relevant to their Zone/State, based on the national research agenda. To facilitate OR in programme areas the **National Standing Committee on Operational Research will be relocated at NTI**.

The scientific agenda, developed by the Central TB Division and partners, articulates opportunities to understand RNTCP weaknesses, develop solutions, and refine policies to better achieve the programme objectives. The RNTCP will continue to promote and support research on issues which are of key relevance to guide interventions and to monitor and evaluate the impact of the programme through collaboration with specialized institutions.

Activities:

- Implementation research for demonstration of resource optimization for implementation of newer diagnostic algorithms
- Conduct implementation research for feasibility of active case finding among key population for prioritization
- Feasibility of scale-up chemoprophylaxis / preventive therapy in different risk groups, contacts of TB / DR-TB etc
- Initiate testing / evaluation of at least 3 new diagnostic/prognostic tests (preferably of Indian origin) for diagnosis of TB, DR-TB and latent TB
- Initiate pilot of at least 3 novel regimens for drug sensitive and drug resistant TB in implementation research mode for those already piloted elsewhere and in clinical trial mode for completely novel ones
- Initiate testing of at least 1 candidate vaccine in Indian population
- Initiate at least one large scale genetic susceptibility study, preferably from the same sample of that of TB prevalence survey

- Initiate TB elimination project on implementation research mode in at least 3 districts in the country
- Feasibility studies for uptake of new tools including smear replacement at Microscopy level (eg. indigenous molecular tests) or other point of care tests
- Strengthen Operational research through an institutional mechanism at NTI
- Operations Research for feasibility of introduction and scale up of IGRA
- Build capacity for tuberculin production/identify new tuberculin or sub-unit Antigen for TST

Research consortium

The NSP will embrace the research consortium activities which include the following.

- Forge partnerships, build capacity of PSUs to manufacture diagnostic tests, anti-TB drugs and products including vaccines. This will also include building capacity for tuberculin production/identify new tuberculin or sub-unit Antigen for TST.
- Invest and fund at least,
    - 3 incubators with potential to develop low cost, indigenous, Point-Of-Care (POC) diagnostic test
    - 3-5 incubators with potential candidate molecules with anti-TB properties in phase I or II trial
    - 3-4 incubators with potential vaccine candidates for development in phase I or II trial
    - To have at least 1 each of the above final market product co-owned by Government of India by 2025.

Chapter 18
TECHNICAL ASSISTANCE

India has made bold commitments for tuberculosis (TB) elimination, reflected in this National Strategic Plan (NSP) for Tuberculosis Control (2017–2025) and the international commitments under End TB Strategy and U.N. Sustainable Development Goals (SDGs). Delivering on these ambitious objectives requires heightened technical assistance (TA) that has supported the country's Revised National Tuberculosis Control Programme (RNTCP). The World Health Organization Country Office for India (WCO-India) has been, since the year 1999, providing TA to RNTCP through its Technical Support Network (TSN), which comprises consultants who work in coordination with the central and state governments in India to strengthen RNTCP activities through technical support in planning, training, surveillance, monitoring and evaluation.

An evaluation of WHO's TA to RNTCP was undertaken to provide an independent assessment of the performance of WHO-RNTCP TSN and to assess the need and scale for TA from WHO-RNTCP TSN to support TB control activities in India. The most important finding of the assessment pertains to the crucial role the WHO-RNTCP TSN plays in the planning, implementation, and monitoring of RNTCP—right from the national level through to the program activities in the field. The network's consultants in the field have been successful in meeting the various TA needs required for implementation of the strategy to identify and cure persons with TB and in monitoring and evaluation of program performance. Over the years, the TA provided by TSN consultants has evolved from facilitating TB case detection and treatment under RNTCP to addressing more ambitious targets outlined in NSP (2012–2017) and supporting the implementation of recent global advances in TB diagnosis and care, which include, among others, adoption of rapid TB diagnosis through rapid molecular tests and evidence-based policy revisions to move to the daily anti-tubercular treatment (ATT) regime, drug resistant TB management, private sector engagement etc.

Need and scale of TA required:

Considering the ambitious targets and large number of new activities envisaged in the NSP, the technical assistance need to continue and scaled up. Areas requiring high end TA include private sector engagement, drug resistant TB management and establishing TB surveillance system. The present WHO-RNTCP-TSN will be focusing more on these areas. The programme in addition will be hiring technical consultants as regional consultants and over the next 3 years to support programme implementation activities. This dual technical support will be necessary for the next 5 years, then the whole technical assistance can be transitioned to the regional consultants hired by programme.

Translating the ambitious vision of a TB-free India into reality demands scaled-up technical assistance (TA) support, adding new skill sets, improving the capacity to address the rapidly changing landscape, and adapting to address local epidemiologic drivers. The technical support network (TSN) working in coordination with the central and state governments in India, supports the central, state, and local governments in RNTCP activities. The technical consultants are based at the CTD and in the states to provide TA to central, state, and district program management units.

The TA will be considered an integral part of the technical support provided to the RNTCP through the ongoing partnership with various development partners especially at a time when the global community must support India's efforts to end TB.

RESOURCING THE NSP

What does it mean in the context of this NSP for TB elimination in India?
Provide adequate resources, financial, human resources and an enabling ecosystem to undertake the strategic interventions mentioned in the NSP.

What does it entail?

1. Provide uninterrupted supply of good quality diagnostics and anti TB drugs for early diagnosis and treatment of every TB patient under RNTCP.
2. Strengthen RNTCP's regulatory capacity to control TB drugs through appropriate laws, regulations, and policies.
3. Catalyze private sector investment in TB control using public private partnerships.

- **CHAPTER 19: PROCUREMENT AND SUPPLY CHAIN MANAGEMENT**
- **CHAPTER 20: COSTING AND FINANCING THE NSP**
- **CHAPTER 21: IMPLEMENTATION OF NSP**

Chapter 19
PROCUREMENT AND SUPPLY CHAIN MANAGEMENT

Introduction

Continuous and smooth supply of good quality assured Anti TB Drugs and all related commodities is an essential activity under RNTCP. The procurement of Anti TB drugs, equipment and diagnostics is planned, coordinated and done centrally on an annual basis through a well-defined procurement mechanism. The financial support for procurement is provided by Domestic Budgetary Source (DBS), World Bank and The Global Fund. While procurement of consumables is decentralized to the states, drugs may be procured by states in emergency situations after proper authorization from CTD.

The procurement of Anti TB Drugs (first and second Line) under DBS and World Bank mechanism is done through a procurement agency selected by Ministry of Health and Family Welfare (MoHFW). M/s Central Medical Services Society (CMSS), an independent and autonomous body under MoHFW. Procurement under Global Fund mechanism is done through the Global Drug Facility (GDF) of the Stop TB Partnership housed and administered by the United Nations Office for Project Services (UNOPS) and the International Dispensary Association (IDA). The authorized procurement agent is responsible for ensuring all bidding procedures under the International Competitive Bidding (ICB) and supply of anti TB drugs to the consignees happens in a timely manner. These Procurement Agents also ensure that drugs procured are in compliance with the quality policy of the RNTCP, WB and TGF. The procurement, supply chain and logistics activities at the central level are administered by Additional Deputy Director General (TB) with support from consultants and a supply chain management and logistics agency contracted by the program.

Several initiatives have been taken in the period of last NSP to enable uninterrupted supply of good quality diagnostics and anti TB drugs to all TB patients. 2500 LED microscopes were procured, along with 500 CBNAAT machines and 7.8 lakhs cartridges to expand the reach of quality diagnostics across the country and strengthen district level diagnostic capacities. The program also plans to procure additional CBNAAT machines to have at least one rapid molecular test machine installed in all 735 implementing units of the country.

In addition to first and second line drugs, newer formulations like daily regimen for adults and pediatrics and Bedaquiline were also successfully procured in the last NSP period. More advanced tools for logistics and supply chain management were leveraged at the central and state level to ensure streamlined supply of drugs and avoid stock out situations.

The current NSP will take the work forward through introduction of newer ICT solutions and further strengthening of HR structures and capacity building at all levels. The Programme plans to implement a logistics and supply chain management solution to enable real time visibility into stock status at all levels and enable forecasting and quantification for TB drugs and diagnostics. Being implemented through Centre for Development of Advanced Computing (C-DAC), the software is expected to be operational in 2017.

Achievements

1) **LED Microscopes: 2500 LED microscopes were procured and installed at various designated microscopy centers to** provide more accurate and faster diagnostic equipments for management of drug sensitive TB
2) **CBNAAT:** 500 CB-NAAT machines and over two million cartridges were procured to strengthen diagnostic capacity and enable scale up of rifampicin sensitivity testing. There are plans to procure around 1.2 million cartridges in 2017.
3) **Daily Regimen:** Daily regimen was procured and supplied to field level for treatment of drug sensitive TB in adult and paediatric patients in the five states covered under phase one implementation along with all ART sites in the country for TB treatment in PLHIV. Trainings of state and field level staff were conducted to ensure proper logistics and supply chain management of fixed drug combinations at state and district drug stores.
4) **Bedaquiline (BDQ):** Bedaquiline, a new class of drug for treatment of DR TB was procured in a timely manner for roll out in six selected RNTCP sites under a Conditional Access Programme (CAP) covering 6 sites in 5 states.
5) **Training on Procurement and Supply Chain Management:** Several capacity building initiatives were taken to enable new drugs, diagnostics and regimens introduction and train the staff on corresponding supply chain and logistics practices for stock management and transportation.
6) **Quality assurance of anti TB drugs:** While all anti TB drugs procured are required to meet internationally approved and accepted quality standards, the program contracts an independent Quality Assurance Laboratory to conduct quality checks on random samples of first and second line anti-TB drugs drawn from GMSDs, state drug stores and district drug stores.
7) Uninterrupted supply of first and second line drugs over the last plan period.

Challenges

1) **Long lead time for procurement**: There has been a delay in the procurement of Anti TB Drugs, CBNAAT machines and other commodities in the past. These delays are generally due to procedural issues and ensuring compliance of codal formalities.
2) **Inadequate infrastructure at State and district level stores:** Space is a major concern in the State Drug Stores. In addition basic infrastructure like racks, temperature and humidity monitoring systems, firefighting equipment, computers with internet facility, manpower, communications, funds for transportation of commodities are inadequate.
3) High turnover of contractual pharmacists
4) Packaging/repackaging of 2nd line drug boxes: Following PMDT guideline, boxes for 2nd Line drugs need to be re-packed at State drugs store and to be supplied to districts. However, there are also instances wherein loose drugs are re-packed in polythene bags or may be sent in loose forms only to districts. There is no uniformity in the packing and distributions of the Second Line Drugs.
5) Lack of ICT platform for capturing real time information on stock levels, expiry of batches and potential stock out situations results in increased operational strain on supply chain apparatus and can also impact forecasting and procurement planning given delays in reporting from the field.

Strategic Intervention and activities

1. Strengthening of Procurement and Supply Chain Management units

National Level

2. Prepare and circulate guidelines for facilitating procurement of commodities at state level for:
    a. Lab consumables, CBNAAT cartridges, packaging materials
    b. Local procurement of drugs in case of emergency (i.e. national level drug stock is less than 3 months or as may be directed)
    c. Identifying and hiring at least 10 PSM experts who are competent to assist the programme in procurement, supply chain management, distribution and effective inventory management.
    d. Strengthening of infrastructure at State and district level for storage of medical commodities and supplies including drugs.
    e. Use of ICT solution for real time inventory and stock data for forecasting and quantification.
    f. Institutional learning: Training on Procurement and Drug Logistics Management for regions, Inclusion of the Chief Medical Officers, Assistant Depot Managers and the dealing Pharmacists of the Six Regional Government Medical Stores Depots which will be the new primary stocking points for all the anti-TB drugs both First Line and Second Line.

    State Level
    a. Set up state level PSM unit comprised of STO, consultants, Technical Officer – Procurement and supply chain management, etc. with periodical support from central level at RNTCP
    b. A new position for inventory manager / PSM coordinator for district level proposed.
    c. Additional store assistant at SDS (>3000 boxes being packed)
3. Enable capacity building for all staff through
    a. Revamped and refresher trainings and adaptation of methodologies including e-modules, video conference discussion forums, supervisory checklist
    b. Develop booklets on drug inventory management for sub district levels
    c. Update of SOPs and training manual for supply chain management for all levels PSM activities
    d. Induction trainings for new recruits and appointees under drug management
    e. One central level training for all states in a year including the officials from Government Medical Stores Depots.

    a. State level trainings and field visits to be conducted by CTD over a period of 2-3 years
4. Supervision and M&E
    a. Periodic field visit by representatives of central team to 1 SDS , 2 DTCs , 4 TUs and PHIs in a state
5. Gap analysis and upgradation of infrastructure at all storage facilities including
    a. Provision of ACs for 1st and 2nd line drugs store up to TU levels
    b. Storage space assessment at state level
    c. Implement connectivity solution for drug, laboratory consumables and commodities, especially 628 rapid molecular test machines to get real time data on performance and ensure quality assurance
    d. Upgrade store infrastructure to ensure good storage practices and good distribution practices.
6. The states will be allowed to write off 5% of annual supply of drugs, cartridges and laboratory consumables, on moving to DST guided and individualized treatment regimen and considering shorter shelf life of drugs especially 2nd line and daily regimen drugs
7. Policies/guidelines for the following will be devised during this plan period.
    a. Insurance policy for in-transit drugs and commodities
    b. AMC's

c. Transportation system for inter and intra state transfers.
d. Packaging of anti TB drugs-development of Technical specifications and revision as may be necessary from time to time.
e. Disaster management processes at all levels from inventory perspectives

CHAPTER 20
COSTING AND FINANCING THE NSP

Budget & Funding for National Strategic Plan for TB

To achieve Government of India's ambitious targets of eliminating TB, the National TB program require an escalated resource envelope to ensure uninterrupted and timely implementation of the program activities. An estimated budget of ₹16649 crore will be required over next three years to transform TB control and achieve the national goal of ending TB as a major public health problem by 2025. This resource envelope envisages to cover the following activities as has been detailed in the prior chapters.

1. Large scale strengthening of the existing program activities
2. Introduction of new activities to reach patients seeking care from private providers
3. Increase case detection by systematic screening in key populations
4. Deploy a world-class national surveillance and tracking system for TB patients
5. Provide patient support via DBT to address catastrophic costs and improve nutrition
6. Further strengthening of supply chain management and financial management systems using ICT tools

Detecting and treating all TB and MDRTB patients will require wide spread use of newer diagnostic tools, newer treatment regiments and innovative methods to manage TB patients using information technology. This will require large scale investments. The details of the resources required are given below in the tables.

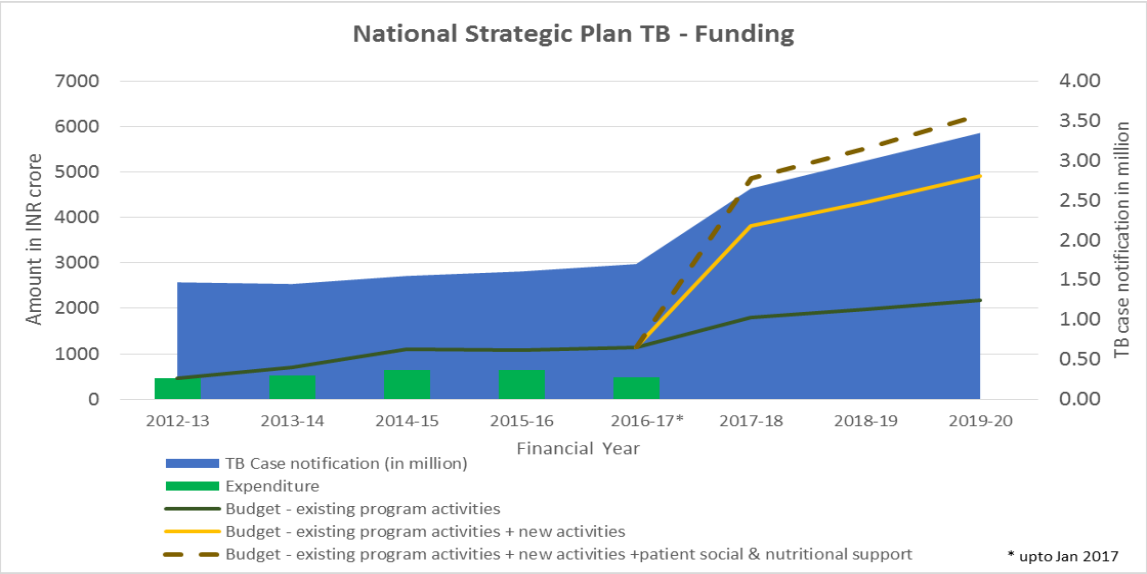
Summary of the funding for TB Control in India:

(Amount in ₹ crore)

Financial year	Budget - existing program activities	Budget - existing program activities + new activities	Budget - existing program activities + new activities +patient social & nutritional support	Expenditure	TB Case notification (in million)
2012-13	467.00			466.15	1.47
2013-14	710.00			516.55	1.45
2014-15	1100.04			639.94	1.55
2015-16	1076.82			639.86	1.61
2016-17*	1146.29			490.00	1.70
2017-18	1800	3810	4870		2.65
2018-19	1980	4327	5527		3.00
2019-20	2178	4912	6252		3.35

2016-17 upto Jan 2017*

2017-18 onwards - projections



Existing activities:

In addition to passive screening for symptoms based on diagnostic algorithm for all patients attending health facilities; targeted 120 million key population will be actively screened in the community. Out of all individuals screened actively and passively, it is expected that over 30 million persons will be offered tests for diagnosis of TB with at least half of them getting highly sensitive rapid molecular diagnostics. Over 4.5 million TB patients and 0.18 million DR TB patients are targeted to be diagnosed and notified to the programme. Daily regimen with fixed dose combination of first-line anti-TB drugs will be expanded nationwide in 2017 itself. Over 2500 molecular diagnostics and over 120 specialized culture and DST laboratories will be established for further decentralization of diagnostic services. Compared to the prior 5 years, this will double the number of TB patients detected and treated, and increase by 3-fold the number of MDR TB patients and 10-fold increase in Pre XDR/XDR TB patients including >20,000 patient treated with newer drugs in next three years.

New Activities:

Includes coverage of the patients from private sector by way of reimbursement of diagnostics, notification by the private providers, provision of the FLD drugs and provision of incentive for treatment support for 4.5 million TB patients. It also includes coordination mechanism for 2.2 million TB patients for extending the program drugs through innovative mechanisms in private sector. Support for 9 million culture test for TB patients follow-up after TB treatment. It also includes the world class ICT support with establishment of call centres with provision for 10 crores minutes call time for supporting all the TB patients, SMS reminders to 4.5 M TB patients and provision of 50,000 PDA devises for digitalization

Patient Social & Nutritional support:

The programme will provide a monthly support of Rs.500 per month to patients to incentivize treatment completion via DBT for treatment support (notification, travel, monthly collection of drugs and follow-up examinations) for all TB patients to address catastrophic costs. The cost to provide this social and nutritional support is for all the projected 9 Million TB patients.

National Strategic Plan for Tuberculosis - Budget for (Financial year - 2017-18 to 2019-20)							
						(Amount in ₹ crore)	
Sr. No.	**Particulars**	**Major Activities**	**2017-18**	**2018-19**	**2019-20**	**Total**	**%**
A	**Programme budget for existing activities**	*Includes management of the 4.5 M DSTB patients through the public sector system with 30.9M presumptive TB / TB patients examination, including 15.5 M CBNAAT tests through additional ~2500 CBNAAT machines, and notification of 180,500 DRTB patients including 63,000 Pre-XDR / XDR patients with shorter regimen and using newer drugs through additional 400 DRTB centres. Establishment of additional 55 C&DST Laboratories and doubling the C&DST capacity for diagnosis and monitoring of the TB patients including laboratory digitalization. ACF to screen 10 M population among key population and priortized districts for early case detection.*	**1800**	**1980**	**2178**	**5958**	**36%**
B	**Additional budget for new activities**		**2010**	**2347**	**2734**	**7091**	**43%**
a	*Diagnostics: (additional)*	*Includes diagnostics (CBNAAT, X-ray etc) for 4.5M patients and their follow-up with 9.0 M cultures through direct services / reimbursements for patients in public and private sector*	*240*	*300*	*360*	*900*	*9%*
b	*Drugs:(additional)*	*Includes 4.5 M patients with private sector and their management with anti-tuberculosis drug cost through direct services from program / reimbursements.*	*300*	*390*	*486*	*1176*	*11%*
c	*Coordination, Engagement & Treatment adherance:*	*Includes management of the 4.5 M patients for notification, treatment adherance and provisions of program drugs to private sector patients through social marketing mechanisms and support systems for public health action.*	*336*	*420*	*504*	*1260*	*12%*
d	*ICT Platform:*	*Includes the ICT platform with 50,000 PDA devises for management of 4.5 M TB patients through the 400 seats call centres with adherance mechanisms through 99-DOTS, SMS reminders and other ICT based platforms.*	*74*	*36.5*	*44*	*154.5*	*1%*
e	*Incentivize Treatment Completion*	*Includes monthly support of Rs.500 per month to patients to incentivize treatment completion via DBT for treatment support (notification, travel, monthly drug collection and follow-up examinations) for all TB patients to address catastrophic costs.*	*1060*	*1200*	*1340*	*3600*	*34%*
C	**Patient Social & Nutritional Support:**	*Includes sustenance of Rs.500 per month during treatment of TB via DBT to the patient as social and nutritional support for all the projected 9 Million TB patients.*	**1060**	**1200**	**1340**	**3600**	**22%**
TOTAL		*(in INR ₹ crore)*	**4870**	**5527**	**6252**	**16649**	**100%**
		(in million USD @67 INR)	***727***	***825***	***933***	***2485***	

Implementing the financial aspect of NSP

RNTCP will be implemented in line with National Strategic Plan with effect from 01st April 2017 with the proposed allocation as given in Annexure J. The implementing agency will continue to be the Central TB Division (CTD), Ministry of Health and Family Welfare (MoH&FW), Government of India (GOI). The Controller of Aid, Accounts and Audit (CAA&A) of Department of Economic Affairs (DEA), Ministry of Finance (MoF), Government of India will maintain a Special Account in the Reserve Bank of India that will be operated. This will be a centrally sponsored scheme wherein, the State Health Societies, District Health Societies /Municipal Corporation Health Societies will maintain a separate

sub-account for receiving the funds from the Ministry of Health and Family Welfare for TB Control Activities and implementation of the project activities within the concerned State/ District/ Municipal Corporation. All State Governments who have agreed to implement the project as per RNTCP Guidelines have signed a Memorandum of Understanding.

There is adequate experience at the Central and State level for the disbursement and financial management of the project funds. The project has provided training to the finance staff at State level in maintenance of the records and forwarding the necessary reports. The Finance staff at central level has also provided training to staff at **State/District** level during their visits to the states **and conducting group training**. The program is now scaling up the use of the Public Financial Management System (PFMS) for financial reporting. RNTCP has planned to initiate the state level trainings and it is expected that by end of 2017, use of PFMS will be streamlined in all states of the country. The states have sufficient capacity to plan and utilize the funds for project activities as also maintain requisite records and generate the required reports to be provided to the CTD, MOHF&W and other agencies. The project at the central level has a Finance Unit **(staffed by Finance consultants, Finance Manager, Jr. Consultant - Accounts, Consultant - Accounts)** at the Central TB Division. At the State level, there is an **Accounts Officer/Accountant** (Two accountants in larger states) and the districts to have a full time accountant. The CTD will continue to make efforts to enhance the capacity for financial management at state and district level by visits by central staff for internal reviews, identifying training needs and providing the necessary training.

The project has been making financial performance-based disbursements to the states in the earlier phase. Releases of funds to the states has been based on the expenditures incurred, balances held in the states and districts and expected expenditures in the next two quarters. There has been however no direct linkage between the budgets of the states, action plans, programmatic progress, records of proceedings (ROP) and releases of funds to the states. These linkages will be developed and states will be encouraged to prepare budgets related to action plans every year. The states will also be required to monitor their performance regularly based on the budgets versus expenditures.

TB program will be implemented in mission mode and adequate structural changes will be adopted at central, state and district level for local resource generation to implement the local solution to the local challenges being faced by TB program. Necessary registrations with appropriate authorities will be acquired and fund management systems with transparency would be established at all the necessary levels to enable acceptance of the resources, through banking channel or in kind, for investments in TB program activities. All efforts will be made to ensure to prevent duplication of funding for same activities.

Budgeting and flow of funds

The funding for RNTCP will be through the MOHF&W budget with project funds as a special allocation. Flow of funds from CTD to State societies will be in two to three instalments to the concerned State Health/TB society. The initial allocation will be based on cash flow forecasts of societies (based on their action plan and budgets) **and allocation made available by the MOH&FW for RNTCP**. Subsequent funds will be released based on expenditures and projected requirement for release of funds.

The budgets will be prepared by the states. These will be compiled from the district budgets that have been examined and consolidated at State level. Budgetary norms have been specified for planning of activities. The budgets will be supported by State and District annual action plans. These will be approved by the Executive Committee of the State NHM, followed by the final approvals of the **National Programme Coordination Committee (NPCC) Meeting under the MoHFW** and will form the basis of release of funds and monitoring project implementation by State and CTD.

Accounting, Internal Controls and Finance Indicators

Societies will maintain books of accounts using double entry book keeping principles. A Chart of Accounts will be provided to capture the expenditure under various categories that will match closely with the budget heads to enable measurement of financial performance. The Societies will incur expenditures based on guidelines as given in the 'Financial Manual for RNTCP'. The financial records will be reviewed periodically by Finance staff at CTD and State to identify weaknesses and take measures for capacity building.

The following financial indicators shall be used to review the key financial activities in the states/districts:

	Activities	**Indicator**	**Source (s) of Verification**
1	Key Financial personnel in place in Centre and States	Staff in position	Appointment orders
2	Disseminate "Financial Manual" containing set of accounting procedures and policies for all levels.	Manual disseminated	Dissemination Report on the Manual
3	Undertake financial management performance evaluation of entities based on agreed criteria and methodology	Quarterly / Annual Financial Monitoring Reports	• Report on variance between estimated date of fund receipt and actual date of release. • Financial management proforma
4	Ensure streamlined system of funds-flow (centre to state and State to District)	• Action plans and Budgets prepared and forwarded by States/Districts to State and CTD respectively in time • Audit reports of previous FY of acceptable quality submitted by 30 September every year • Consolidated SOEs forwarded by states to CTD within 30 days of end of quarter	• Action Plan and Budget of State and District • Audit reports / Consolidated SOEs

Internal control system will include the following:

(a) Establishment of appropriate budgeting systems and regular monitoring of actual financial performance with budgets and targets;

(b) Adoption of simple, clear and transparent financial and accounting policies. These policies will include identification of expenditures that can be charged to the project and the categories under which it can be charged; policies and procedures for transfer of funds and accounting of expenditures

(c) Establishment of standard controls such as verification of expenditures, levels of authorization, reconciliation and physical verification.

Financial reporting

The financial reporting will commence at districts that will provide SOE to the state with an electronic copy to CTD. The state in turn will consolidate the SOE and forward to CTD. CTD will

compile the SOEs from all entities and claim reimbursement, if any from the **external funding agencies**. However, once PFMS is streamlined, the process of submission of SOE will be withdrawn. After audited statements are received the balances at STCS and DTCS will be revised. The reports will include comparison of budgeted and actual expenditures and analysis of major variances. The release of first installment will be based on consolidated SOEs of state for **year ending 31st March**. The second and third installment will be released on receipt of consolidated audit report, utilisation certificate and SOE of the latest quarter.

Auditing arrangements

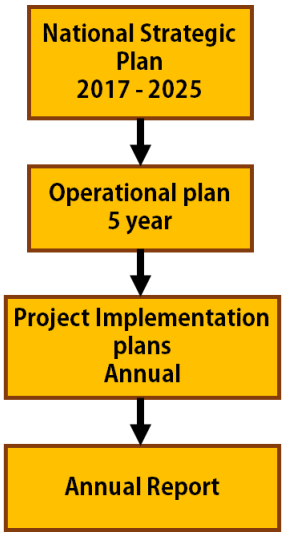
The Director General of Audit (Central Expenditure) (DGACE) under Comptroller and Auditor General (CAG) will audit the accounts of CTD. Local Chartered Accountant firms on the panel of CAG/State AG appointed by state/NHM will audit the State and District Societies on an annual basis. The STCS/NHM will contract the firm for audit of all State and district societies. It is primarily a performance audit which looks into the economy, efficiency and effectiveness of scheme implementation

The auditors will carry out such tests and controls as deemed necessary by them. This may include visits to districts, verification of bank accounts, physical inspection etc. as per the Terms of Reference which will be forwarded by CTD as per Operational Policies of **funding agencies/NHM**. The Audit reports will be forwarded to CTD within **four** months of close of financial year (as per external funding agencies, if any, Operational Policies). All SHS, DPMUs, CHCs, PHCs along with other implementing agencies are responsible to make compliance of audit observations made in the audit report within the timeline prescribed by the controlling authority. CTD will compile these and forward to appropriate authorities in Government/External Funding Agencies, if any

Chapter 21
IMPLEMENTATION OF THE NSP

Introduction

The aspirations of the NSP cannot be achieved without the planning and provision of sufficient resources such as time, money, assets and people. The implementation approach is crucial in the planning process that the programme undertakes when developing the operational plans and the annual project implementation plans. A process of monitoring and reporting allows these strategies to be evaluated and alterations incorporated to ensure strategies and actions continue to be in line with delivering the aspirations detailed in the NSP.



Implementation approach

A twin track approach will be used for the Implementation of the NSP. Prioritized strategies for achieving a rapid decline in the incidence and mortality of TB to be able to meet the SDG goal for TB five years ahead of time will be undertaken with increased intensity while the ongoing programme strategies will be reinvigorated to support these ambitious targets.
Implementing the NSP will see the development of 5 year operational plans followed by the annual plans of the programme at the State and National levels, which will draw from this NSP. The results framework (RF) will guide the development of the annual plans and also for tracking the progress of the interventions.

Structures

To take full advantage of the high level commitment for TB control nationally, the programme will make functional and organizational changes and rebalance the skill-mix composition of its staff and management. This entails the creation of the TB Elimination Board and other structures as detailed in the chapter on HSS and the section **BUILD**, to ensure highest level of political commitment, adequate finances and other resources and support from all the ministries. Strengthening programme capacity to sharpen focus on NSP results, including private sector collaborations, health system strengthening and building an enabling environment is costly in the short term but will yield

significant dividends over the next decades. Over the next 5 years the programme is expected to save XXXX lives and Rs XXXXX to the Indian economy. The requisite skill-mix adjustment will be undertaken with the least amount of disruption in programme activities.

Partnerships

To harmonize national TB control efforts, increase selectivity and achieve complementarity with global and local partners, the national programme will seek agreements with them on collaborative partnerships. The national programme will continue to concentrate its knowledge creation and policy advice activities on its areas of comparative advantage. It will seek its partners' advice on areas in which it has limited or no comparative benefit. Synergistic efforts of all stakeholders involved in TB control in India are the key towards realizing the goal of "Universal access to TB care and treatment for all". It is known that the government is not the sole provider of services for TB and optimum efforts will be made to utilize the resources in the private sector. In this context an enabling environment will be created through regular interaction with partners involved in TB control and promoting innovative TB control initiatives at district, state and national level.
The programme defines partnership as an arrangement between any two or more entities; most often, government owned entity on one side and a private sector entity on the other, for the provision of public assets and/or public services, through investments being made and/or management being undertaken by the private sector entity, for a specified period of time. Such arrangements may have options of receiving performance linked incentives that conform (or are benchmarked) to specified and pre-determined performance standards, measurable by the public entity or its representative.
This concept of partnership is much broader as compared to previous approaches of Public Private Mix (PPM) under RNTCP which entailed strategies that link all entities within the private and public sectors (including health providers in other governmental ministries) to the national TB programme.

RNTCP has formed the National Technical Working Group on Public Private Mix to provide a forum for dialogue, to ensure sustained attention on the issue, and guide innovation and learning. Institutional mechanisms to support the States for effective contract management, hiring interface agencies to manage activities of engaging private sector and other partnership-strengthening functions need to be developed.

Details of partnerships are available in the National Guideline for Partnerships which provides information on how different stakeholders can supplement the efforts of the government for TB control in India. Further details can be referenced in the National Guidelines and the TOG available on www.tbcindia.org.

Developing capacity to produce first-line drugs for RNTCP

5 public sector units (PSUs) are already manufacturing anti-TB drugs in India. Under the 'Make in India' thrust of the government of India, it is proposed to explore the possibility of developing capacity to produce first-line drugs for RNTCP in the public sector with following options:

1. Assess the current capacity and further build the capacity so that PSUs manufacture first-line anti-TB drugs for all patients of RNTCP with GOI's own investment
2. Partnership of PSUs with major India manufactures manufacture first-line anti-TB drugs with arrangement for sharing total products with minimal / free drugs for RNTCP patients and allowing partner manufactures to sell for other NTPs in high burden and African countries with co-branding of GOI (Make in India). Consider waving off of customs duty, import/export facilitation and sales tax.

The anticipated benefits include the following:

1. Country's branding gives strategic role in global development agenda
2. Cost effectiveness over current arrangement

3. Better control over drugs availability (prevention of stock outs)
4. Enhanced employment for skilled youths

There exists successful example from a Brazil.

Outsourcing and procurement of services from the private sector

With a heavy workload expected owing to the ambitious strategies of this NSP, outsourcing of select functions will make such functions efficient and ultimately improve the access of TB services to hitherto unreached populations. These functions include:

a. Enlist private laboratories to support diagnostic functions through a policy intervention.
b. The programme also envisages a shift away from a quality assured laboratory to an empaneled laboratory.
c. Promote sputum collection and transport through a courier company.
d. Outsourcing of HR management structure to an HR management agency – Ensures a 60% of burn rate with enhanced efficiency of HR management processes and systems. Outsourcing also saves the district programme manager from time consuming administrative functions and also decreases the legal liability for the government.