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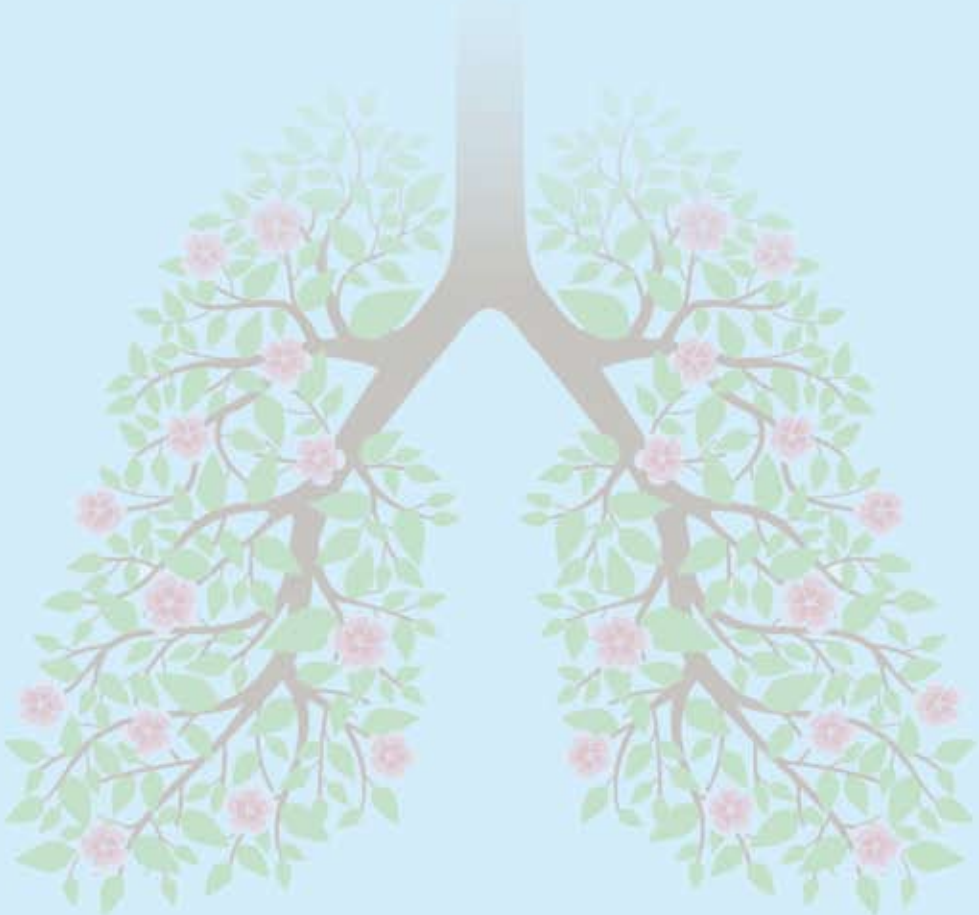
Government of India

TB INDIA 2016

REVISED NATIONAL TB CONTROL PROGRAMME

ANNUAL STATUS REPORT



UNITE TO END TB

DOTS

Pura course. Pakka ilaaj.

Central TB Division

Directorate General of Health Services

Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi - 110108

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NATIONAL HEALTH MISSION

राष्ट्रीय स्वास्थ्य मिशन

जगत प्रकाश नड्डा
Jagat Prakash Nadda

सत्यमेव जयते

स्वच्छ भारत
एक कदम स्वच्छता की ओर

स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India

FOREWORD

Tuberculosis remains a major public health problem despite noteworthy socio-economic development, advances and availability of technology. It is a curable disease but still millions of people suffer every year and a number of them die from this infectious disease resulting in devastating social & economic impact.

2. India is a signatory to "The End TB Strategy" that calls for a world free of tuberculosis, with measurable aims of a 50% and 75% reduction in incidence and related deaths, respectively, by 2025, and corresponding reductions of 90% and 95% by 2035. Sustainable Development Goals (SDGs) which came into effect from 1st January 2016 require that all three dimensions of sustainable development – economic, social and environmental – are addressed in an integrated manner to ensure that "no one is left behind". As a step towards achieving the SDGs and End TB Strategy, the Revised National Tuberculosis Control Programme (RNTCP) is adopting newer strategies and tools to ensure universal access to quality TB care.

3. The RNTCP is coping with challenges like development of resistance to anti-TB drugs with expansion of rapid molecular diagnostic by CBNAAT and use of Bedaquiline, a new anti-TB drug through conditional access under Programmatic Management of Drug Resistant TB.

4. The program is also expanding collaborative activities to address co-morbidities like associated HIV, diabetes, smoking and making great progress in Case Based Web Based IT system (Nikshay) for tracking of individual TB cases. For reaching unreached TB patients and to link them to RNTCP services, citizen centric missed call centre have been launched in the states of Punjab, Haryana, Chandigarh and Delhi.

5. The Union Government is firmly committed and will ensure all necessary help to achieve vision of "TB-free India."

(Jagat Prakash Nadda)

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Ministry of Health & Family Welfare

MESSAGE

Tuberculosis has remained a disease of Public Health Importance since ages and is known to inflict large quantum o socio-economic cost on the society.

Each year, about 2.2 million people develop TB in India and an estimated 220,000 people die from the disease. The Revised National TB Control Programme (RNTCP) till date has treated over 19 million patients and thus saved an additional three million lives. The cure rates under RNTCP have consistently been above 85%. TB Millennium Development Goals of 50 per cent reduction in the prevalence of TB and reducing TB death by 50 per cent as compared to 1990 have been achieved.

Policymakers, administrators, RNTCP programme managers, staff and health workers across the country have shown a high degree of dedication and commitment in working towards the common goal of TB free India. Challenges of drug resistance, HIV, diabetes, smoking and other social determinants of TB are being addressed with appropriate measures. "Nikshay" the case based web based reporting system developed under RNTCP will ensure better surveillance and treatment of TB cases. Launch of citizen centric missed call centre in the states of Punjab, Haryana, Chandigarh and Delhi will help to reach unreached TB patients. Massive network of molecular diagnosis being established well improve services for MDRTB.

Despite notable successes, RNTCP faces many challenges including of enhanced case notifications rate, Drug Resistances achieving higher treatment success rates, addressing co-morbidities etc. All stakeholders will need to work together to successfully address these challenges.

I am glad that the central TB Division is bringing out its annual publication "TB India 2016" that highlights all that has been done in the last year and where the program has the scope to improve.

I take this opportunity to retreats the commitment of Department of Health and Family Welfare, Government of India, to provide all support to achieve the mission of TB Mukt Bharat.

(B.P. Sharma)

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MESSAGE

We have adopted new ideas and strategies under TB Control for Zero deaths, disease and suffering due to tuberculosis. By year 2020 our goal should be to significantly reduce TB burden in India by ensuring universal access to quality assured TB care.

The Revised National TB Control Program (RNTCP) will soon roll-out daily regimen for treatment of new drug sensitive TB cases using fixed dose combination in 104 districts in five states. The results from the ongoing National Drug Resistance Survey result will help to formulate strategies to design appropriate regimen for controlling DR-TB.

All districts in the country are linked with rapid molecular diagnostics CBNAAT and LPA. The program is enhancing its diagnostic capacity by additional CBNAAT machines for diagnosis of MDR-TB and TB in selected key populations such as people suspected of having drug resistance TB, People Living with HIV-AIDS, children as well as extra pulmonary cases. With 24 laboratories certified for performing second line DST, we are poised to detect additional resistance to second line anti-TB drugs that will allow modification of regimen early to improve treatment outcome of patients. To improve outcome amongst DR-TB patients, a new drug bedaquiline is planned to be introduced in six referral sites initially to establish its safety profile among Indian patients.

In the coming years our case based web based IT system e-Nikshay will help to achieve 100% notification including that from the private sector. IVR calls, SMS will be sent to patients to confirm the drug uptake. To enhance Nikshay implementation, reduce the time lag in data entry and also for managing information at the supervisory level, tablets will be soon provided to supervisory staff.

The involvement of multiple stakeholders including the civil society is essential for TB control activities in the country. With notification of all TB cases being mandatory, efforts are being made to ensure that all cases treated outside the program are notified and TB patients are diagnosed and treated with existing Standards of TB care in India.

(Dr. Jagdish Prasad)

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PREFACE

TB India 2016 is an annual publication from Central TB Division wherein a comprehensive status of TB control activities in the country has been compiled. The compilation is released every year on 24 March, World TB Day.

The Revised National TB Control Programme (RNTCP) has been applauded for its public health prospective. The program has seen many new initiatives and policy changes in the last one year. RNTCP has envisaged "Universal Access to Quality TB Diagnosis and Treatment" in line with "Standards of TB Care in India." We have planned to roll-out daily regimen for treatment of new drug sensitive TB cases in 104 districts in five states. The Fixed Dose Combination of anti-TB drugs will be according to patient's weight. The implementation of daily regimen will thus ensure optimum dosage and reduced pill burden with improved treatment outcomes.

Bedaquiline has been given approval for use along with the background regimen under conditional access through the RNTCP PMDT programme. RNTCP recently rolled-out base line second line drug susceptibility testing to detect additional resistance to second line anti-TB drugs. At present there are 24 laboratories certified for performing second line DST across the country. In addition to the existing 121 CBNAAT machines, the program will provide enhanced rapid molecular diagnostics for drug resistance suspects, PLHIV, paediatrics and extra pulmonary TB by addition of another 500 CBNAAT machines.

To make RNTCP service more patient centric a dedicated toll free number with a call centre is being started by making use of ICT to provide patient counselling and treatment support services in states of Punjab, Haryana, Chandigarh and Delhi.

RNTCP and National Program for Prevention and Control of Cancer, Diabetes, CVD & Stroke (NPCDCS) jointly developed framework for collaboration which aim to reduce morbidity and mortality by doing bi-directional screening, early detection and prompt management of Diabetes Mellitus (DM) and TB. In another initiative, National Tobacco Control Program is working in synergy with RNTCP for development and implementation of collaborative framework.

We have laid down strategies for involvement of all care providers to strengthen notification, promote ban on serology, rational use of anti-TB drugs, early identification and referral of TB suspect for diagnosis and increase community awareness. The WHO Global TB report 2015 praised India's efforts for 29% increase in notifications during last year.

I'm thankful to officers and staff of Ministry of Health and Family Welfare, Directorate General Health Services, and State Governments for their continued support and endeavours for betterment for the program. I also acknowledge the support of partners who have pledged to come together for a common cause. RNTCP fraternity will strive further to do the good work as the years continue with renewed enthusiasm and dedication.

(Dr. Sunil D. Khaparde)

ABBREVIATIONS

ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immune Deficiency Syndrome
AIIMS	All India Institute of Medical Sciences
ANSV	Annual Negative Slide Volume
ART	Anti-Retroviral Therapy
ARTI	Annual Risk of Tuberculosis Infection
ASHA	Accredited Social Health Activist
CBCI	Catholic Bishop's Conference of India
CGHS	Central Government Health Scheme
CHAI	Catholic Health Association of India
CHC	Community Health Centre
CII	Confederation of Indian Industries
CMAI	Christian Medical Association of India
CTD	Central TB Division
DALYs	Disability Adjusted Life Years
DBS	Domestic Budgeting Source
DDG	Deputy Director General
DFID	Department for International Development
DGHS	Director General of Health Services
DMC	Designated Microscopy Centre
DOTS	Directly Observed Treatment Short Course
DRS	Drug Resistance Surveillance
DRTB	Drug Resistant Tuberculosis
DST	Drug Susceptibility Testing
DTC	District Tuberculosis Centre
DTO	District Tuberculosis Officer
E	Ethambutol

EPTB	Extra-pulmonary Tuberculosis
EQA	External Quality Assessment
GMSD	Government Medical Store Depot
GoI	Government of India
GFATM	The Global Fund to Fight against AIDS, Tuberculosis and Malaria
H	Isoniazid
HBCs	High Burden Countries
HIV	Human Immuno Deficiency Virus
HRD	Human Resource Development
IAC	IEC Advisory Committee
ICB	International Competitive Bidding
ICELT	International Centre for Excellence in Laboratory Training
ICMR	Indian Council of Medical Research
ICTC	Integrated Counselling and Testing Centre
IDSP	Integrated Disease Surveillance Project
IEC	Information, Education and Communication
IMA	Indian Medical Association
IPT	Isoniazid Preventive Therapy
IRL	Intermediate Reference Laboratory
IUALTD	International Union Against Tuberculosis and Lung Disease
JMM	Joint Monitoring Mission
KAP	Knowledge, Attitude and Practices
LT	Laboratory Technician
MDGs	Millennium Development Goals
MDRTB	Multi Drug Resistant TB

MIS	Management Information System
MO	Medical Officer
Mo-HFW	Ministry of Health and Family Welfare
MOTC	Medical Officer-Tuberculosis Control
MoU	Memorandum of Understanding
NACO	National AIDS Control Organisation
NACP	National AIDS Control Programme
NCDC	National Centre for Disease Control
NEP	New Extra Pulmonary
NGO	Non Governmental Organisation
NIRT	National Institute of Research in Tuberculosis
NJI-MOD	National Jalma Institute of Mycobacterial and Other Diseases
NRHM	National Rural Health Mission
NRL	National Reference Laboratory
NSN	New Smear Negative
NSP	New Smear Positive
NTF	National Task Force
NTI	National Tuberculosis Institute
NTP	National Tuberculosis Programme
NUHM	National Urban Health Mission
OR	Operational Research
OSE	On-Site Evaluation
PHC	Primary Health Centre
PHI	Peripheral Health Institution
PLHIV	People Living with HIV and AIDS
PP	Private Practitioner
PPM	Public-Private Mix
PSU	Public Sector Unit
PTB	Pulmonary Tuberculosis

PWB	Patient-Wise Box
QA	Quality Assurance
R	Rifampicin
RBRC	Random Blinded Re-Checking
RCH	Reproductive and Child Health
RNTCP	Revised National Tuberculosis Control Programme
S	Streptomycin
SDS	State Drug Store
SHGs	Self Help Groups
SOP	Standard Operating Procedure
SPR	Slide Positivity Rate
STC	State TB Cell
STDC	State Tuberculosis Training & Demonstration Centre
STF	State Task Force
STLS	Senior TB Laboratory Supervisor
STO	State TB Officer
STS	Senior Treatment Supervisor
TB	Tuberculosis
TU	Tuberculosis Unit
UHC	Urban Health Centre
UNOPS	United Nations Office for Project Services
USAID	United States Agency for International Development
WHO	World Health Organization
WVI	World Vision India
XDR-TB	Extensively Drug Resistant TB
Z	Pyrazinamide
ZTF	Zonal Task Force

CONTENTS

Executive Summary

The Revised National TB Control Programme (RNTCP) is bringing out its Annual Status report "TB India 2016" summarizing implementation status, various policy updates and activities undertaken during the year 2015.

RNTCP aims for Universal Access for quality diagnosis and treatment for all TB patients in the community and a target of "reaching the unreached". We have achieved the TB Millennium Development Goals and STOP TB target of 50 per cent reduction in TB prevalence and mortality due to TB. India is a signatory to World Health Assembly which has endorsed Sustainable Development Goals and global 'End TB Strategy' that calls for a world free of tuberculosis, with measurable aims of 50% and 75% reduction in incidence and related deaths, respectively, by 2025, and corresponding reductions of 90% and 95% by 2035 as well as zero catastrophic expenditure due to TB. Our Vision 2020 is to significantly reduce TB burden in India by ensuring universal access to quality assured TB care as per Standards for TB Care in India (STCI).

In 2015, RNTCP covered a population of 1.28 billion. A total of 91,32,306 TB suspects were examined by sputum smear microscopy and 14,23,181cases were registered for treatment. 79% of all registered TB cases knew their HIV status. 93% HIV infected TB patients were initiated on CPT and 92% were initiated on ART.

To ensure quality case management, notification of all TB cases in Nikshay is the first step to close the gap of missing TB cases in India. WHO Global TB report 2015 appreciated India's efforts for substantial increase of TB case notification. Strengthening Surveillance System will ensure that appropriate measures can be taken by the programme to implement quality TB diagnosis and treatment as per STCI. In other words, mandatory TB Notification, STCI, Nikshay are the tools for strengthening surveillance.

RNTCP has quality assured laboratory network of 13,886 microscopy centres for sputum smear microscopy. At present under the program there are 64 RNTCP certified Culture & DST laboratories in the country which includes laboratories from Public sector (IRL, Medical College), Private and NGO laboratories. Twenty five laboratories under the program are certified for SLD. To improve outcome amongst DR-TB patients, a new drug bedaquiline is planned to be introduced in six referral sites initially to establish its safety profile among Indian patients. The entire country is covered for baseline SLD for MDR-TB patients. Currently 121 Cartridge Based Nucleic Acid Amplification (CBNAAT) sites provide rapid decentralized diagnosis of MDR-TB, TB in high risk group PLHIV and Paediatric presumptive including EP-TB case. Procurement of another 500 CBNAAT machines is being undertaken.

RNTCP has planned to roll-out daily regimen for treatment of new drug sensitive TB cases in 104 districts in five states. The Fixed Dose Combination of first-line anti-TB drugs will be according to patient's weight for adults also. The implementation of daily regimen will thus ensure optimum dosage and reduced pill burden with expectedly improved treatment outcomes.

To make RNTCP service more patient centric; a dedicated toll free number with a call centre has been started using ICT to provide patient counselling and treatment support services in states of Punjab, Haryana, Chandigarh and Delhi, named as missed call campaign.

The NRL Coordination Committee deliberated on roles and responsibilities of the NRL and stewardship for DR-TB services, SLDST and inclusion of drugs for panel testing, DST guided treatment and single comprehensive training for laboratory personnel. The National Committee of Operational Research has approved a study for the Validation of second line LPA for detecting resistance to Fluoroquinolones, Aminoglycosides (Kanamycin, Amikacin) and Cyclic Peptides (Capreomycin).

RNTCP and National Program for Prevention and Control of Cancer, Diabetes, CVD & Stroke (NPCDCS) have jointly developed a framework for collaboration which aims to reduce morbidity and mortality by doing bi-directional screening, early detection and prompt management of Diabetes Mellitus (DM) and TB. RNTCP and National Tobacco Control Programme are also working in synergy for development and implementation of a framework for collaboration.

To replace the Binocular Microscopes and to provide better and faster diagnostic equipments for the management of drug sensitive TB, programme has procured 2500 LEDs during the year 2015 for distribution to high work load settings. Further, 1500 BMs have been procured during the year.

In 2015, the Joint Monitoring Mission (JMM) brought together a team of national and international experts from the Ministry of Health, civil society, implementing partners, technical and developmental agencies to review the progress, challenges, gaps and strategies of India's tuberculosis (TB) control efforts.

The first National Consultation on 'Nutritional Support to Tuberculosis Patients' was organized to discuss challenges and highlight resources needed to effectively develop and implement a nutrition support plan for TB patients across the country.

'Call to Action' initiative was launched in India by the Hon'ble Minister of Health and Family Welfare. This is an initiative under the global Challenge TB project funded by USAID and led by The Union South East Asia (USEA) office in India.

CTD has been a Principal Recipient (PR) of the Global Fund grants. The program has completed the implementation of Single Stream Funding Grant on 30th September 2015 with 100% utilization of funds. The next implementation period under TGF Funding Model (FM) grant is from 01st October 2015 to 31ST December 2017. The grant would support in scaling up of program activities across country including establishment of 15 Liquid culture laboratories, deployment of additional 200 CBNAAT machines, procurement of First line and Second line drugs, strengthening of supply chain management system, scale up of Public Financial management system (PFMS), etc. The proposed sub- recipients under the FM are: States of Andhra Pradesh, Bihar, Chhattisgarh, Haryana, Jharkhand, Karnataka, Orissa, Telangana, Uttarakhand, Catholic Bishops Conference of India (CBCI), Indian Council for Medical Research (ICMR), Indian Medical Association (IMA), Foundation for Innovative and New Diagnostics (FIND), Tata Institute of Social Sciences (TISS), Tibetan Voluntary Health Association (TVHA) and World Health Organization (WHO).

With support from World Bank, CTD is implementing the "Accelerating Universal Access to Early and Effective Tuberculosis Care" Project with an IDA Credit (5376-IN) of US$ 100 million. The development objective of the project is to support the aims of India's National Strategic Plan (NSP) for Tuberculosis Control to expand the provision and utilization of quality diagnosis and treatment services for people suffering from tuberculosis.

Synergistic efforts of all stakeholders involved in TB control in India are the key towards realising the goal of "Universal access to TB care and treatment for all". RNTCP has successful partnerships with Indian Medial Association (IMA), Catholic Bishops' Conference of India (CBCI), Foundation for Innovative New Diagnostics (FIND), World Vision and The UNION. From strengthening notification from private sector, scaling up diagnosis for drug resistance TB, engagement of communities and Community Systems Strengthening, partners have complemented RNTCP's efforts towards universal access to TB care. Involvement of more than 360 medical colleges in RNTCP is through DMCs, DOT Centers and DRTB Centers.

The ensuing chapters of the annual report provide detailed description of the activities that have been summarized above.

1
CHAPTER

ACTIVITIES UNDERTAKEN IN 2015

1
CHAPTER

Central TB Division: activities undertaken in 2015

January

1. National RNTCP Review Meeting with State Tuberculosis Officers of all States/Union Territories on 6th – 8th January, 2015 at Bhubaneswar, Odisha. The programme was also attended by RNTCP Consultants and Directors of Central level TB Institutes. The DGHS conducted the review on 6th January, 2015.
2. Zonal Task Force meeting for involvement of Medical Colleges under RNTCP for East Zone on 15th – 16th January, 2015, at Bhubaneswar, Odisha.
3. Management and Leadership training for RNTCP programme managers in collaboration with the International Union against Tuberculosis and Lung Diseases, from 19th to 24th January, 2015.
4. Zonal Task Force meeting for involvement of Medical Colleges under RNTCP for South Zone-1 on 22nd – 23rd January, 2015, at Hyderabad, Telangana State.
5. Training of Trainers (TOT) on Standards for TB Care in India (STCI) for Indian Medical Association (IMA) on 24th – 25th January, 2015, at National Tuberculosis Institute (NTI), Bengaluru, Karnataka.
6. RNTCP Central Internal Evaluation (CIE) of Telangana State was organized from 27th – 31st January, 2015. During the CIE, two districts (Warangal and Mahbubnagar) were visited.

February

7. Training of Trainers (TOT) on Standards for TB Care in India (STCI) on 16th – 17th February and 19th – 20th February, 2015, at National Tuberculosis Institute (NTI), Bengaluru, Karanataka.
8. Zonal Task Force meeting for involvement of Medical Colleges under RNTCP for North Zone on 13th – 14th February, 2015, at Chandigarh.
9. RNTCP Central Internal Evaluation (CIE) of Tripura State was organized from 23rd – 26th February, 2015. During the CIE, two districts (West and South Tripura) were visited.

March

10. Review of RNTCP was taken by Secretary (Deptt of Health & FW) at Nirman Bhawan on 2nd March, 2015.
11. 8th National Co-ordination Committee meeting of Global Fund Single Stream Funding TB Grant, was held on 12th-13th March, 2015 at Patna, Bihar.
12. National Task Force Workshop for Involvement of Medical Colleges under RNTCP from 14th – 15th March, 2015, at Shimla, Himachal Pradesh.
13. World Tuberculosis Day was observed on 24th March, 2015.

April

14. The World Health Organization (WHO), the

Government of India (GoI) and other technical and donor partners conducted the Joint Monitoring Mission (JMM) to review India's Revised National TB Control Programme (RNTCP) from 10 to 23 April, 2015.

15. Modular training in RNTCP at NTI, Bangalore was conducted during 13-25th April

16. The Hon'ble Minister of Health and Family Welfare launched the 'Call to Action for TB Free India' on 23rd April, 2015. The Call to Action for TB Free India is a fore runner to the Intensified TB Control Plan - TB free India, developed by the Revised National TB Control Programme, India. The Call to Action will kick start and catalyse GoI efforts to accelerate TB prevention and care in partnership with all stakeholders.

May

17. Modular training in RNTCP at NTI, Bangalore was conducted during 18-30th May

18. RNTCP Central Internal Evaluation (CIE) of Kerala was organized from 27th April to 01st May, 2015; during the CIE, two districts (Ernakulum and Pathanamthitta) were visited.

June

19. Modular training in RNTCP at NTI, Bangalore was conducted during 15-27th June

20. Modular training at NITRD, New Delhi on 20th April to 2nd May 2015 & 29th to 11th July 2015

21. Training of master trainers on STCI was held on 01st to 2nd June, 2015 at NTI Bangalore

22. RNTCP Central Internal Evaluation (CIE) of Jammu and Kashmir was organized from 15th – 19th June, 2015; during the CIE, two districts (Jammu and Srinagar) were visited.

July

23. Modular Training on RNTCP conducted at NITRD from 31st August to 1st September 2015

24. Review meeting with civil societies representatives by JS (Public Health) on 14th July 2015

25. Programme Management of Drug Resistant TB and TBHIV regional reviews conducted for East Zone (15th to 17th July)

August

26. Review of RNTCP by Hon'ble HFM on 14th August and 21st August 2015

27. Programme Management of Drug Resistant TB and TBHIV regional reviews conducted for west zone on 25th to 27th August 2015

28. Workshop on development of Guidelines for EPTB 14- 18 July, 2015 at AIIMS, New Delhi

29. Workshop for reviewing and updating the Technical and Operational Guidelines of RNTCP at NITRD from 17th to 19th August 2015

30. National Task force core committee meeting on 21st August 2015

September

31. National Biannual RNTCP Review meeting of State TB Officers at Nagpur from 14 to 16 September 2015

32. Training on procurement & Logistics Management for North East States representative at NTI, Bangalore on 28-30 September 2015

33. Workshop on initiation Validation for 2nd Line DST on LPA version 2.0 at NTI, Bangalore on 30th September 2015

October

34. Global fund HFM Grant Framework agreement signed by DEA for grant implementation from 01st October 2015

35. Scoping meeting for roll out of daily regimen under RNTCP in Mumbai from 27 to 28 October 2015

November

36. Zonal Task force meeting for North zone held on 18-19 November 2015 at Lucknow
37. Zonal Task force meeting for South zone held on 23-24 November 2015 at Kerala
38. Zonal Task force meeting for East zone held on 26-27 November 2015 at Kolkata
39. National Technical working group meeting for PPM held on 23rd November 2015 at Delhi
40. Meeting on Bedaquilline conditional access programme at ICMR HQ on 6th November 2015
41. National level sensitization for CBNAAT at NTI, Bangalore from 16- 17 November 2015
42. National level sensitization for CBNAAT at Jaipur from 23-24 November 2015
43. National level sensitization for CBNAAT at Jalma Agra from 26-27 November 2015
44. Capacity building workshop on Roll out of daily therapy in Sikkim state from 17- 18 November 2015
45. National level capacity building workshop on TBHIV on 23-24 November 2015 at Bangalore
46. AIC assessment on ART centres ongoing

December

47. Meeting of all partners from other than public sector held on 18th December, 2016
48. Zonal Task Force meeting conducted for the for South 1 Zone on 10-11 December 2015 at Visakhapatnam.
49. Training on expansion of CBNAAT testing was conducted in 300 sites across 35 states/ UTs except A & N Island from 16-22 December 2015 at different venues

2

CHAPTER

TB DISEASE BURDEN IN INDIA

2 CHAPTER

TB disease burden in India

Though India is the second-most populous country in the world one fourth of the global incident TB cases occur in India annually. As per WHO Global TB Report, 2015, out of the estimated global annual incidence of 9.6 million TB cases, 2.2 million were estimated to have occurred in India.

WHO estimated burden of tuberculosis in India

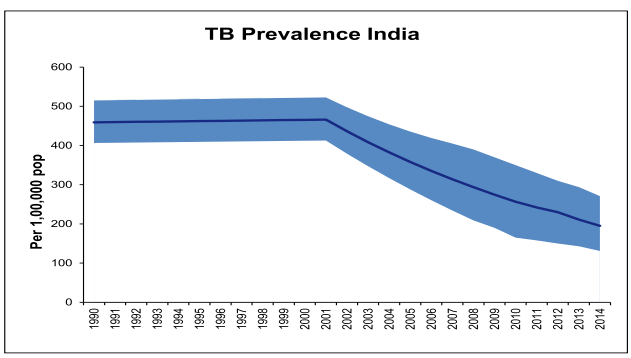
TB burden	Number (Millions) (95% CI)	Rate Per 100,000 Persons (95% CI)
Incidence	2.2 (2.0–2.3)	167 (156–179)
Prevalence	2.5 (1.7–3.5)	195 (131–271)
Mortality	0.22 (0.15–0.35)	17 (12–27)

TB burden	Number (Millions) (95% CI)	Percentage (95% CI)
HIV among estimated incident TB patients	-	5.0% (4.5%–5.4%)
MDR-TB among notified pulmonary TB patients	0.071 (0.057–0.085)	-
MDR-TB among notified New pulmonary TB patients	0.024 (0.021–0.029)	2.2% (1.9–2.6%)
MDR-TB among notified Re-treatment pulmonary TB patients	0.047 (0.035–0.059)	15% (11–19%)

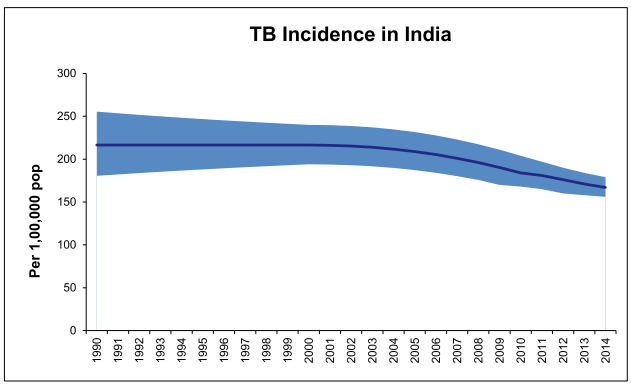
As per current WHO estimates, India's TB control progrtamme is on track as far as reduction in disease burden is concerned. There is 58% reduction in TB mortality rate by 2014 as compared to 1990 level. Similarly there is 55% reduction in TB prevalence rate by 2014 as compared to 1990 level and also, the incidence is on declining trend.

These estimations were based on RNTCP data, 7 Prevalence surveys in India conducted between 2007-2010, National ARTI surveys, mortality surveys conducted in 2005.

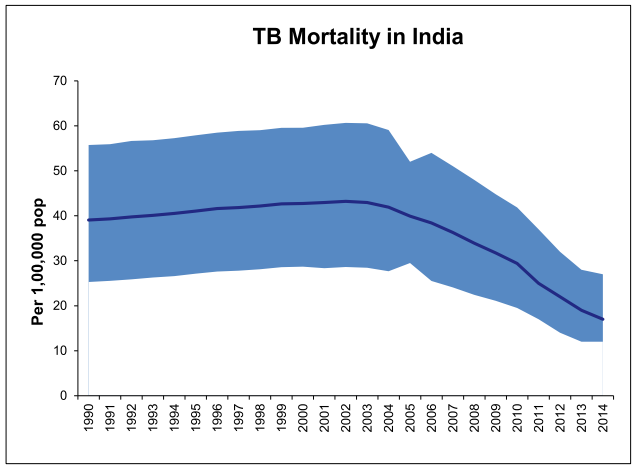
Tuberculosis prevalence per lakh population has reduced from 465 in year 1990 to 195 in 2013. In absolute numbers, prevalence has reduced from 40 lakhs to 25 lakhs annually.



Tuberculosis incidence per lakh population has reduced from 216 in year 1990 to 167 in 2014.



Tuberculosis mortality per lakh population has reduced from 38 in year 1990 to 17 in 2012. In absolute numbers, morality due to TB has reduced from 3.3 lakhs to 2.2 lakhs annually.



3
CHAPTER

RNTCP Implementation status

3
CHAPTER

RNTCP implementation status

3.1 Diagnosis

Diagnosis of Tuberculosis is done primarily using Smear Microscopy. The nationwide network of designated sputum smear microscopy laboratories under RNTCP provides appropriate and accessible quality assured services for TB diagnosis. Quality assurance for the sputum smear microscopy is implemented through a three tier system consisting of National Reference Laboratories (NRL), Intermediate Reference Laboratory (IRL) and Designated Microscopy Centres (DMCs). To meet the standards of internationally recommended diagnostic practices for TB, the programme provides quality reagents and equipment to the laboratory network. An inbuilt routine system has been designed for sputum microscopy External Quality Assessment (EQA) and for supervision and monitoring of the diagnostic systems by the RNTCP Senior TB Laboratory Supervisor (STLS) locally and by the Intermediate (State level) and National Reference Laboratory network for RNTCP at higher levels. The programme has a certification procedure for the Culture and Drug Susceptibility Testing performed by solid, liquid and Molecular (Line Probe Assay) diagnostic methods, with a quality assurance protocol based upon WHO and Global Laboratory Initiative recommendations.

Quality Assured Laboratory services: RNTCP has established a nationwide laboratory network, encompassing 13,886 DMCs, which are being supervised by the IRL at State level, and the NRL & Central TB Division at the National level.

National Reference Laboratories (NRL): The six NRLs under the programme are National Institute for Research in Tuberculosis(NIRT), Chennai; National Tuberculosis Institute (NTI)Bangalore; National Institute of TB & Respiratory Diseases (NITRD)Delhi, and National Japanese Leprosy Mission for Asia (JALMA) Institute of Leprosy and other Mycobacterial Diseases, Agra., Regional Medical Research Centre (RMRC), Bhubaneswar and Bhopal Memorial Hospital and Research Centre, (BMHRC),Bhopal . The last two NRLs have been designated recently and the states have been redistributed among the 6 NRLs. The NRLs work closely with the IRLs, monitor and supervise the IRL's activities and also impart periodic training for the IRL staff in EQA sputum smear microscopy, Culture & DST, LPA and CB NAAT.

Human Resource comprising of three microbiologists and four laboratory technicians have been provided by the RNTCP on a contractual basis to each NRL for supervision and monitoring of laboratory activities.

The NRL microbiologist and laboratory supervisor / technician visits each assigned state at least once a year for 2 to 3 days as a part of on-site evaluation under the RNTCP EQA protocol.

NRL	States and Union Territories (UTs) Assigned for EQA	Total nos. of IRLs assigned	Total nos. of states/ UTs assigned	No of OSE conducted during the year (2015)
NTI, Bangalore	Karnataka, Maharashtra, Rajasthan	5	3	5
NIRT , Chennai	Tamil Nadu, Puducherry, Kerala, Gujarat, Andaman & Nicobar, Telangana, Andhra Pradesh, Dadar & Nagar Haveli, Daman & Diu, Lakshadweep	5	9	0
NITRD, New Delhi	Delhi, Jammu & Kashmir, Chandigarh, Punjab, Haryana, Bihar, Himachal Pradesh	8	7	8
JALMA Agra	Uttar Pradesh, Uttarakhand	3	2	2
RMC, Bhubaneshwar	Odhisa, Meghalaya, Assam, Tripura, West Bengal, Sikkim, Arunachal Pradesh, Manipur, Nagaland, Mizoram	6	10	10
BMHRC, Bhopal	Madhya Pradesh, Chhattisgarh, Jharkhand, Goa	4	4	4

Intermediate Reference Laboratory (IRL): One IRL has been designated in the STDC / Public Health Laboratory /Medical College of the respective state. In larger states like Uttar Pradesh, Madhya Pradesh and Maharashtra two IRLs have been designated. The functions of IRL include supervision and monitoring of EQA activities, providing Mycobacterial culture and DST services and conduct of Drug Resistance Surveys (DRS). The IRL ensures the proficiency of staff in performing smear microscopy activities by providing technical training to district and sub-district laboratory technicians and STLSs. The IRLs undertake on-site evaluation to each district in the state, at least once a year, during which the STLSs are panel tested.

Culture and DST Laboratories(C & DST): In additional to IRLs, the programme also involves the Microbiology Department of Medical colleges for providing diagnostic services for drug resistance Tuberculosis, Extra-Pulmonary Tuberculosis (EP-TB) and research. The RNTCP provides additional human resources, equipments and trainings to C & DST laboratories.

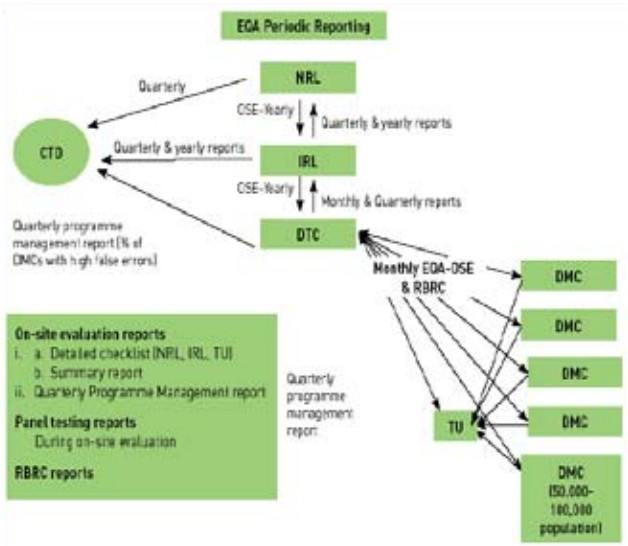
Designated Microscopy Centre (DMC): The most peripheral laboratory under the RNTCP network is the DMC which serves a population of around 100,000 (50,000 in tribal and hilly areas). Currently all the districts in the country are implementing EQA. For quality improvement purposes, the NRL OSE recommendations to IRLs and districts are discussed in the RNTCP laboratory NRL coordination committee meetings and National Expert Committee for Diagnosis and Management of Tuberculosis. Quality improvement workshops for the state level TB officers and laboratory managers are conducted at NRLs based on the observations of the NRL-OSEs. These workshops focus on issues such as human resources, trainings, AMC for binocular microscopes, quality specifications for ZN stains, RBRC blinding and coding issues, bio-medical waste disposal, infection control measures etc.

External Quality Assurance

The Quality Assurance activities include:

- On-Site Evaluation (OSE),
- Panel Testing –(PT)
- Random Blinded Rechecking (RBRC)

The schematic representation of the EQA reporting process is shown in the diagram.



The National Expert Committee on Diagnosis and Management of Tuberculosis under RNTCP is a merger of the National Laboratory Committee and National DOTS Plus Committee. This expert committee provides technical guidelines for diagnosis and management of all forms of Tuberculosis.

At present under the program there are 64 RNTCP certified Culture and DST laboratories in the country which includes laboratories from Public sector (IRL, Medical College), Private and NGO laboratories. The breakup of these laboratories by technology is given below:

- **Solid Culture Certification:** 45 laboratories certified for solid C & DST.
- 6 NRLs (NTI-Bangalore, NIRT-Chennai, JALMA-Agra, NIRTD- New Delhi, BMHRC-Bhopal and RMRC-Bhubaneswar)
- 22 IRLs (Hyderabad, Raipur, Delhi, Ahmedabad, Karnal, Ranchi, Thiruvananthapuram, Goa, Nagpur, Indore, Dharampur, Cuttack, Puducherry, Ajmer, Lucknow, Kolkata, Dehradun, Chennai, Pune, Jammu , Srinagar and Patiala)
- 7-Medical colleges (PGIMER-Chandigarh, AIIMS-Dept. of Medicine-New Delhi, JJ Hospital-Mumbai, SMS- Jaipur and MGIMS-Wardha,

MPSMS, Jamnagar; B J Medical College, Pune)

- 4 NGOs (BPHRC-Hyderabad, Choithram Hospital - Indore and DFIT Nellore, SVIMS-Tirupati)
- 4 -ICMR institutes (RMRC-Port Blair, RMRC Dibrugar, DMRC Jodhpur and RMRC- Jabalpur)
- 2 Private laboratories (CMC-Vellore and Microcare- Surat)

The proficiency testing for solid is in progress for 5 IRLs (Assam, Karnataka, Manipur, and Arunachal Pradesh,) for RNTCP certification. RNTCP also encourages the Laboratories from Medical Colleges, ICMR, Private sector and NGO sector to apply for certification by providing technical assistance and training of the human resources at National Reference Laboratories.

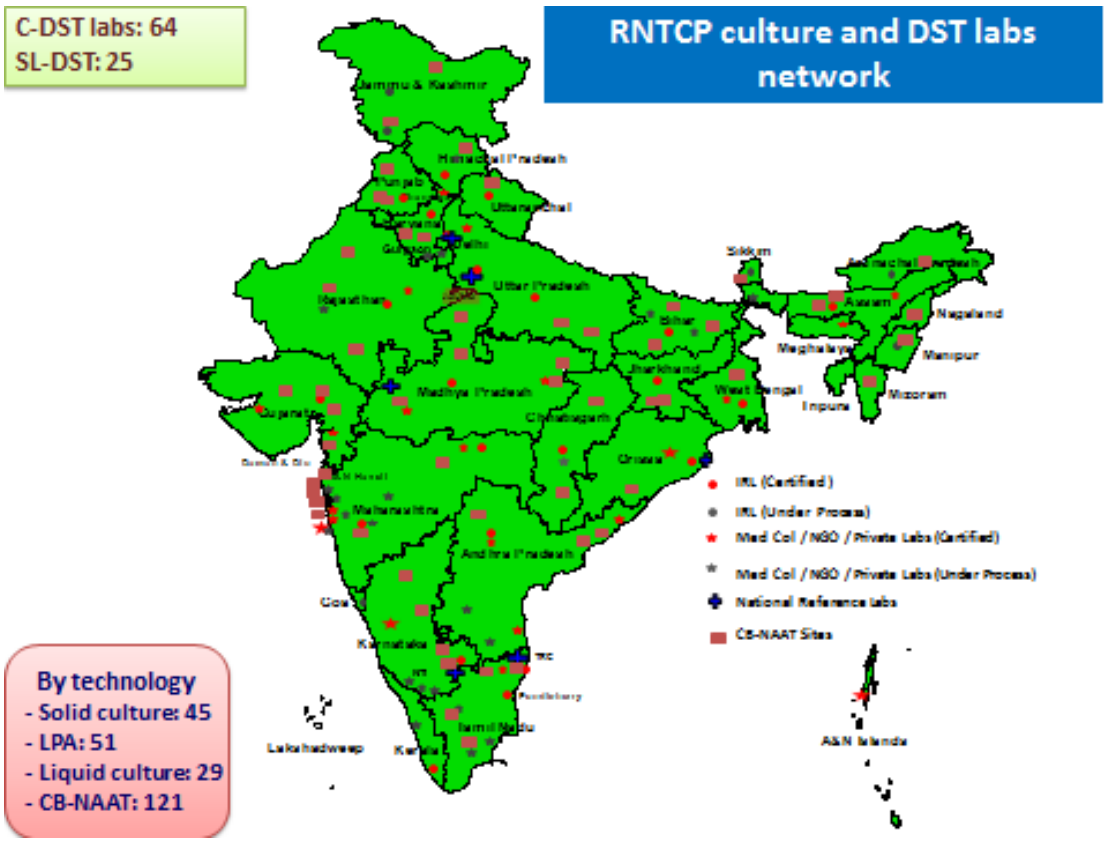
- Liquid Culture Certification: 28 laboratories certified by RNTCP for liquid culture.
- 4 NRL (NTI, Bangalore, NIRT-Chennai, JALMA - Agra and NITRD-New Delhi)
- 14 IRLs (Ahmedabad, Kolkata, Nagpur, Delhi, Trivandrum, Puducherry, Bangalore, Pune, Indore, Chennai, Cuttack, Guwahati, Lucknow and Hyderabad)
- 5 Medical Colleges (SMS Jaipur, MPSMS Jamnagar, JJ Mumbai, AIIMS Medicine, PGI Chandigarh)
- 4 Private laboratories (Metropolish, SRL-Mumbai, SRL –Kolkata, Shankar Nethralaya-Chennai)
- 1 NGO Laboratories (P D Hinduja- Mumbai)

Proficiency testing for liquid culture is ongoing for other IRLs and C & DST labs) for certification. RNTCP is in process of establishing 40 Bio safety level-3 laboratories for liquid culture as per laboratory scale up plan for liquid culture in selected Intermediate Reference laboratories and C & DST laboratories at Medical Colleges.

- Line probe Assay (LPA): The Line Probe Assay is a molecular diagnostic test which can provide the DST results within one day. RNTCP has completed the demonstration and evaluation phase in selected laboratories and based upon the evidence adopted the policy for rapid diagnosis of MDR-TB by LPA. Total 51 laboratories are certified by RNTCP.
- 6 NRLs (NTI-Bangalore, NIRT-Chennai, JALMA -Agra , BMHRC-Bhopal and NITRD- New Delhi, RMRC Bhubaneswar)
- 24 IRLs (Guwahati, Hyderabad, Delhi, Dehradun, Ahmedabad, Karnal, Raipur , Ranchi, Thiruvananthapuram, Nagpur, Pune, Patna, Indore, Cuttack, Chennai, Puducherry, Ajmer, Kolkata, Lucknow, Dharampur, Bangalore , Agra, Srinagar and Patiala)
- 14 Medical Colleges (Aurangabad, Vishakhapatnam, AIIMS-Dept. Of Medicine-New Delhi , Govt. Med. College-Jamnagar, JJ Hospital-Mumbai , SMS- Jaipur, SNM-Jodhpur , NBMC-Silliguri, PGI Chandigarh , KIMS Hubli, BHU Varanasi, AMU Aligarh, AIIMS-Dept. of Laboratory Medicine-New Delhi and GTB Sewaree Mumbai)
- 5 NGOs (DFIT-Darbanga, DFIT-Nellore, BPHRC-Hyderabad, Nazerath-Shillong and P D Hinduja-Mumbai)
- 2 private laboratories (Metropolis-Mumbai and Subharti Medical College, Meerut)

The work for establishment of LPA laboratories at (GMC Bhagalpur-Bihar, GMC Madurai-Tamil Nadu, Raichur Medical College -Karnataka, Gwalior Medical College -Madhya Pradesh and IRL Jammu – Jammu & Kashmir) is in various stage and will be completed in due course of time.

Figure showing C&DST laboratory network under RNTCP



Second Line DST(SLD) : 25 laboratories that certified for SLD that includes 5 NRLs (NIRT-Chennai, NTI-Bangalore and NIRTD-New Delhi, JALMA-Agra and RMRC -Bhubaneswar.), 13 IRLs (Trivandrum, Delhi, Pune, Nagpur, Ahmedabad, Cuttack, Chennai, Puducherry, Guwahati, Indore, Kolkata, Lucknow and Bangalore); 5 Medical colleges (Jamnagar, JJ Mumbai, AIIMS Medicine, SMS Jaipur and PGI Chandigarh),1 NG0- P D Hinduja and 1 Private-SRL Mumbai) are certified under RNTCP for SLD. Baseline SLD for MDR-TB patients has been rolled out across the country by linking States and UTs to the certified laboratories. The RNTCP has plans to scale up liquid culture facilities for Second Line DST to 40 laboratories.

Training of the Human resource for Laboratories:

RNTCP's National Reference Laboratories conduct trainings of Microbiologist, Senior Laboratory Technician and Laboratory Technician in modular training in solid culture DST, EQA in sputum smear microscopy, Liquid Culture DST, Second Line DST, Preventive maintenance of Microscope.

International Centre for Excellence in Laboratory Training (ICELT): The center at NTI Bangalore is supporting training of the laboratory staff in technologies like Line Probe Assay, CB-NAAT, Liquid culture, Biosafety & safe practices in laboratories.

National Reference Laboratories Coordination Committee Meeting:

The CTD conducts NRL coordination meetings to update on the laboratory issue, newer development, discussing finding on on-site evaluation visit of IRLs and C & DST labs, study finding, and deliberate on coordination issue with state and IRLs as per RNTCP plan. NRL Coordination Committee Meeting was held

on 19th -20th May 2015 at NITRD New Delhi. The discussions included: Roles and responsibilities of the NRL and stewardship for DR-TB services, SLDST and inclusion of drugs for panel testing, DST guided treatment- pilot, Modifications in certification and recertification of laboratories under RNTCP, Recording and reporting (EQA, Quarterly Performance), Training and Retraining plan and on-site training, Planning for 300 CBNAAT machines and Annual Maintenance Contract (AMC) for lab equipment.

Newer initiatives by the RNTCP for diagnostic services:

Expanding CBNAAT Services:

The time to diagnosis of TB and Drug Resistant TB has been significantly reduced with the availability of Cartridge Based Nucleic Acid Amplification Testing, which is a rapid molecular assay that detects M. tuberculosis and Rifampicin resistance. The test is fully automated and provides results within two hours. Currently, there are 121 Machines providing services to the Programme. To enhance laboratory capacity for the diagnosis of MDR-TB and TB in special populations such as children and People Living with HIV/AIDS, 300 additional CBNAAT machines have been provided by Government of India to cover all states. With the availability of these machines all districts in the country will either have a machine or will be linked to the neighbouring district having the machine. Ten batches of National level training of trainers was organized for the State and District officials with the objective to review the sites preparation, train the state/district level officials and key technical staff as master trainers on expanding CBNAAT services , to develop operation plans to expand access to CBNAAT for diagnosis of DR TB and TB among key populations including innovative models for private sector engagement, to understand technical aspects on handling and troubleshooting on the Xpert machines and to orient on the recording reporting requirements. The schedule of the trainings conducted is as below:

SL. No	Venue	Participating states	No of Sites	Dates
1	NTI, Bangalore	Karnataka, Odisha	28	16-17 November 2015
2	NIRT, Chennai	Tamil Nadu, Telangana, Kerala, Lakshadweep, Puducherry, Andhra Pradesh	30	21-22 December 2015
3	Jaipur	Gujarat, Daman & Diu, Dadra & Nagar Haveli, Rajasthan	30	23-24 November 2015
4	Patna	Bihar	25	07-08 December2015
5	Guwahati	Tripura, Sikkim, Nagaland, Manipur, Meghalaya, Mizoram, Assam, Arunachal Pradesh	28	17-18 December 2015
6	JALMA, Agra	Uttar Pradesh, Uttarakhand	42	26-27 November 2015
7	Pune	Maharashtra, Goa	28	14-15 December 2015
8	NITRD, Delhi	Delhi, Haryana, Punjab, Chandigarh, Jammu and Kashmir, Himachal Pradesh	30	04-05 December 2015
9	Kolkata	West Bengal	25	10-11 December 2015
10	BMHRC, Bhopal	Madhya Pradesh, Chhattisgarh, Jharkhand	34	01-02 December 2015

Second line LPA Validation:

The National Committee of Operational Research has approved a study for the Validation of LPA for detecting resistance to Fluoroquinolones, Aminoglycosides (Kanamycin, Amikacin) and Cyclic Peptides (Capreomycin) in Programme Setting in India using MTBDRsl® test (Hain Lifescience). A workshop was conducted on 30th September 2015 for Laboratory In charge and Microbiologist study sites at NTI Bangalore. The sites are, NIRT Chennai, NITRD-Delhi, NDTBC-Delhi, IRL Ahmedabad and JJ hospital, Mumbai. The objectives of workshop were: to sensitize about the study protocol, study procedure, recording and reporting and supervision and monitoring. Following the workshop, site trainings were conducted and the sites have initiated sample intake for the study.

Baseline 2nd line DST services

Having covered the entire country under PMDT services the next step was towards providing universal DST, was rolling out baseline 2nd line DST. Initial experience of roll out in six states showed encouraging results in terms of interim patient outcomes. There are 25 laboratories certified for performing SLDST and other laboratories in the process of being certified. Baseline 2nd line DST services are provided across the country by linking all states and UTs to these certified laboratories.

TB Lab Bio-Safety Training:

Proper operation of diagnostic TB laboratories requires the implementation of modern biological safety (biosafety) standards. These standards target protecting laboratory personnel from infection within the laboratory (primary containment) and protecting the environment outside the laboratory (secondary containment). They also include a system for the safe shipment/delivery of diagnostic materials.

Training on TB Laboratory Biosafety was held at NTI Bangalore on the 26th and 27th November 2015. This training was organized by the Central TB Division (CTD) with the support from FIND under EXPAND TB

project. Microbiologists from 30 C& DST Labs across the country nominated by CTD participated in this training.

The training emphasized on the need and scope for bio-safety in a TB lab, risk based grading system for TB labs, understand available infrastructural, equipment and work related issues in the TB Lab for bio-safety and their importance to reduce risk of infection and safety requirements from NABL/ISO perspective.

TB Lab Management Training:

The Laboratory Management Training was organized at The Park Hotel at Hyderabad from 14-18 December 2015 jointly by CTD, FIND and NRLs under EXPAND TB Project. It was attended by Microbiologists and Technical Officers from 45 TB C&DST labs across the country. The training aimed at providing overview

of various aspects of TB Lab management through experience sharing. It covered various aspects of lab management under broader ambit of Quality Systems Essentials including Equipment management, Stock management, Sample management, Human resource management, Data management and Nikshay application, Work/activity management, Safety including bio safety management.

Comprehensive training:

It was decided in the NRL coordination committee meeting that independent training for each of the laboratory technologies need to be replaced with a comprehensive training. Following which all phenotypic and genotypic methods of Mycobacterial Culture and DST have been integrated into a single comprehensive training for laboratory personnel. From June 2015 on wards comprehensive training is being provided for all lab personnel.

List of laboratories under RNTCP certification

Sr. No	Name of the States	Sr. No of Laboratory	Name of Laboratory	Type of Technology		
				Solid	LPA	Liquid
1	Andaman & Nicobar	1	RMRC Port Blair	C	B	B
2	Andhra Pradesh	2	IRL Hyderabad	C	C	C
		3	Govt Medical College, Vishakhapatnam	P	C	
		4	BPHRC, Hyderabad	C	C	
		5	DFIT Lab, Nellore	C	C	
		6	SVIMS Medical College, Tirupati	C		
3	Arunachal Pradesh	7	IRL Naharlagun	P		
4	Assam	8	IRL Guwahati (Guwahati Medical College),	P	C	C
		9	RMRC Dibrugarh	C		
5	Bihar	10	IRL Patna	P	C	
		11	RMRI Patna	P		
		12	Central Diagnostics, Patna		P	P
		13	DFIT Lab, Darbhanga	P	C	
6	Chandigarh	14	PGI Chandigarh	C	C	C
7	Chhattisgarh	15	IRL Raipur	C	C	P
8	Delhi	16	NITRD, Delhi	C	C	C
		17	IRL Delhi (New Delhi TB Centre)	C	C	C
		18	Department of Medicine, AIIMS	C	C	C
		19	Department of Laboratory Medicine, AIIMS		C	P
		20	Department of Microbiology, AIIMS,	P		P
		21	Department of Microbiology, Safdarjung Hospital	P		
9	Goa	22	IRL Goa	C		
10	Gujarat	23	IRL Ahmedabad	C	C	C
		24	Govt Medical College, Jamnagar	C	C	C
		25	Govt Medical College, Surat	P		
		26	Microcare, Surat	C		

Sr. No	Name of the States	Sr. No of Laboratory	Name of Laboratory	Type of Technology		
				Solid	LPA	Liquid
11	Haryana	27	IRL Karnal	C	C	P
		28	Quest Diagnostics, Gurgaon			P
		29	SRL, Gurgaon			P
12	Himachal Pradesh	30	IRL Dharampur	C	C	
		31	Govt Medical College, Tanda	P		
13	Jammu & Kashmir	32	IRL Jammu (Jammu Medical College)	C		
		33	IRL Srinagar	C	C	
		34	Sher-I-Kashmir Institute of Medical Sciences Soura Srinagar			
14	Jharkhand	35	IRL Ranchi (Itki TB sanatorium)	C	C	P
		36	RIMS, Ranchi			P
15	Karnataka	37	NTI, Bangalore	C	C	C
		38	IRL Bangalore	P	C	C
		39	SRL, Bangalore			P
		40	KIMS, Hubli	P	C	
		41	KMC, Manipal		P	P
		42	JSS Medical college, Mysore	P		
16	Kerala	43	IRL Thiruvananthapuram	C	C	C
		44	Calicut Medical College,Calicut	P		
17	Madhya Pradesh	45	IRL Indore	C	C	C
		46	BMHRC, Bhopal	C	C	
		47	Choitram Hospital Indore	C		
		48	RMRCT, Jabalpur	C		
18	Maharashtra	49	IRL Nagpur	C	C	C
		50	IRL Pune	C	C	C
		51	PD Hinduja Hospital, Mumbai		C	C
		52	Government Medical College, Aurangabad	P	C	
		53	SRL, Mumbai			C
		54	JJ hospital Mumbai	C	C	C
		55	KJ Soumiya Medical college, Mumbai	P		

Sr. No	Name of the States	Sr. No of Laboratory	Name of Laboratory	Type of Technology		
				Solid	LPA	Liquid
		56	KEM Hospital Mumbai	P		
		57	Sewari TB Hospital, Mumbai	P	C	
		58	Metropolis Healthcare, Mumbai		C	C
		59	B J Medical College, Pune	C		
		60	MGIMS, Wardha	C		
19	Manipur	61	IRL Imphal, Manipur	P	P	
20	Meghalaya	62	Nazreth Hospital, Shillong		C	P
21	Orissa	63	IRL Cuttack	C	C	C
		64	RMRC, Bhubaneswar	C	C	
22	Puducherry	65	IRL Pondicherry	C	C	C
23	Punjab	66	IRL Patiala	C	C	P
		67	Govt. Medical College, Faridkot	P		
		68	Dayanand Medical College , Ludhiana		P	
		69	SRL Amritsar		P	
24	Rajasthan	70	IRL Ajmer	C	C	P
		71	SMS Jaipur	C	C	C
		72	SN Medical college, Jodhpur	P	C	
		73	DMRC Jodhpur	C		
		74	RNT Medical College, Udaipur	P		
		75	Kota Medical College, Kota	P		
25	Sikkim	76	IRL Gangtok, Sikkim	P		
26	Tamil Nadu	77	NIRT (TRC) Chennai	C	C	C
		78	IRL Chennai	C	C	C
		79	VRF Referral Laboratory, SankarNethralaya			C
		80	CMC Vellore	C		P
		81	Madurai Medical College, Madurai	P		
		82	PSG Medical College, Coimbatore	P		
		83	Trichy Medical Colleges, Trichy	P		
27	Uttar Pradesh	84	JALMA, Agra	C	C	C
		85	IRL Lucknow (CSMMU, earlier KGMU)	C	C	C

Sr. No	Name of the States	Sr. No of Laboratory	Name of Laboratory	Type of Technology		
				Solid	LPA	Liquid
		86	IRL Agra	P	C	P
		87	Sri Ram Murti Medical College, Bareilly			P
		88	IMS,Banaras Health University, Varanasi	P	C	P
		89	MLN Medical College, Allahabad	P		
		90	Subharti Medical college, Meerut		C	P
		91	JN Medical College, Aligarh	P	C	
		92	SGPGIMS., Lucknow			P
		93	RMLIMS, Lucknow			
		94	RIIMS, Etawah	P	P	
28	Uttarakhand	95	IRL Dehradun	C	C	
		96	Microbiology Department IGMC Shimla			P
29	West Bengal	97	IRL Kolkata	C	C	C
		98	SRL Kolkata			C
		99	North Bengal Medical college, Siliguri	P	C	P
		100	Bengal TB Association ,Kolkata		P	

(The UT's of D&N Haveli, Daman & Diu, Lakshwadeep and the States of Mizoram and Tripura are linked to their nearest CDST laboratories)

C: RNTCP Certified Laboratories

P: Certification in process

Chapter 3.2: Treatment of TB

Treatment of TB:

Worldwide, 9.6 million people are estimated to have fallen ill with TB in 2014. India, Indonesia and China had the largest number of cases: 23%, 10% and 10% of the global total, respective. India is implementing WHO endorsed DOTS strategy under a national programme-RNTCP. National coverage of DOTS strategy was achieved in the year 2006 and RNTCP is currently the world's largest DOT programme. Since inception RNTCP has treated more than 19 million TB patients under DOTS by utilizing a network of over 4 lakh DOT providers. This has resulted in saving more than 3.5 million additional lives. RNTCP has tested 9,21,390 presumptive DR TB cases, >1,05,000 MDR TB/ Rif resistance diagnosed and initiated >93,000 DR TB patients on treatment. The 3rd phase of RNTCP implementation started in 2012 as National Strategic Plan 2012-17 which envisions "Universal access to quality TB care".

The success rate of >85% has been accomplished by the use of standardized treatment regimens, delivered in an uninterrupted manner in patient-wise boxes, provided to patients free of cost under direct observation of a DOT provider. With an ambitious goal of providing universal access to high quality diagnosis and treatment for all TB patients (including HIV-associated and drug resistant TB) the programme has adapted new treatment strategies in light of changing global treatment guidelines, TB epidemic and knowledge gained from in country research and programme implementation.

DOT being the back bone of RNTCP, the programme is also taking measures to make it more patients friendly and flexible i.e., decentralized community based DOT with enhanced provider incentives, patient incentives especially in difficult areas, improved use of IT and telecommunication to track patients in a setting of improved web-based, case-based surveillance systems. The programme is taking cautious and informed decisions to ensure that the core elements of success to date are not lost while innovations are evaluated and incorporated into the programme.

Treatment regimen

A standardized four drug (Category –I, HRZE), six month, intermittent (thrice weekly) regimen is used to treat all new TB cases under RNTCP. The non-responders and failures of first line treatment are offered C&DST (At least Rif -Xpert MTB/Rif® or INH & Rif- Line Probe Assay). The Drug sensitive treatment experienced TB patients are treated using

a standardized five drug (Category II, HRZES), eight month and intermittent (thrice weekly) regimen.

In order to transition the country to the updated guidelines for pediatric treatment in the STCI, which follow the current WHO dosing guidelines, the government has decided to introduce a daily dosing regimen using child-friendly fixed dosage combinations (FDCs). The procurement of anti-TB drugs in daily fixed dose combination (FDC) has been initiated. Treatment with FDCs of anti-TB drugs will be in six weight bands for pediatric patients. An option for family members to provide Directly Observed Treatment (DOT) to pediatric patients has been incorporated in the guidelines

The Rif resistant/ Multi Drug Resistant TB (MDR TB) patients are treated with a standardized six drug (Category IV, Ethionamide, Cycloserine, Levofloxacin, Kanamycin, Ethambutol and Pyrazinamide), 24-27 month, daily regimen. The non-responders and failures are offered second line anti TB drug DST (Floroquinolone and aminoglycoside). The Extensively Drug Resistant (XDR) TB cases are treated with the drugs to which MTB is sensitive (Category V) for up to 30 months daily regimen.

Country expanded access to baseline 2nd line DST to all Rifampicin resistant / MDR TB cases at the initiation of treatment. The patients diagnosed with FLQ/Inj resistance are treated with modified category IV regimen whereas the FLQ/ Inj resistance among non-responders and failures of Category IV are treated with category V regimen.

Organization of treatment services under Programmatic Management of Drug Resistant TB

Treatment of Drug resistant TB is much more complex and lengthy in comparison to treatment of Drug sensitive TB and requires special care during treatment which is made more cumbersome due to adverse drug reactions. Under RNTCP, DR TB patients are treated primarily on ambulatory basis after a brief period of in-patient care at initiation of treatment. The facilities for initiating treatment are designated as DR TB centres and are normed at 1 per 10 million population across the country. The DR TB centre has a formal committee which comprises of various specialities and is the committee which decides regimens and dosages. A DR TB patient once stabilized on treatment is then referred to a decentralized identified DOT centre from where he is provided DOT. A linked DR TB centre is a decentralized clinical unit under a DR TB centre which provides treatment services but reporting lies with the parent DR TB centre

Currently there is a network of 136 DR TB centres across the country supported by 50 linked DR TB centres, district level DR TB centres and DR TB OPDs.

Outcomes:

Indian RNTCP is the world's largest DOTS programme achieving global targets of case finding and treatment success rate but the same success has not been achieved with PMDT. The treatment success rates under the programme are well below 50% (46%) with ~ 20% each death and lost to follow up. The HIV rates among Drug sensitive and Drug resistant TB are comparable at 4%-5%. The major attributable factors observed for poor treatment outcomes in the country are resistance to FLQ, Ethambutol, lower BMI and previously treatment episodes. Cumulative outcomes of 31365 MDR TB patients have been reported till date out of which 14632 (47%) have been successfully treated whereas 6811 (22%) and 6229 (20%) died and defaulted respectively

Newer initiatives

- Daily regimen for all forms of TB in five states
- Daily regimen for all TBHIV co-infected patients across the country
- Pilots for Universal access to TB care
- Bedaquiline Conditional Access Program

Please refer to the section on policy updates and new initiatives for details

4

CHAPTER

TB Surveillance in India

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TB surveillance in India with Nikshay (Case Based online software)

Background: RNTCP since implementation followed international guidelines for recording and reporting for Tuberculosis Control Programme with minor modifications. Epi-info based EPI-CENTRE software was being used for the purpose of electronic data transmission from district level upwards. Initially DOS version was in use and the programme shifted to windows version in 2007. However, the data available at district, state or national level was in aggregated form, with a lead time of >4 months, excluding private sector and neither could help much for TB burden estimation or individual case management or monitoring. To address this Central TB Division (CTD) in collaboration with National Informatics Centre (NIC) undertook the initiative to develop a Case Based Web online (cloud) application named Nikshay.

Initial Objectives:

1. Facilitate tracking and monitoring of individual TB patient
2. Automated reporting
3. Online referral / transfer mechanism
4. Eliminate lead time in reporting
5. Aid focused supervision areas
6. Database for higher analysis
7. Real-time programme management

Long term Objectives:

1. Linking the TB Database with UID (2016-17)
   a. social protection schemes
   b. e-payments / incentives

2. GIS based disease pattern studies (geographical understanding for epi-foci, using GIS for Contact tracing/identification of local / focal epidemics of MDR-TB, outbreaks investigation of XDR-TB)

This software was launched in May 2012 and has following functional components.

- Master management
- User details
- TB Patient registration & details of diagnosis, DOT Provider, HIV status, Follow-up, contact tracing, Outcomes
- Details of solid and liquid culture & DST, LPA, CBNAAT details
- DR-TB patient registration with details
- Referral and transfer of patients
- Private health facility registration and TB Notification
- Mobile application for TB notification
- SMS alerts to patients on registration
- SMS alerts to programme officers
- Automated periodic Reports
  - Case Finding
  - Sputum conversion

  - Treatment outcome
- TU and District level Programme Management

Data security / confidentiality:

Security audit of Nikshay application is done as per guidelines of Department of IT. Password protection is applicable for each level of user. Password reset facility is available at higher users in hierarchy. Access to relevant information for each user, based on defined functions.

Data quality:

Since the software do not itself generate information and almost all information is digitized from the source which exists in the programme; the inherent quality of data of the programme is transferred. Transcription errors if any are being evaluated by the programme in implementation research mode. However, Nikshay already has internal validations for most of the variables based on the logic flow and conditionality's. But a judgement of choice of stricter validations against the availability of complete and accurate information; is also an opportunity to improve processes in the programme. It started with certain mandatory fields which were defined and these now ensure completeness of information regarding those variables e.g. DOT provider details. Unwanted characters avoided at entry. Regular feedback from administrator to check bugs if any, has been established. Most importantly data point formats of Metadata and Data Standards (MDDS) have been followed in the development of this could application. In future, this will be the basis for system integration and interoperability to set an example of EMR/EHR.

Implementation challenges:

Many of the PHCs in the country do not have adequate ICT infrastructure like computer, internet connectivity and Data Entry Operator. Also intermittent electricity supply hampers the data entry and use of Nikshay. Also patient treatment cards need to be brought to TU/Block level or even at district level in certain areas for data entry. Slow internet / web connectivity in some places and incomplete treatment cards at many places also slows down the process.

However, support from NRHM in terms of ICT infrastructure and data entry operators has significantly contributed to use of Nikshay software across the country.

Ongoing progress in Nikshay:

Till 31st December 2015, over 5.5 million TB cases have been digitized.

System integration for Notification:

Currently many medical software are in use especially in private sector being used by private practitioners and hospitals to manage information on patients. API has been developed for system integration for web service to successfully receive information in Nikshay from these various medical software, so that TB notification is simplified for these private users and they do not need to separately use Nikshay application or its portal. This API has been successfully used by initiatives like UATBC and Apollo chain of hospitals for use by private sector.

Use of Tablet computers (PDA):

Mobile / Tablet version of Nikshay application has been developed and tested. This will be deployed after procurement of tablet PCs for all TB Units in the country in 2016. To ensure higher connectivity for updation of TB treatment details, Follow-up details, outcomes etc the Tablet PC / smart phone for each TB Unit (STS & STLS) would help in utilization of Nikshay and its effectiveness will be enhanced. Hand held devices will also be useful for capturing GPS coordinates of patient and facility for GIS mapping and identifying clustering and epidemic prediction. The tablets will be used by the peripheral supervisory staff for maximum patient and programme benefit. GIS based mapping of TB patients and identification of hot-spots / epidemic prediction ability will be

developed in Nikshay with predictive analytics in 2016.

Bar coded system for drugs supply chain management:

Drugs management has been a challenge in RNTCP since the beginning. Programme has devised mechanism to provide patient wise drug boxes. All these boxes of anti-TB drugs are supplied with GS-1 compliant car codes. Next module in Nikshay is being developed to use this bar coding to manage 'drug supply chain system' right from manufactures till point of consumption. The tracking of each drug box will be possible using the bar code scanners using Nikshay at GMSDs, State Drug Stores, District Drug Stores, TB Units and Peripheral Health Facilities. Each drug box will be finally linked with TB patient record. This module will help in tracking drug stocks at all level including the shelf life, also reconciliation of each box for tally with patients will be possible in 2016. This would prevent pilferage (if any) and aid in preventing stock-outs. Also, reporting on drugs will be real-time, delay in information compilation will be avoided and automation in reporting will smoothen drugs management.

Way ahead:

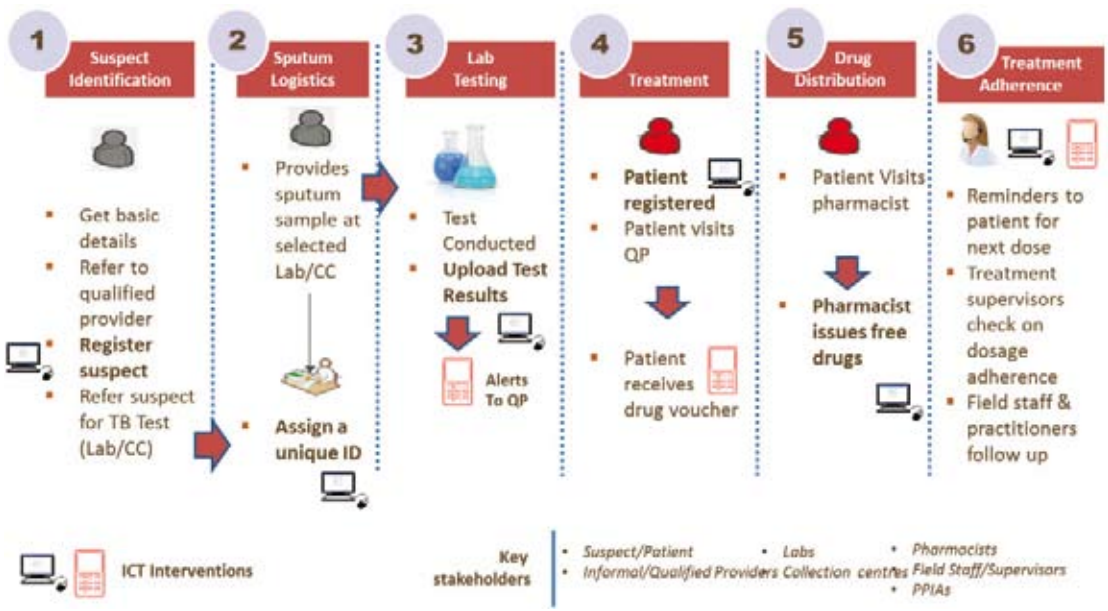
Nikshay is continuously evolving and still not yet fully developed following functionalities are planned in Nikshay which will be developed & deployed by CTD and NIC.

1. Scale-up of e-Payments to DOT Provider remuneration
2. E-Payments of salaries of contractual staff
3. Treatment Adherence with SMS gateway
4. Operational Research Proposal tracking system
5. HRD module (e-trainings)
6. Financial Management module (SOE)
7. GIS based patient mapping (epidemic prediction)
8. Call Centre for Notification support, incentives to private practitioners, linking with PDS for nutritional support, drug cost reimbursement with e-voucher

Most of these modules will be developed in 2016-17.

However, most important component of call center based Notification support system for country-

e-Nikshay enabling TB Control Programme



wide scale-up of universal access to Free TB care, including private sector will only be possible after implementation of 'e-Nikshay'.

'e-Nikshay':

Electronically enabled Commitment and Accountability for Treatment (Rx) and Empowerment of stakeholders is a ECARE proposal for enhanced NIkshay with a Goal to-

"Enhance Nikshay to engage ecosystem stakeholders towards effective, timely and quality assured diagnosis & effective treatment of TB through ICT enabled state-of-art surveillance system."

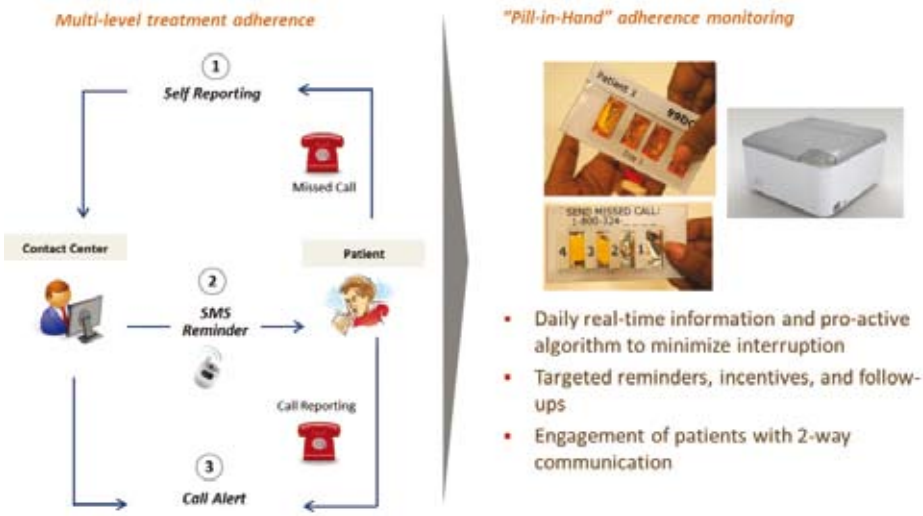
Detailed Project Report (DPR) approved by Ministry of Health & Family Welfare (MOHFW) is could not be funded previously by submitted to Department of Electronics and Information Technology (DEITY under e-Governance as a Mission Mode Project (MMP).

Now e-Nikshay is proposed to be funded under World Bank loan to RNTCP.

The key objectives of e-Nikshay are as below:

1. Establish ICT enabled state-of-art surveillance system with system utilization by 100% stakeholders by 2017
2. Ensure 100% notification of TB cases at diagnosis (microbiologically confirmed & clinical) by 2017
3. Facilitate continuous monitoring and treatment adherence for all TB patients registered with eNikshay by 2018
4. Enable tracking of all registered TB patients across TB control lifecycle, geographies, transfers and referrals by 2018
5. Ensure registration of all healthcare establishments across public and private sector by 2016
6. Ensure participation of 30% private practitioners in e-Nikshay by 2015 & 100% participation by 2017.
7. 50% reduction in patient and health system delays by 2016
8. Ensure universal access to free drugs across public and private sector by 2016.
9. Ensure 100% access to clinical decision support to frontline health workers and practitioners by 2018.
10. Enable real time & direct transfer of incentives to private providers, chemists & frontline health workers by 2018.
11. Improving treatment outcomes including case detection rates to 85% and cure rates to 90% by 2017.
12. Enabling timely nutritional support to all registered TB patients during the course of TB control lifecycle by 2018.
13. Identification of each and every TB suspect (chest symptomatic) by 2020

TB treatment adherence will be enhanced using innovations:



TB patient database in e-Nikshay will be linked with Aadhar (UIDAI) and online Public Distribution System (PDS) for transferring benefits to the TB patients; while the call center / clinical decision support contact center will be central to notification and treatment related support.

To achieve the overall goal and underlying objectives, e-Nikshay will require revision across key activities and processes. It will also result in improvement across critical service parameters and levels.

Following process reengineering will be required in addition to maximize patient benefit:

- Notification at diagnosis linked to treatment initiation
- Workflow support to remind providers, patients, and programme for collection of DST specimens
- Tracking all DR TB suspects from sending sample to initiating treatment.
- Alerts to staff and patient as soon as patient is diagnosed with MDR TB
- Accountability for treatment initiation of diagnosed results

TB Notification:

Background: India's National TB Control programme provides quality assured diagnostic and treatment services to all the TB patients including necessary supportive mechanisms for ensuring treatment adherence and completion. But these services cannot be made available to large number of patients availing services from private sector, as they are not currently reported to the programme. The National Programme is unable to support TB patients and facilitate effective treatment as there is no information on TB and M/XDR TB diagnosis and treatment in private sector and unable to monitor and act for this looming epidemic. The country has a huge private sector and it is growing at enormous pace. Private sector predominates in health care and TB treatment. Extremely large quantities of anti-TB drugs are sold in the private sector. Poor prescribing practices among private providers with inappropriate and inadequate regimens and unsupervised treatment continues in private sector without supporting patient for ensuring treatment adherence and completion with unrestricted access to first and second line TB drugs without prescription. High cost of TB and M/XDR TB drugs for privately treated patients is leading to further poverty and treatment interruptions.

A large number of patients are not benefitted with these programme services and leads to non-adherence, incomplete, inadequate treatment leading to M/XDR TB, mitigating all the efforts of the programme to prevent emergence and spread of drug resistance. If the TB patients diagnosed and treated under private sector are reported to public health authorities, the mechanisms available under the programme can be extended to these patients to ensure treatment adherence and completion. The impending epidemic of M/XDR TB can only be prevented to a large extent by this intervention.

To curb this situation, Govt of India declared Tuberculosis a notifiable disease on 7th May 2012 with the following objectives.

Objectives:

1. To have establish Tuberculosis surveillance system in the country
2. To extend mechanisms of TB treatment adherence and contact tracing to patients treated in private sector
3. To ensure proper TB diagnosis and case management and further accelerate reduction of TB transmission
4. To mitigate the impeding Drug resistant TB epidemic in the country

Implementation tools & methods:

For the purpose of notification, the contact details of the nodal officer at district level and the reporting formats are available on the website www.tbcindia.gov.in. All the health establishments throughout the country in public as well as private and non-governmental sector are expected to notify TB cases.

For the purpose of notification the definition of TB cases is as below:

- Microbiologically-confirmed TB case – Patient diagnosed with at least one clinical specimen positive for acid fast bacilli, or Culture-positive for Mycobacterium tuberculosis, or RNTCP-approved Rapid Diagnostic molecular test positive for tuberculosis.

or

- Clinical TB case – Patient diagnosed clinically as tuberculosis, without microbiologic confirmation and initiated on anti-TB drugs.

List of RNTCP endorsed TB diagnostics are as below:

Smear Microscopy (for AFB):

– Sputum smear stained with Zeil-Nelson Staining or

– Fluorescence stains and examined under direct or indirect microscopy with or without LED.

Culture:

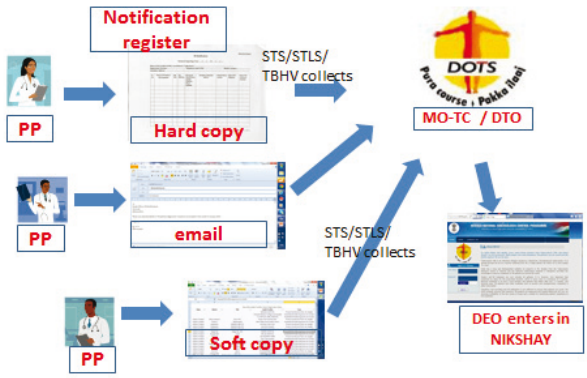
– Solid(Lowenstein Jansen) media or

– Liquid media (Middle Brook) using manual, semi-automatic or automatic machines e.g. Bactec, MGIT etc.

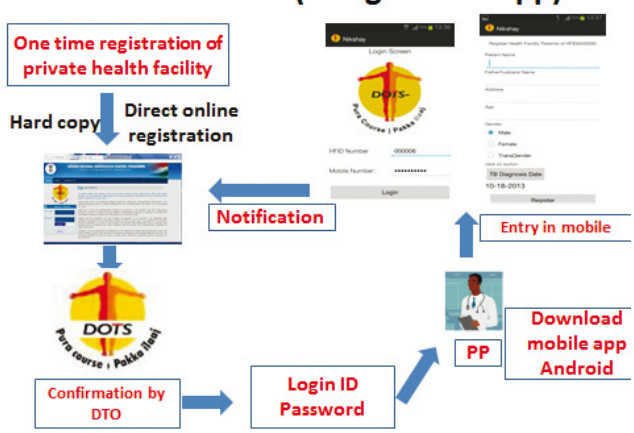
Rapid diagnostic molecular test:

– Conventional PCR based Line Probe Assay for MTB complex or

TB Notification using Nikshay



TB Notification (using mobile app)



– Real-time PCR based Nucleic Acid Amplification Test (NAAT) for MTB complex e.g. GeneXpert

Sputum Smear Microscopy (for AFB): Sputum smear stained with Zeil-Nelson Staining or Fluorescence stains and examined under direct or indirect microscopy.

Sputum Culture: Sputum culture on solid (Lowenstein Jansen) media or liquid media (Middle Brook) using

manual, semi-automatic or automatic machines e.g. Bactec, MGIT etc.

Rapid diagnostic molecular test: Line Probe Assay for MTB or Nucleic Acid Amplification Test (CB-NAAT)

Options of Notification modalities:

Option of registration and login for private facilities for TB notification indirectly in Nikshay has made available since June 2014.

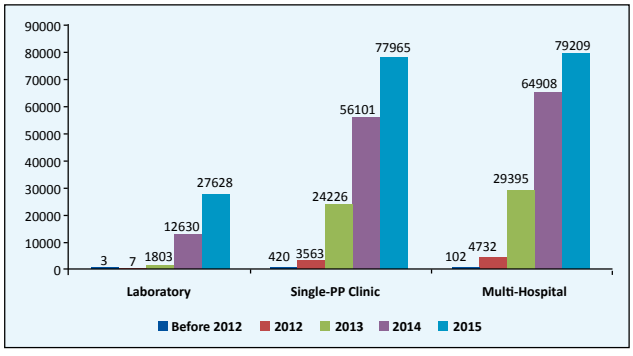
Challenges:

Sensitization of huge number of private health care providers especially with inadequate human resources is a big challenge. Also, following up notified cases as a public health responsibility in a manner acceptable to patients and the community is another challenge. Managing huge information at different levels and creating a national TB register and ensuring deduplication for converting the information in burden statement is also challenging.

However, with support of various partners like The Union, World Vision, IMA & CBCI notification is progressing.

TB notification status:

With efforts for sensitization of programme officials & staff and then subsequently to private sector, the number of private health facilities registered in Nikshay for TB notification further increased in 2015 as compared to 2014. More than 1 lakh private health facilities are registered till now. With increasing number of health facilities registered notification of TB cases also increased many fold. Till December 2015, >3.8 lakh TB cases have been notified.



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Partnerships

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Partnerships

Revised National TB Control Programme is working towards the goal of "Universal access to TB care and treatment for all" and making optimum efforts should be made to utilise the resources in the private sector. In this context an enabling environment has been created through regular interaction with partners involved in TB control and promoting innovative TB control initiatives at district and state level. RNTCP acknowledges the contribution of different partners which are supplementing RNTCP TB control services in rural and urban areas.

RNTCP through participatory consultation process has developed the National Guideline for Partnership 2014 and pilot training of trainers for PPM coordinators was carried out in Uttar Pradesh for TB control efforts involving private sector.

Indian Medical Association (IMA)

IMA PPM project started in April 2008 in five states & one union territory of India, namely Andhra Pradesh, Haryana, Maharashtra, Punjab, Uttar Pradesh & Chandigarh (UT).Subsequently 10 more states were added. Subsequently, ten more States viz. Bihar, Chhattisgarh, Gujarat, Jharkhand, Kerala, Orissa, Rajasthan, Tamil Nadu, Uttaranchal, and West Bengal were added to promote RNTCP and PPM-DOTS.

IMA GFATM RNTCP PPM Project Annual Review Meeting

The objective of this project has been to improve the access of patients availing services from the private sector to the diagnostic & treatment services of the RNTCP and thereby improving the quality care for the patients suffering from Tuberculosis, through the involvement of the IMA leaders & public sector heath staff.

The salient achievements made under the project are:

- 101579 private practitioners have been sensitized on RNTCP and STCI
- 16396 private doctors have been trained in 15 states and 1 union territory.
- 111450TB cases has been notified by the facilitation of IMA
- IMA has facilitated establishment of 1827 Private PHI

Catholic Bishops Conference of India-Coalition for AIDS & related diseases (CBCI CARD)

CBCI-CARD is a Civil Society Organisation working as a sub-recipient of the Global Fund under the Central TB Division, Government of India. The effort of the project is to involve the Catholic Health Institutions in the RNTCP program in various capacities depending on the program requirements and the institution's capability with a aim to improve access to the diagnostic and treatment services provided by the RNTCP within the Catholic Church Healthcare Facilities (CHFs) and thereby to improve the quality of care for patients suffering from tuberculosis in India.

The salient achievements made under the project are:

- 25366 TB patients were notified to district TB authorities
- 18682 Hospital & Health Centre staffs were sensitized in RNTCP
- 8634medical & paramedical personnel underwent one-day RNTCP modular trainings
- 588 DOT centres formed across 19 states of India
- 670 school health activities were organized
- 106 DMCs were established

Foundation for Innovative New Diagnostics (FIND)

FIND is the technical and implementing partner with RNTCP for the nationwide laboratory network for DR-TB service. 42 Line Probe Assay, 35 Liquid Culture and 38 Xpert facilities are established till now and four Line Probe Assay and five Liquid Culture labs will be made functional shortly. Human resource support is being provided in addition through ~ 300 lab personnel under GFATM project. Under EXPAND TB, FIND as an implementing partner supports the labs with supply of equipment and consumables procured by WHO GDF. Under GFATM, infrastructural upgrades of the labs and additional equipment for processing the specimens are also provided.

Training has been a major focus for FIND, and its key driver is the International Centre of Excellence for Laboratory Training (ICELT) established at the National TB Institute, Bangalore. With support from GLI, WHO, and with funding support from UNITAID through EXPAND TB project, this Centre has trained so far 297 lab personnel at the national level. In addition to the trainings conducted at ICELT, FIND has also provided hands-on onsite training to 2,282 lab staff.

FIND with funding support from USAID has undertaken diagnosis of Paediatric TB cases in four major cities of India, namely New Delhi, Chennai, Hyderabad and Kolkata. More than 25,430 paediatric suspects were tested by Xpert MTB/RIF and a total of 1,971 TB cases were detected out of which 178 were Rifampicin resistant. Overall, Xpert MTB/RIF positivity was 7.6% as compared to 2.1% on smear microscopy. The project is now being scaled-up to additional 5 cities of India.

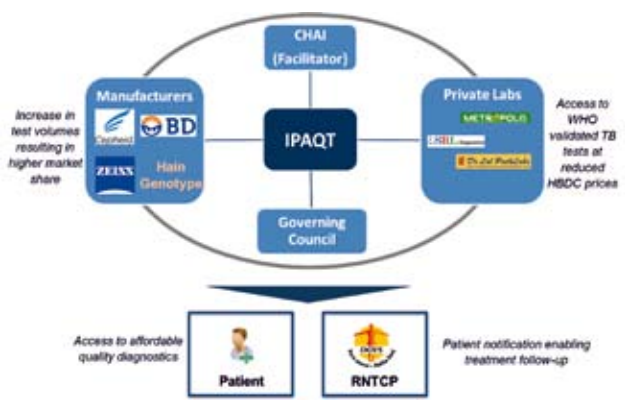
The Clinton Health Access Initiative (CHAI)

Guided by RNTCP's vision for TB control in India, CHAI collaborates and support the program in operational and analytical aspects of PMDT scale up. CHAI is committed to increasing patient access to optimal drugs and diagnostics through data-driven insights by working with the program on several tools and insights on areas such as stock management, analysis of the efficiency of the sample collection and result delivery process to support further increase in patient enrolments.

- CHAI has partnered with private sector labs and RNTCP to improve access to quality TB diagnosis in

the private sector via the "Initiative for Promoting Affordable and Quality TB Diagnostics" or IPAQT. IPAQT has a strong pan-India presence with a network of 112 labs that have 5,500+ collection centers and provide a geographic coverage of ~85% of Indian districts. Under this initiative, participating laboratories, have committed to offering quality WHO-endorsed TB tests at or below agreed upon ceiling price to the patients, discontinuing use of sub-optimal TB tests and notifying all positive cases to the government so that a linkage to quality treatment can be established. CHAI launched a pilot program in October 2014 across five cities called Demand Generation and Notification Effort (DENOTE) to establish a network of on-ground field officers responsible for increasing provider awareness on the need for quality TB diagnostic tests, their associated benefits, availability at affordable prices at IPAQT labs and notification of privately diagnosed patients in these cities to RNTCP.

- A total of 6380 Doctors sensitized trough 39 CMEs across multiple cities (March 2013 – November 2015
- 20371 TB cases notified between October 2014 to October 2015
- 1716 doctors sensitized through in-clinic visits by DENOTE field team between October 2014 to October 2015



World Vision India (WVI)

World Vision India (WVI) and its six Civil Society partners namely ADRA India, Care India, GLRA India, Lepra India, SHIS, TB Alert have been implementing Project Axshya with special focus to difficult-to-reach and low-performing areas of 8 states of India like Andhra Pradesh, Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Orissa, Telengana & West Bengal with assistance of Global Fund. The key interventions of the project involve engaging local grass-root level CBOs and community care givers in TB control and care, linking them with RNTCP through advocacy, capacity building and mobilization activities and strengthening health systems. The key achievements of the project are:

- The project reached 41179 villages and generated TB awareness. 24390 RNTCP & health staff developed their communication & soft skill and 398 HIV Project Managers & knew about TB with the help of the project. The project retrieved 9538 defaulter cases
- The project trained 15584 rural unqualified healthcare providers (RHCPs), 2203 members of district level PLHIV networks on TB including CBOs (mostly women SHGs), small & medium size industries, school-children and conducted TB awareness cum screening camps mostly in difficult-to-reach areas. 2956 villages (out of 13475 villages) developed TB action plan with the help of the project
- The project had referred 240974TB presumptive cases to the DMCs, out of which 193785 got tested, 20728 TB cases were detected and 19175 were put on DOT within 7 days of diagnosis

The International Union Against Tuberculosis and Lung Diseases (The Union)

Project 'Axshya' (meaning TB-Free) is being implemented by The Union South East Asia Office (USEA) since April 2010. The Union has

been working in partnership with 8 sub-recipient partners, over 1000 local NGOs and nearly 15000 community volunteers. The key achievements of the project are:

- The project has introduced an innovative intervention for early diagnosis and treatment initiation through Axshya SAMVAD (Sensitization and Advocacy in Marginalized and Vulnerable areas of District) .During Jan-Sep 2015, over 2.9 million households in vulnerable areas have been reached resulting in identification and testing of over 85,000 TB symptomatics and over 6,100 patients being diagnosed with TB and put on DOTS
- The project is also facilitating testing of TB symptomatics who are unable to reach diagnostic centres through sputum collection and transportation services. Over 170,300 TB symptomatics benefitted from the sputum collection and transportation services during this period.
- A toll free TB helpline (number- 18001022248)' has been initiated in the states of Punjab, Karnataka and Maharashtra. The helpline was launched on World TB Day, 23rd March 2014. Till date 6,261 calls have been answered from the helpline which include 5,323 calls in-bound calls and 938 out-bound calls.
- To address the high loss to follow up amongst the drug resistant TB (DR-TB) patients Axshya has initiated a pilot offering counselling services to facilitate treatment adherence of DR-TB patients (MDR and XDR-TB) across 30 districts in the country.
- The project has introduced the concept of Axshya Villages (TB Free Village) under which the Axshya team identifies villages in the vulnerable and marginalised communities and undertakes interventions to sensitise all the residents about TB and engage them in TB control efforts. The project has so far identified nearly 8700 such villages.

Community Pharmacist Project

Under a MOU signed between Central TB Division and Indian Pharmaceutical Association, Pharmacy Council of India, SEARPharma, All India Organisation of Chemist and Druggist retail pharmacists are being

engaged in RNTCP to work for DOTS provision, referral of TB cases, counselling and awareness generation. Training is carried out by District/City TB Officer along with IPA and Chemist Association. In last one year, total 510 pharmacists have been trained in Maharashtra Madhya Pradesh, Goa, Uttarakhand and Tamilnadu.

Involvement of Medical Colleges in RNTCP (Task Force Mechanism)

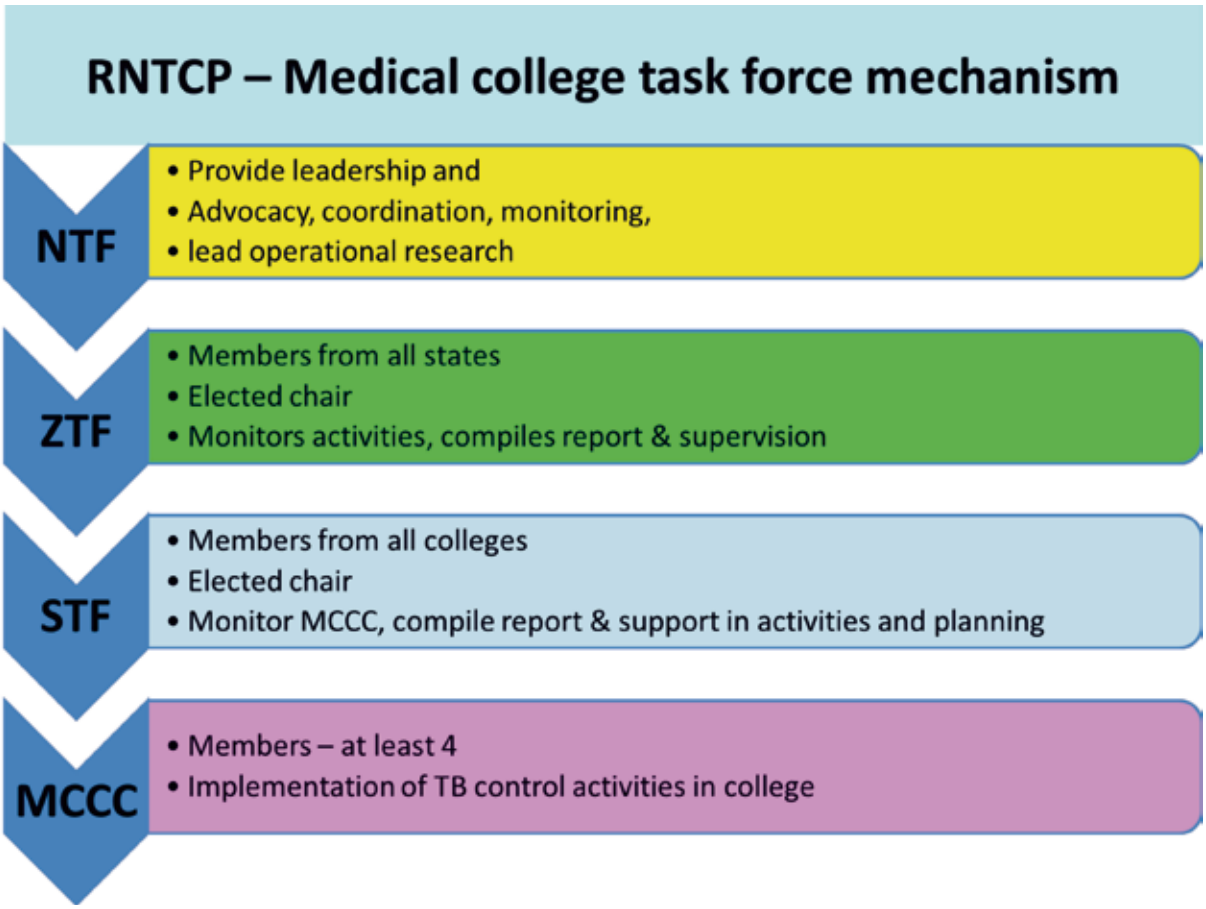
Involvement of medical colleges in the RNTCP is a high priority. Continuing success of RNTCP requires involvement of all large providers of health care including medical colleges. Under RNTCP Medical Colleges play important roles in service delivery, advocacy, training and operational research.

Evolution of Medical College involvement in RNTCP

A consensus conference in 1997, attended by leading medical professors throughout the country and subsequent national workshops at AIIMS and

National Tuberculosis Institute, Bangalore in 2001, lead to growing professional consensus among public health and medical opinion leaders , that the RNTCP approach is appropriate and feasible.

Subsequent to that increasing number of medical colleges are participating in the programme as tuberculosis units, microscopy centers, treatment observation centres, etc. The initial period saw 7 nodal centres in different parts of the country which facilitated in the development of the State and Zonal task forces and involvement of the individual medical colleges through the State task forces. The



involvement includes the presence of medical college core committees at each medical college, State Task Forces with representation from medical colleges, Zonal Task forces and National Task Force.

Each Medical College is provided with a Medical Officer, Lab technician and a TB Health Visitor to facilitate the RNTCP activities through the respective District Health Societies. The logistics for the laboratory and all the reporting formats are provided by RNTCP.

In India, more than 360 out of about 390 medical colleges are involved (formation of core committee, DMC and DOT Center) under RNTCP. The annual Zonal Task Force (ZTF) CMEs cum Workshops are held every year. For the year 2015 the ZTF Workshops were held between November 2015 – January 2016 for all the Six Zones in India.