



सत्यमेव जयते

GOVERNMENT OF INDIA

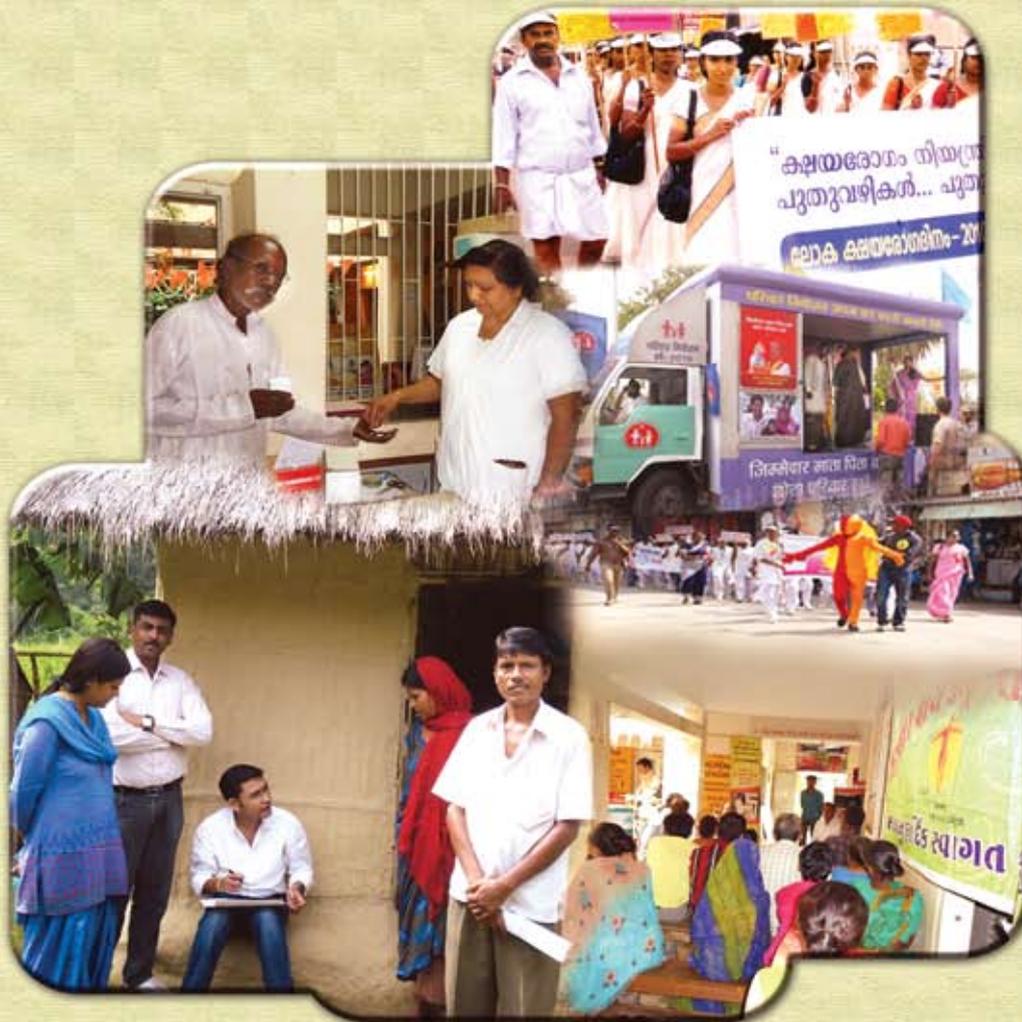
Central TB Division

Directorate General of Health Services

Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi - 110 108

TB INDIA 2011

Revised National TB Control Programme ANNUAL STATUS REPORT



ON THE MOVE AGAINST TUBERCULOSIS

Transforming the Fight

TOWARDS ELIMINATION



Repositioning DOTS Logo

The focus of DOTS communication during the Stage-I of the communication was to create awareness about DOTS as the sure cure for TB.



DOTS provides a sure cure for tuberculosis and is available free of cost to the patient. But the entire strategy to combat tuberculosis becomes ineffective if the patient does not have the will and patience to complete the course, which spans to 6-8 months. The visual icon of DOTS represents this major communication shift.

The visual icon, when deciphered, presents a graphic of human anatomy divided in two parts – half red and half orange. While the orange part symbolizes the diseased state, the red represents healthy metabolism. On the other level, the icon suggests a transition from the state of tuberculosis to a healthy life, which is the very promise of DOTS.

Rationale for new Logo

Approach to the Creatives is Two-Pronged:

1. Continuity
- 2 Change

1. Building on Existing Foundation

Through a consistent communication for over last six years, a lot of awareness has been created about tuberculosis – about its cause, symptoms and cure, as well as various misconceptions and stigmas attached to it. The net outcome is that today people are more educated about the disease and less people fear it now than was the case a few decades ago. By generating confidence about DOTS as the sure cure for tuberculosis, the communication has ensured awareness that TB is not a death sentence and is curable.

While the expanse of awareness has widened to new scales and the communication has penetrated to deeper levels, there are still areas of tuberculosis education that remain untouched. TB as a challenge has now assumed a new dimension in the form of MDR-TB (and XDR-TB) and co-infection with HIV.

This needs a new thrust on the ongoing communication, building on the DOTS education that has been generated so far. It needs, at the same time, a strategic shift in the message to deal with these new complexities.

2. Change, with Continuity

To meet the emerging challenges regarding tuberculosis and its manifestations in the form of MDR TB, the communication has been taken to a new level. The message 'DOTS: Sure cure for TB' has been given a logical extension by saying;

'DOTS: Pura course, pakka ilaaj.'

The element of 'Hinglish' is to bring some freshness into a communication that has been around for a long time. The visual element in the old logo has been retained for the new one, as the old logo had already successfully established a connect with communities.



This new logo of RNTCP will be in use from World TB Day 2011.



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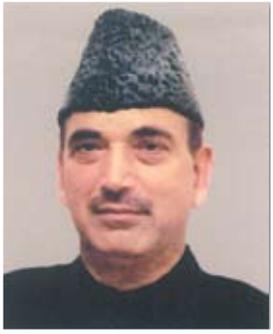


गुलाम नबी आज़ाद
GHULAM NABI AZAD



स्वास्थ्य एवं परिवार कल्याण मंत्री
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FOREWORD



India has the highest burden of Tuberculosis (TB) in the world, accounting for approximately one fifth of the global incidence – an estimated 2 million cases annually. TB is a curable and preventable disease and yet it causes significant morbidity and mortality, which is a cause of serious concern. The Revised National Tuberculosis Control Programme (RNTCP) has completed 13 years of its implementation with four years of full nation-wide coverage. Since its inception the programme has initiated over 12.6 million patients on treatment thus saving more than 2.2 million lives. RNTCP has definitely made strong strides towards achieving the Millennium Development Goals of relating to the prevalence and mortality due to TB by 2015 as compared to the 1990 levels. In 1997, when the programme was initiated, an estimated 5 lakh deaths occurred due to TB each year in the country, in 2010 estimated deaths stood at 2.8 lakh. Population surveys conducted by Tuberculosis Research Centre, Chennai, in a sub-district population in Tamil Nadu, show a 12% annual decline in prevalence of TB disease after implementation of RNTCP services. Since 2007 the programme is achieving the global targets of 70% case detection and 85% cure rates in new smear positive patients. These are encouraging trends for RNTCP as it steadily works towards achieving the Millennium Development Goals (MDGs) by 2015. The ultimate goal of the programme remains a “TB-free India”, and clearly it is a long journey towards this goal.

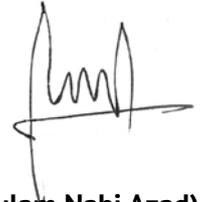
RNTCP is now moving beyond the objectives of 70% case detection rate and 85% cure rate in new smear positive patients, so that all TB patients have access to good quality diagnostic and treatment services. Further, the programme has initiated actions to address the challenges of Multi Drug Resistant-TB (MDR-TB) and TB-HIV co-infection. Though the key focus of the programme is to prevent the emergence of drug resistance by provision of quality DOT services, the management of Multi Drug Resistant-TB (MDR-TB) patients is considered as a ‘standard of care’ issue and is being undertaken in DOTS-plus services. The programme has established 19 accredited Culture and Drug Sensitivity Test laboratories including 4 National Reference Laboratories, 10 State level Intermediate Reference Laboratories and 5 other sector laboratories for the diagnosis and follow-up of MDR-TB patients. 29 such labs are in the process of being accredited. All such laboratories would also be equipped with some of the latest diagnostic tests such as the Line Probe Assay, liquid culture etc. The DOTS plus services which were initiated in 2007 in Gujarat and Maharashtra have now been scaled up to the states of Andhra Pradesh, Delhi, Haryana, Kerala, West Bengal, Tamil Nadu, Rajasthan, Daman-Diu, Orissa and Jharkhand. All states are expected to initiate DOTS-plus services by 2012. Till date 140 districts with over 287 million population has been covered with DOTS Plus services. Over 15700 MDR-TB suspects have been examined and over 2985 MDR-TB patients initiated on treatment up to Sep '10.

The other major challenge faced by the programme is TB-HIV co-infection. To address this challenge, RNTCP and National AIDS Control Programme (NACP) have jointly drafted ‘The National TB-HIV framework’, which articulates the policy of TB/HIV collaboration in the country. Coordination mechanism have been established at the National, State and District levels for regular monitoring and joint review of the collaborative activities. As per the frame work, all clients attending HIV care settings are to be screened for TB and all TB patients are to be offered HIV counseling and testing. This leads to early diagnosis of HIV-infected TB patients, who then are linked to RNTCP & NACP for treatment of TB and HIV care and support including ART (anti retroviral therapy) and CPT (co-trimoxazole preventive therapy). The TB/HIV collaborative activities have been hailed as successful by the joint monitoring mission conducted in 2009.

We have come a long way over the last thirteen years and the achievements of RNTCP make us really proud. But I would like to emphasize that the irrational and unsupervised use of first and second line anti-TB drugs for

the treatment of TB patients is threatening the progress made by the programme and needs to be actively discouraged. At the same time it is very essential that quality DOTS services are able to reach each and every TB patient in the country.

On the occasion of publication of the eleventh annual report of RNTCP, I would like to congratulate all those involved in TB control efforts across the country for all their hard work and commitment to achieve the goal of a TB-free India. I, in my personal capacity, and my Ministry are fully committed to support this noble mission of TB control efforts and urge all to continue your efforts with same vigour and zeal to achieve the goal.



(Gulam Nabi Azad)

Union Minister for Health & Family Welfare

March 2011

K. Chandramouli

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MESSAGE

Tuberculosis, a disease that dates thousands of years, is a challenge in India even today, with high morbidity and mortality rates. Despite it being curable, the burden of TB bears heavy on our Nation in terms of lives lost in their prime and life stress on account of inability to work.

Being the managers of the largest TB control programme in the world, it is not accidental that India has the most diverse experience in this field. The Revised National Tuberculosis Control Programme has been innovative and community-responsive in its approach, as can be seen by the nation-wide recognition of "DOTS" representing a sure cure for TB.

In this moment I acknowledge the enormous management challenge the RNTCP faces, in particular with the scale up of services of DOTS Plus and TB-HIV services across the nation, along with the sustenance of an established DOTS programme. The rich technical capacity of the RNTCP and political commitment from the Government of India towards a "**TB-free India**," will ensure that the programme is able to overcome these challenges successfully.

I believe, serving for TB Control is a rare opportunity to serve the economically and socially disadvantaged and bring about a substantive social change in India. And as the programme moves towards its new objective of **Universal Access** for quality diagnosis and treatment of all TB patients, it will contribute to developing a healthy and economically productive population.

The Annual Report on TB Control Activities in India published every year, is a very important historical document for national and global TB control efforts. This report describes not just progress achieved in the previous year but showcases inspiring success stories from the community, and the way forward for the programme. The RNTCP Annual Report "TB India 2011" is in your hands.

I am privileged to be associated with the RNTCP and wish all success to this national programme, as well as the entire team committed to this noble cause.


K. Chandramouli
16/3/11



National Rural Health Mission



Vision and Future of RNTCP: Universal Access - “Reaching the Unreached”

TB control efforts in India have achieved notable gains in the past decade. Since achieving national coverage in 2006, the twin objectives of RNTCP (70% case detection rate and 85% treatment success rate) have been achieved consistently for the past 4 years. Since its inception, the programme has initiated over 12.8 million patients on treatment, thus saving more than 2.3 million additional lives in comparison to earlier programme. Over the years, RNTCP has implemented most of the additional components of the WHO Stop TB strategy - including TB/HIV, management of drug resistant TB, engagement of NGO and Private sectors, Infection control and Operational Research. There is evidence on the effectiveness of the RNTCP DOTS programme on significantly decreasing the burden of TB in the community from the collaborative TRC/WHO MDP project area in Tiruvullar district, Tamil Nadu. There is an annual decline of 12.3% in prevalence and of 5.3% in ARTI since the implementation of RNTCP in 1999. National ARTI Survey conducted 2000-03 showed that the Annual Risk of TB Infection (ARTI) in the country has reduced from 1.7 to 1.5. Further impact studies are under progress. Recognizing the opportunity to accelerate TB control further, RNTCP is in the process of developing the next phase of the project for 2012-17.

The vision of the Government of India is for a “TB-free India” until it is no longer a major public health problem. To achieve this vision, the programme has now adopted the new objective of Universal Access for quality diagnosis and treatment for all TB patients in the community. This entails sustaining the achievements of the programme to date, and extending the reach and quality of services to all persons diagnosed with TB. In particular, by end-2015, the programme aims to achieve the following:

- ◆ Early detection and treatment of at least 90% of estimated TB cases in the community, including HIV-associated TB;
- ◆ Initial screening of all re-treatment smear-positive TB patients for drug-resistant TB and provision of treatment services for MDR-TB patients;
- ◆ Offer of HIV Counseling and testing for all TB patients and linking HIV-infected TB patients to HIV care and support;
- ◆ Successful treatment of at least 90% of all new TB patients, and at least 85% of all previously-treated TB patients;
- ◆ Extend RNTCP services to patients diagnosed and treated in the private sector.

The programme plans to achieve this by deploying new rapid diagnostics, expand services for management of MDR-TB, closely co-ordinate with NACO in achieving the TB-HIV national scale-up, strengthen urban TB control, strengthen PPM initiatives in addition to improving the quality of basic DOTS services and aligning with NRHM supervisory structures.

Dr. R. K. Srivastava



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PREFACE

The Central TB Division has been publishing the Annual Status Report on the Revised National TB Control Programme (RNTCP) and the same is released at the occasion of World TB Day on 24th March every year.

The main purpose of this Annual Status Report on RNTCP is to provide a comprehensive and up-to-date assessment of TB control activities in India and progress made at district, state and country level.

The Eleventh edition of "Annual Status Report on RNTCP 2011" provides an overview on the burden of the disease, programme implementation, state and district wise performance indicators and success during the calendar year 2010. It also provides updated information on recent advances in the programme. The Central TB Division whole heartedly appreciates the dedicated efforts made by the concerned authorities and functionaries of all the 35 States/ UTs as well as various experts towards facilitating the efficient implementation and achieving the objectives of RNTCP in our country.

The Central TB Division is also thankful for the invaluable contributions and collaboration of the multilateral & bilateral agencies and donors like Global Fund, World Health Organization, World Bank, USAID, BMGF, UNION, World Vision, FIND, PATH to name a few of the many other non-governmental agencies and institutions; in sharing their resources and expertise in helping RNTCP which is being recognized as one of the best disease Control programme not only in the country but also globally.

This Annual Status Report is a Reference Material on RNTCP. The information contained in the report will prove useful to policy makers, programme implementers, health administrators, researchers and academicians as well as to the community at large for providing better services for care and control of TB in our country. We at Central TB Division thank our esteemed readers for popularizing the document and solicit their suggestions and valuable comments for improving the future editions.

We are grateful to all the authorities, officers & staff of the Ministry of Health and Family Welfare and DteGHS, Govt. of India for their continued support to RNTCP for its efficient implementation. We also appreciate Dr. L.S. Chauhan, the former Deputy Director General (TB) who committedly steered the RNTCP till early February 2011.

(Dr. Ashok Kumar)
16th March 2011



TB is fully curable with complete course of DOTS

Abbreviations

ACSM	Advocacy, Communication and Social Mobilisation	DTC	District Tuberculosis Centre
AIDS	Acquired Immune Deficiency Syndrome	DTCS	District TB Control Society
AIIMS	All India Institute of Medical Sciences	DTO	District Tuberculosis Officer
ANSV	Annual Negative Slide Volume	E	Ethambutol
ART	Anti Retroviral Therapy	EPTB	Extra-pulmonary Tuberculosis
ARTI	Annual Risk of Tuberculosis Infection	EQA	External Quality Assessment
ASHA	Accredited Social Health Activist	GMSD	Government Medical Store Depot
CBCI	Catholic Bishop's Conference of India	Gol	Government of India
CDC	Centre for Disease Control and Prevention	H	Isoniazid
CDR	Case Detection Rate	HBCs	High Burden Countries
CGHS	Central Government Health Scheme	HIV	Human Immuno Deficiency Virus
CHAI	Catholic Health Association of India	HRD	Human Resource Development
CHC	Community Health Centre	IAC	IEC Advisory Committee
CII	Confederation of Indian Industries	ICB	International Competitive Bidding
CMAI	Christian Medical Association of India	ICELT	International Centre for Excellence in Laboratory Training
CTD	Central TB Division	ICMR	Indian Council of Medical Research
DALYs	Disability Adjusted Life Years	ICTC	Integrated Counselling and Testing Centre
DDG	Deputy Director General	IDSP	Integrated Disease Surveillance Project
DFID	Department For International Development	IEC	Information, Education and Communication
DGHS	Director General of Health Services	IMA	Indian Medical Association
DMC	Designated Microscopy Centre	IPT	Isoniazid Preventive Therapy
DOTS	Directly Observed Treatment Short Course	IRL	Intermediate Reference Laboratory
DRS	Drug Resistance Surveillance	ISTC	International Standards for Tuberculosis Care
DRTB	Drug Resistant Tuberculosis	IUALTD	International Union Against Tuberculosis and Lung Disease
DST	Drug Susceptibility Testing		

JMM	Joint Monitoring Mission	PSU	Public Sector Unit
KAP	Knowledge, Attitude and Practices	PTB	Pulmonary Tuberculosis
LT	Laboratory Technician	PWB	Patient-Wise Box
MDGs	Millennium Development Goals	QA	Quality Assurance
MDP	Model DOTS Project	R	Rifampicin
MDR-TB	Multi Drug Resistant TB	RBRC	Random Blinded Re-Checking
MIFA	Management of Information For Action	RCH	Reproductive and Child Health
MIS	Management Information System	RNTCP	Revised National Tuberculosis Control Programme
MO	Medical Officer	S	Streptomycin
MoHFW	Ministry of Health and Family Welfare	SDS	State Drug Store
MOTC	Medical Officer-Tuberculosis Control	SHGs	Self Help Groups
MoU	Memorandum of Understanding	SOP	Standard Operating Procedure
NACO	National AIDS Control Organisation	SPR	Slide Positivity Rate
NACP	National AIDS Control Programme	STC	State TB Cell
NCDC	National Centre for Disease Control	STDC	State Tuberculosis Training & Demonstration Centre
NEP	New Extra Pulmonary	STF	State Task Force
NGO	Non Governmental Organisation	STLS	Senior TB Laboratory Supervisor
NRHM	National Rural Health Mission	STO	State TB Officer
NRL	National Reference Laboratory	STS	Senior Treatment Supervisor
NSN	New Smear Negative	TB	Tuberculosis
NSP	New Smear Positive	TRC	Tuberculosis Research Centre
NTF	National Task Force	TU	Tuberculosis Unit
NTI	National Tuberculosis Institute	UHC	Urban Health Centre
NTP	National Tuberculosis Programme	UNOPS	United Nations Office for Project Services
NUHM	National Urban Health Mission	USAID	United States Agency for International Development
OR	Operational Research	WHO	World Health Organization
OSE	On-Site Evaluation	WVI	World Vision India
PHC	Primary Health Centre	XDR-TB	Extensively Drug Resistant TB
PHI	Peripheral Health Institution	Z	Pyrazinamide
PI	Protease Inhibitor	ZTF	Zonal Task Force
PLHIV	People Living with HIV and AIDS		
PP	Private Practitioner		
PPM	Public-Private Mix		
ProMIS	Procurement Management Information System Software		

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RNTCP Overview 2010

- India is the highest TB burden country accounting for one fifth (21%) of the global incidence (Global annual incidence estimate is 9.4 million cases out of which it is estimated that 2 million cases are from India). India is 17th among 22 High Burden Countries in terms of TB incidence rate. (Source: WHO global TB report 2010).
- The Revised National TB Control Programme (RNTCP), based on the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, was launched in 1997 expanded across the country in a phased manner with support from the World Bank and other development partners.
- The objectives of the programme are to
 - a. To achieve and maintain cure rate of at least 85% among New Sputum Positive (NSP) patients
 - b. To achieve and maintain case detection of at least 70% of the estimated NSP cases in the community
- Current focus of the programme is on ensuring “universal access” to good quality early diagnosis and treatment for all TB patients from which ever provider they choose to seek care.
- The program is covering the entire nation since March 2006 reaching over a billion population (1164 million) in 632 districts/reporting units. In 2008 1.51 million patients were put on treatment and in 2009 1.53 million patients and in 2010 1.52 million patients have already been placed on treatment.
- Since its inception, the Programme has initiated more than 12.8 million patients on treatment, thus saving nearly 2.3 million additional lives.
- Since 2007 programme is achieving a treatment success rate of >85% and has consistently maintained the NSP case detection rate (CDR) of >70%. In 2010, RNTCP has achieved the NSP CDR of 71% and treatment success rate of 87% which is in line with the global targets for TB control.
- Monitoring, supervision and evaluation: All states are currently implementing the ‘Supervision and Monitoring strategy’ – detailing guidelines, tools and indicators for monitoring the performance from the PHI level to the national level. The quality program implementation is ensured by frequent Internal and external evaluations. The program is focusing on the reduction in the default rates among all new and retreatment cases and is undertaking steps for the same.
- Quality assured sputum smear microscopy facilities are available through more than 13000 sputum microscopy laboratories in the health system across the country. As a result, the suspect’s examination has increased substantially from 397 per 100000 population per annum to 642 per 100000 population over the last 10 years, reaching out to the population.
- Quality assured, anti-TB drugs for the full course of treatment is provided to the patients through patient wise boxes. Decentralized treatment is provided through a network of more than

400,000 DOT providers, to provide treatment to the patients as near to their home as possible.

- The utilization of Pediatric patient wise boxes is on the increase ever since its introduction under the programme for the treatment of pediatric patients suffering from TB, since 2006. These boxes are designed according to the dosages used for different weight bands.
- The programme has now revised its categorization of patients from the earlier 3 categories (Cat I, Cat II and Cat III) to 2 categories (New and Previously treated cases) based on the recommendations of experts and endorsement by National Task Force for Medical colleges.
- Sound training materials have been developed for all categories of staff. The training materials are modular in content and a number of them have been recently revised keeping in view the new developments in RNTCP. Modular trainings ensures uniform standard and avoids possible subjectivity and bias of the trainers.
- To improve access to tribal and other marginalized groups the programme has developed a Tribal action plan which is being implemented with the following provisions:
 - a. Provision of additional TB Units and DMCs in tribal/difficult areas
 - b. Provision of TBHVs (peripheral health worker) for urban areas
 - c. Compensation for transportation of patient & attendant in tribal areas
 - d. Higher rate of salary to contractual staff posted in tribal areas
 - e. Enhanced vehicle maintenance and travel allowance in tribal areas
 - f. Studies to document utilization by marginalized groups
- Drug Resistance Surveillance (DRS) of Gujarat and Maharashtra, estimated the prevalence of Multidrug Resistant TB (MDR-TB) to be about 3% in new cases and 12-17% in retreatment cases. These surveys also indicate that the prevalence of MDR-TB is not increasing in the country.
- The programme is progressing in establishing a network of accredited Culture and Drug Susceptibility Testing (DST) Intermediate Reference Laboratories (IRLs) across the country in a phased manner for diagnosis and follow up of MDR TB patients. Currently 23 functional labs in the country, these include 4 NRLs (Tuberculosis Research Centre [TRC], Chennai, National Tuberculosis Institute [NTI], Bangalore, Lala Ram Swarup Institute of Tuberculosis and Respiratory diseases [LRS], Delhi and JALMA Institute, Agra) 12 State level IRLs (Gujarat, Maharashtra, Andhra Pradesh, Kerala, Delhi, West Bengal, Tamil Nadu, Rajasthan, Orissa, Jharkhand, Haryana and Puducherry). 7 other labs (BPRC-Hyderabad, PD Hinduja-Mumbai, CMC-Vellore, SMS-Jaipur, RMRCTe [ICMR]-Jabalpur, JJ Hospital-Mumbai, DFIT Nellore) more labs are in the process of accreditation in a phased manner.
- The RNTCP will be initiating the evaluation of the GeneXpert TB-RIF in line with the global consultation guidelines to gather evidence for use within the country in various settings including non-risk settings. This project has been funded by USAID Country mission with technical assistance from WHO India and will include 18 sub-district level settings.
- LAMP (Loop mediated isothermal amplification) is a manual NAAT that can be performed at microscopy level is currently undergoing validation by FIND in IGMS Wardha.
- The MDR TB services were initiated in 2007 in Gujarat and Maharashtra. Currently, 12 States namely Gujarat, Maharashtra, Andhra Pradesh, New Delhi, Haryana, Kerala, Tamil Nadu, Rajasthan, Daman & Diu, West Bengal, Orissa and Jharkhand are implementing DOTS Plus services. The states of Himachal Pradesh, Madhya Pradesh, Uttar Pradesh, Chhattisgarh, Uttarakhand, Karnataka and Puducherry are preparing to initiate services shortly. The rest of the states will be covered in 2011.
- At the end of the 4th quarter of 2010 the MDR TB treatment services have been scaled up to cover ~ 287 million population in 139 districts across 12 states. Since the inception of DOTS Plus services in India, a total of 19178 MDR TB Suspects

have been examined for diagnosis; 5365 MDR TB cases have been confirmed and 3610 MDR TB cases have been initiated on Category IV treatment through 20 DOTS Plus Sites.

- The “National framework of Joint TB/HIV Collaborative activities” was revised in 2009 which establishes uniform activities at ART centres and ICTCs nationwide for intensified TB case finding and reporting, and set the ground for better monitoring and evaluation jointly by the two programmes with a new monitoring framework and revised reporting formats and mechanisms. The vision is to scale up Intensified TB-HIV package in the entire country by 2012.

The year 2010 saw continued increase in the quantum of referrals between the programmes. In 2010, about 393,110 TB suspects (7.4% of all clients counseled) were referred from ICTCs to RNTCP and of them about 35,547 were diagnosed as having TB and provided TB treatment. In the same period, about 480,752 TB patients (59% of total TB patients registered in states implementing Intensified TB/HIV package) were tested for HIV and of them about 41,476 were diagnosed as HIV-infected and linked to HIV care and support including CPT and ART.

- Public Private Mix (PPM) activities: RNTCP has involved more than 1900 NGOs and more than 10,000 Private Practitioners. 150 Corporate Hospitals and 282 Medical Collages are implementing RNTCP
- The programme is having successful partnership with IMA, CBCI, PATH, The Union and World Vision India.
- Operational research (OR): OR agenda based on the RNTCP priority research areas has been developed and disseminated through www.tbindia.org. Financial provisions simplified to facilitate and encourage research in TB. National level ARTI surveys, disease prevalence surveys, besides Drug Resistance Surveillance (DRS) and Knowledge Attitude & Practices (KAP) have been undertaken to monitor the impact of RNTCP and progress towards MDG and results are expected by middle of 2011. The program will be shortly under taking large multicentric study on risk factors of relapse.

- Impact of the programme:

- a. TB mortality in the country has reduced from over 42/100,000 population in 1990 to 23/100,000 population in 2010 as per the WHO Global TB Report 2009.
- b. The prevalence of TB in the country has reduced from 568/100,000 population in 1990 to 249/100,000 population by the year 2010 as per the WHO Global TB Report, 2010.
- c. The studies on ARTI and the prevalence of TB have been completed and are currently being analyzed; the results of this study are likely to be available by June 2011.

- ACSM:

An effective advocacy, communication & social mobilization (ACSM) strategy is in place. As envisaged under the Stop TB Strategy ACSM plays a major role, in order to maintain high visibility of TB and RNTCP amongst policy makers, opinion leaders and community.

- a. Four regional level ACSM capacity building workshops were held by the program, wherein key functionaries in the field (STO, DTO, and implementing NGOs).
- b. The new R K Swamy BBDO has developed new TV and radio spots focusing on adherence to treatment and stigma reduction. New logo has also been designed '**Pura Course Pakka Ilaz**'.
- c. A training module for the private practitioners has been revised by Central TB division to update them on the technical and operational aspects of the programme. A patient information booklet (PIB) has been developed to help patient know about tuberculosis in simple terminology which is provided to private providers.

- Vision and Targets for RNTCP (2012-17):

The vision of the Government of India is for a “TB-free India” with reduction of the burden of the disease until it is no longer a major public health problem. To achieve this vision, the programme has now adopted the new approach of Universal Access for quality diagnosis and treatment for all TB patients in the community. This entails sustaining the achievements of the programme

to date, and extending the reach and quality of services to all persons diagnosed with TB. In particular, by end-2015, the programme aims to achieve the following targets:

- ◆ Early detection and treatment of at least 90% of estimated TB cases in the community, including HIV-associated TB;
- ◆ Initial screening of all re-treatment smear-positive TB patients for drug-resistant TB and provision of treatment services for MDR-TB patients;
- ◆ Offer of HIV Counseling and testing for all TB patients and linking HIV-infected TB patients to HIV care and support;
- ◆ Successful treatment of at least 90% of all new TB patients, and at least 85% of all previously-treated TB patients;
- ◆ Extend RNTCP services to patients diagnosed and treated in the private sector.

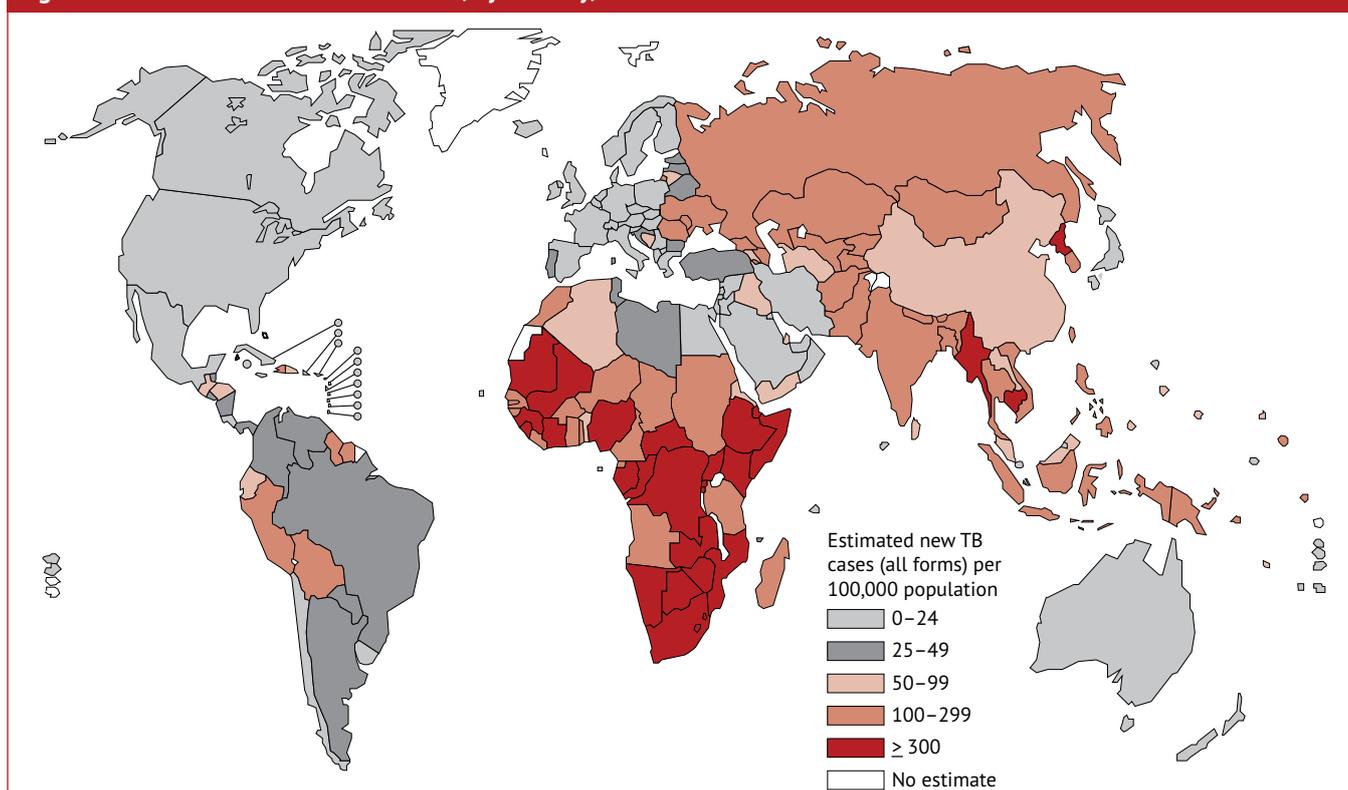
Tuberculosis Burden

Global Scenario

Tuberculosis, or TB, is an infectious bacterial disease caused by *Mycobacterium tuberculosis*, which most commonly affects the lungs. It is transmitted from person to person via droplets from the throat and lungs of people with the active respiratory TB disease. In healthy people, infection with *Mycobacterium tuberculosis* often causes no symptoms, since the person's immune system acts to "wall off" the

bacteria. The symptoms of active TB of the lung are coughing, sometimes with sputum or blood, chest pains, weakness, weight loss, fever and night sweats. Tuberculosis is treatable with a course of antibiotics.¹ It is a disease of poverty affecting mostly young adults in their most productive years. The vast majority of TB deaths are in the developing world. Left untreated, each person with active TB disease will infect on average between 10 and 15 people every year and this continues the TB transmission.

Figure 1: Estimated TB incidence rates, by country, 2009



¹ Health Topics, WHO-Geneva, <http://www.who.int/topics/tuberculosis/en/> accessed 10th Jan, 2011.

Overall, one-third of the world's population is currently infected with the TB bacillus. 5-10% of people who are infected with TB bacilli (but who are not infected with HIV) become sick or infectious at some time during their life. People with HIV and TB infection are much more likely to develop TB.² The risk for developing TB disease is also higher in persons with diabetes, other chronic debilitating disease leading to immune-compromise, poor living conditions, tobacco smokers etc.

Estimated Global TB Incidence, Prevalence and Mortality, 2009 (Source: WHO-Global TB Report, 2010)

In the year 2009, it is estimated that globally there were 9.4 million incident TB cases and there were 1.3 million TB deaths. The incidence rate, prevalence rate and mortality rate due to TB is highest in the WHO Africa region. However, in terms of the absolute number of incident and prevalence cases, South-East Asia Region has the highest TB burden globally contributing 35% to the global TB incidence.

There are 22 high burden countries which account for 80% of all estimated incident cases worldwide. The five countries that rank first to fifth in terms of number of incident cases in 2009 are India (2 million), China (1.3 million), South Africa (0.49 million), Nigeria (0.46 million) and Indonesia (0.43 million). India and China alone account for an estimated 35% of TB cases worldwide. There were an estimated 14 million prevalent cases of TB in 2009 equivalent to 164 cases

per 100,000 populations. In terms of the percentage of total deaths, TB is ranked 7th in the world accounting for 2.5 percent of all deaths as per the WHO global burden of disease estimates for the year, 2004.

TB-HIV co-infection and drug resistant tuberculosis aggravate the TB situation globally. TB is a leading cause of death in HIV infected persons and HIV infection is the most potent risk factor for developing active TB disease from a latent TB infection. Of the 9.4 million incident cases in 2009, an estimated 1.1 million (12%) were HIV-positive. Of these HIV-positive cases, 78% were in the African region and 13% were in the South-East Asia region.

Globally, the emergence of Multi drug resistant TB (MDR-TB, defined as the disease caused by TB bacilli resistant to at least isoniazid and rifampicin, the two most powerful anti-TB drugs) and Extensively Drug resistant TB (XDR-TB, defined as MDR-TB that is also resistant to fluoroquinolones and injectable classes of second-line drugs) is a major threat to TB Control. Resistance to anti-TB drugs in populations is a phenomenon that occurs primarily due to poorly managed TB care such as inconsistent or partial treatment, when patients do not take all their medicines regularly for the required period because they start to feel better, because doctors and health workers prescribe the wrong treatment regimens, or because the drug supply is unreliable or erratic. There were an estimated 440,000 cases of multi-drug resistant TB (MDR-TB) in 2008 (range, 390,000–510,000). The 27 countries (15 in the European Region) that

TABLE 1: Estimated global epidemiological burden of TB, 2009

WHO region	Incidence ^a			Prevalence ^b		Mortality (excl. HIV)	
	No. in thousands	% of global total	Rate per 100,000 pop ^c	No. in thousands	Rate per 100,000 pop ^c	No. in thousands	Rate per 100,000 pop ^c
Africa	2,800	30%	340	3,900	450	430	50
The Americas	270	2.9%	29	350	37	20	2.1
Eastern Mediterranean	660	7.1%	110	1,000	180	99	18
Europe	420	4.5%	47	560	63	62	7
South-East Asia	3,300	35%	180	4,900	280	480	27
Western Pacific	1,900	21%	110	2,900	160	240	13
Global total	9,400	100%	140	14,000	164	1,300	19

a Incidence is the number of new cases arising during a defined period.

b Prevalence is the number of cases (new and previously occurring) that exists at a given point in time.

c Pop indicates population.

account for 85% of all such cases have been termed the 27 high MDR-TB burden countries. The four countries that had the largest number of estimated cases of MDR-TB in absolute terms in 2008 were China (100,000; range, 79,000–120,000), India (99 000; range, 79,000–120,000), the Russian Federation (38,000; range, 30,000–45,000) and South Africa (13,000; range 10,000–16,000). By July 2010, 58 countries and territories had reported at least one case of extensively drug-resistant TB (XDR-TB).

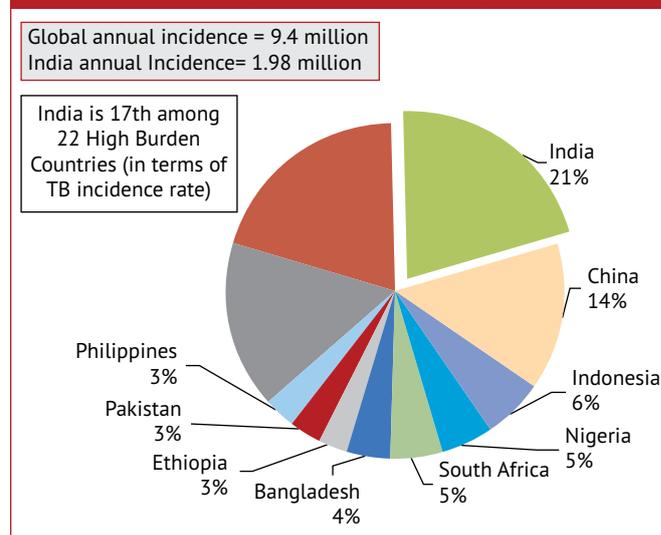
TB Burden in India

Though India is the second-most populous country in the world, India has more new TB cases annually than any other country. In 2009, out of the estimated global annual incidence of 9.4 million TB cases, 2 million were estimated to have occurred in India, thus contributing to a fifth of the global burden of TB. It is estimated that about 40% of Indian population is infected with TB bacillus. The incidence of TB in India is estimated based on findings of the nationwide annual risk of tuberculosis infection (ARTI) study conducted in 2000-2003. The national ARTI being 1.5%, the incidence of new smear positive TB cases in the country is estimated as 75 new smear positive cases per 100,000 population. The prevalence of TB has been estimated at 3.8 million bacillary cases for the year 2000, by an expert group of Govt. of India. However the recent estimate by WHO gives a prevalence of 3 million.

On a national scale, the high burden of TB in India is illustrated by the estimate that TB accounts for 17.6% of deaths from communicable disease and for 3.5% of all causes of mortality (WHO, 2004). More than 80% of the burden of tuberculosis is due to premature death, as measured in terms of disability-adjusted

life years (DALYs) lost. WHO estimated TB mortality in India as 280,000 (23/100,000 population) in 2009. With RNTCP implementation, death due to TB has come down to half in the country. It was estimated that the TB mortality was over 5 million annually at the beginning of the revised national TB control programme (RNTCP). Data from specific surveys, however, suggest that case fatality rates prior to RNTCP were generally greater than 25%. In RNTCP era, case fatality has remained less than 5% for new cases registered under the programme.

Figure 2: India is the largest TB burden country accounting for one fifth of the global incidence



India's Progress towards Millennium Development Goals (MDGs) with respect to reduction in prevalence and mortality rate

The indicator 23 of the MDGs mentions that between 1990 and 2015 to halve prevalence of TB disease and deaths due to TB.

TABLE 2: Estimated burden of tuberculosis in India

	Number (Millions) (95% CI)	Rate Per 100,000 Persons (95% CI)
Incidence		
All cases (2009 WHO estimate)	2.0 (1.6-2.4)	168
Period Prevalence (2000 Gol estimate)		
AFB positive	1.7 (1.3–2.1)	165 (126–204)†
Bacillary*	3.8 (2.8–4.7)	369 (272–457)†
Prevalence, all cases (2009 WHO estimate)	3.0 (1.3-5.0)	249

* Defined as a person with at least one AFB smear positive by sputum microscopy, or at least one sputum culture positive for *M. tuberculosis*.

† Prevalence rate calculated from estimated number of persons with disease in 2000, divided by 2000 population estimate.

TB-related Millennium Development Goal

Goal 6 – to combat HIV/AIDS, malaria and other diseases.

Target 8 – to have halted by 2015 and begun to reverse the incidence of malaria and other major diseases, including tuberculosis.

Indicators for Target 8 to be used to evaluate the implementation and impact of TB control (Derived from Stop TB Strategy):

Indicator 23: Between 1990 and 2015, to halve the prevalence and death rates associated with tuberculosis; and

Indicator 24: by 2005, to detect 70% of new smear positive TB cases arising annually, and to successfully treat 85% of these cases.

With respect to the progress towards indicator 23, as per the recent WHO estimates, in the year 1990, the prevalence rate of TB in India was 338 per 100,000 populations (best estimates) and the mortality due to TB was 42 per 100,000 populations. In comparison, in the year 2009, the prevalence of TB in India was estimated to be 249 per 100,000 populations, and the mortality due to TB is 23 per 100,000 populations [WHO Global TB Report, 2010]. These estimate are derived based on mathematical and have its own inherent limitations. Government of India has undertaken nationally representative Annual Risk of TB Infection survey and TB Prevalence surveys in 7 sites of the country. The results of these surveys will be available during the mid 2011 and are expected to provide more realistic population based estimates.

As far as the progress towards indicator 24 is concerned, the country has achieved the targets on case detection and treatment outcomes, in the year 2007 onwards (after whole country coverage).

Impact of Other Determinants of TB Burden

WHO has suggested that the expected effect of improved diagnostic and treatment services may be negated by an increase in the prevalence of risk factors for the progression of latent TB to active disease in segments of the population. A population level increase in vulnerability may tend to increase incidence despite reductions in transmission achieved under the Stop TB strategy. Broadly described, these risk factors may be biomedical (such as HIV infection, diabetes, tobacco, malnutrition, silicosis, malignancy), environmental (indoor air pollution, ventilation) or socioeconomic (crowding, urbanization, migration, poverty).

The impact of these other determinants on TB epidemiology in India has yet to be fully understood. India is clearly experiencing an epidemic of diabetes, with an estimated 20-30 million diabetics in 2000, and an estimated 80 million diabetics by 2030. Diabetes has been shown to be an independent risk factor for tuberculosis in community based study from South India and multiple studies globally. Modeling has suggested that diabetes accounts for 14.8% of all tuberculosis and 20.8% of smear-positive TB. While the HIV epidemic in India appears to have peaked, the total number of persons living with HIV/AIDS remains high, and with time the level of immune deficiency and TB vulnerability may increase. Malnutrition remains highly prevalent in India, and will remain a significant factor for years to come. India is urbanizing at a fantastic pace, bringing larger numbers of persons into urban areas with documented higher rates of TB transmission. Tobacco use is highly prevalent in India, and has been suggested to be a potent contributor to TB-related mortality. The confluence of these and other risk factors could well influence the TB epidemiology in India.

TB/HIV Co-infection

The tuberculosis situation in the country is further affected by the emergence and spread of HIV among the population. India, the third highest HIV burden country, had an estimated 2.39 million (translating to a prevalence of 0.31%) people living with HIV/AIDS (PLHAs), about 1.2 lakh new HIV infections and 1.72 lakh deaths due to AIDS related causes in 2009. The worst affected states are Andhra Pradesh, Karnataka, Manipur, Maharashtra, Nagaland and Tamil Nadu. These six states account for about 57% of PLHA in India and are classified as High Prevalence States. Another three states namely Gujarat, Goa and Puducherry have been classified as Moderate HIV prevalence states.

This is the first time HIV incidence estimates have been calculated and the 6 high prevalence states accounts for only 39% of these infections indicating new pockets of transmission in low prevalence states, emphasizing the enormous challenge ahead. The HIV epidemic pattern in the country shows great variance but 2009 estimates indicate an overall decline in HIV prevalence and incidence.

Tuberculosis is one of the earliest opportunistic diseases to develop amongst persons infected with HIV. HIV infection is the most powerful risk factor for the progression of TB infection to TB disease. An HIV positive person has many times higher risk of developing TB disease in those infected with TB bacilli, as compared to an HIV negative person.

Although the TB epidemic in the country is predominantly driven by the non-HIV positive TB cases, TB mortality could well be influenced by the TB/HIV co-infection at least in certain districts in the country with high prevalence of HIV in TB patients. It has been estimated that in 2007, about 4.85% of the incident TB cases in India were HIV-positive.

MDR and XDR-TB

The emergence drug resistant TB, and particularly MDR-TB, has become a significant public health problem in a number of countries and an obstacle to effective TB control. A large scale population based survey in the state of Gujarat and Maharashtra has indicated multi drug resistance levels of 3% among new TB cases and 12-17% among previously treated TB patients. Though the rate of MDR-TB is relatively low in India, this translates into a large absolute number of cases, with an estimated annual incidence of 99,000 cases of MDR-TB in the country.

XDR-TB has been reported in India by isolated studies with non-representative and highly selected clinical samples. The magnitude of the problem remains to be determined due to the absence of laboratories capable of conducting quality assured second line DST. However, what is frightening is the potential threat of XDR-TB in India with unregulated availability and injudicious use of the second line drugs along with non-existence of systems to ensure standardized regimens and treatment adherence for MDR-TB outside the national programme. The problem of MDR and XDR-TB in India and across the world raises the possibility that the current

TB epidemic of mostly drug susceptible TB will be replaced with a form of TB with severely restricted treatment options. If this happens it would jeopardize the progress made in recent years to control TB globally as well as in India and would also put at risk the plans to progress towards a world where TB ceases to be a public health problem.

Socio-economic Impact

Besides the disease burden, TB also causes an enormous socio-economic burden to India. TB primarily affects people in their most productive years of life with important socio-economic consequences for the household and the disease is even more common among the poorest and marginalized sections of the community. Almost 70% of TB patients are aged between the ages of 15 and 54 years of age. While two thirds of the cases are male, TB takes a disproportionately larger toll among young females, with more than 50% of female cases occurring before 34 years of age. The direct and indirect cost of TB to India amounts to an estimated \$23.7 billion annually*. Studies suggest that on an average 3 to 4 months of work time is lost as result of TB, resulting in an average lost potential earning of 20-30% of the annual household income. This leads to increased debt burden, particularly for the poor and marginalized sections of the population. The vast majority (more than 90%) of the economic burden of TB in India is caused by the loss of life rather than by morbidity. This is due to the fact that TB mortality incurs a greater loss in the number of life-years per event than does TB morbidity - despite the fact that there are many more prevalent cases than deaths. A study on the economic impact of scaling up of RNTCP



in India in 2008 shows that on average each TB case incurs an economic burden of around US\$ 12,235 and a health burden of around 4.1 DALYs. Similarly, a death from TB in India incurs an average burden of around US\$ 67,305 and around 21.3 DALYs.

A total of 6.3 million patients have been treated under the RNTCP from 1997-2006. This has led to a total health benefit of 29.2 million DALYs gained including a total of 1.3 million deaths averted. In 2006, the health burden of TB in India would have

risen to around 14.4 million DALYs or have been 1.8 times higher in the absence of the programme. The RNTCP has also led to a gain of US\$ 88.1 billion in economic wellbeing over the scale-up period. In 2006, the gain in economic wellbeing is estimated at US\$ 19.7 billion per annum - equivalent on a population basis to US\$ 17.1 per capita. In terms of TB patients, each case treated under DOTS in India results in an average gain to patients of 4.6 DALYs and US\$ 13,935 in economic wellbeing.

Universal Access to TB Care “Reaching the Unreached”

“No one ever said this would be an easy fight. We are now at the start of a road that should take us towards the achievable goal of TB elimination”

Mario Raviglione, Director, WHO Stop TB Department

WHO Stop TB Strategy and Stop TB Plan

In 2001, the Stop TB Partnership launched the Global Plan to Stop TB 2001- 2005.

World Health Organization (WHO) in 2005 developed the Stop TB Strategy as an evidence-based approach to reducing the burden of TB. Subsequently in 2006, a more advanced plan for transforming these principles into action was issued: the Global Plan to Stop TB 2006-2015. Since then the Plan has garnered the world’s confidence.

October 2010 the plan was updated with a focus on the final five years (2011-2015). Major reasons for an update were, a need to take into account actual progress made since 2006, to include the policy updates in ART and MDR-TB component, updates to estimates of epidemiological burden and trends, the importance of giving a higher profile to laboratory strengthening and the need to address the full spectrum of research (from fundamental to operational research).

The updated plan sets out what needs to be done to achieve the 2015 targets set within the context of the MDGs. To achieve these targets, the document depicts how to transform TB control in the years up to 2015 – through scaling up existing interventions for the diagnosis and treatment of TB and introducing new technologies, notably new diagnostic tests. Looking beyond the targets set for 2015, the Research and Development component of the plan shows what needs to be done to develop the new diagnostics, drugs and vaccines that are

required to revolutionize the prevention, diagnosis and treatment of TB, as the foundation for the elimination of tuberculosis in the coming decades.

Governments around the world have voiced their commitment to its key principles of achieving universal access to high-quality TB care, reducing human suffering, reaching out to vulnerable populations, protecting human rights and supporting the development and use of new tools.

World Health Organization **THE STOP TB STRATEGY**

VISION : A TB-FREE WORLD

GOAL To dramatically reduce the global burden of TB by 2015 in line with the Millennium Development Goals and the Stop TB Partnership targets

OBJECTIVES

- Achieve universal access to quality diagnosis and patient-centred treatment
- Reduce the human suffering and socioeconomic burden associated with TB
- Protect vulnerable populations from TB, TB/HIV and drug-resistant TB
- Support development of new tools and enable their timely and effective use
- Protect and promote human rights in TB prevention, care and control

TARGETS

- MDG 6, Target 6.c: Halt and begin to reverse the incidence of TB by 2015
- Targets linked to the MDGs and endorsed by Stop TB Partnership:
 - 2015: reduce prevalence of and deaths due to TB by 50%
 - 2050: eliminate TB as a public health problem

COMPONENTS

- PURSUE HIGH-QUALITY DOTS EXPANSION AND ENHANCEMENT**
 - a. Secure political commitment, with adequate and sustained financing
 - b. Ensure early case detection, and diagnosis through quality-assured bacteriology
 - c. Provide standardised treatment with supervision, and patient support
 - d. Ensure effective drug supply and management
 - e. Monitor and evaluate performance and impact
- ADDRESS TB/HIV, MDR-TB, AND THE NEEDS OF POOR AND VULNERABLE POPULATIONS**
 - a. Scale-up collaborative TB/HIV activities
 - b. Strengthen prevention and management of multidrug-resistant TB (MDR-TB)
 - c. Address the needs of TB contacts, and poor and vulnerable populations
- CONTRIBUTE TO HEALTH SYSTEM STRENGTHENING BASED ON PRIMARY HEALTH CARE**
 - a. Help improve health policies, human resources development, financing, supplies, service delivery and information
 - b. Strengthen infection control in health services, other congregate settings and households
 - c. Upgrade laboratory networks, and implement the Practical Approach to Lung Health (PAL)
 - d. Adapt successful approaches from other fields and sectors, and foster action on the social determinants of health
- ENGAGE ALL CARE PROVIDERS**
 - a. Involve all public, voluntary, corporate and private providers through Public-Private Mix (PPM) approaches
 - b. Promote use of the International Standards for Tuberculosis Care (ISTC)
- EMPOWER PEOPLE WITH TB, AND COMMUNITIES THROUGH PARTNERSHIP**
 - a. Pursue advocacy, communication and social mobilization
 - b. Foster community participation in TB care, prevention and health promotion
 - c. Promote use of the Patients' Charter for Tuberculosis Care
- ENABLE AND PROMOTE RESEARCH**
 - a. Conduct programme-based operational research
 - b. Advocate for and participate in research to develop new diagnostics, drugs and vaccines

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Addressing Stop TB Strategy Under RNTCP

RNTCP in Phase I (1997-2006) focused on high quality DOTS expansion in the country addressing the five primary components of the DOTS Strategy. RNTCP Phase II (2006-11) is in line with the new WHO Stop TB Strategy for TB control and covers all the activities proposed under the strategy. The RNTCP is collaborating with the National AIDS Control Programme (NACP) to address challenges of TB-HIV co-infection. RNTCP has developed guidelines for management of MDR-TB and has rolled out DOTS Plus services. By strengthening diagnostic and drug delivery systems, and by providing additional contractual staff, RNTCP continues to strengthen the general health system in the country. 'Practical Approach to Lung health' (PAL), a defined activity to strengthen health systems, is being piloted in the state of Kerala. In the area of involvement of all care providers, public as well as private, RNTCP has been a global leader. An effective advocacy, communication and social mobilisation (ACSM) strategy is in place, in order to maintain high visibility of TB and RNTCP amongst policy makers, opinion leaders and the community to sustain long term political and administrative commitment and greater community involvement. The international Union Against TB and Lung Disease (The Union) and World Vision under Round 9 TB Project supported by Global Fund for AIDS, TB and Malaria (GFATM) have launched intensified ACSM activities in 374 identified districts of the country.

With the active support of the Premier institutes in TB research like TB Research Centre, Chennai, National TB Institute, Bangalore and Lala Ram Swarup Institute of TB and Respiratory Diseases, Delhi, both fundamental and operational researches are taken up, which is again coherent with the Global Stop TB Plan 2011-2015.

RNTCP promotes operational researches by Post graduate students and faculty members of medical college through an inbuilt mechanism.

Political and Administrative Commitment

TB control program is one among The Government of India's top priority programs. This commitment comes as uninterrupted financial commitments,



Hon'ble Minister of Health and Family Welfare Govt of India addressing a review meeting of State Health Ministers and Secretaries being reviewed by Union Health Minister at Hyderabad

administrative support and human resource support. One of major initiative from the Govt in 2010 was the frequent review of the RNTCP by the Honorable Union Minister of Health and Family Welfare and Joint Secretary. These frequent reviews helped in ensuring sustained political commitment from the Individual States. More over this political commitment channeled resources in the states to sustain the program success.

Hon'ble Minister of Health and Family Welfare Govt. of India while addressing a review meeting of State health secretaries, Mission Directors of NRHM and Directors of health services stated that his ministry has placed TB control at high priority and exhorted all states to give special attention to the TB control programme.

Good Quality Diagnosis Through Sputum Microscopy

Sputum microscopy continues to be the primary tool for detection of infectious. However in line with



the stop TB strategy the programme is exploring all possible avenues with newer and innovative technologies for early detection of TB including use of LED microscopes.

Uninterrupted Supply of Good Quality Drugs

RNTCP uses intermittent short-course chemotherapy (SCC) regimens to facilitate the direct observation of treatment. RNTCP ensures that there is no interruption in treatment due to shortage of drugs, once a person is diagnosed with TB. Sufficient anti-TB drugs in patient-wise boxes are made available at all the appropriate levels (Peripheral Health Institution/TB unit/District/State/National). The uninterrupted supply of drugs to each patient is made possible through the "patient-wise box." Patient-wise drug boxes (both adult and paediatric) are an innovation of RNTCP wherein a box of medications for the entire duration of the treatment is earmarked for every patient registered. This ensures the availability of the full course of medication to the patient the moment s/he is registered for treatment.



Patient-wise drug boxes have helped to improve patient care, adherence, drug supply and drug stock management. Under RNTCP, all sub-centres, primary health centres, community health centres, and other health facilities provide DOTS services to patients. Since TB patients may also seek treatment from private physicians, the government has taken initiatives to provide DOTS services through the private sector and through community volunteers.

Directly Observed Treatment

Directly observed treatment (DOT) is one of the key elements of the DOTS strategy. In DOT, an observer (health worker or trained community volunteer who is not a family member) watches and supports the patient in taking drugs. The DOT provider ensures that the patient takes the right drugs, in the right doses, at the right intervals, for the right duration.

DOT thus facilitate release free cure for TB and also helps to reduce development of drug resistance, because direct observation ensures adherence.



Systematic Monitoring and Accountability

RNTCP has a systematic monitoring mechanism which accounts for/tracks the outcome of every patient put on treatment. There is a standardized recording and reporting structure in place. The cure rate and other key indicators are monitored regularly at every level of the health system and regular supervision ensures quality of the programme. RNTCP shifts the responsibility for cure from the patient to the health system.



RNTCP: Implementation Status and Activities in 2010

TB control efforts in India over the past decade have achieved notable gains. Whole country coverage under RNTCP was achieved in 2006. Since 2007, the bench marks of 70% new sputum smear positive case detection and 85% treatment success rate of such patients have been achieved. The program already has a strategic vision for TB control to achieve the TB-related UN Millennium Development Goals. Going by the trend in reduction in prevalence and mortality the program expect to achieve Millennium Development Goals by 2050. High quality implementation of RNTCP resulted from a sustained commitment from Government of India. However the programme is already responding to the emerging challenges like management of drug resistant TB, TB-HIV co-infection, migration, smoking and co-morbidities like Diabetes Mellitus. The program has recognized that all persons affected by TB deserve quality diagnosis and treatment for effective public health and equitable healthcare. Now the program is gradually shifting focus to ensure adequate TB care for all population groups. This would be achieved by increasing the access of TB services to marginalized groups in hard-to-reach areas with intensive monitoring, supervision and evaluation. One of the major policy decision taken by RNTCP in the year 2010 is to change the focus of the NSP case detection objective of at least 70% to the concept of universal access including good quality care for TB patients. Most of the states and districts have prepared universal access action plan in line with the universal access document.

Recognizing the opportunity to accelerate TB control further, RNTCP is in the process of developing the next phase of the project for 2012–2017, which seeks

to achieve universal access for quality TB diagnosis and treatment for all TB patients in the community.

RNTCP Activities 2010

The Revised National Tuberculosis Control Programme (RNTCP) has incorporated all elements of the Stop TB strategy and already covered the entire country since March 2006. Since its inception, the Programme has initiated more than 12.8 million patients on treatment, thus saving nearly 2.3 million additional lives.



RNTCP review by JS (PH) Dr Rajendra S Shukla with State Health Secretaries and Director of Health Services at Bhopal

Pursue Quality DOTS Expansion and Enhancement

The TB control strategies started in India, with the establishment of the first open-air sanatorium during the year 1906 at Tilonia near Ajmer. The Tuberculosis Association of India was established in February 1939.

As a preventive measure, Bacillus Calmette Guerin (BCG) BCG was extensively used in most of the European countries in 1920s. BCG vaccination was introduced in India by 1948. The National Sample Survey (1955 to 1958) was an eye opener, which revealed that the problem of TB was uniformly distributed, both in the urban and rural population of the country. At that time, the standard treatment for TB in India, and throughout the world, called for isolation of TB patients in sanatoria. Thereafter, in 1962 a National TB Control Program was initiated under which District TB centers were established. The NTP created an extensive infrastructure for TB control, with a network of 446 District TB Centres and 330 TB Clinics. The idea was to set up a clinic where patients could come and collect their drugs.

In 1992, the Government of India, together with the World Health Organization (WHO) and the Swedish International Development Agency (SIDA), reviewed the NTP and concluded that the Programme suffered from:

- ◆ Inadequate budget and insufficient managerial capacity
- ◆ Shortage of drugs
- ◆ Less than 40% of patients completed the treatment
- ◆ Emphasis on x-ray diagnosis resulting in inaccurate diagnosis
- ◆ Poor quality sputum microscopy
- ◆ Multiplicity of treatment regimens.

The Government of India considering the recommendations of the Review Committee, evolved a revised strategy (Revised National TB Control Programme - RNTCP) with the goal of reducing TB burden to a level where it ceases to be a major public health problem. This strategy was based on the Directly Observed Treatment – Short Course (DOTS) recommended by WHO and adopted in over 200 countries currently. The RNTCP built upon the infrastructure already established by the NTP, whilst incorporating the five core elements of the DOTS strategy viz.

(i) government commitment to sustainable TB control;
(ii) diagnosis through quality assured sputum-smear microscopy mainly among symptomatic patients reporting to health services; (iii) standardized short-course chemotherapy provided under proper case

management conditions, including direct observation of treatment (DOT); (iv) a functioning drug supply system ensuring a regular, uninterrupted supply of quality assured essential anti-tuberculosis drugs; and (v) a recording and reporting system allowing assessment of treatment results from all patients registered.

Large scale expansion of the revised strategy was undertaken after the successful demonstration of its technical and operational feasibility from 1993–97 in the pilot sites covering a population of 2.35 to 20 million. Successful negotiation of a soft loan of USD 142 million with the World Bank, which was effective from 8th May 1997, supported implementation of RNTCP in 102 districts covering a population of 271 million and strengthening 203 SCC districts with a population of 447 million in a phased manner. In early 2002, the World Bank assisted TB control project was extended for another 2 years, within the same budgetary provision, to cover a population of 700 million. A further one year no-cost extension of the project was approved to cover the period from October 2004 to September 2005 to enable coverage of the whole country as per schedule. In addition, the RNTCP was also supported by the Danish International Development Assistance (DANIDA), the UK Department for International Development (DFID), the Global TB Drug Facility (GDF), the Global Fund for AIDS, Tuberculosis and Malaria (GFATM), and the United States Agency for International Development (USAID) to expand DOTS coverage. Full national wide coverage was achieved in March 2006, and this rapid large scale expansion was hailed by the Joint Monitoring Mission (JMM) 2006 as the fastest expanding DOTS programme



Joint Donour Mission visit to Kerala

in the world. The latest JMM 2009 commented “The RNTCP is a leader in terms of its organization, its adoption/adaption of policy and periodic revision of strategy, its scale-up capacity, monitoring and evaluation systems, and results. It is committed to increase the epidemiological and social impact of its actions within a broader health and development agenda”.

Consolidation and scale up of RNTCP: The first phase of the project saw the establishment of over 600 state and district TB control societies to facilitate decentralized programme planning and implementation. The programme has achieved all the proposed goals in terms of expansion of DOTS services, case finding and treatment success during the Xth Five Year Plan Period (2002–2007).

The RNTCP Phase II of the World Bank project has been approved by the CCEA for the period Oct 2006 to Sep 2011 for a total outlay of USD 256.9 million which includes credit from World Bank of USD 170 million and commodity assistance of anti-TB

TABLE 1: Year wise allocation for the 11th Five Year plan

Sl No.	Year	Actual Allocation as per Planning Commission (Rs. Crore)
1	2007–08	267.00
2	2008–09	275.00
3	2009–10	285.00
4	2010–11	300.00
5	2011–12	320.00
Total		1447.00

drugs from DFID through WHO for USD 62.5 million, and the balance by Gol.

New financial norms in respect of certain expenditure heads have been approved by Cabinet Committee on Economic Affairs which have been implemented with effect from April 01, 2009.

However, to achieve the desired epidemiological impact where TB ceases to be a major public health



National Rural Health Mission Review and Thematic Workshop Chaired by Sujatha Roa



problem, it was essential to support the programme for the next 15-20 years.¹ In view of the above fact, the government had expressed its due commitment to support the programme as a 100% centrally sponsored programme for the coming 15-20 years, and sustainability of all activities of the programme has been ensured through continued financing of the phase II of RNTCP till Sept 2011, which has been approved by the 'Cabinet Committee on Economic Affairs'. This will consolidate, maintain and further improve the achievements of the first phase and enable India's progress towards achieving the TB-related Millennium Development Goal (MDG) targets.

World Bank Support

World Bank financing has supported RNTCP since it started expanding the coverage of DOTS over a decade ago, with a first credit of US\$ 142 million in between 1997-2005 and a second credit of US\$ 170 million in between 2006-12. The closing date of the second credit is March 2012 and an extension of three years (until March 2015) is proposed along with additional financing of US\$ 396 million. The additional World Bank funding would also support the program in meeting its ambitious new Universal Access goals, adequately addressing the challenge of drug-resistant TB, and introducing and scaling-up innovations and new approaches. The World Bank financing would therefore focus on new challenges in areas including:

- ◆ health system improvements necessary for diagnosis and treatment of MDR-TB;
- ◆ public-private partnerships and contracting-out of services (including the necessary accreditation, contract management and quality-control systems);
- ◆ introduction and scale-up of new diagnostics;
- ◆ strengthening state-level capacity and integration with the primary health care system;
- ◆ improving capacity and results in lower-performing states and districts;
- ◆ performance-based financing and incentive systems; and
- ◆ impact evaluation.

¹ The Government of India provides 100% grants-in-aid to the implementing agencies i.e. States/UTs besides free drugs. The programme is implemented through the general health infrastructure of the states. The States also provides some manpower resources.

Global Fund Support

The Global Fund has supported (by grants) DOTS expansion in India under different rounds. DOTS expansion in the 3 States of Chhattisgarh, Jharkhand, and Uttarakhand (56 million populations) was supported by grants for USD 8.78 million under Round 1 of GFATM from April 2003-September 2006. In addition, the Round 2 of GFATM supported DOTS expansion in 56 districts of Bihar and Uttar Pradesh with a population of 110 million for USD 29.10 million (April 2004 to March 2009). Round 4 of GFATM is supporting strengthening of RNTCP implementation in the states of Andhra Pradesh and Orissa w.e.f November 05 and January 2006 respectively for USD 26.63 million till March 2010. The programme has successfully obtained GFATM Rd 6 grant proposal for USD 24.3 million to continue support for strengthening RNTCP services in the 3 Round 1 project states (Chhattisgarh, Jharkhand, and Uttarakhand). All the GFATM grants involved innovative PPM projects to seek and strengthen involvement of NGO, private and corporate providers. The Rd 6 grant proposal has a substantial PPM component in the form of Indian Medical Association (IMA) sub-project for USD 3.87 million, with an objective to sensitize and enroll private practitioners in 167 districts across 6 states (Andhra Pradesh, Chandigarh, Haryana, Maharashtra, Punjab and Uttar Pradesh).

In order to consolidate and scale up the programme activities under Round 2 (which is ending in March 2009) and ensure alignment with all other existing GFATM TB grants (Round 4 and Round 6), the current RCC TB proposal against the expiring Round 2 grant envisages to consolidate all GFATM grants.

Under global fund round 9 one of the main agenda is to engage civil society partners to achieve the universal access.

TABLE 2: Year-wise allocation of global fund

Round	Period	Funds (in m USD)
1	2003-06	8.6
2	2004-09	29
4	2005-10	25.8
6	2006-11	26.24
RCC	2009-15	216
9	2010-15	199.54

Planning 12th Five Year Plan (2012-2017)

Universal Access: Reaching the Unreached – the New Vision of RNTCP

Over the years, RNTCP has implemented most of the additional components of the WHO Stop TB strategy – including TB/HIV, management of drug resistant TB, engagement of NGO and Private sectors, Infection control and Operational Research. Since its inception, the programme has initiated over 12 million patients on treatment, thus saving more than 2.2 million additional lives in comparison to earlier programme. Since achieving national coverage in 2006, the twin objectives of RNTCP (70% case detection rate and 85% treatment success rate) have been achieved consistently for the past 4 years. There is evidence on the effectiveness of the RNTCP DOTS programme on significantly decreasing the burden of TB in the community from the collaborative TRC/WHO MDP (Model DOTS Project) project area in Tiruvullar district, Tamil Nadu. There is an annual decline of 12.3% in prevalence and of 5.3% in ARTI since the implementation of RNTCP in 1999. National ARTI Survey conducted 200003 showed that the Annual Risk of TB Infection (ARTI) in the country has reduced from 1.7 to 1.5. The second National ARTI Survey (200709) and Disease Prevalence Survey (200709 in 7 sentinel sites) is under progress which will shed more light on the impact of RNTCP.

The vision of the Government of India is for a “TB-free India” with reduction of the burden of the disease until it is no longer a major public health problem. To achieve this vision, the programme has now adopted the new objective of Universal Access for quality diagnosis and treatment for all TB patients in the community. This entails sustaining the achievements of the programme to date, and extending the reach and quality of services to all persons diagnosed with TB. In particular, by end-2015, the programme aims to achieve the following targets:

- ◆ Offer of HIV Counseling and testing for all TB patients and linking HIV-infected TB patients to HIV care and support;
 - ◆ Successful treatment of at least 90% of all new TB patients, and at least 85% of all previously-treated TB patients;
 - ◆ Extend RNTCP services to patients diagnosed and treated in the private sector.
- The programme plans to achieve this by deploying rapid diagnostics for the diagnosis of TB and DRTB, expand services for management of MDR-TB, strengthen urban TB control, strengthen PPM initiatives in addition to improving the quality of basic DOTS services and aligning with NRHM supervisory structures.
- Synergies and convergence under NRHM:** The National Rural Health Mission (NRHM) was launched in April 2005. The primary goal of the NRHM is to improve the availability of and access to quality health care by people, especially those residing in rural areas, and the poor and vulnerable groups. NRHM aims to carry out the necessary architectural correction in the basic health care delivery system of the country by increasing public expenditure on health, reducing regional imbalances in health infrastructure, pooling resources, integration of organizational structures, optimization of health manpower, decentralization and district management of health programmes, community participation and ownership of assets, and the induction of management and financial personnel into district health system. As part of the Mission, Indian Public Health (IPH) Standards have been defined for the minimum level of infrastructure, human resource, equipment and drugs/consumables needed for effective functioning of the health institution (primary, secondary and tertiary units). This large scale investment into the health system would have positive ripple effects on the overall functioning of the health system and the disease specific interventions, including TB.
- The NRHM is an effort at integrating resources and optimizing the delivery of health services through an omni-bus approach, wherein the MoHFW seeks to adopt a sector-wide approach (rather than a programme-specific approach) and subsumes key national programmes such as the Reproductive and Child Health programme (RCH II), the National Disease Control Programmes (NDCP) and the Integrated Disease Surveillance Programme (IDSP).
- ◆ Early detection and treatment of at least 90% of estimated TB cases in the community, including HIV-associated TB;
 - ◆ Initial screening of all re-treatment smear-positive TB patients for drug-resistant TB and provision of treatment services for MDR-TB patients;

RNTCP, as other national disease control programmes is an integral part of the NRHM and would continue to deliver its services under the umbrella State/District Health society created under NRHM. As RNTCP is being implemented through the general health system, NRHM would further help in strengthening delivery of DOTS services and increasing accountability of general health system. ASHA workers recruited under NRHM, are being trained for DOT provision and support to decentralize DOT services to the doorstep of the patients, thereby increasing patient convenience and thus compliance.

However, to meet the existing gap in infrastructure (for laboratory and drug store) and key human resource (laboratory technician/Medical officers/IEC officer etc), the TB programme has been supplemented by provision of funds for improving infrastructure (up gradation of microscopy centers and drug stores) and additional staff to cover this gap and ensure decentralized diagnostic and treatment services, and strengthening supportive supervision and monitoring of all key programme activities. It is also submitted that TB related services (microscopy centres, drug stores and DOT centres) and personnel (LTs) have been included under the Public Health Standards. These inputs are proposed to be continued under the current project, till the public health system has been strengthened enough to at least absorb the critical requirements of the programme for diagnosis, treatment and monitoring of TB patients.

The National Rural Health Mission though integrates the various National Disease Control Programs and the Family welfare Programs at the executive level, it continues to maintain individual identity of projects/programmes at the technical and financial level. As RNTCP is being funded and supported through the World Bank loan, and the Global Fund grants, the financial management and reporting of the project would continue to be independent (State/District RNTCP account), with the programme officer being an signatory to its management.

Case Detection through Quality Assured Bacteriology

A nationwide network of RNTCP quality assured designated sputum smear microscopy laboratories has been established, which provides appropriate,



affordable and accessible quality assured diagnostic services for TB suspects and cases. To meet the standards of internationally recommended diagnostic practices for TB, the programme provides the supply of quality reagents and equipment to the laboratory network. An in-built routine system has been designed, External Quality Assessment (EQA) for supervision and monitoring of the diagnostic systems by the Senior TB Laboratory Supervisor (STLS) of RNTCP locally and by the intermediate (state level) and national reference laboratory network for RNTCP at higher levels. Introduction of LED Fluorescent Microscopy is being phased in at high load centres and will be scaled up as per requirements at all levels.

Quality Assured Laboratory Services

RNTCP has established a nationwide laboratory network, encompassing over 13,000 designated sputum Microscopy Centers (DMCs), which are being supervised by Intermediate reference laboratories (IRL) at state level, and National Reference laboratories (NRL) & Central TB division at the national level. RNTCP aims to consolidate the laboratory network into a well-organized one, with a defined hierarchy for carrying out sputum microscopy with external quality assessment (EQA), in line with the new guidelines of WHO. RNTCP is gradually phasing in routine surveillance among the previously treated cases in states where PMDT has been initiated. Drug Resistance Surveillance (DRS), mycobacterium culture and Drug Susceptibility Testing (DST) are undertaken only among new cases in specific selected settings.

National Reference Laboratories (NRL)

The four NRLs under the programme are Tuberculosis Research Centre [TRC], Chennai, National Tuberculosis Institute [NTI], Bangalore, Lala Ram Swarup Institute of Tuberculosis and Respiratory diseases [LRS], Delhi and JALMA Institute, Agra. The NRLs work closely with the IRLs, monitor and supervise the IRL's activities and also undertake periodic training for the IRL staff in EQA, culture & DST activities.

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 visit each assigned state (Table 1) at least once a year for 2 to 3 days as a part of on-site evaluation under the RNTCP EQA protocol. Regular supervisory visits are undertaken by the NRL microbiologists to the IRLs to provide technical support for establishing quality assured C&DST services, including facility design for the introduction of newer diagnostic tools (liquid culture and molecular tests) for the rapid diagnosis of MDR TB in consultation with other technical agencies like FIND. NRLs also undertake periodic proficiency testing of the IRLs as part of the accreditation process under RNTCP.

The National RNTCP Laboratory Committee, constituted with microbiologists of the NRLs, CTD and WHO India representatives as members, works as a task force to guide laboratory related activities of the programme. This

technical body advice RNTCP on key policy issues regarding the laboratory services of the TB Control Programme.

Intermediate Reference Laboratory (IRL)

One IRL has been designated in the STDC/Public Health Laboratory/Medical College of the respective state. The functions of IRL are overall supervision and monitoring of EQA activities of the districts, mycobacterial culture and DST including drug resistance surveillance (DRS) in selected states. The IRL ensures the proficiency of staff in performing smear microscopy activities by providing technical



BSL III laboratory at STDC, Hyderabad, Andhra Pradesh

training to district and sub-district laboratory technicians and STLSSs. The IRLs undertake on-site

TABLE 3: States assigned to NRLs for monitoring of laboratory activities

NRL	States and Union Territories (UTs) assigned for EQA	Total nos. of IRLs assigned	Total nos. of states/UTs assigned	Nos. of districts in the states
TRC	Andhra Pradesh, Chhattisgarh, Goa, Gujarat & (Dadra Nagar Haveli, Daman & Diu), Kerala & (Lakshadweep), Sikkim, Tamil Nadu, Punjab & (Chandigarh), Puducherry, Andaman & Nicobar	10	11	150
LRS	Delhi, Arunachal Pradesh, Haryana, Manipur, Nagaland, Mizoram, Meghalaya, Tripura	4	8	93
NTI	Maharashtra, Orissa, West Bengal Rajasthan, Karnataka, Bihar, Madhya Pradesh, Jharkhand, Jammu and Kashmir	12	12	275
JALMA	Uttar Pradesh, Uttarakhand, Himachal Pradesh, Assam	5	5	118

evaluation and panel testing to each district in the state, at least once a year.

The 23 C&DST labs are accredited after undergoing the process of accreditation as per RNTCP guidelines to undertake C&DST activities for the diagnosis and follow up of MDR TB patients as part of the National Laboratory Scale up Plan. Till date 12 IRLs (Gujarat, Maharashtra, Andhra Pradesh, Delhi, Kerala, Tamil Nadu, West Bengal, Rajasthan, Orissa, Jharkhand, Haryana and Puducherry) have been accredited and are already undertaking C&DST for the MDR-TB patients from the respective states. 7 other labs such as Blue Peter Health Research Centre (BPHRC)-Hyderabad, PD-Hinduja Hospital Mumbai, Christian Medical College (CMC) Vellore, Sawai Maan Singh (SMS) Medical College-Jaipur, Regional Medical Research Centre (RMRCT) for Tribals (ICMR) – Jabalpur, Grant Medical College Sir JJ Hospital – Mumbai, Damien Foundation of India Trust (DFIT) – Nellore are also accredited by the program to perform C&DST for the MDR TB services.

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).

At present, more than 13,000 DMCs are available and fully functional for conducting quality assured sputum smear microscopy.

External Quality Assessment for Smear Microscopy

A process has been established under RNTCP to assess the laboratory performance utilizing the RNTCP External Quality Assessment (EQA) guidelines and currently > 95% of the districts in the country are implementing quality assurance protocol. (Figure 1 & 2)

Recommendations of the annual supervisory visits to the states by the NRLs have focused on operational and technical problems of the laboratories and staff in conducting effective OSE visits to districts/diagnostic centres, panel testing of STLSs, operationalization of RBRC procedures and identifying and correcting DMCs with errors.

For capacity building of state level programme managers (STOs and STDC/IRL directors) in EQA, training is imparted to make them aware of their roles and responsibilities regarding issues such as setting up of IRLs, management and training of the human resources, conducting effective on site evaluations

Figure 1: External quality assessment activities of RNTCP

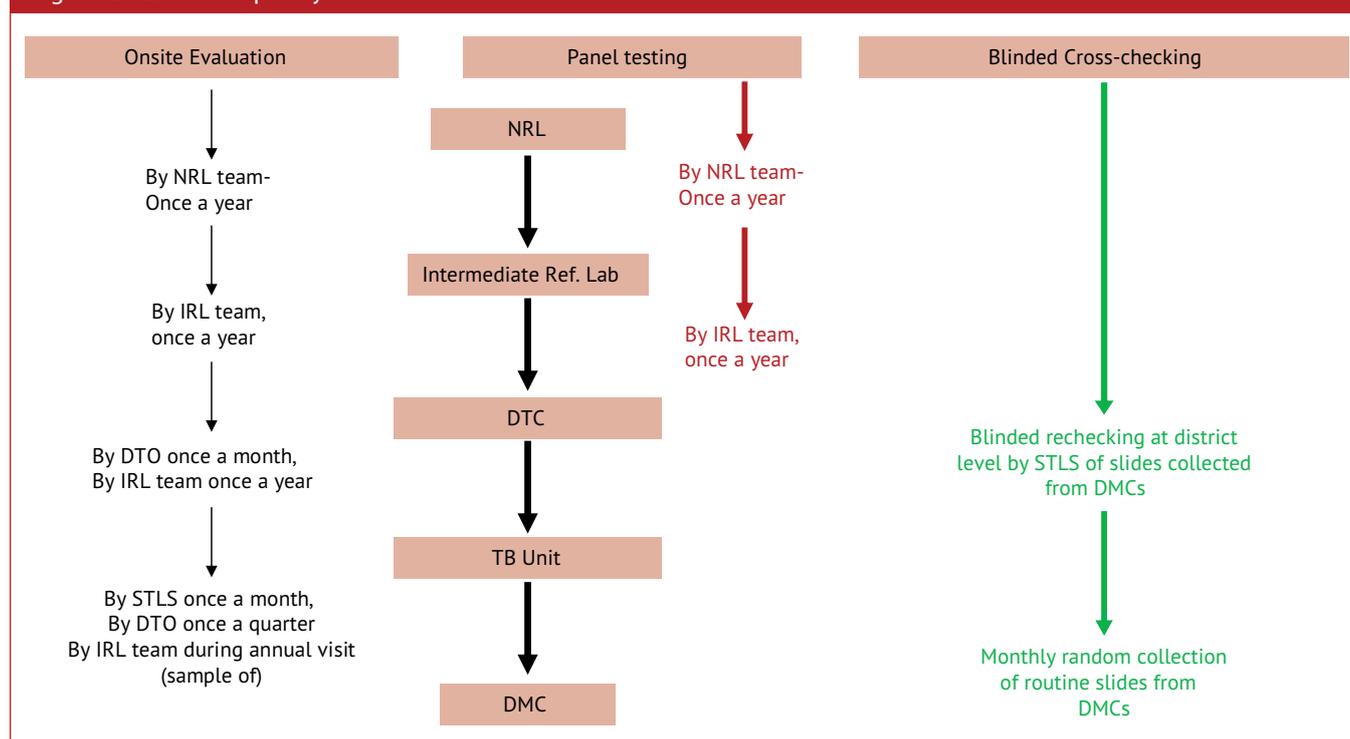
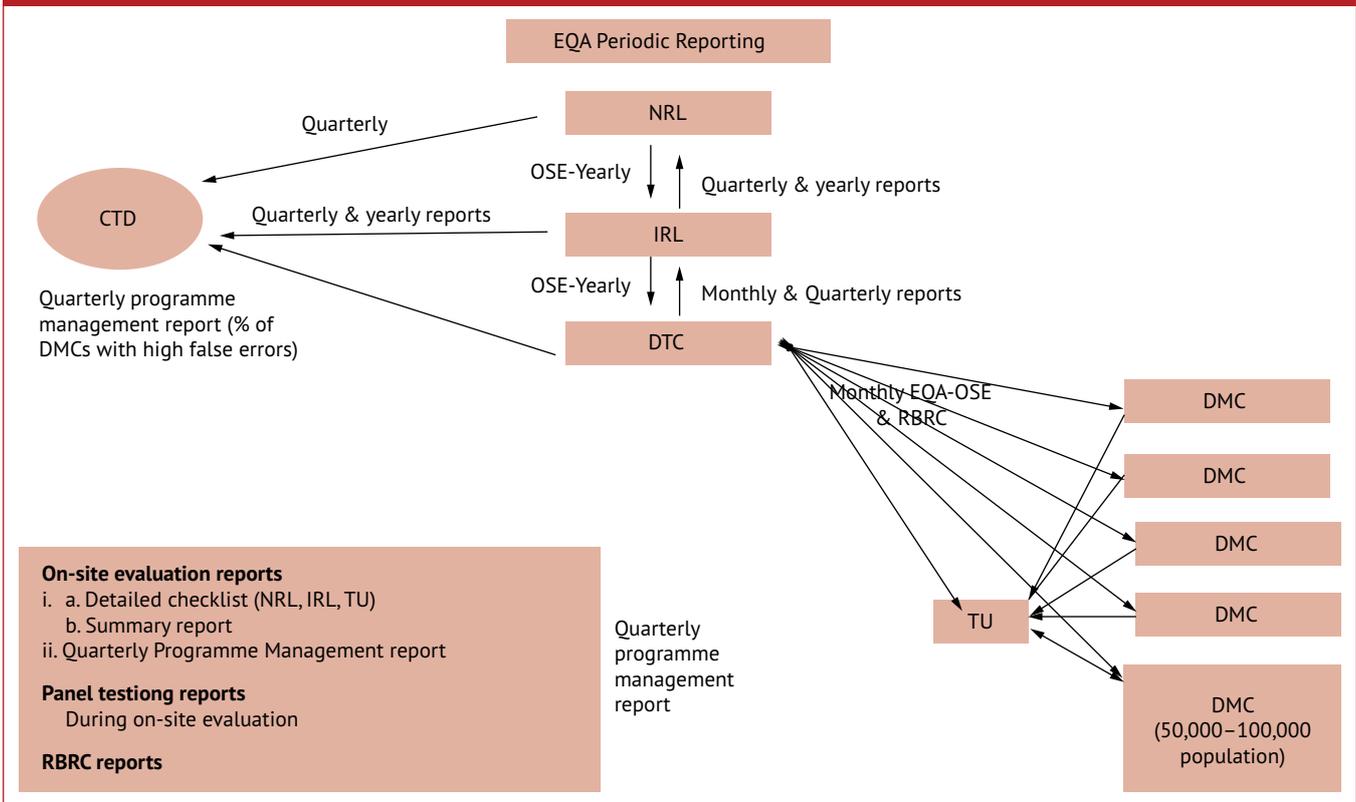


Figure 2: Reporting procedure



by the IRL staff at the DMC level, bio-medical waste management, airborne infection control measures and other operational and technical issues. A separate training, which focuses mainly on technical aspects of EQA protocol, is also provided to the microbiologists and lab technicians of the IRLs by the NRLs.

Establishment of C&DST labs

RNTCP has adopted a rigorous C&DST Laboratory accreditation procedure (see Figure 3) to provide accurate and reliable services for MDR TB diagnosis and follow-up of treatment. In order to meet demands of the programme, accreditation of C&DST laboratories both in Public and Private sectors is being pursued vigorously. Overall supervision is entrusted with the NRLs, to maintain uniformity in testing procedures NRLs are conducting Culture and DST trainings of 2-4 weeks duration for the Microbiologists and Laboratory technicians of the laboratories undergoing accreditation. The accreditation process has three main stages.

Stage 1. A pre-assessment visit of 1-2 days to the laboratories by the NRL/CTD team during which a laboratory is assessed for infrastructure facilities,

qualified trained personnel, work-load requirements, SOPs (Standard Operating Procedures), technical procedures, bio-safety and infection control measures. Corrective actions recommended in case of deficiencies.

Stage 2. Laboratories are assessed for performance based on first 100 patient samples processed for Culture and DST. The indicators are - mainly - (a) rate of smear positive and culture negatives, and (b) rate of contamination (c) proficiency for setting-up correctly interpretable DST tests.

Stage 3. NRLs provide external blinded proficiency testing panel of 20 cultures for susceptibility testing for anti-TB drugs namely Isoniazid, Rifampicin, Ethambutol and Streptomycin. NRLs, would also retest 10 selected cultures provided by the IRLs. Accuracy of results is assessed based on sensitivity, specificity, and positive and negative predictive values for resistance and susceptibility. Accreditation is done on obtaining a proficiency of >90% for Isoniazid and Rifampicin. Regular annual proficiency testing is done to maintain the quality standards for DST. Separate proficiency schedule has also been developed for molecular based DST.

Figure 3: The C&DST laboratory accreditation process

RNTCP Accreditation Process for Culture & DST Laboratories

C&DST trainings at NRLs for Laboratory personnel

2- 4 weeks ↓ Solid (L)/Liquid, 1% Proportion method DST

Application by Labs & Pre-assessment visit by NRL/CTD team

1-2 days ↓ Lab Design, HR, Equipment, & Bio-Safety norms
Action-plans for lab accreditation

Developing C&DST skills by the IRL-IQC

3 months ↓ Data of 100 cultures assessed for performance indicators

Proficiency testing-DST (at NRL)-EQA

3 months ↓ Exchange of 20 Panel cultures (Blinded to IRL)
Concordance for H,R>=90%

Assessment visit-Evaluation

1-2 days

Non-conformities
(causes, solutions)
Technical and/Administrative

Full-Conformities

RNTCP Accreditation of Lab

Approx Time *(Minimum) for accreditation of a Conventional Lab: 6-7 months for new laboratories, and 4-5 months for already functioning laboratories after the submission of application

As per the recommendation of Joint Monitoring Mission (JMM) 2009, the process of establishing a National Laboratory Task force to accelerate the process of accreditation of C&DST labs across the country has been initiated. USAID has agreed to support this initiative through WHO-India.

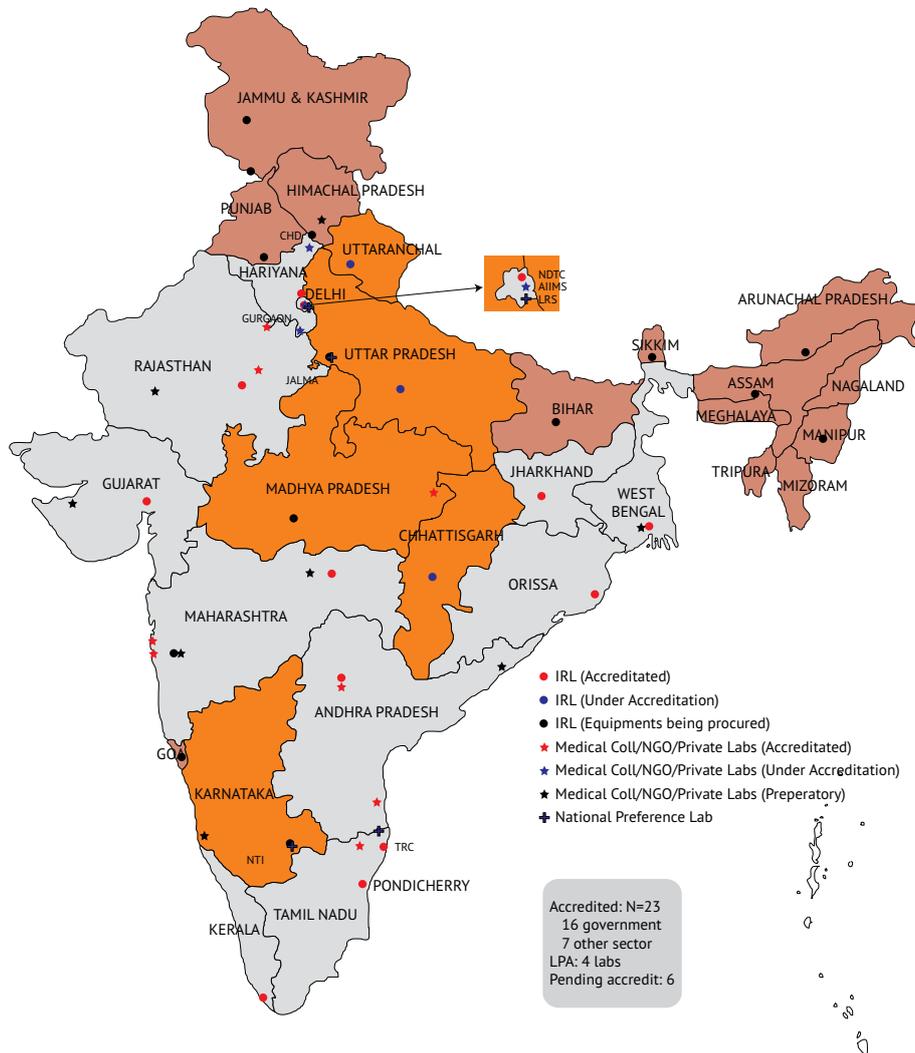
Private Medical Colleges and NGO are increasingly providing C&DST services to enhance the programmes reach for MDR-TB diagnosis which includes Blue Peter Health Research Centre (BRHRC) Hyderabad, PD-Hinduja Hospital Mumbai, Christian Medical College (CMC) Vellore, Sawai Maan Singh (SMS) Medical College-Jaipur, Regional Medical Research Centre for Tribals (RMRCT ICMR) – Jabalpur, Grant Medical College Sir JJ Hospital – Mumbai, Damien Foundation of India Trust (DFIT) –Nellore and will shortly also include Choitram hospital (NGO of Indore).

Newer and Rapid technologies being introduced globally would enhance the diagnostic capacity for

MDR-TB and cut short the turnaround times. Some of these technologies are now endorsed by WHO Strategic and technical advisory group for TB. RNTCP has initiated projects to validate & demonstrate large scale studies of newer TB diagnostic technologies in collaboration with Foundation for Innovative New Diagnostics (FIND), India. Molecular Line probe assay (LPA), Automated Liquid culture systems for C&DST, Capilia TB and LED Fluorescence microscopy are being validated in selected IRLs and NRLs. The results of these projects, specially the rapid MDR-TB test-LPA will guide the nationwide rollout of these technologies for MDR-TB diagnosis.

By 2012, the programme aims to provide universal access to laboratory based quality assured MDR diagnosis for all re-treatment TB cases on entry and new cases who have failed treatment and by 2015, the universal access to MDR diagnosis and treatment will be made available for all smear positive TB cases under RNTCP.

RNTCP Culture and DST Labs Network (February, 2010)



Drug Resistance Surveillance (DRS)

The prevalence of anti-TB drug resistance in the community can be taken as an indicator of the effectiveness of the TB control activities in the community over a period of time. RNTCP has adopted steps to measure this important indicator across the country. For determining the prevalence of anti-TB drug resistance among new and previously treated patients, state-wide DRS surveys are being conducted periodically by the programme. The state wide DRS surveys of Gujarat and Maharashtra were completed in 2007. The reports from these states showed the level of multi drug resistance TB amongst new cases is 2-3% and amongst re-treatment cases 12-17%. Currently, DRS survey is recently completed in Andhra Pradesh and ongoing in Uttar Pradesh. AP has completed the study with the report likely to be submitted in early 2011. The UP study is likely to be completed by mid 2011.

Introduction of Newer Tools

Introduction of Newer Tools for the PMDT has been implemented after an in-country validation and demonstration phase that was completed in 2010. Line probe Assay has been implemented in the IRLs of Ahmedabad (Gujarat), Hyderabad (Andhra Pradesh) and IRL Nagpur (Maharashtra) for the diagnosis of MDR TB patients in these states. In addition the IRLs of Trivandrum (Kerala), NDTB (Delhi), Kolkata (West Bengal), Cuttack (Orissa), Ajmer (Rajasthan), IRL Pune (Maharashtra), IRL Chennai (Tamil Nadu) will be initiating the LPA proficiency testing shortly and services will become available by end 2011. The introduction of all newer diagnostic tools is being supported by the EXPAND TB project (WHO GLI, UNITAID and FIND) and Global Fund Round 9, which is supporting the National Laboratory Scale up plan for 43 LPA and



Microbiologist performing LPA procedure

33 Liquid Culture units to provide an incremental capacity by 2014 of approximately > 160000 DSTs and > 220000 follow-up cultures.

Liquid Culture DST is available to the RNTCP through some of the private and corporate providers (NGO PP scheme for C and DST) like Hinduja hospital that is providing services for Mumbai City. In addition, these schemes will be extended to other areas with additional private laboratories like Quest and Super Religare from 2011 onwards.

The RNTCP will be initiating the evaluation of the GeneXpert TB-RIF in line with the global consultation guidelines to gather evidence for use within the country in various settings including non-risk settings. This project has been funded by USAID Country mission with technical assistance from WHO

India and will include 18 sub-district level settings.

LAMP (Loop mediated isothermal amplification) is a manual NAAT that can be performed at DMC level and will be validated by FIND in Wardha Medical College of Maharashtra shortly.

FIND has also supported in establishing a National Training Centre (International Centre for Excellence in laboratory training) in the premises of the National Tuberculosis Institute, Bangalore which is one of the National Reference Laboratories of India. The training center will cater to the recurrent training needs of the laboratory staff that will man the 43 LPA and 33 liquid culture units to be established by 2014.

The infrastructure up gradation that is required for the introduction of newer tools is also being supported by PATH which is upgrading 15 labs for LPA and 8 labs for BSL III facility.



Laboratory personnel working on MGIT

TABLE 4: The Status of the functional and proposed Culture and DST laboratories in the country

S. No	NRL	S. No	State	Name of the Laboratory	Type*	Status
1	NRL	1	Delhi	LRS, Delhi	G	Accredited
2	NRL	2	Karnataka	NTI, Bangalore	G	Accredited
3	NRL	3	Tamil Nadu	TRC, Chennai	G	Accredited
4	NRL	4	Uttar Pradesh	JALMA, Agra	G	Accredited
5	JALMA	1	Assam	IRL Guwahati, Assam (Guwahati Medical College)	G	In process
6	JALMA	2	Himachal Pradesh	IRL Dharampur, Himachal Pradesh	G	In process
7	JALMA	3	Himachal Pradesh	Govt Medical College, Tanda	GM	In process
8	JALMA	4	Uttar Pradesh	IRL Lucknow, Uttar Pradesh (CSMMU, earlier KGMU)	G	In process
9	JALMA	5	Uttar Pradesh	IRL Agra, Uttar Pradesh	G	In process

S. No	NRL	S. No	State	Name of the Laboratory	Type*	Status
10	JALMA	6	Uttarakhand	IRL Dehradun, Uttarakhand	G	In process
11	LRS	1	Arunachal Pradesh	IRL Naharlagun, Arunachal Pradesh	G	In process
12	LRS	2	Chandigarh	PGI Chandigarh	GM	In process
13	LRS	3	Delhi	IRL Delhi (New Delhi TB Centre)	G	Accredited
14	LRS	4	Delhi	AIIMS, Delhi	GM	In Process
15	LRS	5	Haryana	IRL Karnal, Haryana (Public Health Laboratory)	G	Accredited
16	LRS	6	Manipur	IRL Imphal, Manipur	G	In process
17	NTI	1	Bihar	IRL Patna, Bihar	G	In process
18	NTI	2	J&K	IRL Jammu, J&K (Jammu Medical College)	G	In process
19	NTI	3	J&K	IRL Srinagar, J&K	G	In process
20	NTI	4	Jharkhand	IRL Ranchi, Jharkhand (Itki TB sanatorium)	G	Accredited
21	NTI	5	Karnataka	IRL Bangalore, Karnataka	G	In process
22	NTI	6	Karnataka	KIMS, Hubli	GM	In process
23	NTI	7	Madhya Pradesh	IRL Indore, Madhya Pradesh	G	In process
24	NTI	8	Madhya Pradesh	IRL Bhopal, Madhya Pradesh	G	In process
25	NTI	9	Madhya Pradesh	Choithram Hospital Indore	N	In process
26	NTI	10	Madhya Pradesh	Bhopal Memorial Hospital, Bhopal	G	In process
27	NTI	11	Maharashtra	IRL Nagpur, Maharashtra	G	Accredited
28	NTI	12	Maharashtra	IRL Pune, Maharashtra	G	In process
29	NTI	13	Maharashtra	JJ hospital Mumbai	GM	Accredited
30	NTI	14	Orissa	IRL Cuttack, Orissa	G	Accredited
31	NTI	15	Rajasthan	IRL Ajmer, Rajasthan	G	Accredited
32	NTI	16	Rajasthan	SMS Jaipur	GM	Accredited
33	NTI	17	West Bengal	IRL Kolkata, West Bengal	G	Accredited
34	TRC	1	A & N Islands	RMRC Port Blair	G	In process
35	TRC	2	Andhra Pradesh	IRL Hyderabad, Andhra Pradesh	G	Accredited
36	TRC	3	Andhra Pradesh	Govt Medical College, Vishakapatnam	GM	In process
37	TRC	4	Andhra Pradesh	BPHRC Hyderabad	N	Accredited
38	TRC	5	Andhra Pradesh	DFIT lab Nellore	N	Accredited
39	TRC	6	Assam	RMRC Dibrugarh	G	In process
40	TRC	7	Bihar	RMRC Patna	G	In process
41	TRC	8	Chhattisgarh	IRL Raipur, Chhattisgarh (Regional Leprosy Training and Research Institute)	G	In process
42	TRC	9	Goa	IRL Goa (GMC, Bambolim)	G	In process
43	TRC	10	Gujarat	IRL Ahmedabad, Gujarat	G	Accredited
44	TRC	11	Gujarat	Govt Medical College, Jamnagar	GM	In process
45	TRC	12	Gujarat	Govt Medical College, Surat	GM	In process
46	TRC	13	Gujarat	Microcare Lab, Surat	P	In process
47	TRC	14	Haryana	Quest Diagnostics, Gurgaon	P	In process

S. No	NRL	S. No	State	Name of the Laboratory	Type*	Status
48	TRC	15	Haryana	SRL, Gurgaon	P	In process
49	TRC	16	Kerala	IRL Thiruvananthapuram, Kerala	G	Accredited
50	TRC	17	Madhya Pradesh	RMRCT Jabalpur	G	Accredited
51	TRC	18	Maharashtra	PD Hinduja Hospital, Mumbai	P	Accredited
52	TRC	19	Maharashtra	SRL, Mumbai	P	In process
53	TRC	20	Orissa	RMRC Bhubaneswar	G	In process
54	TRC	21	Puducherry	IRL Puducherry	G	Accredited
55	TRC	22	Punjab	IRL Patiala, Punjab (Patiala Government Medical College)	G	In process
56	TRC	23	Sikkim	IRL Gangtok, Sikkim	G	In process
57	TRC	24	Tamil Nadu	IRL Chennai, Tamil Nadu (Institute of Thoracic Medicine)	G	Accredited
58	TRC	25	Tamil Nadu	CMC Vellore	P	Accredited
59	TRC	26	Tamil Nadu	Madurai Medical College	G	In process
60	TRC	27	Tamil Nadu	Global Hospital	P	In process

*'G' is Government, 'P' is Private, 'N' is NGO, 'M' is Medical college, 'GM' Government Medical college and 'PM' Private Medical college.

TABLE 5: The performance of eleven* RNTCP accredited Culture and DST laboratories serving the states in the country

Workload and DST results – report SPECIMENS processed on culture or DST, NOT PATIENTS

Month	Culture workload (from culture register)		DST workload and results (from DST register) [DST results summary combined all methods]					
	Diagnostic Sputum Specimens inoculated	Follow-Up Specimens inoculated	Solid DST Processed	LPA DST done	Total H+R Sens	Total H+R Res	Total H only Res	Total R only Res
January to June 2010	6541	6112	2503	635	840	1349	347	237

Performance indicators

	Numerator (No.)	Denominator (No.)	Percent
(1) Specimens (all) received within 7 days of sputum collection	11934	12416	96%
(2) Specimens (all) with cultures reported as <i>Mtb. complex</i>	5478	12280	45%
(3) Smear-positive diagnostic specimens reported as culture-positive	3700	4797	77%
(4) Specimens (all) with culture-contaminated results (by culture system)	674	12414	5%
(5) Specimens (all) with culture results reported as NTM	83	11698	1%
(6) Patients (with diagnostic specimens) with DST completed within the benchmark turn-around time (by culture system)	1318	2619	50%
(7) Patients (all) with final culture results reported to providers within 3 days of declaration of result	5423	6618	82%
(8) Patients with final DST results reported to providers within 3 days of declaration of result	1899	2329	82%

Procurement & Drug Logistics

Central Procurement

Procurement, Supply & Logistics Unit in Central TB Division (CTD) functioning under the supervision of a Chief Medical Officer is supported by a Procurement & Supply Management Consultant and an agency outsourced with the assistance from WHO for drug logistics management.

Contract to the newly selected procurement agency (M/s RITES Ltd.) was awarded by the Ministry of Health & Family Welfare (MoHFW) in January, 2010 to undertake procurements of various Programme Divisions of the MoHFW including RNTCP. The Procurement of 1st Line Anti TB Drugs (through World Bank & GFATM funding), 2nd Line Anti TB Drugs (through World Bank funding), Laboratory Equipment, MMR X Ray Rolls and Purified Protein Derivative (PPD) is presently being undertaken at the Central level.

Anti TB Drugs

An uninterrupted supply of good quality Anti TB Drugs is an essential component of DOTS strategy under RNTCP. Supplies of 2nd tranche each of 1st and 2nd Line Anti TB Drugs to various consignees for the procurement year 2009–10 have been completed during the year.

(a) First Line Anti TB Drugs

While procurement of Drugs for 500 million population of the country continued to be done by



State Drug Store at Patna (Bihar)

the Global Drug Facility (GDF) through financial support by DFID, for the rest of the population, the procurement of these drugs (both for World Bank and GFATM funded states) is done through International Bidding from 'WHO Pre-Qualified suppliers' only by the procurement agency of MoHFW (Govt. of India), following the World Bank procurement guidelines. Injection Streptomycin is procured through International Competitive Bidding.

Contracts were awarded by the previous procurement agency (UNOPS) for procurement of these Anti-TB Drugs for the year 2009–10. Procurement of these drugs for the year 2010-11 are being done by the new procurement agency M/s RITES Ltd.

(b) Second Line Anti TB Drugs

The procurement of 2nd Line Anti TB Drugs for the World Bank funded states is continued to be done through International Competitive Bidding (ICB) by



Second line drugs boxes packed for IP and CP at SDS Nagpur

the procurement agency of MoHFW. RNTCP has taken similar measures, as described above for ICB for Inj Streptomycin, to procure good quality 2nd Line Anti TB Drugs. For the states funded by GFATM, these drugs are procured through Green Light Committee (GLC) of Stop TB Partnership.

The 2nd Line Anti TB Drugs for 2350 patients under DOTS Plus were procured during the year 2009-10 by UNOPS for World Bank funded states (Assam, Delhi, Goa, HP, Jammu & Kashmir, Karnataka, MP, Gujarat, Maharashtra, Puducherry, Chandigarh, UP, Kerala). For

the year 2010-11, the procurement of the drugs for 3,450 patients for World Bank funded states (Assam, Delhi, Goa, HP, Jammu & Kashmir, Maharashtra, Puducherry, Chandigarh, Punjab) through International Competitive Bidding (ICB) by M/s RITES Ltd. is currently underway. Procurement of 2nd Line Anti TB Drugs for 800 patients for GFATM funded states (Andhra Pradesh, Chhattisgarh, Haryana, Jharkhand, Orissa and Uttarakhand) and 4,850 patients funded by UNITAID was also done through Green Light Committee (GLC) and Global Drug Facility (GDF) which are part of Stop TB Partnership. The supply of drugs procured during the year through GDF is in process.

Quality Assurance of 1st & 2nd Line Anti TB Drugs

Quality Assurance (QA) of Anti-TB Drugs has been accorded special importance by RNTCP and measures are taken at the time of procurement and also Post Procurement to maintain quality of Anti-TB Drugs.

(a) QA Measures at the Time of Procurement

1st line Anti-TB Drugs - Since 200809, procurement of 1st Line Anti-TB Oral Drugs has been limited to 'WHO Pre-Qualified suppliers' and pre-dispatch inspection and testing of all batches is done. Injection Streptomycin is procured through International Competitive Bidding (ICB) from WHO-GMP suppliers only, Joint Inspection for verification of WHO-GMP Certificates by a team under DCG(I) is ensured and pre-dispatch inspection of all batches is done.

2nd line Anti-TB Drugs: Procurement for the World Bank funded States is done through ICB by Procurement Agency of Ministry of Health & Family Welfare. For this procurement, WHO-GMP Certification is required, Joint Inspection for verification of WHO-GMP Certificates by a team under DCG(I) is ensured and pre-dispatch inspection of all batches is done. For GFATM funded states, procurement is done through Green Light Committee (GLC) and Global Drug Facility (GDF) of Stop TB Partnership from the "WHO Pre-Qualified suppliers" only.

(b) QA Measures Post Procurement

Drugs procured (both 1st & 2nd Line) are tested at an Independent Quality Assurance Laboratory selected by RNTCP. Every quarter, random samples of Anti-TB Drugs are drawn from one GMSD, one State Drug Store & 5 District Drug Stores and sent for testing to the independent QA Lab. The test reports are presented to a Committee headed by Drug Controller General (India). In addition to this, samples are also picked up randomly from the GMSDs, State Drug Stores & District Drug Stores by various Central and State Drug Inspection Authorities and send for testing. Based on the test reports, further necessary action is taken by the Programme.

Laboratory Equipment for Culture & DST for IRLs

RNTCP is in the process of establishing 14 more IRLs at Assam, Bihar, Goa, Himachal Pradesh, J&K (Jammu), J&K (Srinagar), Karnataka, Madhya Pradesh, Maharashtra (Pune), Manipur, Punjab, Sikkim, Uttar Pradesh and Arunachal Pradesh. The Contracts for all the remaining items of Lab. equipment for solid Culture & Drug Sensitivity Testing (DST) for establishing these IRLs in the country were awarded during the year, delivery of all the equipment has been completed and the installation of most of the equipment's has been done.

New Initiatives for Diagnosis of TB

RNTCP is linking development of MDR-TB diagnostic capacity to the expansion of MDR-TB treatment services under DOTS-Plus. During the year, the Programme has utilized the support provided by EXPANDx TB Project funded by UNITAID to accelerate the availability of rapid diagnosis of MDR-TB nationwide. Among the newer TB diagnostics approved by WHO, molecular Line Probe Assay (LPA) and Liquid Culture have already been implemented in STDC, Ahmedabad and STDC, Nagpur. A Memorandum of Understanding (MoU) was signed on 8th March 2010 between Ministry of Health & Family Welfare (GoI) and EXPANDx TB for technical assistance, supply of equipment & consumables for setting up of 40 identified LPA labs and 30 Liquid Culture labs. Based on this MoU and to facilitate training of the laboratory personnel from the identified sites, Foundation for Innovative New Diagnostics (FIND)



MoU between MoHFW, Gol and EXPANDx TB, a project funded by UNITAID, March 8, 2010. Dr L S Chauhan (DDG TB), Mr M K Mishra (US, MoHFW) and Dr Giorgio Roscigno (CEO, FIND Geneva)

in coordination with Central TB Division established International Centre for Excellence in Laboratory Training (ICELT) at NTI, Bangalore and supplied equipment & reagents to nine laboratories and the process of supply of these equipment's & consumable items to seven more laboratories is underway during the year 2010–11.

Decentralized Procurement

As a part of strengthening decentralized procurement, states have been repeatedly communicated to follow World Bank procurement guidelines strictly and the revised threshold limits for state/district level procurement of Goods/Works have again been communicated to them. An abbreviated document on state/district level procurement has been sent to all the states and districts for wider circulation. States are sending information about state/district level procurement through “Procurement Reporting Format” circulated to them earlier by CTD, at the end of every quarter through the email ID i.e. distprocurement@rntcp.org.

Capacity Building for Decentralized Procurement

A session on “Decentralized Procurement in TB II” was conducted for all the State TB Officers and RNTCP Medical Consultants by the Chief Medical Officer dealing with RNTCP Procurements in CTD in January, 2010, during the National Review Meeting of STOs and Consultants, held at Gurgaon (Haryana). During the year 2010, trainings on “Decentralized Procurement in TB II” were also conducted for State

level officials in Punjab, Chandigarh, Maharashtra, Tamil Nadu by concerned officials from Central TB Division. Training on “Decentralized Procurement in TB II” was also conducted by Consultant (Procurement), CTD for the Accountants of all the States in February, 2010 at New Delhi.

Post Procurement Reviews

Six Post Procurement Reviews of the Contracts “below prior review threshold levels” at the Central level and in the States have been undertaken so far by World Bank Consultant in 21 states. Based on the reports of the Post Reviews, follow-up corrective actions are being taken by the concerned States. Action taken reports are sent by Central TB Division to the World Bank after each Review. Post Procurement Review of State/District level procurements are also being done during Central Internal Evaluation, Annual Financial Audit and visit to the States by officials from Central TB Division.

Procurement Management Information System (ProMIS) Software

The web based software (ProMIS) to streamline procurement systems, developed by Empowered Procurement Wing (EPW) of the MoHFW has addressed all the key components of International best practices in procurement and logistics. The various modules of the software include Forecasting, Planning, Bid Processing, Bid Evaluation, Supply Orders, Quality Assurance, Stocks, Inter warehouse transfers, Bills & Invoices etc. Live data entry by RNTCP for the procurement details of 1st line and 2nd line anti TB-drugs for the year 2009-10 has been completed.

Drug Logistics Management

Drug requirements, consumption and stock positions, both at State and district levels are monitored at the Central TB Division through the Quarterly Reports submitted by the districts. The 1st Line Anti-TB Drugs procured are stored at the six Government Medical Store Depots (GMSDs) across the country and issued to the States based on the Quarterly District Programme Management Reports and the monthly State Drug Stores (SDS) Reports. The States are required to maintain defined buffer stocks at each levels i.e., at the PHIs, TUs, DTCs & the SDS. The District Quarterly

Reports are analyzed in detail at CTD and any discrepancies arising are notified to the concerned districts & States for necessary corrections.

For long-term sustainability of the programme, decentralization of inventory management practices is very important. To ensure that the States are able to manage their drug logistics as per RNTCP guidelines, regular trainings & re-trainings on Drug Logistics Management were conducted by Central TB Division for the State & district level staff during the year. These trainings were imparted to State level officials, District TB Officers (DTOs), State and District level pharmacists alongwith respective RNTCP Medical Consultants. Such trainings were conducted for the officials in Madhya Pradesh, Kerala, Orissa, Maharashtra, Tamil Nadu, Puducherry, A & N Islands, Punjab and Chandigarh. In addition, all the RNTCP Medical Consultants were also sensitized to Drug Logistics Management practices during the Biannual National Review Meeting held at Gurgaon, Haryana in January, 2010. About 450 RNTCP officials/Consultants have been trained during the year on Drug Logistics Management. The DTOs are expected to further train their sub-district level staff involved in drug logistics in their respective districts.

To assess the impact of such trainings, CTD is also regularly re-visiting some of the States already trained. Jharkhand, Uttar Pradesh, Assam and Bihar were visited during the year by teams from CTD. Some improvements have been noticed but the lack of commitment by concerned officials at State and District levels is still seen as a major drawback. Some of the common observations noticed are:

1. Poor drug storage conditions & lack of infrastructure at the drug store
2. Lack of contracted transportation arrangements from SDS to district drug stores
3. No full time pharmacist/store-keeper at the SDS and no designated officer to monitor drug logistics activities in the states visited.
4. No system of trainings/re-trainings conducted by the states visited for Drug Logistics Management.

Logistics management of 2nd Line drugs is still a challenge under DOTS-Plus in RNTCP. Cycloserine and Ethionamide with a short- shelf life require continuous monitoring & regular Inter-State transfers to ensure maximum utilization and minimum expiry of these drugs. Currently, 10 States viz Andhra Pradesh,



Drug logistics training at STDC Pune.

Delhi, Haryana, Gujarat, Kerala, Maharashtra, Orissa, Rajasthan, West Bengal & Tamil Nadu have already implemented the DOTS-Plus programme in their respective States and more states are preparing to start the treatment services under DOTS-Plus during the next year. Training on 2nd line drug logistics is also being imparted during the regular trainings on Drug Logistics Management to State & district level staff. The same has been included in the Standard Operating Procedures (SOP) Manual for both State & District Drug Stores.

New Initiatives Undertaken during 2010

1. Injection Streptomycin vials & Kanamycin vials procured under RNTCP are now supplied along with Distilled Water vials, Syringes and Needles.
2. Guidelines for storage of 2nd line Anti-TB Drugs at SDS, DTC & TU levels were finalized during the year and have been circulated to all the States for their implementation.
3. State-wise Micro-planning exercise on Drug Logistics was undertaken during the year as part of expansion plan for DOTS-Plus under RNTCP.
4. Funds for appointment of an additional store-assistant for 2nd line Drugs at the State Drug Store level have been made available along with provision for additional funds for improvement in drug storage conditions at State & District Drug Stores.
5. Revision of Drug Logistics Management Module, which is part of Training Modules for State and District TB Officers, undertaken during the year.

Monitoring and Evaluation System

Routine monitoring of the performance of TB control is crucial. The main indicators to monitor DOTS implementation are the number of cases diagnosed and notified, and the percentage of patients who are successfully treated.

The RNTCP has a comprehensive system for regular supervision and monitoring at all levels – national, state, district and sub district. A robust recording and reporting system and a series of review meetings enables early corrections. RNTCP is a programme that is managed both from the technical as well as programmatic point of view. Since it has a set of complex diagnostic, treatment and follow-up modalities, the programme has an intensive and dynamic supervision and monitoring strategy. Dedicated supervisory staff, an intrinsic recording and reporting system and a set of monitoring indicators to cover all the related activities ensures that the programme has an inherent capacity to identify issues and proactively consider remedial measures.

The activities extensively monitored by RNTCP are:

1. **Programme indicators:** These are monitored on the basis of quarterly reports of programme Performance. Suitable feedback is sent to concerned states/districts.
 2. **Logistics and quality control:** This is monitored through the information received from the procuring agency, suppliers, reports of Government Medical Store Depots (GMSD) and the quarterly reports from the States/Districts.
 3. **Progress of training:** Information is received from the quarterly reports on training and the compiled reports from training institutions.
 4. **Progress in filling up of key posts:** Information is received from quarterly reports and reports of supervisory visits.
 5. **Expenditure and budget utilization:** This information is obtained from Statement of Expenditure (SOE), Utilization Certificate (UC), Audit Report (AR) and from reports of state and central level evaluations.
1. **ACSM activities:** It is ensured that the action plan on ACSM submitted by all the States/districts is put into practice as per the plan locally.

The process of monitoring broadly covers supervisory visits, review meetings at various levels and programme evaluation by different levels of health personnel. Measurable indicators for quality control, programme outcomes and operational effectiveness are the basis for programme monitoring.

1. **Analysis and Feedback on Routine Surveillance**

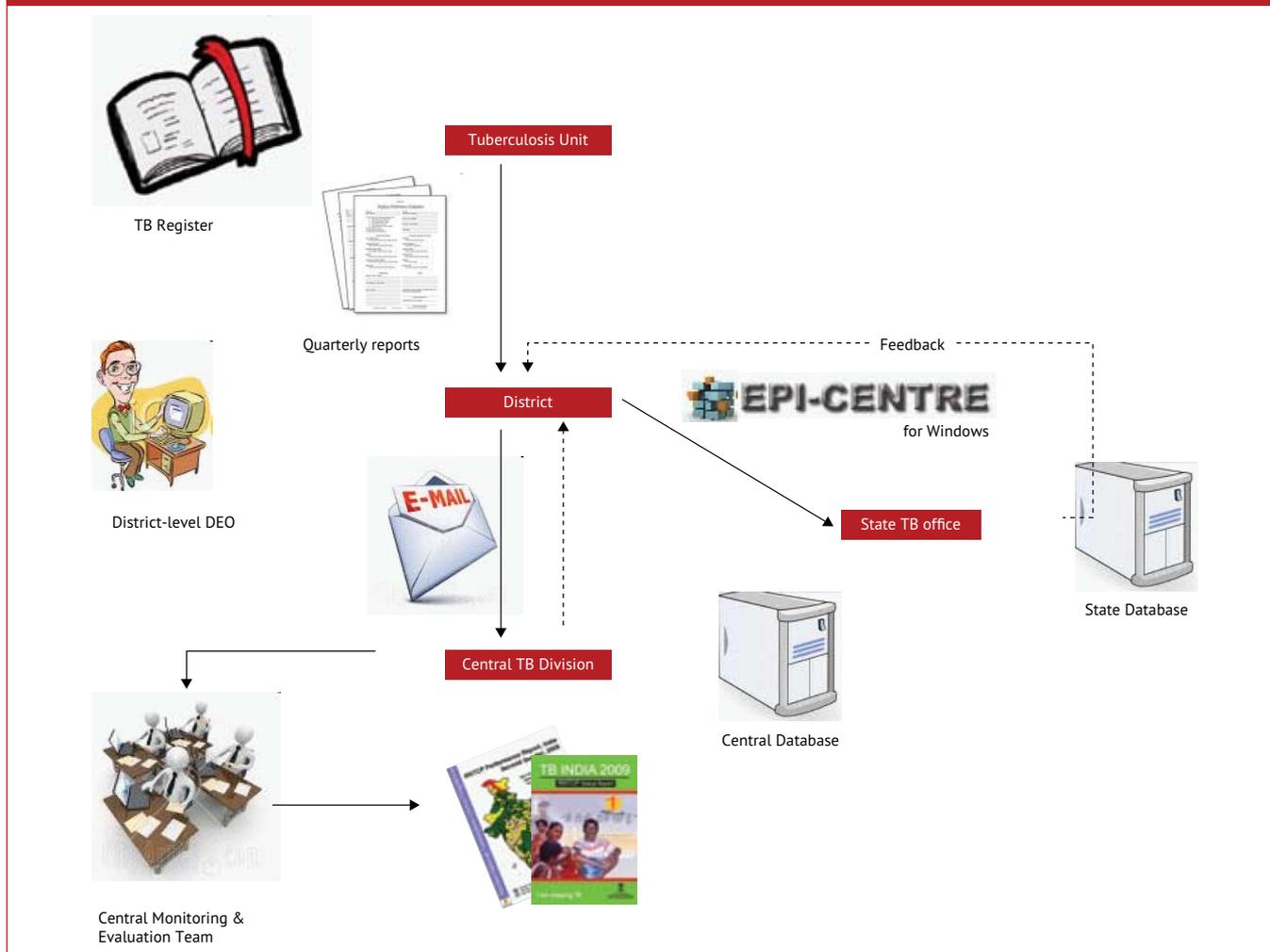
Data: Surveillance data are received through the quarterly reports. An accurately compiled quarterly report provides base level information about the performance of the programme. Central TB Division analyzes these quarterly reports received from the States/Districts. Monitoring capacity at State level has been enhanced so that State TB Officers/Medical Officers-STC/STDC analyzes the quarterly reports and provides feedback to the districts within the state.

Electronic Data Management system: RNTCP has an exceptionally successful system for timely collection, transmission, validation, analysis and feedback of programme surveillance data using electronic data management system. A 'DOS' based software 'EPICENTRE' was used for this till 2009 and a new software based on 'windows' has been successfully piloted and has replaced the existing 'DOS' based software from 1st quarter 2010.

2. **Supervisory visits and feedback:** Monitoring of the performance of the programme is mainly done by supervisory visits. Good supervision helps to increase the efficiency of the staff by updating their knowledge, perfecting their



Data Management System in RNTCP



skills and improving their attitudes towards work. RNTCP lays out clear responsibilities to the respective staff at all levels in relation to supervisory visits. Schedules of supervisory visits by the managers at different levels are as given below:

visits encourage good practices of RNTCP as well as identify and correct inadequate performances. The contact details of the STS, STLS, MOTCs, DTOs and STOs of the country are available on the TB India website (www.tbcindia.org).

STS/STLS	STS to visit all the PHIs/DMC at least once in each month and STLS to visit all DMCs at least once a month.
MO-TC	To travel 7 days in a month on supervisory visits.
DTO	To travel about 20 days in a month and visit all the DMCs at least once in a month and all the PHIs at least once in a quarter.
STO	To visit each district at least twice a year.

STS/STLS, MO-TC and DTO record their observations in a tour diary, a supervisory check list and a supervision register placed in all RNTCP facilities. Supervisory



DTO Verifying records and reports during supervisory visits

3. **Regular review meetings:** RNTCP has a system for periodic review of the programme implementation activities at all levels. The level and the frequency of these meetings are as given in Table 6.
4. **Periodic in-depth evaluations:** Information and action points generated through periodic evaluations are an important tool for evaluation of the programme. States are conducting internal evaluation of 2 districts per quarter.

TABLE 6: Review Meetings

Level	Frequency of review
Peripheral Health Institutions (PHIs) & Designated Microscopy Centres (DMCs)	MO i/c PHI/DMC conducts a meeting of all the staff involved in RNTCP and reviews their activities weekly.
Tuberculosis Unit (TU)	MO-TC reviews the activities of STS/STLS at least fortnightly.
District Level	<ul style="list-style-type: none"> ◆ DTO reviews the monthly activity reports of all MOTCs, STS and STLS within the district during monthly district level review meetings. ◆ CMO and DM also review the programme on a regular basis.
State Level	<ul style="list-style-type: none"> ◆ State level review meetings are held every quarter and chaired by Secretary (Health)/DHS. ◆ STO also reviews the monthly activity reports of DTOs within the states. ◆ Recommendations of all the evaluations and the actions taken are discussed at the meeting.
National Level	CTD conducts review meetings of STOs twice in a year. All important issues covering technical performance, administrative and managerial issues, manpower resources, logistics and financial issues, are reviewed.

TABLE 7: Supervision, monitoring activities and tools under RNTCP for each level of programme implementation

Unit responsible (persons)	S & M activities	Tools
Central Unit (Deputy Director General (DDG)/ Chief Medical Officers (CMOs)/ WHO India team/NRL/CTD RNTCP-WHO Consultants)	<ul style="list-style-type: none"> ◆ Undertake programme reviews with State TB officers at national level twice a year ◆ Conduct periodic review of RNTCP in the states with the DTOs during state level review meetings ◆ Conduct Central level internal evaluations of least 2 districts every month ◆ NRL team to visit IRL (for On-site evaluation and Panel testing) at least once every year 	Programme reviews Annual programme report (National) 6-monthly programme review with State TB Officers (STOs) Quarterly and annual State reports District evaluation reports Monthly activity reports of STOs Monthly reports of RNTCP-WHO Consultants Report from medical college ZTFs
State TB Cell (STO/MO/STDC Director/IRL Microbiologists/ RNTCP-WHO Consultants)	<ul style="list-style-type: none"> ◆ Visit all districts in the state at least once every 6 months ◆ Undertake state level internal evaluations of at least 2 districts every quarter ◆ IRL team to visit DTC at least once a year ◆ Conduct quarterly review meetings with the district TB officers at state level. 	Annual programme report (State and districts) Quarterly programme review with District TB Officers (DTOs) Quarterly District/TU reports District evaluation reports Monthly activity reports/tour diaries of DTOs Tour diary of STO/supervision checklist Report from medical college STF
District TB Centre (District TB Officer/2 nd MO DTC)	<ul style="list-style-type: none"> ◆ Reserve 3-5 days in a week for field visits (between DTO and 2nd MO) ◆ Visit all TB units every month ◆ Visit all microscopy centres every quarter 	Annual district report Quarterly TU reports Monthly programme review Monthly PHI reports Quality assurance report

Unit responsible (persons)	S & M activities	Tools
	<ul style="list-style-type: none"> Visit the homes of at least 3 randomly selected NSP patients and their DOTS providers on every field visit day Visit to medical college if any, every month Conduct DTCS review meeting every quarter to be chaired by DM Conduct monthly review meeting at the DTC to be chaired by DM/CMO 	Tour diary of DTO/supervision checklist Monthly activity reports of MOTCs, STS and STLS RNTCP TB register Supervision register Referral for treatment register Supervisory checklist
Medical Officers (TB Control)	<ul style="list-style-type: none"> Reserve at least 7 days in a month for field visits Visit all microscopy centres every month Visit most of the participating private as well as public Peripheral Health Institutions (PHIs) every quarter Visit the homes of at least 3 randomly selected NSP patients along with their DOT providers on every field visit day Conduct fortnightly review meeting with STS/STLS 	RNTCP TB register RNTCP Laboratory register Supervision register PHI monthly reports OSE QA reports of STLS Supervisory checklist
STLS	<ul style="list-style-type: none"> Visit all the microscopy centres at least once every month. Conduct OSE at the DMC 	Laboratory register OSE checklist
STS	<ul style="list-style-type: none"> STS should visit all DMCs and PHIs at least once every month. The STS should visit all the smear positive patients within one month of starting treatment 	TB register Laboratory register Treatment cards Referral for treatment register Supervisory checklist

In addition, internal evaluations are conducted by the central level with active participation of personnel from the states, Medical Colleges and NGOs.

During the year, the states have evaluated about 107 districts using a standardized format which covers the entire gamut of RNTCP services. The reports are

disseminated amongst the DTOs to enable corrective actions to issues in their districts. Actions taken on the recommendations are regularly reviewed by the state. The central level has visited and intensively evaluated 5 states – evaluated 10 districts in addition to reviewing state level issues. The findings of the central level evaluations were discussed with the highest authorities of health and administration of



Central Internal Evaluation Assam



DOT provider visit during Internal Evaluations.

the state to enlist their active support for TB control activities in the state.

TB/HIV Collaborative Efforts

Scale-up TB-HIV Collaborative Activities

The interaction between HIV infection and tuberculosis (TB) is well documented. HIV-infection is among the strongest known risk factors for progression of latent TB infection to active disease. HIV-infected persons are many times more likely to develop TB than patients without HIV infection. Active TB disease is the most common opportunistic infection and the most common cause of death amongst HIV infected individuals.

India, the third highest HIV burden country, had an estimated 2.39 million (translating to a prevalence of 0.31%) people living with HIV/AIDS (PLHAs), about 1.2 lakh new HIV infections and 1.72 lakh deaths due to AIDS related causes in 2009. The nationwide estimated HIV seroprevalence among TB patients for 2007 was 4.85% (95% CI 4.12%–5.73%). The worst affected states are Andhra Pradesh, Karnataka, Manipur, Maharashtra, Nagaland and Tamil Nadu. These six states account for about 57% of PLHA in India and are classified as High Prevalence States. Another three states namely Gujarat, Goa and Ponducherry have been classified as Moderate HIV prevalence states. This is the first time HIV incidence estimates have been calculated and the 6 high prevalence states accounts for only 39% of these infections indicating new pockets of transmission in low prevalence states, emphasizing the enormous challenge ahead. The HIV epidemic pattern in the country shows great variance and 2009 estimates indicate an overall decline in HIV prevalence and incidence.

TB-HIV coordination activities are being implemented since 2001. Central TB Division (CTD) & National AIDS Control Organization (NACO) have revised the “National framework for Joint TB-HIV collaborative activities” in October 2009 which establishes uniform activities at ART centres and ICTCs nationwide for Intensified TB case finding and reporting, strengthens joint monitoring and evaluation with specified national TB/HIV programme indicators and performance targets.

All the WHO recommended TB/HIV collaborative activities have been incorporated in the national framework and include the following

1. Establish/Strengthen NACP-RNTCP coordination mechanisms at national, state and district levels.
2. Joint Monitoring and Evaluation including standardized reporting shared between the two programmes.
3. Training of the programme and field staff on TB/HIV using standard modules.
4. Scaling up of Intensified TB/HIV Package of Services across the country.
 - a. Routine offer of HIV testing to TB patients
 - b. Decentralized provision of Cotrimoxazole Prophylactic Treatment (CPT) for HIV-infected TB patients
 - c. Linking of HIV-infected TB patients to NACP for HIV care and support (including antiretroviral treatment)
5. Activities to reduce the burden of TB among HIV-infected individuals
 - a. Intensified TB case finding at ICTCs, ART and Community Care Centres (CCC)
 - b. Implementation of feasible and effective infection control measures
6. Involvement of NGOs/CBOs and affected communities working with NACP and RNTCP for all activities on TB/HIV collaboration.
7. Operational research to improve the implementation and impact of TB/HIV collaborative activities.

Intensified TB-HIV Package

The Intensified TB-HIV package is being scaled up in a phased manner to cover the entire country by 2012. Intensified TB/HIV package of services have been rolled out in 29 states (6 high prevalence states and Goa, Mizoram, Puducherry in 2008, Delhi, Gujarat, Assam, Kerala, Punjab, Rajasthan, West Bengal, Orissa and Chandigarh in 2009 and 11 states namely Haryana, Himachal Pradesh, Uttarakhand, Jharkhand, Uttar Pradesh, Meghalaya, Sikkim, Tripura, Arunachal Pradesh, Chhattisgarh, Madhya Pradesh in 2010). Training in all the states where intensified TB/HIV package has rolled out during 2010 is being completed and have started recording and reporting HIV status of TB patients, linking all HIV-infected TB patients for care and support including ART and CPT.

RNTCP has sanctioned a dedicated Senior “TB/HIV and DOTS-Plus supervisor” post in all the districts of the country to support the programme in these activities.

To address the issue of airborne infection control, which is particularly important for HIV care settings, a National Airborne Infection Control Committee (NAICC) was constituted in 2008, and has developed National Guidelines on Airborne Infection Control in health care and other settings. The Guidelines are now available for use nationwide, and NAICC has evaluated the operational feasibility and effectiveness of the guidelines, in the states of West Bengal, Gujarat and West Bengal.

The National Technical Working Group for TB/HIV acknowledges the evidence of IPT among PLHIV and has decided to pilot test the feasibility of its implementation in selected ART centres of the country before decision on nationwide scale-up. As per the recommendation of national TB/HIV consultation at National AIDS Research Centre, Pune, it has been decided to collect efficacy data as well across all CD4 strata under programmatic conditions.

For HIV-infected TB patients requiring co-administration of ATT and ART with protease inhibitors (i.e. second-line ART or alternate first line ART containing PIs), Rifampicin should be replaced by Rifabutin to avoid drug-drug interactions between rifampicin and PIs. States have been permitted by CTD to procure Rifabutin based on local requirement and use as per guidelines.

The year 2010 saw continued increase in the quantum of referrals between the programmes. In 2010, about 393,110 TB suspects (7.4% of all clients counseled) were referred from ICTCs to RNTCP and of

them about 35,547 were diagnosed as having TB and provided TB treatment (Figure 4). In the same period, about 480,752 TB patients (59% of total TB patients registered in states implementing Intensified TB/ HIV package) were tested for HIV and of them about

Figure 4: ICF referral of ICTC clients for TB diagnostic evaluation, 2006–2010

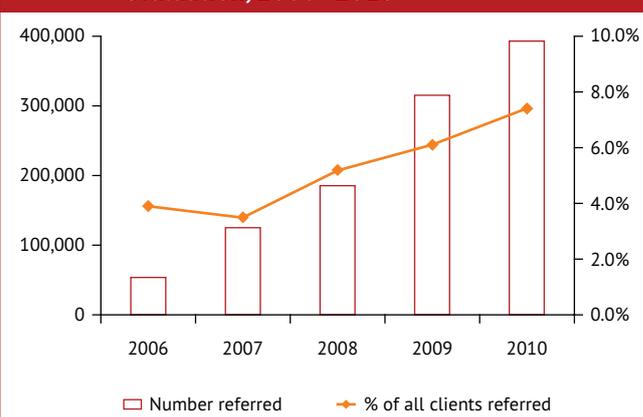


Figure 5: Trends in Number (%) of registered TB patients with known HIV status, 4q08–4q10

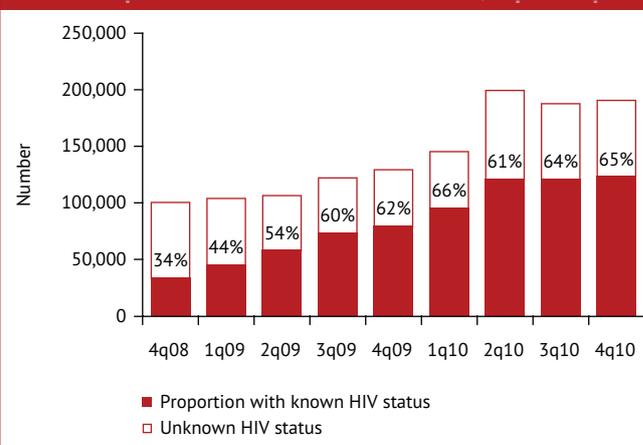
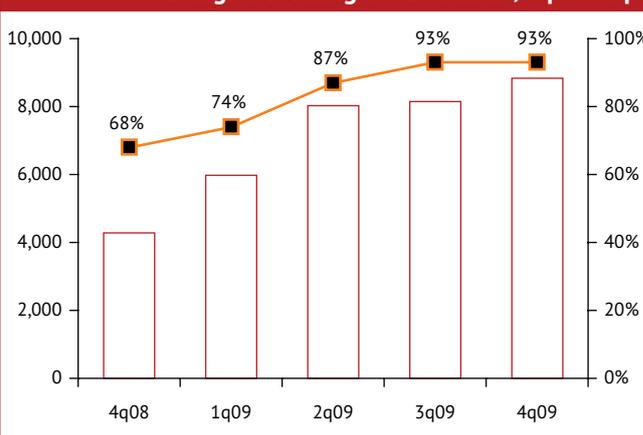
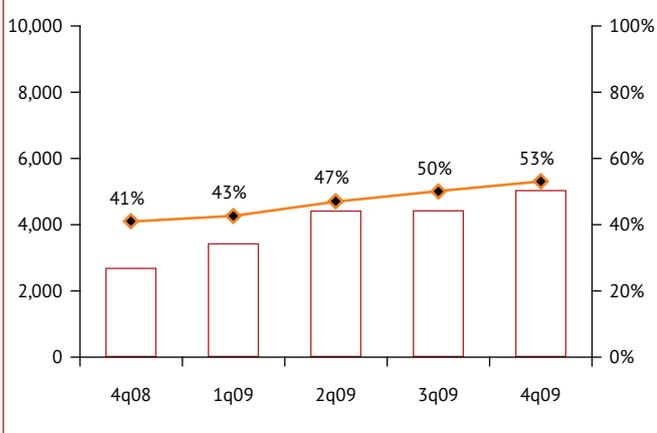


Figure 6: Number (%) of HIV-infected TB patients receiving CPT during TB treatment, 4q08–4q09



TOT Training in Intensified TB HIV package Arunachal Pradesh

Figure 7: Number (%) of HIV-infected TB patients receiving ART during TB treatment, 4q08–4q09



41,476 were diagnosed as HIV-infected (Figure 5). Of these, about 88% received CPT and 49% received ART during TB treatment indicating the enormous challenge of linking to ART centres (Figure 6 and 7). The success of further scale-up would depend on the scale-up of HIV testing services (Facility integrated ICTCs and Whole blood testing). Unless all HIV-infected TB patients are linked to ART as early as possible, the high death rates documented among HIV-infected TB patients would continue. This is the greatest priority for both the programmes.

RNTCP-DOTS Plus - Programmatic Management of Drug Resistant TB

Prevalence of Drug Resistant TB in India

The emergence of resistance to drugs used to treat tuberculosis has become a significant public health problem in a number of countries and an obstacle to effective TB control. Drug resistant tuberculosis has frequently been encountered in India and its presence has been known virtually from the time anti-tuberculosis drugs were introduced for the treatment of TB. There have been a number of reports on drug resistance in India, but most studies were undertaken using non-standardized methodologies and biased or small samples, usually from tertiary level care facilities. To obtain a more precise estimate of Multi-Drug Resistant TB (MDR-TB) burden in the country, RNTCP carried out drug resistance surveillance (DRS) surveys in accordance with global guidelines at in selected states, Gujarat (56 million population) and Maharashtra (107 million) in 2005-2006 and Andhra Pradesh (81 million) in 2007-2008. The

results of these surveys indicate prevalence of MDR-TB to be low i.e. less than 3% amongst new cases and 12-17% in re-treatment cases. These surveys also indicate that the prevalence of MDR-TB is stable in the country as the previous studies conducted by TRC, Chennai and NTI, Bangalore have shown a similar prevalence figures. To substantiate the findings of the earlier surveys, two more DRS surveys are presently ongoing in Western UP (85 million) and one is planned in Orissa in the near future. These surveys will be undertaken periodically to monitor and study the trend of prevalence of MDR in the community.

As per WHO Global TB Report 2010 and Multidrug and extensively drug-resistant TB (M/XDR-TB) – 2010 Global Report on Surveillance and Response, the estimated MDR TB cases emerging annually in India are reported to be 99,000 among incident total TB cases in India in 2008 (range 79,000 – 1,20,000) of which 55,000 were among incident new and relapse TB cases. However, based on the results of the recently undertaken DRS surveys, it is estimated that up to 50,000 detectable MDR cases emerge annually in the country that could be detected by drug-susceptibility testing of smear-positive patients currently notified under the RNTCP.

Emerging Threat of Second-line Anti-TB Drug Resistance and Extensively Drug Resistant TB (XDR-TB)

Extensively drug resistant TB (XDR-TB), subset of MDR-TB with resistance to second line drugs i.e. any fluoroquinolone and to at least 1 of the 3 second line injectable drugs (capreomycin, kanamycin and amikacin), has been reported in India. However, the extent and magnitude of this problem is yet to be determined. Results of the second line DST on MDR isolates from Gujarat DRS survey have shown that there is no XDR amongst new cases and the prevalence amongst re-treatment cases is 0.5%. The same survey, however, showed the finding of 24% (52/216) ofloxacin resistance among MDR-TB isolates, including 19% (7/37) among isolates from TB cases who had reported no previous history of MDR-TB treatment. The extent of fluoroquinolone resistance observed is of great concern, and may compromise MDR-TB treatment outcomes. Efforts to expand surveillance to second-line anti-TB drugs are underway.

RNTCP Response to the Challenge of Drug Resistant TB

The programme has developed a multi-faceted response plan to combat the challenge of drug resistant TB. The key focus of RNTCP is to prevent the emergence of drug resistance by providing quality DOTS diagnostic and treatment services, increasing the visibility and reach of the programme services and promoting adherence to International Standards of TB care by all healthcare providers. Indiscriminate and injudicious use of anti-TB drugs, especially outside the programme, is a significant contributor to the emergence of drug resistance TB. The programme has taken concrete steps to promote rational use of anti-TB drugs; these include the development of a guidance document, popularly called “The Chennai Consensus Statement”, for healthcare providers on the prevention and management of drug resistance TB outside the programme settings. The programme through the aegis of professional medical associations and Medical Council of India is sensitizing, educating and urging healthcare providers on judicious use of anti-TB drugs. The intervention of drug regulatory authority of the country is being sought to strictly enforce sale of anti-TB drugs against valid prescription through a special directive.

Besides initiating and strengthening measures for prevention of drug resistance, the programme has simultaneously initiated diagnostic and treatment services for the management of MDR TB. These services which are considered “Standard of Care” by RNTCP were commenced in 2007 in identified districts in the states of Gujarat and Maharashtra. Over the last years these services have been expanded to 12

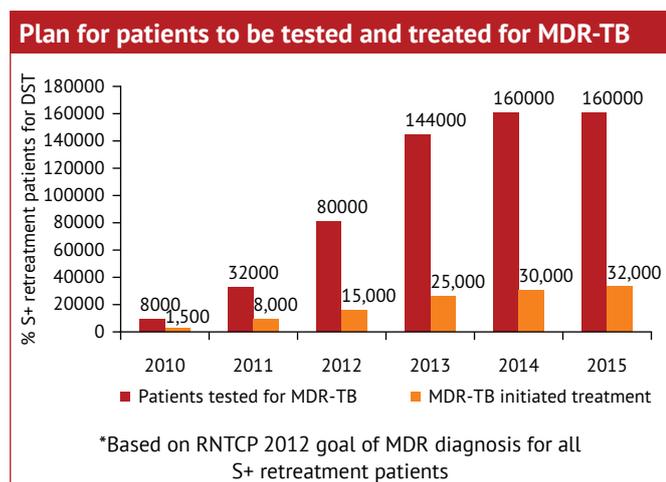
States. Despite the modest beginning, the programme has ambitious plans to rapidly scale up the DOTS Plus services in the country. It is envisioned that by the end of 2011 the MDR TB services will be introduced in all the states across the country in a phased manner. By 2012 it is aimed to extend drug susceptibility testing to all smear positive retreatment cases upon diagnosis, and all new cases who are smear-positive after first-line anti-TB treatment. By 2015 drug susceptibility testing will be made available to all smear positive cases registered under the programme. It is intended to be initiating MDR TB treatment at a rate of 30,000 MDR cases annually by the end of 2012. This is enabled by a nationwide laboratory scale up plan developed by the programme with an ambition to have 43 culture & DST laboratories (Solid & LPA techniques including Liquid Culture in 33 labs) in the public health sectors by 2015.

RNTCP services for MDR TB and plans for scale-up have been the subject of extensive national and international review, including a joint mission of the WHO Green Light Committee (GLC) and Global Lab Initiative (GLI) in April 2010, and the RNTCP joint donor and partner mission of May 2010.

Key Activities During 2010

National DOTS Plus Scale up Micro-plan Developed

A series of state wise DOTS Plus scale-up micro-planning meetings were organized by CTD in November 2010, with 34 states at New Delhi. In these meetings, the key officials of each state revised their respective state micro-plans for rolling out DOTS Plus services in phased manner with the CTD team and aligned their state micro-plans and timelines with the planned resources of the national level including second line anti-TB drugs procurement, available laboratory capacity for diagnosis and follow up of MDR TB, and national laboratory scale up plan. All the states re-worked on their state DOTS Plus scale-up micro-plan with realistic timelines for completion of various preparatory activities to introduce and scale-up of DOTS Plus services in all the districts of the state in a phased manner. This meticulous micro-planning exercise clearly spelt out the demand and timelines for national trainings, central level DOTS Plus appraisals of states and laboratory capacity deficits in states where an external backup need to be arranged.

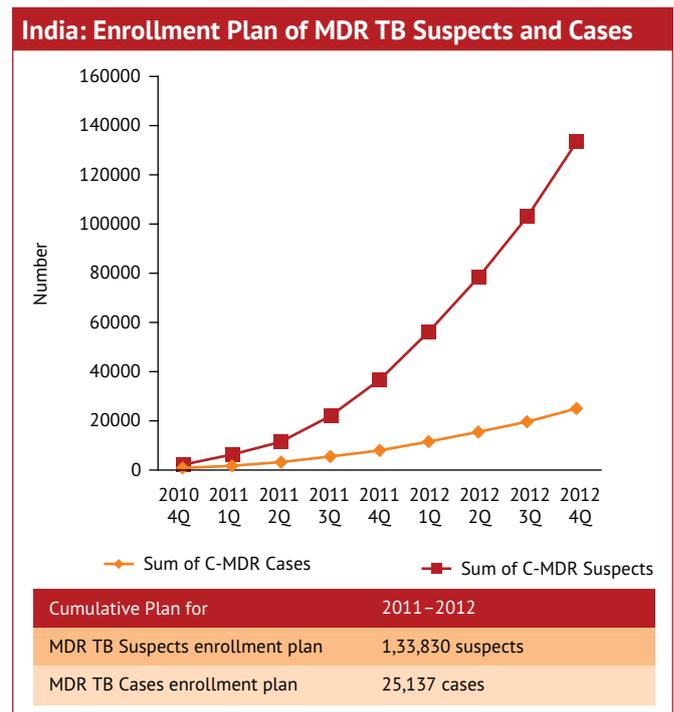


The national DOTS Plus scale-up micro-plan for the year 2011 and 2012 has been evolved by consolidating the state DOTS plus scale-up micro-plans. This national micro-plan was externally validated by a parallel analysis by experts from Clinton Health Access Initiative. The key outputs of the national micro-plan are as follows:

1. Drug quantity calculations were completed for the implementing state to ensure uninterrupted supply of second line anti-TB drugs, and immediate transfer of the requisite quantity of drugs was undertaken from CTD.
2. National MDR TB patient treatment capacity was concisely determined based on the quantities of various second-line drugs planned and their expected delivery timelines over two years for each state.
3. The scale-up of DOTS Plus activities with timelines was planned by geography and by criteria to prompt drug susceptibility testing, which is being scaled up nationwide in a phased manner as under:
 - a. Criteria A: Failures of registered NSP and NSN, Failures and Non-Converters of registered S+ve RT, S+ve contacts of MDR TB cases registered for treatment
 - b. Criteria B: All S+ve RT cases registered for treatment (Relapse, TAD, Failure and Others)
 - c. Criteria C: All S+ve Cases (New and RT) registered for treatment
4. The numbers of MDR TB patients that can be initiated on treatment by states were determined using assumptions based on current national experience of MDR TB rates and rates of patients attritions from services applied to the annual RNTCP performance data by districts for the respective states. The decisions on clear timelines for rolling out services in districts by phases was carefully taken with a view of all preparatory activities like civil works, staffing, trainings and appraisals.
5. These enrollment plans of MDR TB Suspects and Cases were also carefully determined to ensure that these remain within the available laboratory capacity and the second-line drug supply envelope for the respective state over the next two years.

6. To scale up treatment services, against the 120 planned DOTS Plus Sites, 115 sites were identified across 34 states and timelines for their up gradation for airborne infection control and rolling out of services were determined.
7. National DOTS Plus training and appraisal needs to meet the scale-up plan for the states were also determined. A clear strategy to meet these demands for national trainings and appraisal demands under the scale-up plan has been developed by CTD. A core team of experts and consultants from national institutes and experienced states have been developed to support CTD in meeting the training and appraisal needs as per the scale-up micro-plan.

This national plan is being formally documented and the final version will be communicated to all states.



Training Activities

National level DOTS Plus Trainings are conducted at LRS Institute, New Delhi; STDC, Ahmedabad, Gujarat and STDC, Hyderabad, Andhra Pradesh. As a felt need identified in the National DOTS Plus Scale-up Micro-plan, the 4th National DOTS Plus Training Center was strategically initiated at STDC, Trivandrum, Kerala where the 1st national training batch was organized under mentorship of CTD and STDC Ahmedabad in December 2010.



Secretary Health of Kerala inaugurating National DOTS Plus Training at Trivandrum, Kerala on 14th December 2010. STDC Trivandrum recognized as the 4th National DOTS Plus Training Centre

In 2010, National level DOTS Plus trainings were undertaken for the states of Karnataka, Madhya Pradesh, Uttar Pradesh, Uttarakhand, Chhattisgarh, Jharkhand, Jammu & Kashmir, Sikkim, Arunachal Pradesh, Puducherry, Andaman & Nicobar Islands, Andhra Pradesh (Phase IV and V), Delhi (Phase II) and Tamil Nadu (Phase V). As per the National DOTS Plus Scale-up micro-plan, the national trainings of state

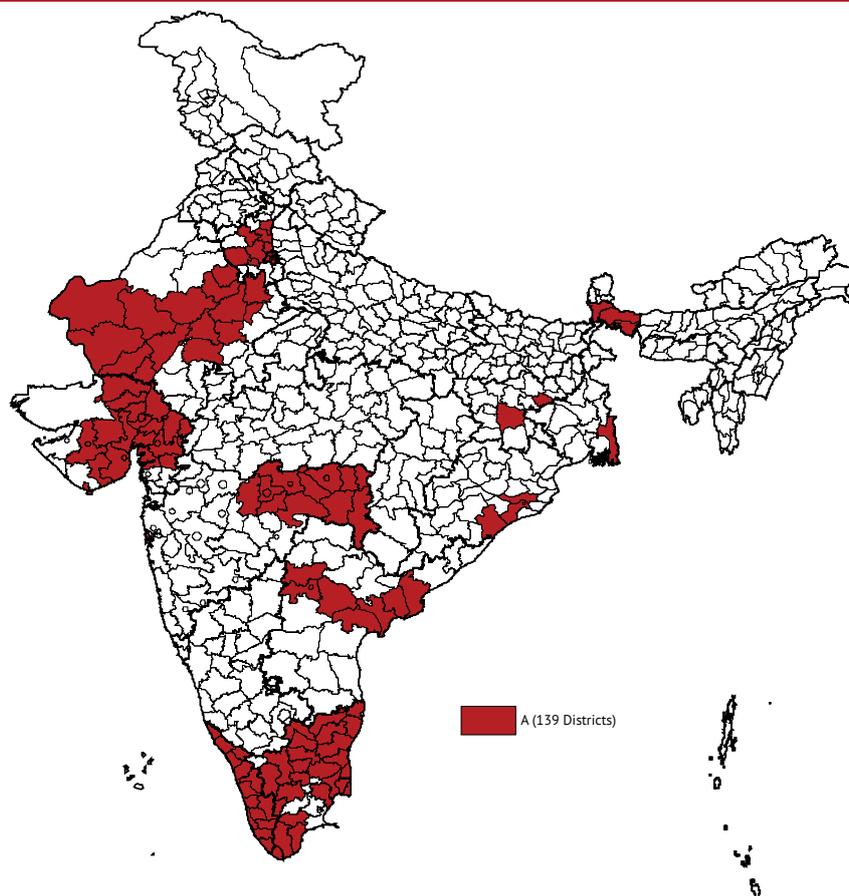
level trainers and 1st phase districts of the remaining states will be completed by end of February 2011.

National DOTS Plus Appraisals

In 2010, National level DOTS Plus appraisal system was introduced with the objective to ensure programme readiness and adequate quality of services in states and districts before initiating DOTS Plus services for MDR TB. These appraisals are being conducted nationwide by external teams of experts nominated by Central TB Division and MDR TB treatment services would be introduced after successful appraisals and corrective action against programme deficiencies.

In the year 2010 national DOTS Plus appraisals were undertaken for Maharashtra (7 districts, 2 DOTS Plus Sites and 3 Laboratories), Himachal Pradesh (2 districts, 2 DOTS Plus Sites and 2 Laboratories), Jharkhand (2 districts, 1 DOTS Plus Site and 2 Laboratories) and Madhya Pradesh (2 districts, 2 DOTS Plus Site and 3 Laboratories). The pace of appraisals is expected to greatly accelerate in 2011 to meet national service expansion needs.

DOTS Plus Coverage by Geography & Suspects Criteria - As on December 2010



Cumulative Status of DOTS Plus at the End of 2010

The MDR TB services were initiated in 2007 in Gujarat and Maharashtra. Currently, 12 States namely Gujarat, Maharashtra, Andhra Pradesh, New Delhi, Haryana, Kerala, Tamil Nadu, Rajasthan, Daman & Diu, West Bengal, Orissa and Jharkhand are implementing DOTS Plus services in some districts. The states of Himachal Pradesh, Madhya Pradesh, Uttar Pradesh, Chhattisgarh, Uttarakhand, Karnataka and Puducherry are preparing to initiate services shortly. The remaining states are preparing to initiate services in 2011.

At the end of the 4th quarter of 2010 the MDR TB treatment services have been scaled up to cover ~288 million population in 141 districts across 12 states. Since the inception of DOTS Plus services in India, a cumulative total of 19178 MDR TB Suspects have been examined for diagnosis; 5365 MDR TB cases have been confirmed and 3605 MDR TB cases have been initiated on Category IV treatment through 20 DOTS Plus Sites.

In the year 2010, 10025 MDR TB Suspects have been examined for diagnosis; 2967 MDR TB cases have been confirmed and 2178 MDR TB cases have been initiated on Category IV treatment. Two DOTS Plus Sites started functioning in the year 2010 namely Group of TB Hospitals, Mumbai and TB Sanatorium,

Itki, Ranchi. MDR TB treatment services were initiated in Jharkhand since December 2010.

The following Table 8 summarizes the implementation status of DOTS Plus services for diagnosis and treatment of MDR TB in various states:

Out of the cumulative total of 984 MDR TB Cases registered for treatment 12-15 months earlier, 549 cases (56%) were reported to be alive, on treatment and culture negative at 12 months of treatment.

Regular reporting and analysis of TB treatment outcomes for programme improvement is an ongoing activity in RNTCP, and MDR TB treatment services are no different. The treatment outcomes of MDR TB for the initial pilot sites in Gujarat and Maharashtra have been reported. These are the first MDR TB treatment outcomes under RNTCP. These patients were generally heavily treatment experienced, chronic cases, and so expectations on treatment outcomes were limited. Out of the cumulative total of 137 MDR TB Cases registered for treatment 31-33 months earlier, 59 cases (43%) have been successfully completed treatment while 28 cases (20%) died, 21 cases (15%) failed and 29 cases (21%) defaulted treatment. Substantial improvements in policies and procedures have been implemented to reduce treatment default, affective 1 in 5 registered MDR TB case. Explanatory research is underway to understand the unacceptable failure rates, but early

TABLE 8: DOTS Plus Implementation Status and Progress – 2007 to 2010

State	Initiation of Diagnostic services	Initiation of Treatment Services	Number of Districts Implementing	MDRTB Suspects examined by C-DST	MDRTB cases diagnosed [§]	MDRTB cases initiated on treatment [#]
Andhra Pradesh	Jun 2008	Oct 2008	8/24	1721	588	425
Delhi	Sep 2008	Dec 2008	24/24	4504	1203	703
Gujarat*	Mar 2007	Aug 2007	21/30	3950	1277	942
Haryana	July 2008	Sep 2008	7/21	679	150	101
Jharkhand	Mar 2010	Dec 2010	2/24	82	8	3
Kerala	July 2008	Sep 2008	14/14	2199	369	262
Maharashtra	Mar 2007	Sep 2007	16/55	1643	604	376
Orissa	Sep 2009	Nov 2009	4/31	134	49	32
Rajasthan	Mar 2009	May 2009	15/32	2084	520	322
Tamil Nadu	Sep 2008	Jan 2009	25/31	722	145	174
West Bengal	Aug 2008	Dec 2008	5/19	1460	452	270
Grand Total			141/658	19178	5365	3610

* Daman & Diu had initiated 1 case of MDR TB in 2008 that was reported under Gujarat.

§ Refers to number of cases whose C-DST results are reported up to 31st Dec 10, with many specimens received in 2010 still pending.

Refers to MDR TB cases initiated on treatment as on 31st Dec 10. These numbers reflect different cohorts of patients and should not be directly compared with the numbers diagnosed.

results suggest poor outcomes have been strongly associated with pre-treatment ofloxacin resistance in this patient cohort. This analysis is being expanded to subsequent sites and cohorts to inform ongoing revision of programme policies and procedures.

Involvement of Private Sector, NGO's, Medical Colleges and Civil Society in DOTS Plus

RNTCP has made significant progress towards establishing successful partnership with private sector, non-government organizations, medical colleges and civil society partners under DOTS Plus in providing services to MDR TB cases in the implementing states. To date, 7 Culture and DST laboratories from these other sector institutes accredited and engaged under DOTS Plus for management of MDR TB viz. Blue Peter Research Centre-Hyderabad, PD Hinduja Hospital-Mumbai, CMC-Vellore, RMRCT (ICMR)-Jabalpur and DFIT- Nellore and laboratories from 2 premium medical colleges of India viz. SMS Medical College-Jaipur and Grant Medical College (JJ Hospital)-Mumbai.

Moreover, 10 more laboratories from the other sector viz. PGIMER- Chandigarh, AIIMS-New Delhi, Quest Diagnostics-Gurgaon, 3 Super Religare Laboratories-Mumbai, Gurgaon & Kolkata, T Choitram – Indore, BMHRC – Bhopal, RMRC Port Blair & Dibrugarh are at the advanced stage of accreditation under RNTCP and their services are proposed to be utilized during rapid expansion phase. It is also noteworthy that 14 out of the 20 functional DOTS Plus Sites are located in Medical Colleges.

Under the Global Fund (Round 9) TB project, a group of NGO's are engaged under the leadership of 2 principle recipients viz. The Union and World Vision. They would extend support to RNTCP in 744 million population of the country in 374 selected districts to improve access to quality DOTS services and prevent emergence of drug resistance. They would also promote the adoption and implementation of Patient Centred Care for all TB patients including those with MDR-TB and HIV co-infection.

To promote treatment adherence under DOTS Plus, successful interventions of vocational rehabilitation



DR TB Training Ahmedabad

International training for Drug Resistant TB Consultants was conducted at Ahmedabad, Gujarat between 4-8 October 2010. National Consultants from >20 countries across the world participated. It was funded by USAID and organized by WHO with local support for field visits by Govt. of Gujarat. WHO SEARO has offered to develop Ahmedabad as one of the regional center of excellence for DR TB to support capacity building initiatives of various countries of South East Asia region.



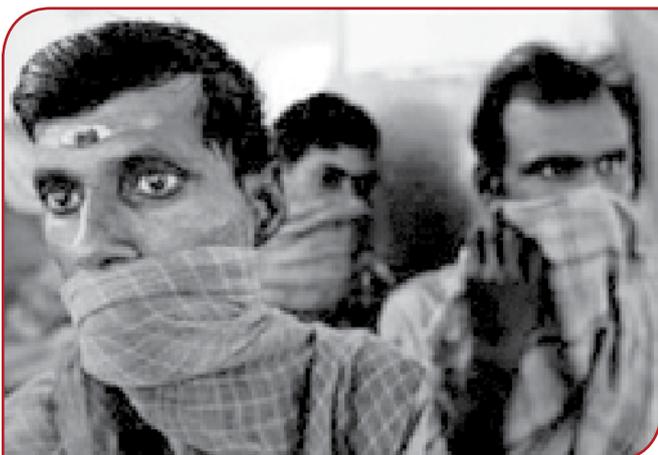


of MDR TB patients has exhibited by two NGOs viz. Shree Hari Seva Trust, Ahmedabad and Shahyog Kushth Yagna Trust, Himmatnagar in Gujarat state with support of the Elli Lily Company as part of their corporate social responsibility with the objective to assist MDR TB cases to uplift their socio-economic status and regain their self-esteem. Various types of earning articles like sewing machines, bicycles, vegetable carts, Idli stall carts etc. that match the skill set and interest of the patients were distributed by Medical Superintendent, Civil Hospital Ahmedabad, Dr. M.M. Prabhakar, Dean B.J. Medical College, Ahmedabad. Dr. Bharat Shah, Nodal Officer-DOTS Plus, Dr. R.N. Solanki, Director STDC, Dr. Pradip Patel, and other dignitaries to the MDR Patients of Ahmedabad Municipal Corporation Area.

significance in management of MDR TB cases and HIV infected individuals. These measures are expected to augment the TB control efforts currently undertaken by the programme through implementation of the STOP TB Strategy under RNTCP. Amidst the challenges of airborne infection control in India like high TB burden, high transmission of TB and other resp. diseases in health care facilities, concentration of vulnerable populations like PLHA, the scale of response and the coordination required; there also exists opportunities in India in terms of the massive health system strengthening investment underway, pandemic flu preparedness initiatives of the ministry through NCDC, growing awareness of infection

Airborne Infection Control

Airborne infection control measures are crucial for preventing spread of TB from person to person and also reducing the risk of spread of TB to health workers in institutional settings. This has greater



Guidelines on Airborne Infection Control in Healthcare and Other Settings

April 2010
 Directorate General of Health Services
 Ministry of Health & Family Welfare
 Nirman Bhawan, New Delhi

control importance and greater number of hospitals seeking accreditation.

In the absence of any existing national guidelines on airborne infection control the Medical College's National Task Force in 2007 had recommended that an "Infection Control Expert group" may be constituted to develop such guidelines which should be implemented in healthcare settings. This was endorsed by the DOTS Plus Committee in its 4th meeting in January, 2008. As a step towards this initiative, the National Airborne Infection Control Committee (NAICC) with representations from Medical Colleges, NCDC, NACO, CTD, WHO, Architects and PWD Engineers was established in 2008. The committee has developed draft National Guidelines on Airborne Infection Control in health care and other settings (April 2010) with the purpose of providing up-to-date information about recommended methods of reducing the risk of airborne infections in health care facilities. A "National Capacity Building Workshop on Air-borne Infection Control in India" was organized by RNTCP with support of CDC and WHO at LRS.

Institute, New Delhi from 20th – 24th October 2009 for National and State AIC Committee members. The NAICC identified the states of West Bengal, Gujarat and Andhra Pradesh to conduct the pilot testing of operational feasibility and effectiveness of the guidelines.

The provisional guidelines were circulated from CTD to all states in April 2010 with the purpose of prioritizing its implementation in high risk settings like MDR TB Wards (DOTS Plus Sites), TB Culture and DST Labs, ART Centres, Bronchoscopy Suits etc.

As part of this pilot, the following activities were undertaken by CTD and the 3 pilot states:

- ◆ A state airborne infection control committee (SAICC) was established to ensure smooth implementation and regular review of adoption and integration of the national AIC guidelines in hospital infection control plans of various health care facilities in the states.
- ◆ The states developed an action plan to implement the National Guidelines on Airborne Infection Control in 2010-11. Funds required for conducting the AIC pilot were made available through the NRHM Flexi-pool by the respective states.
- ◆ 35 health care facilities ranging from tertiary level institutes like Medical Colleges to

primary level health centers and sub-centers spread across 13 districts were identified by the 3 states for this purpose. These included 7 Medical Colleges and 2 high end Private Hospitals as well as high risk settings like 10 ART Centres, 4 MDR TB wards, 7 Bronchoscopy Suits, 2 TB Culture and DST labs.

- ◆ A state level capacity building workshop on Airborne Infection Control was conducted for state, district and facility administrators included in the pilot in all 3 states between March '10 to July '10.
- ◆ Baseline health care facility risk assessments conducted by State teams with National-level facilitators to assess the prevailing infection control systems, IC human resources, administrative controls and practices, Environmental situation like room volumes and air exchange per hour, personal protective measures and ACSM efforts on AIC.
- ◆ Recommendations to improve airborne infection control measures provided to respective HCF administrators based on national AIC guidelines.
- ◆ Standard AIC Quarterly reporting on indicators developed from national AIC guideline were initiated from all states since 3Q10.

A parallel initiative to build capacity of the Architects and Engineers to adopt the principles of Airborne Infection Control in the design or renovation plan of health care facilities was also undertaken with support of WHO, PATH and USAID. A team of 4 Architects (1 from DGHS and 3 from Pilot States) were trained at an international training course for Architects and Engineers in "Building Design and Engineering

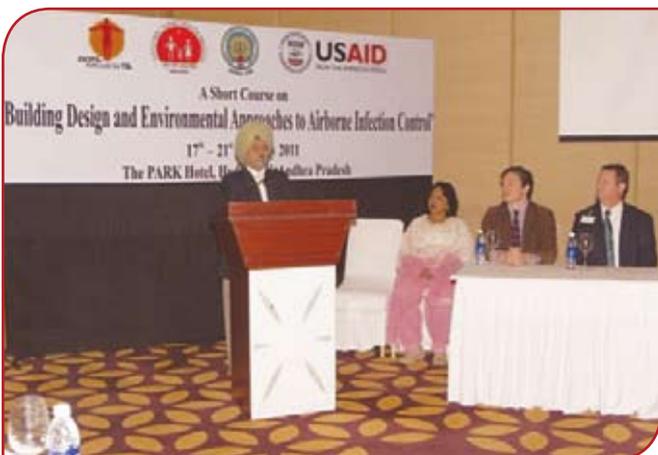




Health Care Facility AIC Risk Assessments conducted in 35 facilities of 3 states

Approaches to Airborne Infection Control” from 2nd – 13th August 2010 at Boston, MA, USA. The course was conducted by experts from Partners in Health and CDC Atlanta at Harvard School of Public Health. This was followed by an in-country training course in “Building Design and Engineering Approaches to Airborne Infection Control” for Architects and Engineers from 6 states viz. Gujarat, West Bengal, Andhra Pradesh, Maharashtra, Rajasthan and Karnataka; from 17th to 21st January, 2011 at Hyderabad, Andhra Pradesh with the support of PATH, USAID and WHO India. The 4 architects of India facilitated the training with support from external facilitators from Partners in Health, Boston and CDC Atlanta.

The progress made by India in establishing Airborne Infection Control systems and the initial results of the pilot implementation were presented at the at 41st Union World Conference on Lung Health at the International Congress Centre in Berlin, Germany, on 11-15 November 2010. The summary of the initial results of the pilot implementation based on the baseline facility risk assessments of 35 HCFs are as follows:



AIC workshop in Hyderabad

- ◆ Infection control systems in general are poorly developed.
- ◆ Airborne infection control component was absent from Hospital Infection Control Plans.
- ◆ Administrative controls uncommonly practiced
- ◆ About half of departments need minor renovation to achieve minimum environmental standards.
- ◆ AIC capacity building and systems development have resulted in early promising improvements.

The way forward in the pilot implementation of the National AIC Guidelines would be:

- ◆ Follow-up assessments to validate whether the recommendations were implemented.
- ◆ Revision of national guidelines based on feasibility and effectiveness of measures implemented.
- ◆ Integrate AIC into hospital accreditation and routine health system reporting (not TB).
- ◆ Implement integrated infection control training material for frontline HCW (RIPC).

The results of the pilot based on follow up assessments would determine the further expansion to the rest of the country.



Dr Puneet Dewan presenting pilot AIC (India) in Union World Conference, Germany

Contribute to Health System Strengthening

National Rural Health Mission (NRHM) was launched in April 2005, with a goal to improve the availability and access to quality health care by people, especially those residing in rural areas, and the poor and vulnerable groups. NRHM aims to carry out the

necessary structural correction in the basic health care delivery system of the country by increasing public expenditure on health, reducing regional imbalances in health infrastructure, pooling resources, integration of organizational structures, optimization of health manpower, decentralization and district management of health programmes, community participation and ownership of assets, and the induction of management and financial personnel into district health system. Indian Public Health Standards (IPHS) have been defined for the minimum level of infrastructure, human resource, equipment and drugs/ consumables needed for effective functioning of the health institution (primary, secondary and tertiary units). The large scale Health System strengthening exercise will definitely have long standing sustainable effects, than sector wide approach to each disease. Disease specific interventions like RNTCP will get better opportunities for integrating with the health system through NRHM.

Key NRHM Strategies

- ◆ The Accredited Social Health Activists (ASHA) programme is one major component of NRHM. Every village/large habitat will have a female ASHA chosen and accountable to the panchayat to act as the interface between the community and the public health system. ASHA would act as a bridge between the Auxiliary Nurse Midwife (ANM) and the village and be accountable to the Panchayat. She will be an honorary volunteer, receiving performance-based compensation for promoting universal immunisation, referral and escort services for Reproductive and Child Health (RCH), construction of household toilets, and other



ASHA working providing DOT

healthcare delivery programmes. Since its implementation ASHA is the closest health personal to the community. In the context of RNTCP ASHA have helped in decentralizing the DOT service to reach the door step of the patient which is evidenced by the tremendous increase in number of community DOT providers when compared to pre NRHM years.

- ◆ Provision of untied funds and flexible financing is another component at all levels, from sub center to district hospital, empowering local health care providers and addressing many critical gaps in service delivery.
- ◆ The Health system strengthening by bridging the gaps of human resources, especially filling up of vacancies of Medical Officers, Laboratory Technicians and Peripheral Health Workers ensured seamless DOT service delivery.
- ◆ The untied funds and flexible utilization has added to infrastructure development, like laboratory strengthening, DOT centres and additional human resources.
- ◆ By forming registered societies at PHCs, CHCs and district hospitals, legal entities are created that have greater flexibility in discharge of their functions. Rate of utilization of these funds is increasing each year. These flexibilities have resulted in faster solutions to the local issues.
- ◆ Formation of Hospital Development Societies (Rogi Kalyan Samiti) in states with provision of untied funds to them for enabling facility development.
- ◆ Involvement of Panchayat standing committees members in District Health and Family Welfare Societies, Rogi Kalyan Samiti (RKS), the Village Health and Sanitation Committee (VHSC) and selection of ASHAs.
- ◆ Indian Public Health Standards (IPHS) formulated as valuable benchmark for facilitating states to reach desirable levels of both infrastructure and human resource. This has led to filling up of vacant existing positions and creation of new posts. Multi-skilling of the nurses and medical officers for specialist tasks is additional strategy taken up by few states.
- ◆ Setting up of an integrated State and District Health society with representation from all

programme divisions on financial management, monitoring and use of human resources.

- ◆ Decentralized district level planning through preparation of District Health Action Plans, which is based on specific health needs of the people. The state plan is a consolidation of district health plans.
- ◆ Setting up of district and state Programme Management Units (PMUs): To strengthen capacities for data collection, assessment and review for evidence based planning, monitoring and supervision, for strengthening management systems, finance management, logistic/procurement and infrastructure systems and inculcate management skills in health team for the techno-managerial role to be played by the respective district programme officers. Provision of Programme Management Units (PMUS) for all districts through recruitment of contractual Master in Business Administration (MBA), Chartered Accountants (CA), Masters in Computer Application (MCA) & Data Entry Operators (DEO) has been made.
- ◆ Improvement in Financial management procedures with the use of e-transfer for funds upto districts and induction of personnel with financial management skills.
- ◆ Another important intervention under NRHM is the provision of a Mobile Medical Unit (MMU) at District level for improved outreach services.
- ◆ Fourth Common Review Mission report elaborates about the NRHM Health System Strengthening initiatives like, nearly 8 lakh Accredited Social Health Activists (ASHAs) have been engaged; 1572 specialists, 8284 MBBS doctors, 26734 staff nurses, 53552 auxiliary nurse midwives (ANMs), 18272 Paramedics employed on contract basis and a total of 16338 Primary Health Centres (PHCs), Community Health Centres (CHCs), and other Sub District facilities have been made functional on 24 x 7 basis.

TB related objective of the Mission is “Prevention and control of communicable and non-communicable diseases, including locally endemic diseases” with expected outcome of “maintaining 85% cure rate through entire Mission period and also sustain planned case detection rate”.

RNTCP is an integral part of the NRHM and would continue to deliver its services under the umbrella State/District Health society created under NRHM. As RNTCP is being integrated with the general health system, NRHM would further help in strengthening delivery of DOTS services and increasing accountability of general health system. ASHA workers recruited under NRHM, are being trained by RNTCP for DOT provision and support to decentralize DOT services to the doorstep of the patients, thereby increasing patient convenience and thus compliance. Additionally, in the context of Universal Access, the ASHA can be mobilized to identify chest symptomatics in the community and refer them for sputum examination. Further options of sputum collection and transportation to the nearest DMC by ASHA could be explored in the coming years.

Human Resource Development

Introduction

Human resources are central to all public health systems and a considerable share of resources allocated to public health goes towards them. Health workforce in adequate numbers, in proper places, and appropriately trained, motivated and supported are the backbone of an effective, equitable, and efficient public health care system.

As an important input to health programs, ensuring adequate numbers of health workforce is critical to achieve the ambitious target of Universal access in Revised National Tuberculosis Control Program (RNTCP). The program continuously focuses on issues around staffing and capacity building to address the newer challenges of Universal Access.

The program is conscious that isolated implementation of HR interventions may not yield results as RNTCP is a subsystem of the country's health workforce and is deeply integrated with the general health system. Increasing the numbers and competence of health workforce for the program is considered from the perspective of the larger health care system.

Significance and Goal of Human Resources in Revised National Tuberculosis Control Program

The program recognizes that human resources for health are among the most important resources in

program delivery and improving HR management of RNTCP staff will eventually impact program performance in a positive manner at the state and district levels. The development and maintenance of a competent workforce for TB control through well planned training and capacity building interventions is therefore key component of the activities of RNTCP.

The program consistently works with the state health systems to ensure that there are minimal staffing and skill gaps at all levels of the health system leading to roadblocks in achieving program objectives. Despite challenges related to compensation, working conditions, reward and motivational deficits which tend to stifle initiative and change, the program constantly endeavors to address key HR issues at the field level through advocacy and constant communication with the general health system and National Rural Health Mission (NRHM).

Human resource development (HRD) under RNTCP has adopted a holistic approach which includes management of personnel, while maintaining constant standards of training, leading to professional competence development in TB control activities that will benefit every patient being treated in the programme.

Who is the “Human Resources” for RNTCP?

Human resources for RNTCP are not limited to those posts established under RNTCP. Rather, it includes all those who deliver services for RNTCP with the aim of achieving program objectives related to diagnosis, treatment and management of Tuberculosis, including Contractual Staff and government staffs of general health systems, partner NGOs, Medical Colleges, institutions supporting the program, professional bodies advocating the cause of TB care et al. It also includes people who influence non-health actions with the aim of improving TB control initiatives.

The overall aim of Human Resource Development is to constantly strengthen the supervisory and managerial capacity of programme personnel and to ensure optimal utilisation of available staff to achieve maximum advantage for the programme.

Some of the strategies amongst others, adopted by the program to achieve this objective are:

- ◆ Encourage continuity of key staff such as STO, DTO and MO-TC through constant communication of program leadership with key decision makers at national and local levels.
- ◆ Systematic Training and Capacity building programs and initiatives implemented in conjunction with the general health system.
- ◆ Reinforcement of healthy contractual management practices through supervisory visits and Internal Evaluations.
- ◆ States are encouraged to plan human resource related activities in a systematic manner.

HRD Activities in RNTCP

RNTCP carries out the following activities in HRD:

Training and Capacity Building

Training and Capacity building is an integral part of RNTCP and structured training programs targeting specific audience are imparted on a regular basis by the program at National, State and district levels. Properly directed and managed training and follow up is an integral component of RNTCP. The concept of HRD is not just limited to organizing training courses but focuses on the larger issue of Health system strengthening through important component of Human Resources.

The programme has a mandate to ensure that at least 80% of key health personnel in place are trained. They include Medical Officer (MO), Senior Treatment Supervisor (STS), Senior TB Laboratory Supervisor (STLS) and Laboratory Technician (LT). These are continuous activities performed at state and district level.

Establish and Improve Existing Training Programs

Many staff involved in the program activities at different levels exercise considerable supervisory and managerial responsibilities; however they have acquired managerial expertise, mainly through “hands-on” experience. The program is attentive to this need and is looking at managerial capacity building initiatives including adding the Managerial skills module in the basic training pack for program managers who are primarily the State TB Officers/ District TB Officers and Medical Officers of the general health system.

RNTCP has developed a series of modular training courses with printed material for all levels of staff ranging from the State TB Officers to the community DOT providers. These trainings are conducted at various levels as under:

There are three tiers of training which address as different needs of the staff providing RNTCP services:

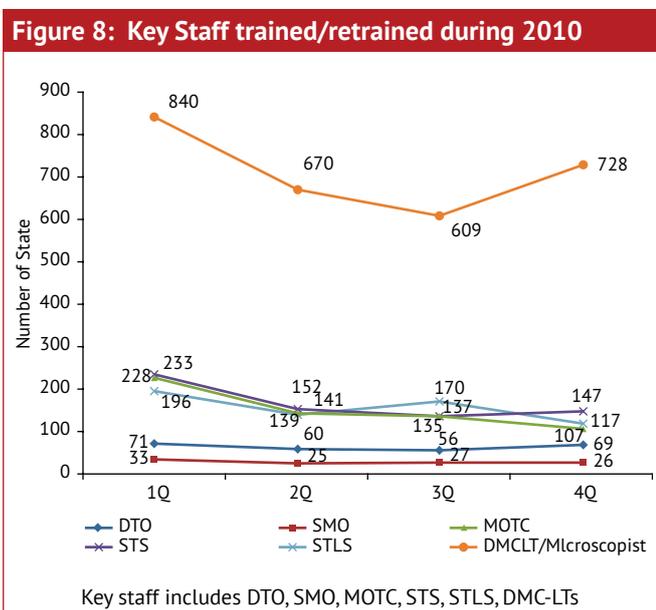
1. Initial RNTCP training: This includes all induction trainings in RNTCP of newly placed

Level of Training	Staff Category trained
Central level	State TB Officers, District TB Officers, faculty of State TB and Demonstration Centers (STDC) and Master trainers.
State level (State Training and Demonstration Centers)	Medical Officer TB Control, STS and STLS
District	Medical Officers, LT, MPWs and Community DOT providers

There are four National level Institutes where training and research related activities for the program are undertaken. They are National Tuberculosis Institute (NTI), Bangalore, Karnataka, Tuberculosis Research Centre (TRC), Chennai, Tamil Nadu, Lala Ram Swaroop (LRS) Institute of TB and Respiratory Diseases, New Delhi and JALMA, Agra, Uttar Pradesh

In the context of training and capacity building, it is important to highlight that to date at least 750,000 people have been trained/retrained in RNTCP in various areas of the program. Apart from RNTCP contractual staff, staff from general health system, this includes staff from NACP, Medical colleges, NGOs and private practitioners.

Figure 8 depicts the total number of key staff trained in various areas of RNTCP in 2010 alone.



staff or replacement staff following staff turnover. It also includes the initial training of NGO and private practitioners on RNTCP, in addition to the basic modular trainings for Medical Officers, STS, STLS, LTs and MPWs.

2. Re-training: These trainings would be mainly for individuals who have already received initial RNTCP training, but during supervision have been identified as requiring re-training on basic RNTCP activities.
3. Updates on new activities and initiatives. As the RNTCP introduces new activities and initiatives, it is imperative that the field staff is updated on these areas. These updates are given mainly by utilizing time under routine activities like regular programme review meetings such as the monthly district level meeting of the DTO, MO-TCs, STSs and STLSs and the quarterly state level review meetings.

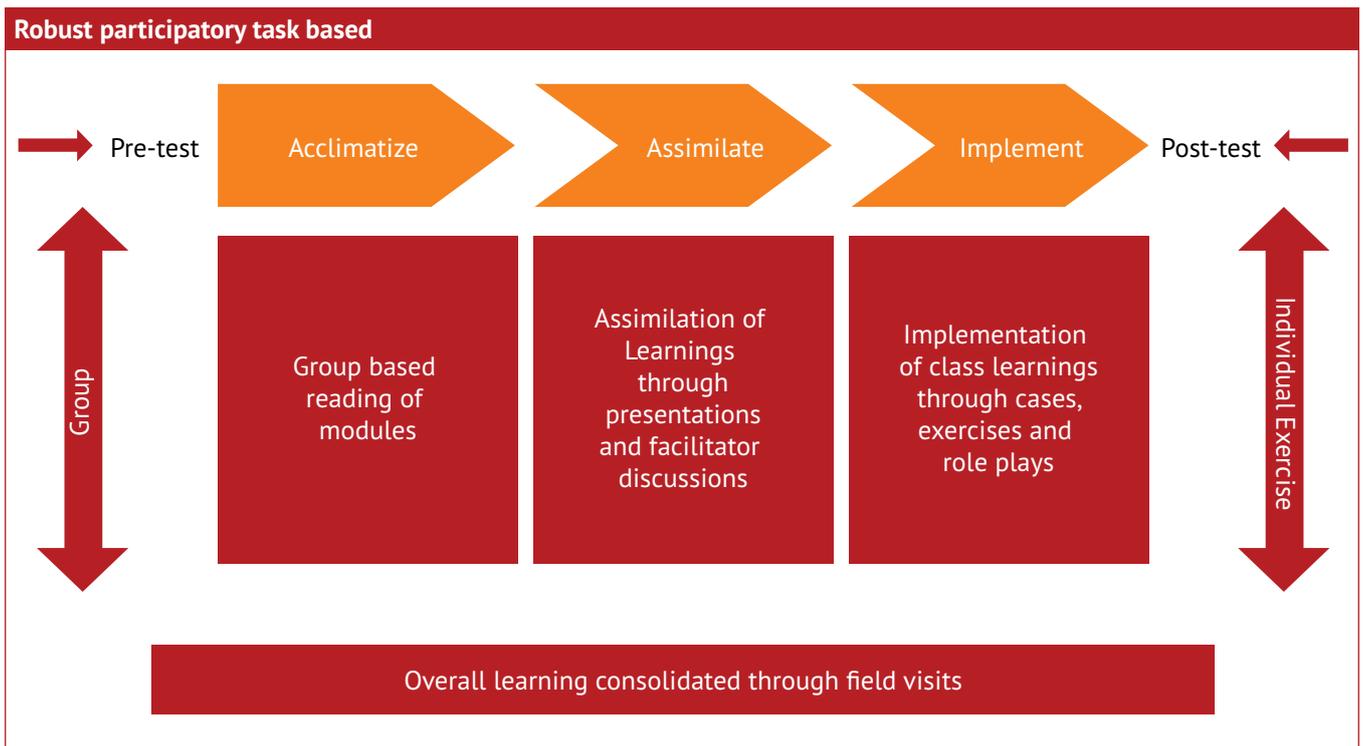
RNTCP Training Methodology

The overall learning methodology encourages participatory approach through:

- ◆ Reading of Modules
- ◆ Interactions among participants & facilitators
- ◆ Module based Presentations
- ◆ Problem based learning
- ◆ Group exercises
- ◆ Individual exercises
- ◆ Role plays
- ◆ Practical demonstrations
- ◆ Presentations
- ◆ Exposure to field situations

Basic Training Modules Used in the Program





1. Medical Colleges in RNTCP Training

Involvement of medical colleges in the Revised National Tuberculosis Control Programme (RNTCP) is a high priority. Continuing success of RNTCP requires involvement of all large health care providers including medical colleges. Professors of Medical Colleges have an important role in TB control as opinion leaders and trendsetters. By teaching and practicing DOTS they act as role models for practicing physicians. More than 350 faculty members from medical colleges across the country have been trained at National institutes as “Master Trainers” and they participate in State/district level trainings.

2. Co-ordination of TB-related and HIV/AIDS Training with the National AIDS Control Organization

Central TB Division, in collaboration with NACO, has developed a range of training packages which address the issues of TB-HIV. These training courses are targeted at various levels of health workforce from District Program Managers, MOs, VCTC counselors, and Peripheral field workers. Thus HIV/AIDS programme staff are being trained on RNTCP and vice versa. Training is also provided to NGOs who are involved in TB related and/or HIV/AIDS activities.

All TB-HIV training modules have been revised and updated and uploaded on the program website.

3. Managing Information for Action (MIFA)

The program produces invaluable data at all levels and it is essential to ensure that districts and states know how to analyze and utilize their data for improving the program. Trainings have been conducted in many states by the National level consultants and based on feedback received from states, the quality of trainings have also improved to make them more interactive and participatory. The number of trainings conducted for program managers at state and district levels and consultants from various states across the country have also increased. In the year 2010, one National level Training of Trainers (TOT) at NTI Bangalore and 2 state level trainings for DTOs, consultants and State staff were organized in Bihar and Chhattisgarh to equip them to leverage the strength of information to improve quality of data and reporting.

4. Training in Advocacy, Communication and Social Mobilization

Advocacy, Communication and Social Mobilization (ACSM) has crucial role in increasing the reach of services of the program by involvement of other sectors, civil society organizations, NGOs etc.,

Selected feature films that have good lessons for advocacy and social mobilization (Manthanand Ruka Huaek Faisla) were screened followed by Question Answers sessions with an objective to relate Advocacy and Social Mobilization and provide them with clues to translate the communication into the work methodologies. The teams used video-documentation, digital photography and a debriefing session to document the learnings from the workshop. The review form was used as a concluding feedback from participants of the workshop. During the sessions, the participants shared important field experiences.



(ACSM Workshop in Bhopal)

Central TB Division conducted three regional ACSM training workshops:

Dates of the workshop	Venue of the workshop	States covered
8th to 10th Nov	Guwahati, Assam	Tripura, Sikkim, Nagaland, Mizoram, Meghalaya, Manipur, Assam & Arunachal Pradesh
25th to 27th Nov	Bhopal, Madhya Pradesh	Chhattisgarh, Madhya Pradesh & UP
10th to 12th Jan	Ranchi, Jharkhand	Bihar, Jharkhand, Orissa & West Bengal
21st to 23rd Feb	Chennai	AP, Karnataka, TN, Kerala, A & N Islands, Lakshadweep, Puducherry

ACSM Activities in Various States

ANDHRA PRADESH



TB NGO review meeting



TB exhibition



Starting TB rally

BIHAR

TB Forum in Schools

Teachers from selected schools were trained on TB and follow-up will be carried out to plan and execute TB awareness activities in school functions and programs. The teachers will function as nodal officers to push the TB messages in their respective schools. 150 teachers were oriented by a NGO in Bihar with





Operational Research Workshop at NTI, Bangalore

(3) data analysis and scientific writing workshops with the support from National Tuberculosis Institute, Bangalore. A series of 3 workshops of 5-8 days duration is planned during the course of 1 year (Sept-2010- August, 2011).

The first workshop was held in September-2010, the second will be held in February/March, 2011 and the third in the months of July/August, 2011. In between the workshops, the participants are constantly mentored by the training faculty. The cost for holding the workshops, the project mentorship and a funding support for conducting the research will be borne by The Union, as a part of the Global Fund Round 9 India TB project within the budgeted amount under the OR training activity and any further requirement in financial resources will be supplemented by WHO-India.

The trainees for this workshop include the Consultants of WHO RNTCP Technical Assistance Project, the

Programme Managers at the State and District level (STOs, DTOs, STDC officials), faculty from Medical Colleges, programme managers from the Global Fund Round 9 project and the Civil Society representatives (which includes representatives from NGOs, CBCI and IMA etc.). The selection of the trainees (33 nos) was done competitively through an open call for applications, on the basis of a 500 word research concept notes submitted by the candidates/candidate groups. During the first workshop 17 OR protocols to answer the priority RNTCP research questions were developed. All 17 OR protocols developed during the project has been endorsed by Central TB Division for implementation, ethically approved by the Ethics committees of National TB Institute, Bangalore and The Ethics Advisory Group of The Union and a communication has been sent by Central TB Division to the respective State TB Offices to support their implementation.

- ◆ Evaluation of innovative methods of community-based DOT provision for the delivery of RNTCP Category IV treatment
- ◆ Rapid case-control study for risk factors for fluoroquinolone resistance and XDR-TB among patients with MDR-TB.
- ◆ Use of second-line anti-TB drugs and MDRTB diagnostic and treatment practices among providers in urban areas (surveys)
- ◆ Sources of previous TB drug exposure for patients registered in RNTCP as re-treatment cases.
- ◆ Methods to improve sputum transportation for culture and DST
- ◆ Evaluation of the utility of rapid culture and DST methodologies in programme setting (high TB burden low income country)
- ◆ Slide culture to monitor response to treatment in patients on Category IV treatment
- ◆ Impact of PPM interventions on equity in access, diagnostic delay, and costs of care
- ◆ Effect of ISTC dissemination on knowledge, attitudes and practices of proper TB care among specialist physicians
- ◆ Contribution of medical colleges to TB case finding under RNTCP
- ◆ Testing methods to strengthen inter department coordination within medical colleges to improve referral for treatment

Improving Community Access to TB Services

Interventions to Engage All Health Care Providers

- ◆ Evaluation of the quality of TB diagnosis and care among private sector physicians
- ◆ Marketing to private health providers – what messages change referral, diagnostic, and treatment behavior for TB?
- ◆ Evaluation of comparative results and effort required by the different RNTCP schemes to involve private practitioners
- ◆ Knowledge, attitudes and practices of providers of alternative systems of medicine
- ◆ Testing methods to involve providers of alternative systems of medicine in the referral of TB suspects
- ◆ Qualitative (focus groups) and quantitative (pre-and post intervention) evaluation of the effectiveness of communication methods and messages to promote client demand
- ◆ Testing innovative interventions to increase public visibility of TB diagnosis and treatment facilities
- ◆ Efficacy and cost of innovative interventions to increase demand of persons with respiratory symptoms in PHC facilities
- ◆ Qualitative evaluation of the effectiveness of use of 'patients charter' and other tools to promote advocacy and involve local communities fight TB
- ◆ Test the appropriateness of the RNTCP training and information materials for general health staff and private practitioners
- ◆ Develop and test simple methods to evaluate the quality of RNTCP supervision and the usefulness of current instruments

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seeking behavior, missed opportunities for diagnosis, etc.

12. Collaborate with the local authorities to implement pharmacovigilance for anti-TB drugs sold in the district/state with a view to develop locally innovative strategies for improvements in notification of TB cases and promotion of rational use of drugs.

Promising future opportunities for early and complete case detection for which many programme managers would be called to assist:

- ◆ Screening of all patients with TB risk factors, change of TB suspect definition in high risk groups to cough of any duration, or fever with night sweat etc.
- ◆ Intensive case finding in urban slums, and other high risk population groups
- ◆ Front-loading of sputum microscopy (2 spot while patient waits with a minimum gap between the two) with LED/FM microscopy

Universal Access to TB Treatment

Ensure all TB patients diagnosed are given pre-treatment counseling before starting treatment and DOT arranged at a place convenient to the patient.

1. Ensure the following activities
 - a. Prompt visit of the health worker/DOT provider to the patient's home with a local strategy to deal with homeless and people on the move.
 - b. DOT convenient to the patient in time, place and person, including special arrangements for elderly and immobile people, and for travel/migration of patients short/long term.
 - c. DOT provider is trained and well motivated
 - d. Prompt missed dose retrieval action are taken
 - e. Follow up visits and sputum examinations are arranged in a timely, planned and patient-friendly manner.
 - f. Any side effects of drugs are attended promptly
2. Facilitate care for any co-morbidities like HIV/ Diabetes etc
3. Provide counseling and a list of updated social welfare schemes to each patient put on treatment and provide the list of TB patients to the relevant social welfare authorities (Govt and NGO).

Annexure 2

Schemes for NGO and Private Providers for RNTCP Collaboration

Scheme	Eligibility	Functions of NGO	Role of RNTCP	Grant-in -aid
ACSM SCHEME TB advocacy, communication and social mobilization	<ul style="list-style-type: none"> ◆ NGO with at least 2-3 years experience in social mobilization activities and grass root level activities ◆ Local presence and familiarity with local culture 	<ul style="list-style-type: none"> ◆ Community meetings ◆ Street plays /Puppet shows ◆ School activities such as essay competition, painting competition ◆ Sensitization of PRIs and SHGs ◆ Sensitization of DOT Providers/ TB support groups ◆ Patient Provider Meetings in the community ◆ Sensitization of religious groups/ faith healers 	<ul style="list-style-type: none"> ◆ Sharing of ACSM District plan with the NGO ◆ Provision of prototype material to the NGO/s 	Rs 1,50,000 per 1 million population per year
SPUTUM COLLECTION SCHEME	<ul style="list-style-type: none"> ◆ NGO/Private facility with or without an outpatient that is not a DMC ◆ In “underserved” areas (hard to reach, tribal area) ◆ Well ventilated open space for sputum collection 	<ul style="list-style-type: none"> ◆ Sputum collection from TB suspects referred from outpatients of the same facility and other facilities linked in the vicinity ◆ Sputum to be collected following RNTCP diagnostic and Follow-up guidelines ◆ Ensure timely transportation of sputa and timely communication of the results back to referring providers ◆ Standardized kits for transportation to be procured by the NGOs 	<ul style="list-style-type: none"> ◆ Identification of underserved areas and planning in collaboration with Sputum Collection Center and nearby DMC ◆ Arrange for sputum microscopy at DMC and timely transmission of results; treatment initiation and follow up ◆ Training of the concerned staff and provision of material including sputum cups 	Rs 60,000 per annum, per centre

Success Stories from the States

ASSAM

RNTCP staffs saved her not only from TB but also from dangerous traditional healer

Shilpi Namasudra, a resident of Cibitabichia which is one of the most interior area of Cachar District of Assam was going through 'Tantrik' treatment for her chest problems till she was retrieved by the RNTCP staffs of DTC-MC during their field visit. When the RNTCP staffs met her for the first time her situation was grave. Initially, she refused our advice as she had

been going through the spiritual treatment but after much persuasion she finally agreed and was found to be sputum positive. Her treatment started on the 14th Sept 09 and declared cured on 21st March 10. She was provided DOTS by the ASHA worker who stays near to her house.

Shilpi is now fully cured and leading a normal life. Her parents expressed their wholehearted thanks and gratefulness to the RNTCP staffs for saving their daughter's life.

ANDHRA PRADESH

Involving the pharmacists in RNTCP

The State TB Control Society, Andhra Pradesh has taken the initiative to strengthen the involvement of pharmacists in the TB control program and to develop a referral mechanism of TB symptomatic from these pharmacists, to bring TB care services more accessible to all, with technical support of PATH and funding by USAID. Initially the program is piloted in Ongole TB unit in Prakasam District, Andhra Pradesh. On 24th March 2010, a MoU was signed between District TB Control Society, Prakasam in the presence of Chairman & Collector, Prakasam district and the Ongole Retail Chemists & Druggist Association, Ongole. The document was also signed by the Assistant Director, Drug Control Office, Prakasam district.

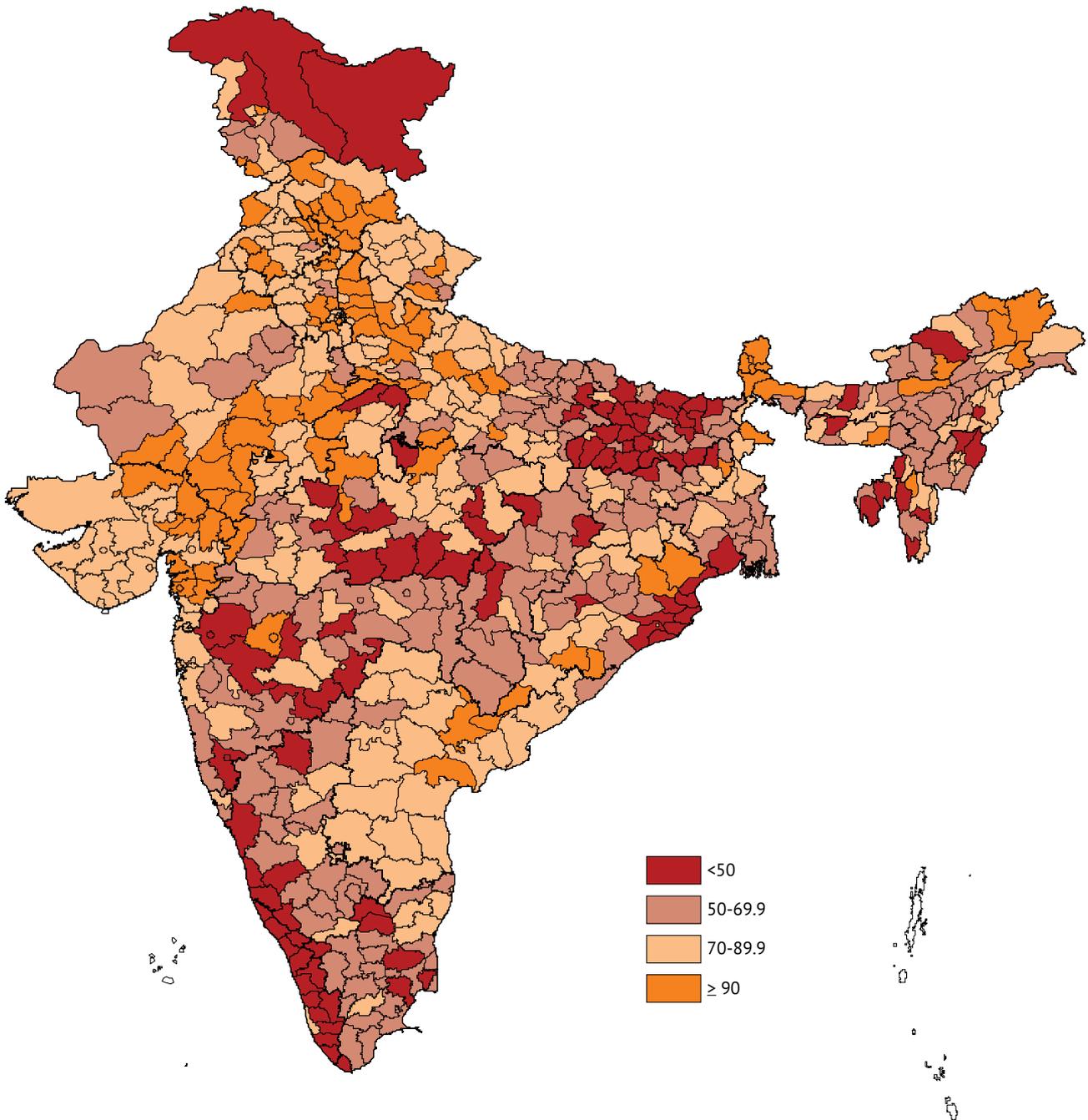
In the initial round all the pharmacists of the Ongole were sensitized on the need for TB control. 79 pharmacists have given their consent to voluntarily participate in the TB control efforts and to refer any

symptomatic to the nearest DMC. Later in a phased manner, all the pharmacists were trained on need for TB control, identification of symptomatic, filling up of the referral slips. Over the last two months 48 TB symptomatic were referred by these pharmacists and 42 have undergone sputum diagnosis and two were found affected by TB.

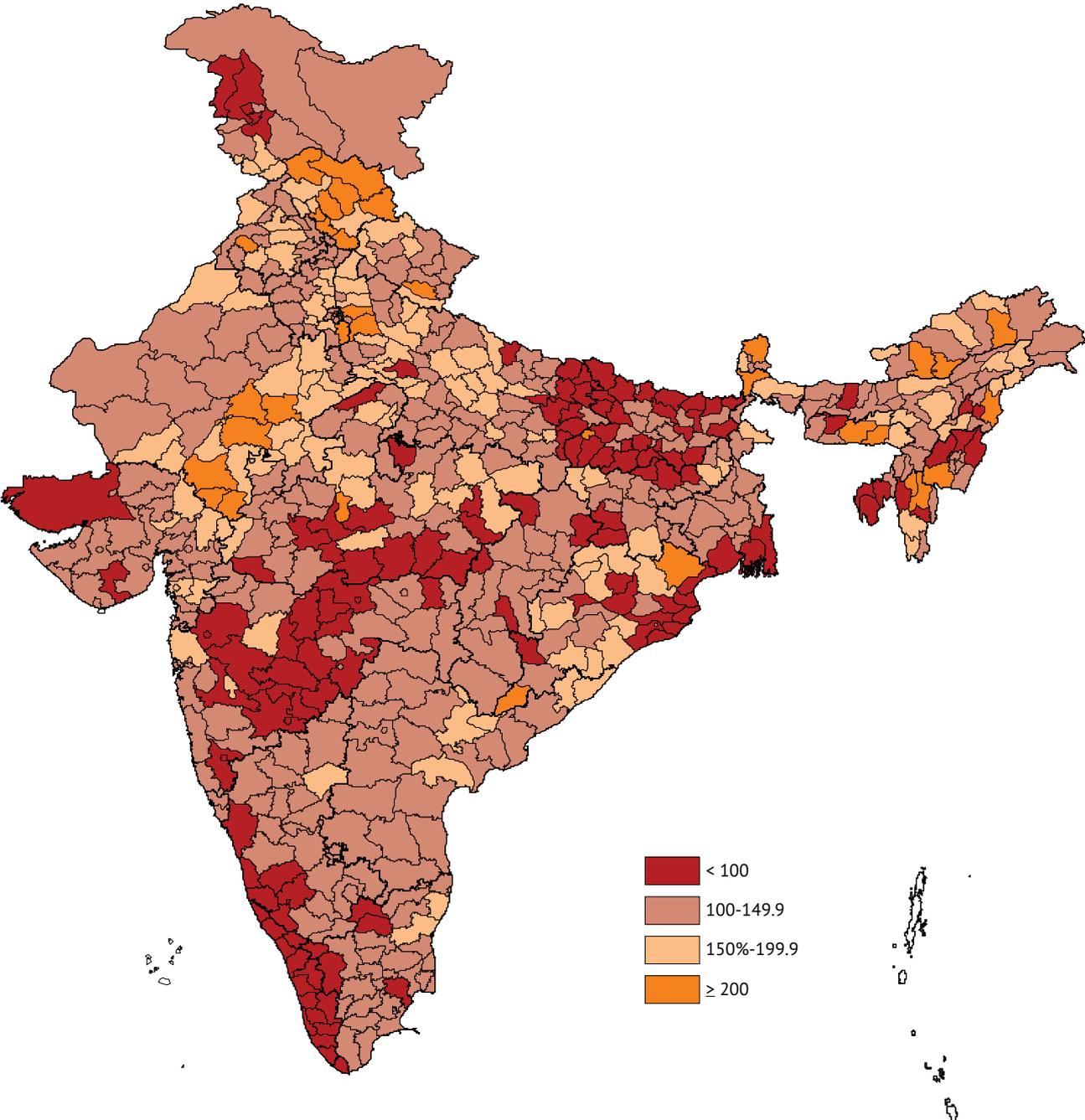


Pharmacists' sensitization in progress

Annual Smear Positive Case Notification Rate (from CFR) by District, India, 2010



Annual Total Case Notification Rate, India, 2010



Zonal Analysis

Zone	Population covered (in lakh) by RN-TCP ¹	No. of suspects examined	Suspects examined per lakh population per quarter	Rate of change in suspects examined per lakh population (compared previous year)	No of Smear positive patients diagnosed ²	Suspects examined per smear positive case diagnosed	Rate of change in suspects examined per s+ case diagnosed (compared to previous year)	Annual smear positive detection rate (from PMR)	Annual positive notification rate [from CFR: sm + Rel + TAD]/ Pop]	Total patients registered for treatment ³	Annual total case notification rate	Annual new smear positive case notification rate	Annual new smear negative case notification rate	Annual new extra-pulmonary case notification rate	Annual previously treated case notification rate	Annual previously treated smear positive case notification rate
North Zone	2971	1908328	161	-3%	278466	7	-2%	94	82	450126	152	62	35	25	29	21
South Zone	2455	2094205	213	9%	185546	11	8%	76	63	293231	119	50	29	20	21	15
West Zone	3334	2005737	150	6%	277377	7	5%	83	72	446288	134	53	32	19	29	20
East zone	2570	1298817	126	1%	164055	8	2%	64	57	271045	105	47	26	13	18	11
North East	438	243435	139	0%	35618	7	-2.0%	77	67	61457	140	55	36	23	26	14

Zonal Analysis (Contd...)

Zone	No (%) of pediatric cases out of all New cases	3 month conversion rate of new smear positive patients ⁴	3 month conversion rate of retreatment patients ⁴	Treatment Success rate of new smear positive patients ⁵	Treatment success rate among smear positive previously treated cases ⁵	No (%) of all Smear Positive cases started within 7 days of diagnosis	No (%) of all Smear Positive cases registered within one month of starting RNTCP DOTS treatment	No (%) of all cured Smear Positive cases having end of treatment follow-up sputum done within 7 days of last dose	No (%) of all registered TB cases with known HIV status	Proportion of TB patients known to be HIV infected among tested	Proportion of TB patients known to be HIV infected among registered	Proportion of HIV infected patients receiving CPT during TB treatment	Proportion of HIV infected patients receiving ART during TB treatment
North Zone	27571 8%	91%	76%	88%	75%	223775 90%	243321 98%	176465 87%	219730 49%	18%	2%	0%	36%
South Zone	18116 7%	90%	69%	86%	66%	136445 86%	152671 96%	101084 81%	161492 55%	76%	12%	9%	89%
West Zone	23579 7%	91%	71%	88%	70%	211605 87%	234090 96%	153592 82%	149912 34%	36%	8%	3%	86%
East zone	13080 6%	88%	69%	87%	70%	123423 83%	142055 95%	93572 78%	108512 40%	14%	3%	0%	18%
North East	3410 7%	88%	68%	85%	65%	26361 87%	28260 93%	18701 79%	22428 36%	19%	5%	1%	66%

HIV Status of the TB Patients - Annual 2010 (Reported by Ten States Implementing Intensified TB/HIV Package)

Implementing states	HIV-infected TB patients (NSP only)										HIV-infected TB patients (All)					
	Registered	Cured	Completed	Died	Failure	Defaulted	Trans out	Registered	Cured	Completed	Died	Failure	Defaulted	Trans out		
Andhra Pradesh	4608	73%	2%	17%	3%	4%	1%	10975	38%	40%	15%	2%	5%	1%		
Goa	33	73%	0%	6%	12%	9%	0%	125	28%	52%	10%	4%	5%	1%		
Gujarat	431	71%	0%	20%	2%	5%	2%	1722	23%	51%	15%	2%	7%	2%		
Karnataka	2352	68%	2%	19%	2%	7%	1%	8422	23%	50%	16%	1%	8%	2%		
Maharashtra	3018	74%	2%	17%	1%	5%	2%	9779	25%	50%	14%	1%	7%	2%		
Manipur	83	61%	18%	7%	5%	7%	1%	200	22%	56%	12%	2%	8%	2%		
Mizoram	17	53%	0%	12%	18%	18%	0%	136	3%	76%	10%	1%	7%	3%		
Nagaland	29	79%	0%	17%	0%	3%	0%	107	19%	56%	9%	2%	2%	12%		
Puducherry	11	73%	0%	9%	18%	0%	0%	34	26%	53%	6%	6%	3%	6%		
Tamil Nadu	1693	70%	3%	16%	1%	5%	4%	4983	25%	55%	13%	1%	5%	1%		
Grand Total	12275	72%	2%	17%	2%	5%	2%	36483	28%	48%	15%	1%	6%	2%		

DOTS Plus Implementation, Diagnosis, 6 months interim, 12 months Culture Conversion and Treatment Outcome of MDR TB Case (Reported by DOTS Plus Sites of Implementing States)

State	Indicators on Coverage of MDR TB Services					Indicators on MDR TB Case Finding					Indicators on 6 months interim report							
	Total Population (In Lacs)	Total number of districts	Number of districts implementing DOTS Plus	Population of districts implementing DOTS Plus (In Lacs)	% population with access to MDR TB services under RNTCP in 2010	Number of DOTS Plus Sites functional in the state	Number of S+ Retreatment cases registered in districts implementing DOTS Plus in 2010	Number of MDR TB Suspects subjected to C-DST in 2010	Proportion of RT cases registered in districts implementing DOTS Plus who were tested for MDR-TB*	Number of MDR TB Cases detected that were registered and initiated on Cat-IV treatment in 2010	Number of MDR TB Cases registered and initiated in the 4 cohorts 6-9 months prior (2Q09 - 1Q10) (a)	Out of a, No. (%) who are alive, on treatment and culture negative	Out of a, No. (%) who died	Out of a, No. (%) who defaulted				
Andhra Pradesh	839.6	24	8	336.9	40%	2	6673	791	12%	311	246	154	84	55%	19	12%	14	9%
Delhi	179.4	24	24	179.4	100%	4	6980	2870	41%	610	406	346	246	71%	19	5%	36	10%
Gujarat*	582.3	30	21	338.2	59%	2	10955	2132	19%	714	559	291	164	56%	19	7%	26	9%
Haryana	250.2	21	7	94.5	38%	1	2857	303	11%	77	54	45	28	62%	6	13%	6	13%
Jharkhand	310.4	24	2	53.8	17%	1	578	82	14%	8	3							
Kerala	343.2	14	14	343.2	100%	2	2376	878	37%	136	127	155	111	72%	9	6%	12	8%
Maharashtra	1111.2	55	16	313.2	28%	3	8190	704	9%	288	189	120	75	63%	10	8%	10	8%
Orissa	403.9	31	4	80.9	20%	1	965	94	10%	46	29	4	3	75%	1	25%	0	0%
Rajasthan	667.5	32	15	371.2	56%	1	10717	759	7%	315	215	155	119	77%	7	5%	8	5%
Tamil Nadu	670.1	31	25	537.7	80%	1	7195	485	7%	91	120	84	45	54%	4	5%	0	0%
West Bengal	886.7	19	5	232.1	26%	2	4573	927	20%	371	230	78	53	68%	3	4%	4	5%
India Total	11767.4	658	141	2881.1	24%	20	62059	10025	16%	2967	2178	1432	928	65%	97	7%	116	8%

DOTS Plus Implementation (Contd...)

State	Indicators on 12 months Culture Conversion Report							Indicators on Treatment Outcome of MDR TB Cases																
	Number of MDR TB cases registered in the 4 cohorts, 12-15 months prior (4Q08-3Q09) (b)	Out of b, No. (%) who are alive, on treatment and culture negative	Out of b, No. (%) who are alive, on treatment and culture positive	Out of b, No. (%) who are alive, on treatment and culture not known	Out of b, No. (%) who died	Out of b, No. (%) who defaulted	Number of MDR TB cases registered in the 4 cohorts, 31-33 months prior (5Q07-2Q08) (c)	Out of c, No. reported as Cured	Out of c, No. reported as Treatment Completed	Out of c, Success Rate	Out of c, No. (%) who died	Out of c, No. (%) who defaulted	Out of c, No. (%) who failed treatment											
Andhra Pradesh	101	41	41%	11	11%	25	25%	11	11%	13	13%													
Delhi	209	128	61%	13	6%	15	7%	23	11%	28	13%													
Gujarat*	164	98	60%	33	20%	0	0%	18	11%	15	9%	92	38	1	42%	21	23%	19	21%	13	14%			
Haryana	28	13	46%	0	0%	5	18%	7	25%	3	11%													
Jharkhand																								
Kerala	92	66	72%	1	1%	5	5%	11	12%	9	10%													
Maharashtra	87	48	55%	10	11%	8	9%	8	9%	13	15%	45	16	4	44%	7	16%	10	22%	8	18%			
Orissa																								
Rajasthan	66	41	62%	6	9%	0	0%	12	18%	7	11%													
Tamil Nadu	27	7	26%	8	30%	8	30%	4	15%	0	0%													
West Bengal	28	19	68%	1	4%	0	0%	3	11%	5	18%													
India Total	802	461	57%	83	10%	66	8%	97	12%	93	12%	137	54	5	43%	28	20%	29	21%	21	15%			

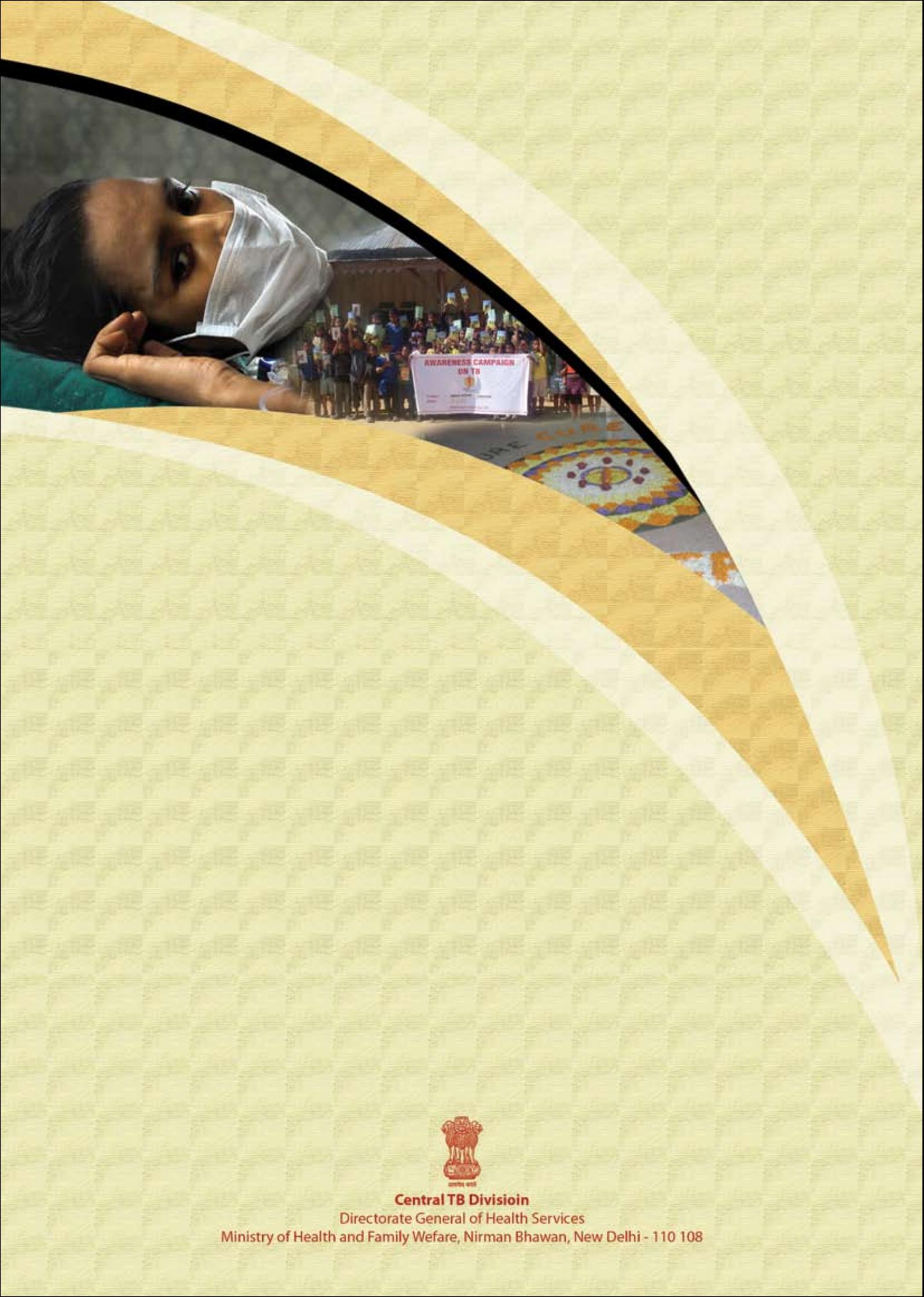
* Data from Daman & Diu is included in Gujarat.

§ This indicator will be more relevant when S+ve RT cases are considered as MDR TB suspects in all districts in the state.

For 2010, these numbers are NOT from the same cohort of patients from which MDR diagnosed are reported, but rather from treatment initiation registers only. The current DOTS Plus information system does not allow for cohort-based reporting of MDR TB suspects, hence this should not yet be taken as a proportion of MDR TB diagnosed and used as an indicator for efficiency of initiation on treatment. Future versions of the DOTS Plus reporting system will be based on cohorts of patients tested in laboratories, and will be used for monitoring of timeliness and efficiency of diagnosis and initiation on treatment.

Central TB Division Team





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