Revised National Tuberculosis Control Programme

National Strategic Plan for Tuberculosis Control 2012–2017

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Abbreviations

AIDS	Acquired Immuno- Deficiency Syndrome
ACSM	Advocacy Communication & Social Mobilisation
ANM	Auxiliary Nurse Midwife
ART	Anti Retroviral Therapy
ARTI	Annual Risk of Tuberculosis Infection
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
BPHC	Block Primary Health Centre
BPL	Below Poverty Line
CCC	Community Care Centres
CDHO	Chief District Health Officer
CDMO	Chief District Medical Health Officer
CFR	Case Finding Report
CSO	Civil Society Organisation
CGHS	Central Government Health Scheme
CHC	Community Health Centre
CIDA	Canadian International Development Agency
CMO	Chief Medical Officer
CTD	Central TB Division
CPT	Cotromoxole Preventive Therapy
DCC	District Coordinating Committee
DDG (TB)	Deputy Director General, TB
DEO	Data Entry Operator
DFID	Department For International Development, of the United Kingdom
DGHS	Directorate General Of Health Services
DLN	District Level Network of PLHIV
DM	District Magistrate
DMC	Designated Microscopy Centre
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment, Short-Course
DPM	Deputy Programmer Manager

DRS	Drug Resistance Surveillances
DST	Drug Sensitivity Testing
DTC	District Tuberculosis Centre
DTCS	District TB Control Society
DTO	District Tuberculoses Officer
EPTB	Extra pulmonary Tuberculosis
EQA	External Quality Assessment
ESI	Employees State Insurance
ESR	Erythrocyte Sedimentation Rate
FBO	Faith Based Organisation
FICTC	Facility Integrated Counselling and Testing Centre
FNAC	Fine Needle Aspiration Cytology
GDF	Global Drug Facility
GFATM	Global Fund for AIDS, TB and Malaria
HA	Health Assistant
HIV	Human Immune- Deficiency Virus
HRD	Human Resource Development
IEC	Information, Education and Communication
ICF	Intensive Case Finding
ICTC	Integrated Counselling and Testing Centre
IL&FS	Infrastructure Leasing and Financial Services
IPT	Isnoid Preventive Therapy
IRLs	Intermediate Reference Laboratories
LAC	Link ART Centres
LQAS	Lot Quality Assurance Sampling
LRS	Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases. New Delhi
LT	Laboratory Technician
LWS	Link Worker Scheme
MBPH	Market Based Partnerships for Health
MDG	Millennium Development Goal
MDR-TB	Multi Drug Resistant Tuberculosis
MO	Medical Officer
MOHFW	Ministry of Health & Family Welfare
MO-TC	Medical Officer –Tuberculosis Control

MPHS	Multi –Purpose Health Supervisors
MPW	Multi-Purpose Workers
NACP	National AIDS Control Programme
NAICC	National Airborne Infection Control Committee
NARI	National AIDS Research Institute
NCRL	National Commission on Rural Labour
NGO	Non Governmental Organization
NRLs	National Reference Laboratories
NRHM	National Rural Health Mission
NSP	New smear positive
NSP-RNTCP	National Strategic Plan for Tuberculosis Control
NTF	National Task Force
NTI	National Tuberculosis Institute Bangalore
NTP	National Tuberculosis Programme
NUHM	National Urban Health Mission
OPD	Out Patient Department
OR	Operational Research
ORW	Out Reach Worker
OSE	On-Site Evaluation
PPIA	Private Provider Interface agency
PHC	Primary Health Centre
PHI	Peripheral Health Institution
PHW	Peripheral Health Worker
PLHIV	People Living with HIV/AIDS
PPM	Public Private Mix/ Partnership
PMR	Programme Management Report
PP	Private Practitioner
PRI	Panchayati Raj Institution
PTB	Pulmonary Tuberculosis
PWB	Patient Wise Box
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement
RBRC	Random Blinded Rechecking
RKS	Roji Kalyan Samity

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

Executive Summary

'Towards universal access for quality TB diagnosis and treatment'

TB was declared as a global health emergency in 1993. In the same year, India established the RNTCP as a small pilot project. This project was scaled up nationwide between 1998–2006. The overall vision of RNTCP is "A TB free India"—a situation in which TB is no longer a major public health problem. Over the last 15 years, the RNTCP became one of India's largest and greatest public health achievements. By 2006, decentralized basic TB control services had been established nationwide. In 2006–11, in its second phase RNTCP sought to improve the quality and reach of services, and reach global case detection and cure targets. These targets were achieved by 2007-08, and from 2006–10 alone more than 27 million chest symptomatic have been examined and 6 million treated. In the process, the programme implemented activities effectively, delivering Rs. 1545 crores (as of March 2012) expenditure against Rs.1447 crores planned expenditure in the 11th five year plan. There is compelling evidence that the tide has turned for TB. The burden of TB has begun to fall, and there are now fewer TB-related deaths each year than the year before.

Despite these achievements, undiagnosed and mistreated cases continue to drive the epidemic such that TB remains an enormous public health problem for India. In 2011 alone an estimated 1.2 million TB cases occurred, and 60,000 people died of TB – nearly 165 deaths per day. Nearly 1 in 6 deaths among adults aged 15–49 are due to TB. More adult women die of TB every year than from peri-partum complications or HIV/AIDS. TB remains the leading cause of illness and death among persons living with HIV/AIDS. Nearly 100,000 cases of serious multidrug resistant TB (MDR-TB) are estimated to occur in the country every year, mostly attributable to prior inadequate treatment, and each MDR TB case costs more than Rs 1 lakh to diagnose and treat. TB affects anyone, but predominantly the poor and marginalized, perpetuating poverty through health and economic shocks to families least able to cope.

This document lays out the next 5 year plan towards achievement of the long-term vision of a "TB free India". This strategic plan takes into account all the key issues and challenges and outlines the framework for tackling each of these over the next 5 years. The central theme of this plan is the goal of **Universal Access to quality TB diagnosis and treatment for all TB patients in the community**. This entails sustaining the achievements till date, finding unreached TB cases before they can transmit infection, and treating all of them more effectively, preventing the emergence of MDR-TB.

These ambitious goals are achievable because the TB programme has established a robust programme management infrastructure, focused on effective

implementation, decentralizing patient-friendly services to impoverished and vulnerable populations, and improving quality of care for all.

To reach Universal Access, the RNTCP will pursue the following approaches:

- Ensuring early and improved diagnosis of all TB patients, through improving outreach, vigorously expanding case-finding efforts among vulnerable populations, deploying better diagnostics, and by extending services to patients diagnosed and treated in the private sector.
- Improving patient-friendly access to high-quality treatment for all diagnosed cases of TB, including scaling-up treatment for MDR-TB nationwide.
- Re-engineering programme systems for optimal alignment with NRHM at block level and human resource development for all health staffs.
- Involvement of private sector at a scale commensurate with their dominant presence in the healthcare in India. New and innovative approaches for involvement of sectors currently outside the reels of RNTCP will be piloted & successful model will be scaled up in order to move towards universal access to TB cure and control.
- Enhancing supervision, monitoring, surveillance, and programme operations for continuous quality improvement and accountability for each TB case, with programme-based research for development and incorporation of innovations into effective programme practice.

If the RNTCP is successful at achieving it's objectives by the end of 5 years, modelling has indicated over the next 15 years that TB incidence may decline by 40%, and MDR TB will be reduced by 50% compared to today. This translates to 750,000 lives saved, 1.7 million lives over 15 years, and with 100,000 MDR TB cases averted.

Finding more cases earlier

Rather than waiting for patients to present themselves at public health facilities with symptoms, general health and field staff will be better utilized, to detect and mobilize symptomatics earlier, supported by outreach, communication, and social mobilization. Active screening for TB among socially and clinically-vulnerable populations—e.g. slum-dwellers, contacts of TB cases, diabetics, smokers —will detect patients earlier and reduce transmission. As patients seeking care usually first visit private providers, effective engagement of private providers will capture TB cases at their initial point of care, reducing delay and transmission. Widespread deployment of new higher-sensitivity TB diagnostic tests will detect more patients earlier - especially among persons living with HIV/AIDS who rapidly die when TB and MDR TB are not quickly and accurately diagnosed and treated. Those patients who are diagnosed will be counted to enable better programme monitoring and continually improve case management.

During the 5 year period of 2012–2017, the RNTCP intends to evaluate 4.8 crore (48 million) people for TB, with reduced time for diagnosis. The RNTCP also aims that >90% of TB patients have been HIV tested, that improved high-sensitivity rapid diagnostic tests for TB and drug-resistant TB are deployed in all districts and medical colleges nationwide, and all confirmed TB cases are screened at the outset or early in their course of treatment for drug resistance. Better case-finding

is central to achieving RNTCP's goals, and hence Rs. 2,115 crore or 32% of the 5-year budget is proposed for these activities.

Making treatment more patient-friendly

Early diagnosis must lead to high quality patient-friendly treatment. Universal Access requires that treatment be improved for patients treated in both the public and private sectors. Testing patients at the onset for drug susceptibility will detect MDR TB earlier and place patients on the right treatment from the beginning, improving treatment outcomes, reducing transmission, and reducing death – especially among HIV-infected TB patients, who die quickly if not promptly and appropriately treated for MDR TB. Flexible treatment options will extend the provision of these services to patients treated in the private sector, seeking to improve the quality of TB treatment than provided today, reducing the ongoing generation of drug-resistant TB. Special support will be provided for the socially vulnerable.

Over 2012–2017, RNTCP proposes to treat 88 lakh (8.8 million) TB patients, including 1.2 lakh (0.12 million) TB patients for MDR TB. Among HIV-infected TB patients, 90% will be provided ART during TB treatment to reduce death. Anti-TB drugs are projected to cost Rs. 1,687 crore, of which 58% is for second-line MDR TB drugs.

Re-engineering RNTCP systems for NRHM alignment and health systems development

RNTCP will re-organize along the health block lines, aligning and integrating sub-district programme management and supervision with NRHM. Improved alignment will place general health staff at the forefront of improved TB case finding, integrated with routine household visits, and improved treatment supervision. RNTCP is developing a comprehensive HRD plan to update and develop the skills of both programme personnel and general health system staff involved with service delivery.

With the proposed integration of programme staff with NRHM health block activities and better utilization of general health and field staff for case-finding and treatment support, extensive training of the general health staff will be required. Manpower will be needed for extending the reach of RNTCP and effectively engaging all health providers, the bulk of which would be re-purposed to existing programme staffs. Human resource costs are estimated to be Rs. 1,408 crore, or 22% of the overall proposed budget.

Public Private Matrix (PPM)

The overall goal is to achieve prompt reporting to RNTCP of TB cases diagnosed in the private sector, increased number of TB cases referred to the programme, and improve the quality of care in the private sector. During 2012-17 the strategic vision of RNTCP is to develop and deploy engagement models that will overcome these past barriers of mutual mistrust, conflicting market forces and fragmentation, to accept, encompass and improve TB care provided by the private sector. The plan for strategic engagement with the private sector in the coming five years focuses on clarifying opportunities, policies and strengthening mechanisms at the

national and state level. A National Technical Working Group on Public Private Mix (PPM) will meet regularly to review and analyze data and provide advice to RNTCP about opportunities to increase private health sector involvement. At the national and state level, a Technical Support Group will be established within RNTCP to focus on effective contract management and other partnership-strengthening functions. Private Provider Interface Agencies (PPIA) will be hired in states to manage the activities of engaging the private sector.

Other approaches include an expanded acceptance by RNTCP of internationally approved diagnostic and treatment protocols, reliance on market forces rather than normative exhortation, increased use of accreditation and contracting, further outreach to private laboratories, increased control of TB drugs, and innovative use of information and communication technologies.

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Supervision, monitoring, programme operations, and research

The RNTCP has defined best programme practices for supervision and monitoring, and will continue to exercise rigorous supervision and evaluation practices. This task will be greatly facilitated in future with the use of electronic case-based notification, extended to the private providers and laboratories, and this information will be used for better programme monitoring and patient case management. The programme plans to innovate with large-scale operational research to develop effective approaches, and deploy the best practices. Substantial local innovation will be required to find regionally-appropriate solutions for better case-finding and treatment for different vulnerable groups suffering from TB. Programme operations, supervision, monitoring and research are estimated to cost Rs 817.24 crore, or 13% of the overall proposed budget.

The overall investment required in 2012–2017 to achieve this Universal Access vision, to save 750,000 lives from TB, and to control MDR TB are estimated to be Rs. **4500.15** crore as under.

RNTCP National Strategic Plan (2012-17) - Budget								
Sl No	**Activity**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**Total**	**Percent of total**
1	**Finding more cases earlier**	2,879	6,485	12,931	15,584	18,277	56,155	12%
2	**Improving patient friendly treatment including first line, second line drugs & co-infected TB patients**	17,594	29,075	40,357	34,508	36,309	1,57,843	35%
3	**ACSM**	1,495	1,627	2,434	2,985	3,175	11,715	3%
4	**Public Private Mix**	2,302	3,839	11,134	12,286	13,758	43,318	10%

5	**Human Resource Development and Capacity building**	17,227	23,829	30,354	30,159	30,357	1,31,926	29%
6	**Programme operations, supervision, monitoring and research**	5,204	6,145	12,794	12,160	12,754	49,057	11%
	TOTAL	**46,700**	**71,000**	**1,10,004**	**1,07,682**	**1,14,629**	**4,50,015**	**100%**

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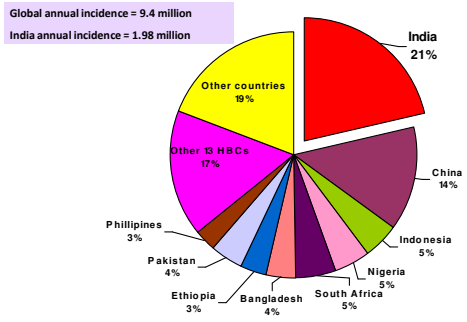
Introduction

Background

India, the country with second highest population in the world, has the highest TB burden accounting for one fifth (21%) of the global incidence - an estimated 2 million cases. In terms of incidence rate, India is 17th among 22 High Burden Countries according to the WHO global TB report 2010.The country's spend on TB control activities, during the period 2007-2012,has been around US$ 70 million per annum. The National Health Policy 2002 and India Vision 2020 commit the country to fight all communicable and preventable diseases. The public spending could double if the government reaches its target spending level of 2 per cent of GDP, up from the current 0.9 per cent, according to the CII-Mckinsey and company report 2002. The National Rural Health Mission

India is the highest TB burden country accounting for one fifth of the global incidence



Source: WHO Geneva; WHO Report 2010: Global Tuberculosis Control; Surveillance, Planning and Financing

has also dramatically increased the investment on health infrastructures and provision of staff through contractual modes.

Also, the Millennium Development Goals (MDGs) commit all countries to achieve decreasing TB incidence by 2015 and STOP-TB partnership urges countries to halve TB related deaths and prevalence by 2015 related to 1990 levels. India is well on track to achieve these and is aiming beyond MDGs to achieve 'Universal access to TB care' by achieving 90% case detection rate and 90 % success rate.

Response to TB in India

History of TB Control: Despite the National TB Programme (NTP) being in existence since 1962, no appreciable change in the epidemiological situation of TB in the country had been observed. The HIV-AIDS epidemic and the spread of multi-drug resistance TB were threatening to further worsen the situation. In view of this, in 1992, GOI, with WHO and SIDA reviewed the TB situation and identified the following limitations:

- NTP, was managerially weak
- Inadequate funding for program activities
- Over-reliance on x-ray for diagnosis
- Frequently interrupted drug supply
- Low rates of treatment compliance

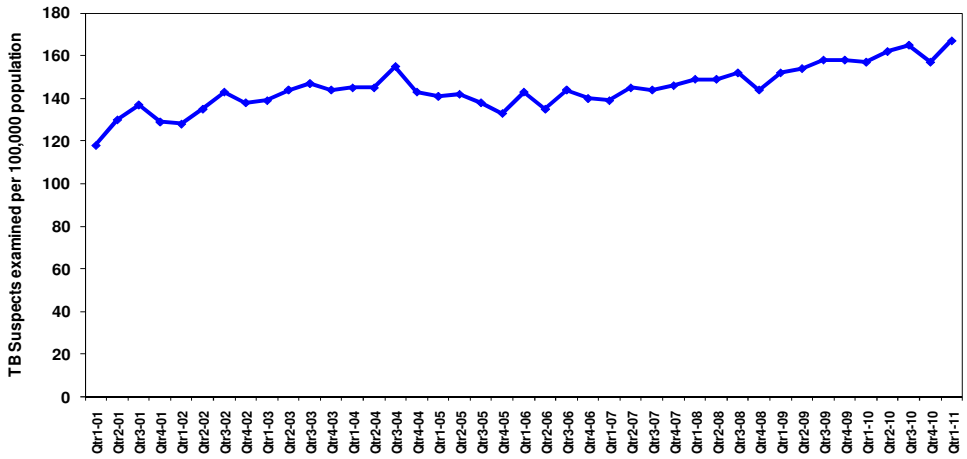
In order to overcome these limitations, in 1993 the GoI decided to reenergize the NTP, with assistance from international agencies. The Revised National TB Control Programme (RNTCP) thus formulated, adopted the internationally recommended Directly Observed Treatment Short-course (DOTS) strategy, as the most systematic and cost-effective approach for TB control in India. Political and administrative commitment, to ensure the provision of organised and comprehensive TB control services was obtained. Adoption of smear microscopy for reliable and early diagnosis was introduced in the general health services. DOTS was adopted as a strategy for provision of treatment to increase the treatment completion rates. The supply of drugs was also strengthened to meet the requirements of the system.

The key objectives of the RNTCP were to achieve and maintain at least 85 per cent cure rate among the new smear-positive cases initiated on treatment, and thereafter a case detection rate of at least 70 per cent of such cases.

RNTCP Growth & Innovations: The RNTCP built on the infrastructure and systems built through the NTP. A key focus area was strengthening the recording and reporting systems. An addition to the RNTCP was the establishment of a sub-district supervisory unit, known as a TU (Tuberculosis Unit), with dedicated RNTCP supervisors. This led to decentralization of both diagnostic and treatment services, with treatment given under the support of DOT providers. The quality of diagnosis of TB patients under RNTCP improved by giving the highest priority to the provision of quality assured sputum smear microscopy services. Another key innovation under RNTCP has been the development of Patient-Wise Boxes, which

contain the full course of treatment for an individual patient. This ensures that treatment of that patient cannot be interrupted due to a lack of drugs. The RNTCP has effectively decentralized supervision via the sub-district TB Units, with in-built systems for monitoring and evaluation.

TB Suspects examined per 100,000 population*, 2001-2011

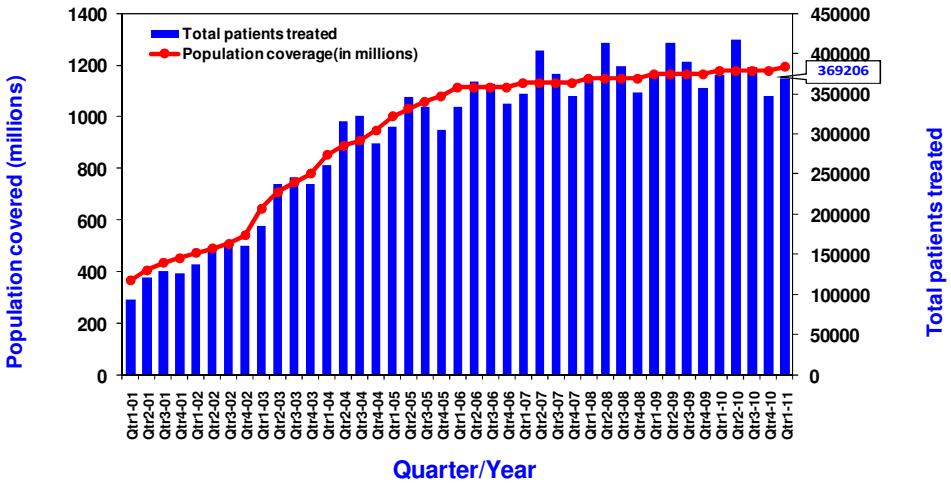


* During RNTCP expansion phase, data for districts implementing partial quarters has been excluded

Scaling up Services: The RNTCP began in October 1993 and was initially implemented in a population of 2.35 million in 5 pilot sites in the states of Delhi, Kerala, Gujarat, Maharashtra and West Bengal. Success at these pilot sites, led to its expansion to a population of 13.85 million in 1995 and 20 million in 1996. Large-scale implementation of the RNTCP began in 1997, following the successful negotiation of a World Bank credit of US$142 million. The initial 5-year project plan was to implement the RNTCP in 102 districts of the country and strengthen another 203 Short Course Chemotherapy (SCC) districts for introduction of the revised strategy at a later stage. In early 2002, the 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 before the next phase of the project began.

The World Bank assistance encouraged the GOI to take up the challenge of

Population in India covered under DOTS and Total Tuberculosis Patients put on treatment each quarter



nation-wide expansion of the RNTCP. As a result of which, the Government committed itself to the targets of nationwide coverage by the RNTCP by 2005 and to reach the global targets for TB control on case detection and treatment success. The structural arrangements for funds transfer and to account for the resources deployed were developed and led to the formation of the State and District TB Control Societies. The systems were further strengthened and the programme was scaled up for national coverage in 2005.

RNTCP II: RNTCP II was developed based on the lessons learnt from the implementation of the programme over a 12-year period (1993-2005). RNTCP II was designed to consolidate the gains achieved in RNTCP I and to initiate services to address TB/HIV, MDR-TB and extend RNTCP to private sector. Systematic research and evidence building to inform the programme for better design was also an important component of the programme. The emerging needs of Advocacy, Communication and Social Mobilization were addressed in the new phase. The challenges imposed by the structures under NRHM were also taken into account for RNTCP II. Since 2007, the programme has been consistently achieving a treatment success rate of >85% and a NSP case detection rate (CDR) of >70%. In 2011, RNTCP achieved the NSP CDR of 72% and treatment success rate of 88%, which is in line with the global targets for TB control.

M**onitoring, supervision and evaluation:** The RNTCP's 'Supervision and Monitoring strategy' includes detailed guidelines, tools and indicators for monitoring the performance from the PHI level to the national level. The quality programme implementation is ensured by frequent Internal and external evaluations. The programme is focusing on the reduction in the default rates among all new and re-treatment cases.

Quality assured sputum smear microscopy facilities are available nationwide through about 13,000 sputum microscopy laboratories in the health system. As a result, chest symptomatic examined has increased from 397 to 642 per 100,000 population per annum over the last 10 years.

Quality assured anti-TB drugs for the full course of treatment are provided to the patients through patient wise boxes. Decentralized treatment is provided through a network of more than 6,40,000 DOTS providers, to provide treatment to the patients as near to their home as possible.

Lessons from implementation

What has worked?

DOTS: DOTS has been an extremely successful strategy and needs to be taken forward in the next phase of the programme. The quality of provision of DOTS needs to be addressed in the next phase to ensure that the observation of taking drugs by the patient takes place through provision of increased incentives.

Availability of diagnostics: The availability of sputum microscopy has been adequately increased. The arrangements for transportation of sputum from the suspects need to be strengthened in order to increase the case finding.

Structure set up: The structure for implementation of the programme has been set up right from the field level upwards. The reduction in population norms for the effective supervision can be considered for effective implementation.

Well-defined information system: The information system is well established and the reporting units provide information within specified time periods. These are analysed and compiled by the programme. There remains, however, a need to strengthen feedback and follow ups.

Availability of guidelines and protocols: The programme has developed guidelines and protocols for every aspect and the providers are trained on these guidelines. This has standardized service provision across the programme and facilitates maintenance of quality.

Review mechanisms: The internal review mechanisms at the state, national and district levels have all been set in place and the programme carries this out according to a schedule drawn up. Compliance to feedback during the reviews can be strengthened.

Technical Committees: The programme technical committees (Laboratory, Operations Research, DOTS Plus Committee) as well as task forces at the zonal levels have been very useful. These bodies are functioning well and facilitating programme implementation. A Treatment Review Committee can be set up to advice the programme on change in regimens based on evidence generated and a Technical Working Group for improving PPM must also be considered.

MDR-TB: The programme has focussed on MDR-TB and it has developed the protocols for treatment and also is in the process of developing the laboratory capacity for strengthening this component. Structural arrangements for early diagnosis and treatment of MDR-TB patients have been put in place. The programme however needs to address issues around management of drug-resistance other than MDR-TB.

Trained human resources: The programme has been able to develop a pool of well-trained service providers at all levels and efforts to retain and maintain this level of training need to be included in the programme. There is a need to develop long term human resource development plan to address issues of sustainability of the programme.

Limitations

Managing TB in the urban areas: In the rural areas, the RNTCP has been able to develop a structure for programme implementation because of the established rural health infrastructure under the general health system. In the urban areas, however, there is no established health structure in the absence of an operational National Urban Health Mission. Until the urban health infrastructure develops, the programme needs to establish its own structure and also forge effective partnerships with the private sector to make quality assured services available.

Strategies to track patients put on treatment (especially the migrant urban slum dwellers) need to be evolved.

Participation from private sector: The private sector is the first point of contact for health services for majority of the population in India**.** This is common for both urban and rural areas. In order to reach the universal access for TB it will be necessary to make the participation of the private sector effective in order to be able to obtain information on notification and treatment success rates from this sector. The involvement of civil society and other private players for communication to bring about behaviour change and in provision of link services such as transportation of sputum need to be galvanized.

Health system involvement: The integration between the health systems and the programme has been achieved in the provision of services. However it is limited in other operational areas such as administration, financial management and monitoring and supervision. This has affected the quality of implementation because of the multiple administrative, financial and operational functions to be carried out by the field level staff. Also numerous vacancies within the health system render it extremely weak. Thus, meeting human resource requirements is critical for optimum system functioning. NRHM has created programme management structures at the block, district and state levels. Hence, opportunities exist to strengthen the involvement of the programme with the health systems in order to utilize the management structures developed by NRHM to handle the administrative and financial functions. There is also the opportunity to further decentralize the field units to make them co-terminus with the block level structures of NRHM. Further, the health system leadership at the different levels can be divested the regular supervisory role of the programme implementation as in the case of other diseases.

Rigidity of the programme: The programme so far has remained rigid in its recognition of other internationally accepted protocols for diagnosis and treatment of TB, both for notification and to determine treatment success rate. This has been an important deterrent for involvement of private sector. The programme needs to take steps to develop Indian Standards of TB care which recognize the evidence based rational treatment for TB even outside the programme as well as gather evidence and examine the necessity of new treatment regimens for TB.

Programme has remained insulated from other programmes: The programme has remained insulated and has confined its operations within the health sector. This may not facilitate the achievement of the goal of reaching universal access for TB. The programme needs to examine mainstreaming TB into other sectors and evolve a collaborative framework to work with other ministries such as Women and Child Development, Ministry of Labour, Ministry of Urban Development, Ministry of railways and Ministry of Coal and Mines in order to be able to tap the notification from these sectors.

Adequate human resource provisioning: There continues to exist several vacancies at multiple levels within the programme making the system constricted with regard to human resources. This is in part due to the low priority accorded by the health system in providing adequate resources. There have been delays in

expediting the contractual appointment mechanisms as well. This needs to be addressed at the earliest to avoid the shortage of human resources.

Limited funding: The programme continues to work with limited funding that is insufficient for it to expand to scale certain critical functions. There has been no concerted advocacy within the political and administrative system to obtain increased funding. Considering the financial implications of achieving the objective of universal access it would be necessary to increase the funding available for the programme.

ACSM: ACSM has been a low-priority area for the programme. This is because it has not been positioned as creating demand for services for TB. Also, it has not strategically developed to bring about desired behaviour change in order to increase uptake of services and adherence to treatment to improve success rates. This function needs to be strategically positioned within the RNTCP as an enabler to creating a supportive environment for the achievement of programme objectives.

Learning from other programmes: The other programmes have successfully developed and increased the scale of outsourcing services and increasing involvement of the private sector and community organizations. The programme needs to examine the processes adopted by the other programmes and examine the possibilities of replicating this in the RNTCP.

Surveillance: The surveillance mechanism has not been able to effectively utilize the programme data to determine incidence and prevalence rate of TB in the country. The ARTI surveys have been the primary method adopted to arrive at incidence and prevalence. This data has been inadequate in decentralized planning as the estimation based on incidence is uniformly applied across the entire country in the absence of geographic area specific estimations. The system of utilizing the routine programme data for surveillance needs to be strengthened and efforts to identify differential TB estimates for the different areas within the country needs to be evolved. The availability of geographic area specific information can enable the programme to plan strategically to achieve its objectives.

Challenges in expanding coverage to achieve Universal access: The challenges involved in achieving universal access would compel the programme to make adjustments in the way it has been working in the past in becoming open to involvement of a number of other players and accepting other protocols if found satisfactory. Further, radical shifts need to be brought about which would require flexibility and out of the box thinking.

National Strategic Plan 2012-17: Preparatory Process

Concept note

A concept note was prepared for submission to Department of Economic Affairs (DEA) and this note outlined the shift in the programme and also the priorities that have been envisioned by the programme in the next five years. This note provided

an outline of the proposed Strategic Plan and funding requirements for the period 2012-2017. This note was intended as a basis for further detailed strategy, programme and budget development. The National Strategic Plan for TB Control 2012-17 (NSP-RNTCP) is expected to be funded by the Government of India under its 12th Plan and will serve as the basis for possible support by external partners, including the World Bank and Global Fund.

Developing the Plan

In order to facilitate the development of the NSP-RNTCP and consult diverse stakeholders, the programme decided to form working groups along the different thematic areas to be covered in the NSP-RNTCP. Each working group was provided with background materials to facilitate discussions. There were eleven working groups and each of the groups met for about 4-5 times during the period May 2011-July 2011 and finalized their recommendations.

A Core Group reviewed the recommendations of the working groups from the point of view of feasibility, cost as well as the suitability in the overall framework of programme priorities. Based on the decisions of the Core Group, the individual sections of the draft NSP-RNTCP were prepared. A panel of external experts then reviewed the drafts in order to synchronize the NSP-RNTCP with the developments of TB Control in other parts of the world. The members of the ministry also reviewed the drafts and the NSP-RNTCP is the final product of this process.

A key feature of the development process has been the extensive consultation with diverse stakeholders and time devoted to strategic thinking on critical issues. The draft NSP-RNTCP was shared with all the members of the working group in order to obtain their feedback. This was a significant step to increase the involvement of the different stakeholders. This consensus building is the highlight of the process adopted for NSP-RNTCP development.

Strategic vision to move towards universal access

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.

With the GOI vision as a long term guide, the programme defined objectives for 2012–2017 are:

1. To ensure early and improved diagnosis of all TB patients including drug resistant and HIV-associated TB
2. To provide access to high-quality treatment for all diagnosed cases of TB
3. To scale-up access to effective treatment for drug-resistant TB
4. To decrease the morbidity and mortality of HIV-associated TB
5. To extend RNTCP services to patients diagnosed and treated in the private sector.

Thrust areas and Strategies

- Strengthening and improving the quality of basic DOTS services
- Further strengthening and aligning with health system under NRHM
- Deploying improved rapid diagnostics to the field level
- Expanding efforts to engage all care providers
- Strengthening urban TB Control
- Expanding diagnosis and treatment of drug resistant TB
- Improving communication, outreach, and social mobilization
- Promoting research for development and implementation of improved tools and strategies

2
Case Finding and Diagnostics

Key Messages

- The first step for effective TB control is timely identification of all TB cases.
- RNTCP has consistently achieved the WHO recommended targets of case finding, but incidence of TB is not decreasing rapidly enough.
- Early and timely identification of all TB cases including drug resistant TB is a pre-requisite for stopping the transmission of TB and effective TB control.
- To achieve universal access to early and improved diagnosis of TB cases and accelerate the reduction of TB incidence, there is a need for improved demand generation, integration of public and private health systems and introduction of new diagnostic technologies.

Abstract

The prompt diagnosis of TB is the highest priority of all TB programs. It initiates a series of events that save the patient's life and interrupt further transmission of disease.

The RNTCP has consistently achieved a global benchmark level of case finding by exceeding the goal of detecting 70% of infectious cases ahead of schedule as enlisted in 11th Five Year Plan. In so doing, RNTCP has saved millions of lives and prevented an enormous number of subsequent cases – all at a modest cost to patients and the health system. However, the decrease in TB incidence has been modest and not as expected according to projections made using mathematical

modelling studies. The priority of this plan is to modify the strategy for better case finding in order to accelerate the reduction in TB incidence.

Fortunately, significant new opportunities for improvement are anticipated in the next 5 years that make the goal of "Universal Access" (defined as early detection of 90% of all TB cases) ambitious, yet attainable. To achieve this goal, RNTCP will need to diagnose more cases at an early stage. This can be accomplished by a number of distinct, but inter-related efforts described throughout this plan. These include a) an increased effort to encourage people with TB symptoms to seek care, b) incorporate all health providers beyond the public health system for an improved diagnostic approach c) ensure that patients and providers have access to "state of the art" diagnostic technologies including those for rapid drug susceptibility testing, and d) create public health system accountable to all TB patients and not just those treated in the public sector. Achieving this goal is not impossible. It will require increased staffing, system changes and investment in new technologies. However, if successful, by 2017, India will have the ability to diagnose more than 1.8 million TB cases each year – a 25% improvement compared to the present figure. More importantly, early diagnosis of drug resistance will play a critical role in abrogating the inhumane and costly epidemic of drug resistant TB. In so doing it will permit the prompt initiation of appropriate therapy and improved tracking of the epidemic and re-establish India as the global leader in TB control.

Introduction

Undiagnosed TB cases and incorrect treatment is fuelling the spread of TB in India. However, once a patient is diagnosed and appropriately treated they rapidly become non-infectious. Thus, prompt case finding and treatment is the principal means of controlling transmission and reducing TB incidence. This can sharply reduce TB prevalence, mortality and ultimately incidence.

The RNTCP was established with a target of detecting at least 70% of the estimated new smear-positive TB cases, and curing 85% of these. After TB was declared a global health emergency in 1993, these targets were the globally agreed minimum standard required to successfully achieve accelerated TB control. Subsequent analysis has determined that these thresholds by themselves were insufficient to achieve predicted declines in TB incidence (5). This is due, in part, to focusing on a high case detection rate, which does not necessarily imply rapid diagnosis. In principle, a majority of cases could be detected after long delays, by which time the infection might have already spread in the community.

The core of the current RNTCP approach to case finding is the identification of people with continued cough for two weeks in public health facilities, and referral of "chest symptomatics" for sputum smear microscopy at a decentralized, quality-assured microscopy centre. The patients that are found to be smear-positive are referred for treatment, and those that are smear-negative are channelled to a clinical diagnostic pathway. Extra-pulmonary TB is largely left to diagnosis on clinical grounds, frequently involving referrals to medical colleges.

Under the Strategic Plan 2012–2017, RNTCP has articulated a new and ambitious case-finding objective of 'early detection of 90% of all TB cases'. Achievement of this objective is expected to further decrease TB transmission, save more lives, and yield accelerated reductions in overall TB mortality and incidence.

This chapter discusses the remarkable achievements of RNTCP till date in case finding and the key challenges facing the programme to achieve the more ambitious objective of 'early detection of 90% of all TB cases'. The chapter also proposes the overall structure of activities needed to actively reach out to vulnerable or high-burden groups, to reach out to all TB cases earlier, irrespective of where they seek care, and to improve the quality of TB diagnosis.

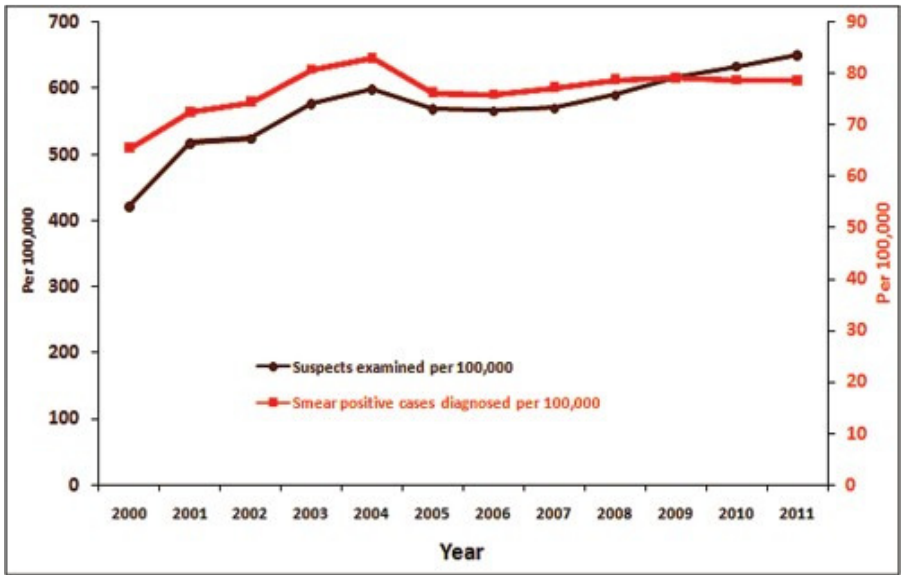
Achievements

Enormous efforts and achievements were highlighted in case finding under the 11th Five-Year Plan (2006–2011). More than 31 million patients were evaluated for TB in all the 5 years, with 7.1 million patients initiated on treatment under RNTCP. About 7.5 million chest symptomatics were examined in the country in the year 2011 alone. Every day in India, more than 24,000 chest symptomatics are examined for TB, more than 3,000 smear-positive TB cases are detected, and more than 4,800 TB cases of all forms are registered and put on treatment.

Indicator	11th Five Year Plan (2006–2011*)	
	Planned	Achieved
Number of TB suspects examined (lakh)	237.2	353.23
Total number of patients put on treatment (lakh)	50.4	79.05
New Smear Positive patients put on treatment (lakh)	23.4	30.91
Number of MDR -TB patients put on treatment	10,000	6994
Success Rate in New Smear Positive patients in RNTCP (%)	≥85%	87%
Estimated annual prevalence per lakh population	Reduced from 299 to 249	
Annual risk of TB Infection (%)	Reduced from 1.5% to 1.1%	

*Data as up to December 2011

Figure 2.1: Rate of TB suspects examined per 100,000 population and smear-positive cases diagnosed, corrected for population covered under RNTCP



A core accomplishment of the RNTCP has been to establish the decentralized availability of quality-assured laboratory testing for TB. A nationwide network of RNTCP quality assured designated sputum smear microscopy laboratories has become an important contribution to the overall public health laboratory system in the country. This system of about 13,000 designated Sputum Microscopy Centres (DMCs) nationwide provides a public sector option for the appropriate, affordable and accessible quality assured diagnostic services for chest symptomatic and cases. DMCs are mostly integrated into the nation's government health facilities at all levels with 1 DMC per lakh population. The quality of microscopy services at DMCs is overseen by Intermediate Reference Laboratories (IRLs) at the state level, and National Reference laboratories (NRLs) & Central TB Division at the national level.

RNTCP has given special emphasis to areas classified as tribal, hard to reach and/or poor and backward, with additional resources for programme implementation. The programme has especially monitored performance in these areas to ensure that quality care reaches populations with poor access to health facilities.

Medical colleges have been effectively organized at a large scale, and provide major contributions to case finding. These partnerships play a major role in detecting smear negative and extra – pulmonary cases. In 2011, 95,272(14.8%) of all cases in the country, smear-positive TB cases were diagnosed at medical colleges; altogether, more than 2.3 lakh TB cases were diagnosed and referred for treatment.

Greater involvement of civil society is predicted to yield reductions in stigma, improvements in access and improvements in case finding. Major initiatives to expand the role of civil society and affected communities in TB care and control are currently underway. A Global Fund grant directly to civil society partners, Project Axshya, is targeted at 374 districts with difficult access to health care or

poor historical TB case-finding results. Activities under project Axshya include sensitization of rural providers; support for sputum collection centres and coordination of Non-Governmental Organisations (NGOs) to engage with RNTCP under the scheme. More broadly, major efforts have been made to involve NGOs and civil society nationwide. The health facilities operated under the aegis of Catholic Bishops Conference of India (CBCI) have been engaged through the parent organization to participate in RNTCP activities in 19 states. Schemes targeted at NGOs to improve access and outreach for slum dweller populations have been established and implemented in several major cities.

Efforts to engage the private sector have revolved around outreach, directly via public-private mix (PPM) schemes and through intermediary groups such as the Indian Medical Association (IMA). The IMA, with a Global Fund grant, has initiated large-scale sensitization of qualified private providers in 16 states. As of December 2011, 46923 providers have been sensitized, and 3,396 DOT centres have been established.

Challenges

One of the biggest challenges facing RNTCP in the coming years is that after more than a decade of RNTCP implementation, case detection rates have clearly plateaued, despite increasing attention to improving the quality of diagnosis in the public sector. The overall reasons are summarized below.

Weak health seeking behaviour

There is a need to encourage people with symptoms, particularly vulnerable populations, to seek care.

Patients not accessing the health system, or accessing late:
Delays in diagnosis can explain the propagation of infection in households, public spaces, clinics, and other points of congregation. Some of these delays are inherent to a system of control that has relied on patients to present themselves at health centres. In a community survey conducted by MBPH (Abt associates, Market based partnerships for health) in Uttar Pradesh and Karnataka, about 25%-42% of patients who had cough beyond 2 weeks had not yet sought any medical attention (6). Many patients are not recognized as chest symptomatics and in turn are not offered efficient diagnostic testing. For example, smear-positive TB patients in the public health facilities in Bangalore had already visited an average of 3 providers (range 2–6 providers) before being correctly diagnosed (7).

The massive investments in the general health system under National Rural Health Mission (NRHM) have not been adequately leveraged for improved TB case finding. An army of field staff – Auxiliary Nurse Midwives (ANMs), Accredited Social Health Activists (ASHA), village health workers, multi-purpose health workers, etc. – has been developed across rural and sub-urban India. These are organized under the Block Medical Officers, and are accountable for all national health programme activities locally including RNTCP; though their full potential is yet to be leveraged for TB case finding. This army of field staff is similarly not

effectively utilized for contact investigation, identification and screening of high-risk individuals, or even for basic TB treatment supervision.

Many populations are known to suffer disproportionately from TB. The most well-known clinical risk group is persons living with HIV/AIDS, but other larger clinical risk groups include contacts of TB cases, diabetics, smokers, malnourished people, alcoholics and geriatric population. There are also socioeconomic risk groups, such as slum dwellers, migrants, patients with occupational risk factors (miners) and tribal groups. Substantial efforts have been made to reach slum dwellers through the urban slum scheme and tribal groups through the tribal action plan, but coverage has been incomplete. Contacts of TB cases are as per current RNTCP policy should be screened for symptoms and referred for microscopy if symptomatic. This is a basic standard of TB care globally and recommended by RNTCP; however, the monitoring of this activity needs to be strengthened. In a study conducted in Andhra Pradesh, India, it was found that only two-thirds of the eligible contacts (<6 years old) were assessed for TB and nearly one-fifth of those eligible were not initiated on IPT; children in rural areas were at significantly higher risk of getting non-evaluated and not initiated on IPT (8). Furthermore, limited efforts have been made to actively seek TB cases in clinical risk groups beyond PLHA; the example of intensified TB case-finding in HIV diagnostic and care centres shows what may be possible. Lastly, in any efforts to diagnose TB earlier in risk groups, patients may be infectious but often have limited disease and hence are frequently initially sputum smear-negative. Fundamental limitations in the sensitivity of microscopy and in the diagnostic algorithm reduce the effectiveness of overall case-finding efforts [discussed in depth below].

Beyond public health system

In India, the private sector is the first point of care in approximately 80% of cases of ill health (9). Studies on TB show that while most patients are ultimately treated in the public sector by RNTCP, they have previously received care in the private sector that is responsible for prescribing half of all TB medication in the country (10). As a result there are delays in diagnosis, unnecessary patient expenditures, and irrational or unsupervised therapy. These factors in totality lead to the continued transmission of TB that is fuelling drug resistance. The earlier attempt to engage the private providers to sensitize them to generate referrals to RNTCP for diagnosis and/or treatment, has met with limited success. The efforts of RNTCP and the IMA in this regard have been limited to qualified private providers, and very few of these have subsequently engaged productively with RNTCP. Presently, the private sector accounts for less than 2% of all TB cases notified in the country and only about 10,000 private providers have signed MOUs to participate in these schemes.

Low-sensitivity diagnostic tools

Ineffective and delayed diagnosis in both the private and public sector:
Many patients are not recognized as chest symptomatics and in turn are not offered efficient diagnostic testing. For example, smear-positive TB patients in the

public health facilities in Bangalore had already visited an average of 3 providers (range 2–6 providers) before being correctly diagnosed (7).

When a patient is recognized as a TB suspect, providers frequently use an incorrect diagnostic test, further delaying TB diagnosis. In a community survey in Uttar Pradesh, patients with prolonged cough visited the private sector, where a 'blood test' was commonly requested compared to the sputum test that ought to have been done (11). Most patients in the private sector are prescribed chest x-rays which are non-specific and often result in over-treatment, and/or ineffective serologic blood tests, which have been discouraged by RNTCP and World Health Organization (WHO) in a policy issued in July 2011 (12). Ineffective TB serological tests are not licensed in most countries, but have been licensed in India by the Drug Controller General of India (DCGI) and by various states. The widespread use of the same has led to patient harm. Researchers have estimated that if used instead of sputum microscopy in India, serology generated an estimated 14,000 more TB diagnoses, but also 121,000 more false-positive diagnoses, 102,000 fewer DALYs averted, and 32,000 more secondary TB cases than microscopy, at approximately four times the incremental cost (US$47.5 million versus US$11.9 million). There are an estimated 1.5 lakh patients who are incorrectly declared TB positive, who in turn are prescribed unnecessary treatment (13).

Sputum smear microscopy using Ziehl Nielson staining technique, only detects approximately 60–65% of patients who could be confirmed with TB. TB culture is still the most-sensitive microbiological diagnostic test for TB, but requires advanced laboratory facilities not available in most settings, and takes 4 – 8 weeks to provide results.

Patients in the public sector who are not initially smear-positive are subject to further diagnostic delays. The internationally recommended algorithm for TB diagnosis used by RNTCP is undeniably complicated, requiring 7-14 days and multiple visits to the health care facility. Completion of the TB diagnostic algorithm is further challenged by the absence of functional chest X-ray facilities in the public health facilities, limited ability by field medical officers to properly read and interpret chest radiographs, and poor ability to discriminate TB from other chest diseases.

Failure to link diagnosed TB patients to the appropriate effective treatment: Not only do patients need to be linked with treatment, but require effective treatment to render them non-infectious, stop transmission, and yield good clinical outcomes. The international standard of care is to conduct drug susceptibility testing to stratify patients to the correct regimen (14). This is routinely done for TB patients in most middle and high-income countries.

Given the high figures of TB burden in India coupled with lack of advanced laboratory facilities, and 3-5 months for diagnosis, previously this was not considered possible. Hence, only the patients, who gave a poor response to treatment and survived that winnowing process, were offered access to drug susceptibility testing and additional treatment. During the interim period, such patients continue to harbour the infection and transmit drug-resistant TB.

New advances in rapid drug susceptibility testing have created the possibility of screening many more TB patients for drug-resistant TB and prescribe the correct regimen from the outset. But these are not yet deployed for TB patients.

Lack of public health system accountability

Failure to notify and register patients diagnosed with TB: Patients diagnosed and treated accurately with TB by qualified private providers, were not registered and notified under RNTCP unless the RNTCP treatment course and regimen was used. There is no existing system which extends RNTCP recognition of patients treated well by the private sector, nor for notifying the cases which fulfil public health functions like treatment adherence support, contact evaluation or outcome recording. There is no legal enforcement for a practitioner to notify TB cases in the community and the states, which have declared TB as a notifiable disease, implement the same poorly.

Even if patients are diagnosed with TB under the RNTCP in public sector facilities, they need to be confirmed, registered, and given treatment to be officially notified as a TB case. In 2011 in RNTCP, although 9,53,032 patients were diagnosed as sputum smear-positive, only 8,44,920 patients were registered, missing over 1,00,000 patients (15). Evaluation of these smear-positive 'initial default' patients found that many were untraceable, had died, or had taken treatment from the private sector (16). Many patients had not even collected their test reports and there was no system to trace the same.

Countless patients were 'referred for treatment' under the RNTCP in 2011, including 170,396 from medical colleges alone (15). But without an accountable and integrated system for completion, referrals and transfers, many referred patients were lost and could not be registered. A further unknown number of patients with smear-negative TB or extra-pulmonary TB were diagnosed but not registered under RNTCP.

In summary**,** the plateau in case-detection and the challenges outlined above indicate that RNTCP requires new strategies and greater efforts to trace the remaining unreached TB cases in the community, and reach all TB patients – wherever they may be seeking care presently.

Strategic Vision for 2012-17

The success of improving TB case finding will directly determine how fast RNTCP can achieve the overall programme goal of reducing TB morbidity and mortality till TB is no longer a major public health problem. In order to find all cases and to find them early, the fundamental approach to case finding in RNTCP will have to evolve.

On one hand, the basic strengths of RNTCP now allow the programme to move beyond simply finding patients in public clinics with a cough. The next level of standard TB control activities needs to be adapted and implemented in India, aligning the programme with the standard of care available in middle income

countries; including better contact investigation, outreach to clinically and socially vulnerable populations, and early screening of TB patients for drug-resistant TB.

On the other hand, challenges specific to India require innovative case-finding solutions. This is possible because of opportunities with national investments in the health system and a vigorous, entrepreneurial private sector. Innovations are required for effectively leveraging India's enormous investments in NRHM and field staff for case finding, engaging the private sector effectively and on a large scale, deploying better TB diagnostics, recording and notifying all patients diagnosed with TB, and linking patients to the right treatment through decentralized screening for drug-resistant TB.

With the effective execution of the strategic response and activities outlined below, by 2017 RNTCP expects to achieve the objective of early detection of 90% of all incident TB cases. This is projected to be an output of approximately 1.8 million TB cases per year diagnosed and treated as per national standards, and annual increase of more than 600,000 incident cases (50%) compared to 2010.

In summary, new and more effective case-finding approaches and diagnostics need to be developed and implemented. All case-finding activities will have to be applied with much greater vigour and oversight.

Challenge	Strategic response and activities
Patients not accessing the public health system, or accessing late	Reach out to the unreached and vulnerable populations • Integrate with general health system under NRHM/NUHM, and leverage field staff for home-based case finding [HSS] • Improve communication, outreach and social mobilization [ACSM] • Screen clinically or socially vulnerable groups for TB • Improve specimen transportation systems and feedback of results to patients • Develop local inventories of vulnerable groups to deploy innovative targeted case-finding activities.
Patients accessing private providers not linked or engaged with RNTCP	Expand efforts to engage all health care providers [PPM] • Establish and disseminate 'Indian Standards of TB Care', and update standards to incorporate new evidence and approaches. • Deploy innovative private sector engagement models, including partial subsidizing quality TB diagnostic testing at private labs, social marketing of TB drugs and flexible treatment options for private providers as per Indian Standards of TB Care.
Ineffective and delayed diagnosis in both the private and public sector	Evaluate and deploy better TB diagnostics and diagnostic approaches • Deploy better, higher-sensitivity diagnostic tests for chest symptomatics and deploy them at a level where diagnostic delays can be potentially reduced. • Develop and deploy better diagnostic approaches, including improved algorithms with existing and new tests.

	• Establish systems for programme-based evaluation of new TB diagnostics. • Support the establishment of minimum performance standards for licensure of TB diagnostic tests. • Work with the DCGI to review and ban ineffective serological tests
Failure to notify and register patients diagnosed with TB	Develop and deploy systems for notifying patients at TB diagnosis from all sources • Develop and deploy systems for recording individual cases during diagnosis, rather than treatment initiation, and including private labs, providers, and pharmacies. [M&E and Surveillance]
Failure to link diagnosed TB patients to the appropriate, effective treatment.	Create public health system accountability for all diagnosed TB patients, and put patients on DST-guided treatment. • Strengthen referral for treatment (& transfer) mechanism, using electronic referral and feedback system. • Strengthen National and State Reference Laboratory Network. • Accelerate deployment of decentralized DST capacity.

Activities

Promoting health seeking behaviour

Improve integration with general health system, and leverage field staff for home-based case finding: The current basic programme management unit for RNTCP, the "Tuberculosis Unit" – an artificial construct for 500,000 persons – will be realigned nationwide with the NRHM health blocks and urban wards anticipating NUHM expansion. The responsible programme officer for that block, the Block Medical Officer, will also be given charge of local TB programme activities. A series of enhanced activities, training, and supervision structure for field staffs will be developed, integrated with their existing duties. With the re-alignment of the programme, the Block Medical Officer will be given charge of RNTCP as well, and will be able to hold field staff accountable for TB as well as immunizations and maternal-child health. As at the local level TB remains an uncommon disease, this will not adversely affect other programme activities. These activities are detailed further under Health Systems Strengthening.

Improve communication and outreach: The programme will also expand the use of innovative communication strategies to reduce stigma, generate demand from patients and improve cooperation from the private sector. Demand generation will include more intensive targeted media and social mobilization activities including hiring of a professional media agency and engaging a famous personality as brand ambassador to spread TB message rather than over-reliance on posters and pamphlets. Sensitization and participation of Panchayati Raj Institutions (PRIs), private practitioners and Self Help Groups (SHGs) will reduce the gap between services and the need. RNTCP will seek to develop support mechanisms

for empowerment of the TB affected community. These activities are discussed in detail in the ACSM chapter.

Screening clinically vulnerable risk groups for TB: The clinically vulnerable population includes people living with HIV, household contacts of TB cases, malnourished children, diabetics, tobacco users, and those living in houses with indoor air pollution who need to be screened for TB regularly (17).

Screening socially vulnerable groups for TB: Efforts for intensive case finding will be made to reach the vulnerable population and screen them for TB. The socially vulnerable population includes migrants, slum dwellers (of notified and non-notified slums). The following interventions will be pilot tested and assessed for feasibility and effectiveness before nationwide scale-up.

- Screening camps at district or sub district levels every quarter.
- House to house visit to underserved populations – at least twice in a year.
- Regular screening camps at medical colleges – at least twice a year.
- Screening of malnourished children at Aanganwadis every quarter.
- National TB screening days to be conducted with the involvement of entire health system for three days once a year, during the months of June to August.

Develop improved sputum collection and transportation systems:
Currently patients submit specimens at Designated Microscopy Centres for chest symptomatic or at District Headquarters for patients suspected of drug-resistant TB. Better systems to move specimens to local and reference laboratories are required to increase the access for diagnosis of TB and drug resistant TB.

- RNTCP will make provision for reimbursing TA for health workers who transport specimens from peripheral health institutes to DMC's.
- Reimbursement will be provided for transportation of DR-TB suspects' sputum samples to DST laboratories.
- An honorarium for ASHAs and TB patients transporting sputum samples to DMC's would be provided to defray transportation costs.

Going beyond public health system

The case-finding goal is to identify patients as chest symptomatic at the first point of care, and link chest symptomatic to the best available diagnostic test. This will require much more successful engagement of the private and NGO sector at a scale commensurate with the importance of private health care provision in India. Increased resources will be required to finance scale-up of innovative approaches to engage the private sector, with flexible development of strategies from state to state. Activities include development of Indian standards of TB Care, establishment of national working group to guide engagement efforts, development and deployment of innovative approaches to private sector engagement including subsidizing quality TB diagnostic testing at private labs, social marketing of TB drugs, and flexible treatment options for private providers as per Indian Standards of TB Care. These activities are detailed in the Engaging the Private Sector chapter.

Ensuring use of "state of the art" diagnostic technologies

Deploy better, higher-sensitivity diagnostic tests for chest symptomatics: The sensitivity of the current sputum-smear microscopy diagnosis is low compared to the other improved newer diagnostics. New diagnostics are required to achieve the programme's Universal Access targets, particularly in HIV-infected patients with TB. The past few years have seen the development of rapid molecular tests for TB that perform nearly as well as cultures, the time-consuming bacteriologic techniques used for many decades. The validation and rapid deployment of these improved TB diagnostics to all levels of the health system is a key programme priority.

The LED Fluorescent Microscope (LED-FM) is WHO-recommended and well validated in India. This incremental improvement on current microscopes offers the major advantages of slightly higher (5-10%) sensitivity than conventional microscopes, higher throughput (less time required per slide), lower maintenance (long life LED bulbs), and battery-capable operation. The microscope is therefore highly suitable for settings with either high TB suspect workloads and/or inconsistent power supply. The LED-FM microscope is being introduced in 200 (65%) of the medical colleges across the country through an externally funded project in 2011-2012. RNTCP envisions (1) replacement in medical college and high workload settings, and (2) routine replacement of existing binocular microscopes after their condemnation, with strategic placement for maximum value. Nearly, 2600 LED FM microscopes will be replaced by 2015. The remaining microscope will be fitted with external LED light source.

An automated nucleic acid amplification test, the Xpert MTB/RIF has been endorsed by WHO in 2010 which provides a diagnosis of TB and rifampicin resistance within 2 hours. This is a disposable cartridge-based assay that can operate in temperatures of 15-30 C, even in high-humidity environments, easy to train health workers to use it with virtually no risk of sample cross-contamination and no need for specialized bio-safety environment. The test is simple enough to apply almost anywhere unlike culture techniques which require specialized laboratory environments. However, some characteristics of this tool can cause operational problems: the shelf life of the cartridge is only 18 months, a very stable electricity supply is required, the instrument needs to be recalibrated annually, the temperature ceiling is critical, high cost per test and the safe disposal of large volumes of plastic cartridges may be problematic (18). Hence, the programme is evaluating the feasibility of cartridge based automated nucleic acid amplification systems (CB-NAAT) for the diagnosis of drug resistant TB. After demonstration in rural and urban settings, a phased deployment of automated CB-NAAT is recommended as an initial TB diagnostic in PLHIV, paediatric TB diagnosis, extra-pulmonary TB diagnosis, and may have broad improved application for decentralizing DST to districts without expensive laboratory structure or staff investments. Deployment of CB-NAAT or the equivalent molecular test for each district and medical college is planned by 2017, with provision of sufficient reagents for the recommended clinical applications.

Establish systems for programme-based evaluation of new TB diagnostics, and support the establishment of minimum performance standards for licensure of TB diagnostic tests: Development of new diagnostics, drugs, and vaccines for TB is in the pipeline, and holds the possibility of greatly facilitating TB control efforts. The programme must rapidly evaluate these improved tools and strategies, collect evidence for scale-up, and if indicated deploy them quickly so that TB control may make advances in saving lives and benefiting the country. A number of diagnostic tests for TB are being developed, including many indigenous options. RNTCP has in the past with the Line Probe Assay (LPA) demonstrated the capacity to partner for the rapid evaluation of new TB diagnostic tests, and rapidly incorporate improved tests into programme protocols. This approach needs to be standardized, and the National Institutes and National Reference Laboratories need to have sufficient capacity and resources to serve this critical function for the programme. RNTCP also intends to work with the DCGI (as NACO has done with HIV tests) to ensure that all TB tests sold and used in India must meet the minimum performance standards outlined by the programme. This could also ensure that tests discouraged by RNTCP and WHO (e.g. serological tests) are banned from clinical use in India.

Develop and deploy systems for notifying patients at TB diagnosis from all sources: Ultimately a very large number of TB patients in India are diagnosed and not notified to RNTCP. With improved notification, RNTCP could exercise public health functions, improve case management, and reduce TB transmission and the spread of drug-resistant TB. Over 2012 – 2013, RNTCP plans to develop the systems for recording individual cases at the stage of diagnosis. From the public sector, patients would be notified by virtue of microbiological confirmation (i.e. from lab register) or by usual clinical means. By requirement, such a system would include private labs, providers, and pharmacies to generate possible notifications, with validation by the public sector or 3rd parties contracted for this purpose into the 'final' TB register. All diagnosed TB cases will be notified irrespective of their treatment or registration status. Different approaches to develop the notification system will be explored and adapted by the programme in a phased manner. These activities are described in greater detail in the Monitoring, Evaluation, and Surveillance chapter.

TB case notification is currently legally required in some settings; efforts should be made with states to use this opportunity and legal approaches like model public health legislation to formalize the legal basis of provider, laboratory, and pharmacy notification of TB cases in all states.

Create public health system accountability for ensuring DST driven treatment for all TB patients

Strengthen referral for treatment (& transfer) mechanism, using electronic referral and feedback system: With development of a system for recording each diagnosed TB case, RNTCP will also leverage that information for improved care through an electronic referral for treatment mechanism. Local programme units would be responsible for accounting for each diagnosed TB case, whether registered on RNTCP treatment, referred out, treated with an ISTC-approved approach by a private provider, or any other pathway. Improved communication

through an electronic system should be able to more effectively reduce patient loss during referral for treatment than the existing paper-based system.

Strengthen national and state reference laboratory network: RNTCP has established 28 state reference laboratories, with capacity for Culture and Drug susceptibility testing (C&DST) for the diagnosis of drug resistant TB. The programme expects to establish a total of 43 C&DST laboratories by 2013, and seeks to increase the capacity by additional 30 C&DST laboratories, established in the government and other sectors through public-private partnerships by 2015. By this the country will have the capacity to meet most DST requirements for re-treatment TB patients, and approximately 15% of new TB patients who fail to respond to standard treatment. Accreditation of private C&DST laboratories will be accelerated.

RNTCP will also invest to develop the capacity of the National Reference Laboratories for effective supervision and monitoring of the State Reference Laboratories, and to conduct research for development and implementation of improved tools and strategies. Given the size of the country and number of State-level laboratories, RNTCP expects to establish two national reference laboratories in existing Institutes, one each for the North - East zone and West zone.

Accelerate deployment of decentralized DST capacity: The most effective system for stratifying patients to the correct treatment would involve decentralized DST capacity at the district level, with the reference labs used for confirmatory testing, second-line DST, and appropriate reference (as opposed to clinical) functions. Previously decentralized DST could not be envisioned, due to extensive and expensive infrastructure and human resource requirements. Now with the development of CB-NAAT, decentralize DST is possible through tests that are easier to conduct than smear-microscopy, and give rapid results allowing for immediate assignment to the correct treatment regimen. The scale-up of CB-NAAT, or the equivalent low-touch field-friendly DST option available at the time, is envisioned for the district level by 2017 to further improve and expand the capacity of the programme to interrupt transmission of drug-resistant TB.

3
Patient Friendly Treatment Services

Key Messages

- Making DOTS more patient friendly will increase access and improve outcomes.
- Prompt and appropriate treatment of TB, increasingly guided by drug susceptibility testing, will save lives and interrupt transmission.
- Improving partnerships between the public and private sectors is critical to expanding treatment services.
- Research and mechanisms to fast track evidence to policy and practice are essential to guide improvements in regimens and delivery systems.

Abstract

Since inception, RNTCP has successfully achieved its objectives as evidenced by the consistently high treatment success rate of at least 85 percent. This has been accomplished by the use of standardized treatment regimens, delivered in an uninterrupted manner in patient-wise boxes, provided to patients free of cost under direct observation of a DOT provider. In keeping with the high burden of TB, RNTCP rapidly increased the geographic coverage, which has yielded impressive results over the past 15 years.

The visionary Strategic Plan proposes an ambitious goal of providing universal access to high quality diagnosis and treatment for all TB patients (including HIV-associated and drug resistant TB). Given this ambitious vision, the changing global treatment guidelines and the evolving nature of the tuberculosis epidemic, the programme will need to remain committed to the fundamentals of basic TB control, while being alert to make judicious technical and operational changes as the evidence emerges so as to strengthen the programme.

Optimizing the use of different treatment regimens, increasingly guided by drug susceptibility results would be one of the key opportunities for programmatic improvement. At present a vast majority of patients are initiated on standard four drug first line therapy and those who fail therapy are investigated and treated with additional drugs if found to be drug resistant. In the coming years, increasing and earlier use of DST will help in stratifying patients, promptly identify and treat drug resistant cases. Early appropriate therapy will save lives and interrupt the transmission of drug resistant tuberculosis.
DOT (Directly Observed Therapy) has been crucial for ensuring patient compliance and will continue to remain the central strategy to ensure patient adherence. However, the programme will explore and evaluate several measures to make it more patient-friendly and flexible. These include strategies such as decentralized community based DOT with enhanced provider incentives, patient incentives especially in difficult areas, improved use of IT and telecommunication to track patients in a setting of improved web-based, case-based surveillance systems. Those found to be effective would be rapidly scaled up nationally.

The goal of universal access will not be achieved unless those patients who receive care in the private sector are better served. The private sector is poorly regulated and unorganised where case management and care is inadequate and referrals to the public sector infrequent. Addressing a number of treatment issues including expanding RNTCP guidelines flexible to accommodate all the recommendations as per ISTC will increase partnership between the public and private sectors.

There exist a number of unresolved questions about TB control and new ones will emerge with the availability of innovative diagnostic tests, improved drug regimens and delivery models. Thus, targeted clinical and operational research and mechanism to fast-track evidence, as it emerges, into appropriate policy and ultimately improved practices under RNTCP will be essential to inform decision-making and guide future activities; a “National Treatment Committee” will be established with representation from diverse stakeholders to serve this purpose.

Introduction

The past five years of TB control in India can largely be characterized by the scale-up of well-established therapies and mechanisms to ensure compliance. The programme has focused on the use of a standardized treatment regimen, delivered in an uninterrupted manner in patient-wise boxes, free of cost, to patients under direct observation of a DOT provider, in a patient-friendly manner, at a place and time convenient to the patient. By focusing on basics, RNTCP rapidly expanded coverage across vast geographic regions and saved millions of lives. By doing so, it consistently achieved treatment success rates in excess of 85% since 2001.

However, the next 5 years promise to be dynamic as new drug regimens, novel diagnostic tests, improved communication technology and evolving health systems will provide opportunities for improving TB control. In order to achieve universal access the programme will need to address a number of challenges in the coming years such as drug resistant TB and HIV-associated TB.

In times of increasing innovation and disease complexity, systematic evaluation of novel drugs, diagnostics and delivery systems is necessary. Consequently, clear mechanisms need to be established to ensure that the core elements of success to date are not lost while innovations are evaluated and (when appropriate) incorporated into the programme to ensure that India has access to state of the art TB care and the programme remains a global leader.

This chapter discusses the various technical and operational achievements and challenges of RNTCP in the past five years in ensuring that treatment services are provided to the patient. It also examines the RNTCP vision and proposed strategies to achieve this vision in the next five years.

Achievements

The aim of TB treatment is to cure the patient while preventing development of resistance and recurrence. To date, the RNTCP has been very successful with short-course intermittent, thrice weekly treatment regimen provided under direct observation and standard regimens for MDR case (19-20). Those patients who failed the first line therapy were subjected to culture and drug susceptibility testing and those identified as MDR-TB are being treated with category IV regimen.

RNTCP – the world's largest DOTS programme

Since inception of RNTCP, more than 15 million TB patients have been treated under DOTS by utilizing a network of over 6 lakh DOT providers. This has resulted in saving more than 2.5 million additional lives (15).

DOT is the core of the treatment delivery system that can create a human bond between the provider and the patient and motivate the patient to complete the treatment. In addition, it fosters rigorous monitoring and rapid retrieval of patients who interrupt treatment. Since these activities are not possible in a setting of self-

administration, RNTCP strongly discourages 'self-administration' as an option in the interest of the patient and public health.

To make this more "patient friendly" the programme has gone to great lengths to bring DOT close to the patients. DOT Centres (providers) are institutions/individuals (health staff/ volunteers) who are accessible and acceptable to the patient and accountable to the system. All public health facilities including sub-centres are enrolled as DOT centres. The programme has been making efforts to identify, sensitize and garner support of community volunteers, cured patients, volunteers working with health and nutrition departments - *Anganwadi* workers, including ASHA volunteers, and workers with PLHIV networks where ever available- who are committed and compassionate to deliver DOT as close to the patient as possible. NGOs and PPs have been enrolled as DOT centres under the different revised NGO/PP schemes. The programme has also been vigilant to ensure continued supervision and monitoring of DOT by sub-district supervisors. Further, the assistance of sub-district supervisors is also sought in the retrieval of patients who are late for treatment and a nominal honorarium is provided to all the community DOT providers at the rate of Rs 250 for every successfully treated patient.

The programme has impressive clinical outcomes. Treatment outcomes of pulmonary sputum positive cases notified under RNTCP are summarized in Table 3.1. Among NSP cases, the treatment success rate has been > 85% since the year 2001. The death rate and failure rate has been about 4% and 2% respectively. The default rates has decreased from 9% for the cohort of TB patients registered in 1999 to 5% for the cohort of patients registered in 2010. The treatment success rates among new smear negative and extra-pulmonary cases have also been more than 85%, indicating the efficacy of the regimens used under RNTCP in all types of TB cases (15).

Table 3.1. Treatment outcomes among notified new TB cases, 1999–2010

	New smear-positive				New smear-negative				New extra-pulmonary			
Year	Success	Death	Failure	Default	Success	Death	Failure	Default	Success	Death	Failure	Default
1999	82%	5%	3%	9%	85%	4%	1%	9%	91%	2%	0%	6%
2000	84%	4%	3%	8%	86%	3%	1%	9%	91%	2%	0%	7%
2001	85%	5%	3%	7%	86%	4%	1%	8%	91%	2%	0%	6%
2002	87%	4%	3%	6%	87%	4%	1%	7%	92%	2%	0%	5%
2003	86%	5%	2%	6%	87%	4%	1%	7%	92%	2%	0%	5%
2004	86%	4%	2%	7%	87%	4%	1%	8%	92%	2%	0%	5%
2005	86%	5%	2%	7%	87%	4%	1%	8%	91%	2%	0%	6%
2006	86%	5%	2%	6%	87%	4%	1%	8%	90%	3%	0%	5%
2007	87%	5%	2%	6%	87%	3%	1%	8%	91%	2%	0%	5%
2008	87%	4%	2%	6%	88%	3%	1%	7%	92%	3%	0%	4%
2009	87%	4%	2%	6%	88%	3%	1%	7%	92%	2%	0%	4%
2010	88%	4%	2%	5%	89%	3%	0.5%	7%	92.6	2%	0%	4%

Quality of treatment delivery

Quality of treatment delivery has consistently been an area of focus throughout the massive scale-up of RNTCP. Districts routinely report on the number of NSP cases who receive treatment within 7 days of diagnosis (i.e. positive smear microscopy

results), and those who were registered within a month of initiating treatment. In 2010, among the NSP registered under RNTCP, about 86% started treatment within 7 days of diagnosis and almost everyone was registered within a month of starting treatment. During the internal evaluation of 1700 smear positive patients from more than 80 districts in the year 2010, it was observed that 77% percent of patients received treatment under direct observation in the Intensive Phase. The proportion of TB patients who are provided treatment by a community DOT provider is an indication of the decentralization of services and reassures that treatment services are being delivered near the patient's residence. In the current setup, about 40% of patients are treated by a community DOT provider (15).

Emphasis on quality of drugs

Recognizing the importance of quality assured anti-TB drugs, a comprehensive RNTCP Quality Assurance (QA) system has been developed and implemented. This ensures quality control from the time of procurement to the point of consumption by the patient. It also ensures the continuous availability of high quality anti-TB drugs at all stocking and/or service delivery points under the programme. Quality assurance procedures include checks at the procurement stage and pre-shipment testing of the drugs at suppliers' locations by the RNTCP procurement agent. In addition, the Central TB Division has hired the services of an independent testing laboratory, which will test samples selected at random from the DTCs, GMSDs and SDSs. All implementing districts, GMSDs and SDSs have been arranged on a zone-wise basis (North, South, East and West) and random collection of drug samples is conducted from each zone every quarter.

Programmatic management of drug-resistant TB

India has the second highest burden of MDR-TB in the world, accounting for more than one-fifth of global burden. Since the inception of PMDT programme in 2006, India has initiated basic PMDT services in all states, including about 50% of districts, with close to about 9000 patients placed on treatment till March 2012.

Challenges

Prompt appropriate treatment

Retreatment Regimens: Decreasing the number and improving the outcome of treatment of people who have been previously treated for TB remains a challenge. Nearly 300,000 patients are retreated each year by the RNTCP. These include patients undergoing relapse, failure, treatment after default and others and about half of them are from the private sector (21). The treatment success rate among these is inadequate - less than 70% since implementation due to high default, death and failure rates (Table 3.2 and 3.3). Thus one specific challenge is to decrease default among retreatment cases, which are currently more than twice that among New Smear Positive TB cases (22).

Table 3.2. Treatment outcomes among notified Re-treatment smear positive TB cases, 1999–2010

Year	Total Smear +ve Re-treatment cases			
	Success	Death	Failure	Default

1999	68%	7%	6%	18%
2000	69%	7%	6%	16%
2001	71%	7%	6%	15%
2002	72%	7%	6%	14%
2003	70%	8%	6%	15%
2004	71%	7%	6%	16%
2005	69%	7%	6%	17%
2006	69%	8%	6%	16%
2007	70%	8%	5%	15%
2008	71%	8%	5%	14%
2009	71%	8%	6%	14%
2010	71%	8%	6%	14%

But much of the poor outcome in these groups is due to high rates of drug resistance, including mono resistance, poly resistance and MDR–TB. Currently, all these cases are treated with a single standardized regimen. This leads to a situation where a patient who has failed a first line treatment, is frequently given a single new drug, as part of the retreatment regimen. This regimen violates a basic tenet of TB chemotherapy – which is to never add a single drug to a failing regimen (23). Thus a major challenge in the coming years will be the rational, but rapid increase in the use of drug susceptibility testing to ensure that drug resistance is identified promptly and treated appropriately. This has started in a few districts and needs to be scaled-up nationwide. It is anticipated that doing so will both save lives and interrupt further transmission of drug resistant TB.

Table 3.3: Outcome of Smear Positive Retreatment cases for India 2010 (Excluding "Others")

Type of retreatment case	Cured	Success	Died	Failure	Default	Transfer out	No. Registered
Relapse	69%	75%	7%	5%	12%	1%	110590
Failure	50%	57%	10%	15%	16%	1%	18439
Treatment after default	60%	68%	8%	4%	18%	3%	72074
Total	64%	71%	8%	5%	14%	2%	201103

Limited access to treatment regimens for MDR–TB and XDR-TB: As more cases of MDR TB are promptly identified with DST, it will further challenge the ability of the programme to provide SLDs. Despite the major efforts to develop and expand PMDT services, in 2011 still only 5% of estimated MDR TB cases under RNTCP were diagnosed and started adequate treatment. Cohort analysis of MDR-TB patients indicates poor outcomes associated with high levels of flouroquinolone (FQ) resistance (24); this calls for early DST for second line drugs, especially FQ and scale-up of management of FQ-resistant MDR-TB and XDR-TB.

Ensuring Quality of drugs:

The challenge in providing SLD is complicated by controversy surrounding the definition of quality. There have been concerns on the quality assurance standards used in procurement of drugs used for treating MDR-TB patients. However, RNTCP while ensuring the highest levels of quality standards continues to be open to align itself with global standards. This is discussed in greater detail in the chapter on procurement and supply management.

Need to move beyond DOT

Challenges in treatment delivery: Directly Observed Therapy (DOT) has been a key component of the RNTCP's DOTs strategy and has helped achieve high treatment success rates. The RNTCP believes that evidence from more than four decades of TB research and experience of treating millions of patients cannot be ignored in the name of supposed 'patient friendliness' and results of few studies of questionable validity.

However, the value of DOT has been questioned in recent reviews and RNTCP's focus on it has been criticized as being rigid, inflexible and insensitive to patients' needs (25-26). Furthermore, DOT can drive patients to the private sector because they think DOT to be an invasion of privacy and feel it is inconvenient and increases the out of pocket costs borne by patient (27-28). Thus, efforts need to be made to align the time, place and observation to patient convenience. Strategies to make the process more respectful and flexible need to be examined and simultaneously the use new monitoring information technologies will also be explored. Both provider and patient incentives need to be re-visited to improve patient adherence.

The progress made in achieving high treatment success rates is threatened by the increased demands on personnel. With the scale-up of many activities under RNTCP like TB/HIV collaboration, programmatic management of drug-resistant TB etc, the burden of the supervisory staff (like STS) has increased, resulting in sub-optimal supervision of treatment in drug-susceptible TB patients.

Furthermore, this progress has not translated uniformly to all states due to regions with high default and death rates. This is an indicator of the strengths/weaknesses of the general health system, as RNTCP is implemented by the general health system. States and districts that have fallen below the rates achieved at the national level need incentivised support, supervision and monitoring.

Even where DOTS systems are working, it is felt that a major opportunity exists to diminish the delay between the onset of symptoms and initiation of appropriate therapy. Many internal evaluations of the programme show that delays are significant and could be one of the reasons for TB deaths, especially in severely ill patients. This is particularly true in high-prevalence HIV settings (such as districts in Northern Karnataka and Southern Maharashtra) where death rates exceed 15% among HIV-positive TB patients. This is mainly due to delayed diagnosis of HIV-infected TB patients and low levels of linkage to HIV care and support. This will need to be addressed in the next five years.

Challenges in engaging the private health sector

The private sector in India is unregulated and unorganized. Several prescription audits, have shown that diagnostic and treatment practices in the private sector are suboptimal and of a standard not in compliance with international guidelines for TB care (29-30). The qualifications of those prescribing these medications and tests are also questionable. And yet a recent analysis of the Indian TB drug market estimated that the volume of first line anti-TB drugs sold in the private sector was sufficient to provide a full course of treatment to 117% of India's estimated incident cases (10). Poor prescribing practices cause prolonged morbidity, increased disease mortality and fuel the emergence and spread of drug–resistance. Universal access will not be achieved without the private sector involvement. Thus the single greatest challenge in improved delivery of patient therapy will be improving treatment practices in the private health sector. In the National Strategic Plan, addressing this issue with effort commensurate to its scale will be critical and is more fully described in the chapter on PPM (Chapter 4).

As the RNTCP approaches the private sector, an immediate priority is to align RNTCP guidelines with International standards of TB care (14). The failure of the programme to acknowledge the acceptability of WHO endorsed daily fixed dose combination therapy administered in the private sector undermines its credibility and creates conflict with private providers. To ensure that the programme captures cases treated in the private sector and achieves the goal of universal access, they will have to pay special attention to make sure RNTCP guidelines are flexible enough to endorse all recommendations of ISTC but remain true to the core elements of success to date.

Additionally, the level and timeliness of incentives such as honorarium to the community DOT providers needs to be re-addressed in order to improve efficiency in under-performing areas. Finally, despite the transformational impacts that modern technology of telecommunication and information systems have had in many aspects of Indian society need to be explored as ways to improve TB control.

Operations research

Innovations in diagnosis and treatment -including diagnostic tests that have higher sensitivity and simultaneously detect drug resistance, new regimens that are faster acting and more effective in specific clinical settings along with information management and communication technology that assists in the management of patients and programmes have the capacity to transform TB control. In view of the rapidly changing evidence and evolution of global guidance that is anticipated in the coming 5 years, there is a need for a more regulated and formal process, including the establishment of a "National Treatment Committee" for providing programmatic guidance on incorporating innovations.

A central challenge to this committee (further described in the operations research chapter, see Chapter 12) will be to access, and in some cases to commission rigorous, targeted and relevant research. This will ensure that their deliberations are informed by data most relevant to the Indian context. Topics to be addressed will need to include evidence regarding the efficacy of intermittent regimens as

compared to daily regimens in special groups of TB patients like HIV-associated TB, INH resistant TB and retreatment cases.

Treatment Regimens

While millions of lives have been saved by the current regimens used by the RNTCP, changes in global treatment guidelines have raised concerns about the regimens currently being used (31). In particular, the issue of the adequacy of intermittent regimens in some special populations like HIV-infected TB patients will require the most urgent attention. RNTCP uses a thrice-weekly rifampicin-containing regimen for all TB patients including HIV-infected ones, whereas, WHO recommends daily TB treatment at least during the intensive phase.

This adequacy of intermittent therapy in HIV infected TB patients was discussed at length in a national consultation held at National AIDS Research Institute (NARI), Pune, in February 2011 (32). It was concluded that the evidence for change was inadequate; hence RNTCP is continuing the current regimen while prioritizing early linkage of HIV-infected TB patients to ART. At the same time, the consultation recommended that the process of collecting direct evidence from randomized controlled trials to inform this question of dosing frequency in HIV-infected TB patients be expedited. Thus, in the coming years, the RNTCP intends to collect additional evidence before changing the national policy on the dosing schedule in HIV infected patients.

Increased rates of non-communicable diseases threaten to undo the progress made to date in TB control. A recent systematic review of the effect of DM on TB treatment outcomes showed that DM may delay sputum culture conversion, may increase the case fatality rate during treatment, and may increase relapse rates of TB after successful completion of treatment (33). An analysis of nutrition and Diabetes Mellitus (DM) changes in India suggested that increased DM prevalence between 1998 and 2008 contributed to an increase in the total number of TB cases in the country (34). High failure rates exceeding 5% among NSP cases have been observed in states like Kerala where about half of adult TB patients are diabetic. Fully integrating measures to control NCDs, such as intensified TB screening and good glycemic control among diabetics and smoking cessation are essential for TB treatment to be effective.

Taken together, better treatment regimens and approaches to their delivery will be the key to reducing TB in all populations, but special efforts may be needed in certain geographic, demographic or socio-economic groups. This is further described in the chapter on special populations and ACSM.

Strategic vision for 2012-17

As RNTCP plans for the next five years, basic principles of DOTS strategy remain and will continue to be strengthened. Treatment of drug-susceptible TB and prevention of drug resistance remains the highest priority.

However, there are 4 sets of activities highlighted in this plan:

- Prompt appropriate treatment, increasingly guided by drug susceptibility testing
- Making DOTS more patient friendly
- Improve treatment partnerships between the public and private sectors
- Research to guide improved regimens and delivery systems

Activities

Early treatment stratification guided by DST results

Though implementation of individualized treatment regimens guided by the initial culture and DST results is beyond the scope under programmatic conditions, broad stratification of patient groups guided by DST early in the course of treatment, is envisioned in the next five years.

- All smear positive cases would be provided access to culture and DST early in the course of treatment and if found to be having MDR-TB would be started on Category IV regimen. This helps in early stratification of TB patients and is expected to improve outcomes among the remaining cases and prevent transmission of MDR-TB.
- Early diagnosis through a combination of improved ACSM activities, use of improved diagnostics (like LED-FM and Xpert MTB/Rif in select subgroups) and initiation of early treatment is expected to achieve high success rates.
- Early diagnosis of HIV-infected TB patients and linkage to both TB and HIV care and support is expected to increase success rates by reducing mortality. The strategies to achieve this are detailed in chapter on “Scale-up of TB/HIV collaborative activities”
- Treatment regimens would be made flexible to accomodate special requirements of some sub-groups of TB patients (TB meningitis, Bone and Joint TB etc)
- New products like continuation phase prolongation pouches will be introduced into the programme due to the reasons mentioned above. Based on the recommendations of the national technical committee, new products will be introduced in the next five years (e.g., new paediatric formulations like dispersible tablets, new drugs etc)

Making DOT more patient friendly

While DOT remains at the heart of the strategy and efforts would be made to make it more convenient, several other measures are envisaged to improve treatment adherence and reduce default rates.

Decentralization of DOT services: In order to make DOT convenient by place and time for the patients, it is necessary that DOT be provided by somebody who is as close to the patient’s residence/workplace as possible. The patient should not need to pay to reach the DOT centre. This requires strengthening and expanding the network of DOT providers in the community by including self-help groups, mahila mandals, ASHAs, anganwadi workers, religious leaders, opinion makers, cured TB patients, NGOs and private providers etc. Flexible strategies like workplace DOT would be proactively explored, wherever feasible. However this

move to decentralize DOT services will be balanced by the need to maintain accountability of the DOT providers to the health services, and continued need for supervision of the involved DOT providers by the STS. The programme will ensure continued supervision and monitoring of DOT services by the STS, and STS assistance to DOT providers in retrieval of patients who are late for treatment.

Choosing the right DOT provider: DOT works well when, there is a human connect between the provider and the patient. The option to choose the DOT provider may be provided to the patient. Experience has shown that there is no single category of providers who are the best DOT providers for all patients; but for each patient, there is a DOT provider who is the 'best' choice. It is the responsibility of the Medical officer of the PHI to enable the patient make this choice.

Need to make DOT flexible: During treatment course, many patients face exigencies in their personal lives which may need them to move out of station and unable to visit the DOT provider on those days. In such circumstances, provision should be made to provide extra drugs required for self-administration while documenting the same on the treatment cards. The empty blister may be collected back from the patient on his/her return and would be used to assess compliance.

Encouraging the community DOT: In order to encourage the community DOT, the honorarium would be enhanced to motivate and incentivize the providers to ensure that they follow-up the patients diligently and ensure cure. It is proposed to increase the honorarium to community DOT providers at the rate of Rs 1000, Rs 1500 and Rs 5000 for every new, retreatment and MDR-TB patient who completes treatment respectively with disbursements split at completion of Intensive and continuation phase.

Travel support for HIV-infected TB patients to reach ART centre: In order to improve the linkage of HIV-infected TB patients to ART centre by addressing access barriers, it is proposed that travel support be provided to the patients to enable them to reach the ART centre.

Incentivizing the patients to complete treatment: RNTCP currently provides incentives to patients in tribal areas, to encourage them to come regularly to health facility for follow-ups and complete treatment. It has been proposed to enhance and extend this incentive at a rate of Rs. 1000 per patient to be disbursed on completion of treatment. This would be piloted in select areas for assessing feasibility and effectiveness before nationwide scale-up.

Use of Information technology and telecommunication facilities to improve patient monitoring and adherence: It is proposed that a web-based, case-based information system be created in RNTCP with details of address and phone number recorded for each patient. This information may then be used by a third party agency, outsourced by the programme, to send text and voice messages (both general messages related to TB and general motivational messages and specific to the patient reminding the follow-up dates) and call at regular intervals to ensure that the patient completes treatment. This system while enabling real-time monitoring from higher levels will also enable automated generation of reports and

is expected to optimize the supervision of supervisors by reducing the time they spend on preparing various reports. The details of development and deployment of such a surveillance system is detailed in the chapter of Monitoring and Evaluation.

Extending RNTCP services to patients treated in private sector

Several audits have documented the suboptimal treatment practices in the private sector (30). They are especially poor in maintaining records and ensuring follow-up of patients till completion of treatment. The treatment of TB is a public health responsibility and as mentioned in ISTC, no provider should prescribe TB treatment unless there is a commitment for ensuring patient compliance for full course of treatment. There is neither commitment nor capacity in the private sector to fulfil this responsibility. The public health system with its army of health care providers across the country is well equipped to perform this function and supplement the private sector efforts. Two important points that can be initiated in this context are:

- Expand RNTCP guidelines to include all WHO and ISTC endorsed regimens used by the private sector.
- Create a system for registering all the TB cases managed under the private sector and monitoring their outcomes, even if they are not treated under RNTCP. Acknowledging limited success with the NGO/PP schemes, several innovative mechanisms are being proposed to achieve this end (including several changes in surveillance mechanism, steps in making TB a nationally notifiable disease, creating mechanisms for notification, contracting of intermediary agencies to foster involvement of private sector, broadening RNTCP guidelines to encompass and endorse all international standards of TB care, extra human resources at district and state level) and will be detailed in PPM chapter.

Research and fast-tracking evidence to policy and practice

RNTCP, while continuing to use its current time-tested regimen, remains open to new drugs and regimens. To guide the programme in the face of constantly evolving evidence and possible introduction of new regimens, a permanent technical committee - **"National Treatment Committee"** - will be constituted consisting of TB experts, clinicians, epidemiologists, researchers, programme managers and civil society and community representatives. This will help in early conversion of evidence to policy and practice. In the interim, many workshops will be planned to develop consensus guidelines in specific areas (like paediatric TB).

A discussion of challenges above indicates many knowledge gaps and would require significant investment of resources to address them in the next five-year period. A detailed list of areas is enlisted in the chapter on Operational Research and only a few key areas are listed below.

- Randomized controlled trials assessing thrice weekly versus daily regimens among several subgroup of patients like HIV-infected TB patients, retreatment cases etc.
- RCTs to find effective regimens for INH resistant TB.

- Pharmacokinetic studies to decide optimum dosages in paediatric TB patients, HIV-infected TB patients on Rifabutin containing TB treatment and second line ART.
- Bioequivalence studies of drugs (both first and second line) used under RNTCP to address quality assurance concerns.
- Efficacy and feasibility of DOT vs. Family DOT (Mother as DOT provider) in paediatric TB patients.
- Operational research in assessing effectiveness and cost-effectiveness of other strategies to improve treatment adherence like provider incentives, patient incentives, improved use of IT and telecommunication etc.

4
Public Private Mix

Key Message

- Partnership between the public and private sector is essential for universal access and early detection.
- The RNTCP needs to set norms and conduct surveillance maintaining flexibility.
- States need to experiment with innovation and scale-up initiatives that have been a success, explicitly include labs and pharmacists to detect patients at the earliest point of care.

Abstract

Prompt, quality-assured diagnosis and treatment are keys to improving both outcomes of patient treatment as well as controlling the epidemic. This section highlights the potentially critical role the private sector can play in ushering higher detection rates and quality treatment. The private sector is defined as everything outside the ambit of the government run public health initiatives. The private sector holds a factual predominance of health care service delivery in India. Engaging the private sector effectively is the single most important intervention required for RNTCP to achieve the overall goal of universal access and early detection.

Systematic efforts to encourage participation of the private sector have been limited to sensitization and referrals, through offer of schemes and these have met with very little success. The fundamental engagement model offered by RNTCP has proved insufficient to attract participation- volumes of patients are low, payments are uncertain, and transaction costs for engagement with the public sector are high.

The strategic vision of RNTCP is to develop and deploy engagement models that will overcome these past barriers of mutual mistrust, conflicting market forces and fragmentation, to accept, encompass and improve TB care provided by the private sector. The plan for strategic engagement with the private sector in the coming five years focuses on clarifying opportunities, policies and strengthening mechanisms at the national and state level. A National Technical Working Group on Public

Private Mix (PPM) will meet regularly to review and analyze data and provide advice to RNTCP about opportunities to increase private health sector involvement. At the state level, a Technical Support Group will be established within RNTCP to focus on effective contract management and other partnership-strengthening functions. Finally, Private Provider Interface Agencies (PPIA) will be hired in states to manage the activities of engaging the private sector. It is envisaged that while the National Programme will be responsible for laying down guidelines and norms, the onus would be on the states to experiment and develop innovative approaches for PPM.

Other approaches include an expanded acceptance by RNTCP of internationally approved diagnostic and treatment protocols, reliance on market forces rather than normative exhortation, increased use of accreditation and contracting, further outreach to private laboratories, increased control of TB drugs, and innovative use of information and communication technologies.

The overall goal is to achieve prompt reporting to RNTCP of TB cases diagnosed in the private sector, increased number of TB cases referred to the programme, and improve the quality of care in the private sector. It is anticipated that these processes and activities will achieve large-scale engagement of private providers, which is essential for RNTCP to achieve the larger goal of universal access set in this NSP-RNTCP.

Introduction

Prompt quality-assured diagnosis and treatment are key in improving patient treatment outcomes and controlling the TB epidemic. Currently, however, there are delays in patients seeking care, receiving appropriate diagnostic tests and prescription of suitable therapy. Most of the activities proposed in this 5-year plan are directed towards addressing these challenges through the public sector. The non-government sector is a critical part of health care delivery in India and hence needs to be tapped if the programme is to achieve the goals of NSP-RNTCP including universal access.

The private sector in India consists of a vibrant but varied set of sub-groups that provide services that are preferred by the majority of the population. The sector offers services that are generally described as being more affordable, accessible, and responsive to the needs of patients. On the other hand, this sector remains largely unorganised, unregulated and un-empowered, with the technical quality of some sections of the sector remaining a concern. The private sector is often kept out of major national health programmes, despite its large size, scope and penetration into micro-communities.

In India, the private sector is the first point of care in about 80% of episodes of ill health (9). Data shows that this is true for TB patients as well (7). While most TB cases are ultimately treated by the RNTCP, most patients by then have already approached the private sector for TB diagnosis and treatment. This can be supported by data indicating that it is the private sector that accounts for at least half of all anti-TB drugs sold in the country (10). As a result, there are delays in diagnosis, unnecessary patient expenditure, and irrational or unsupervised

treatment (35). When patients finally reach the public sector they are financially constrained and in many cases have developed drug resistant TB. Thus, diagnosis and treatment of TB in the private sector is both a problem and an opportunity for the RNTCP.

To achieve the goals of NSP-RNTCP, the RNTCP will need to engage more effectively with the private sector. Specifically, this engagement can ensure earlier detection via faster referral from private practitioners to the public health system. It also has the potential of enhancing detection and treatment rates beyond the public health capability by reaching out to those patients who distinctly prefer paid-for health services.

As was highlighted by the Planning Commission, now is an opportune time for India's public and private health systems to work in partnership (36). This is particularly true for TB given the maturity of the RNTCP. After 15 years of implementation, the programme has established itself as a strong and effective way to deliver care in the public sector providing a firm base upon which PPM efforts can be built. As further described in the section on Integration with Health Systems, these efforts will be even more critical in urban TB control.

This chapter discusses how the public TB control programme will partner with the private sector to improve care and control of TB. While, the reality of this sector creates constraints as well as potential for improvements in service delivery of public health programmes, its integration into public health systems is the way to enable provision of service elements in a seamless continuum of care, increase coverage of health services, decrease delays in treatment and ultimately improve patient outcomes and disease control.

Achievements

The vision of RNTCP-II was that people suffering from TB receive the highest standards of care and support from healthcare providers of their choice. Efforts to involve the other health sectors over the past five years are included in various activities enlisted in the box below.

Activities:
Guidelines on engagement of the private sector adopted in 1999 and revised in 2002 and 2008.
Training of RNTCP staff on public-private collaboration 'schemes' available.
Development of training modules for private practitioners.
Systematic engagement of Medical Colleges under RNTCP
Involvement of the Indian Medical Association for training of qualified, allopathic private providers and establishment of DOTS centres in private clinics and hospitals.
Engagement with professional societies via IMPACT.
Engagement with NGO health facilities via partnership with CBCI.
Training of rural non-qualified providers under GF R9 Project Axshya.
Engagement of Railway, Port, ESI, Mining, NTPC and Defence ministries for deployment of RNTCP services in those health facilities.
Small-scale PPM pilot activities.

Substantial gains in TB control have been achieved through this concerted outreach to other health sectors, particularly medical colleges, public ministries and NGOs. For instance, nationwide 1,900 NGOs and 10,000 private providers are involved (under signed memorandum of understanding) with the TB programme in a variety of ways with more involved in unsigned schemes.

Systematic involvement of medical colleges under RNTCP has been a huge success story. Under RNTCP Medical Colleges play important roles in service delivery, advocacy, training and operational research. Medical colleges have been effectively organized at a large scale through task force mechanisms at state, zonal and national levels, with RNTCP supporting with additional human resources, logistics for microscopy, funds to conduct sensitizations, trainings and research in RNTCP priority areas. Medical colleges have contributed in a major way in finding more TB cases, especially smear negative and extra – pulmonary cases. In 2011, 87,271 smear-positive TB cases, 49,031 smear-negative TB cases and 83,824 extra-pulmonary TB cases were diagnosed at medical colleges and referred for treatment; altogether, this accounts for about 15% of all cases diagnosed and registered for treatment in the country (15). More than 600 faculty members from Medical Colleges are trained as trainers, these trained human resource available in the medical colleges are supporting program beyond the academics and participating in the National as well as local training as facilitators and also participating in Internal Evaluations and appraisals. The enablers provided to Medical Collages is further coordinated and monitored by the structures facilitated by RNTCP. This mechanisms start from the Core Committee within each medical college, State task force at State, Zonal Task Force at Zone and National Task force. Institutionalizing these structures were success of RNTCP in phase II, further strengthening and optimizing these will be the aim of next phase. The task force mechanism helped in bringing accountability and ownership of the Medical College.

However, data from the intensified PPM districts indicate that the actual contribution made by the private sector other than medical college to national case detection remains about 5% and that for case management is better at about 9% (15). There have been various small pilot projects to engage private providers in quality-assured TB control in accordance with national guidelines. Most remained very small scale, and have relied upon normative exhortation for providers for TB suspect and patient referral to the public sector. One manifestation of this limited activity is that PPM activities are a very minor part of the RNTCP II budget. The implementation of schemes is highly uneven occurring almost exclusively in Gujarat and Maharashtra.

Challenges

Fundamental challenges to improve engagement between the public and private sectors include:

Public concern with quality of TB care provided in private sector: Private providers rarely suggest sputum microscopy, in most cases relying on chest X-rays

and inappropriate immunological tests (11, 37). If patients start anti-TB drugs, they can rarely afford the complete treatment and usually abandon therapy prior to completion, which increases the risk of acquiring drug resistance. The costs of inappropriate diagnostics and treatment before therapy under the RNTCP amount to several months of per capita income for patients from low-income households (7, 35).

Apprehensions of private sector: The private sector is weary of the public sector (38), including concerns about the quality of services in the public sector (quality of facilities and provider access) and loss of patients to the public sector.

Limited capacity of the state to engage with large numbers of independent private providers: Programme managers are already over-stretched with the demands of the DOTS programme with limited bandwidth to organize the large and dispersed private sector, manage relationships, organize contracts, and make timely financial reimbursements through existing administrative structures.

Lack of demonstrated financial viability of working with the public sector: TB is not a common condition and volumes of services for which reimbursement could be provided are low. The compensation schemes are considered inadequate, particularly in the light of high transaction costs to retrieve the same.

Lack of an approach, which faces the existing market forces operating in the private sector: Private providers profit from practices that confirm more with clients' expectations of quality care, industry marketing, and referral fees from subsequent diagnostic and treatment services.

Weak regulatory enforcement mechanisms: An example of weak regulatory enforcement mechanisms is the lack of enforcement of Schedule H under which anti-tuberculosis drugs are to be provided only with prescription.

Concerns about the supervision mechanisms employed by the public sector: Typically, supervision of doctors by paramedical providers is considered unacceptable and private providers demand that supervision and monitoring be carried out by a mutually acceptable mechanism.

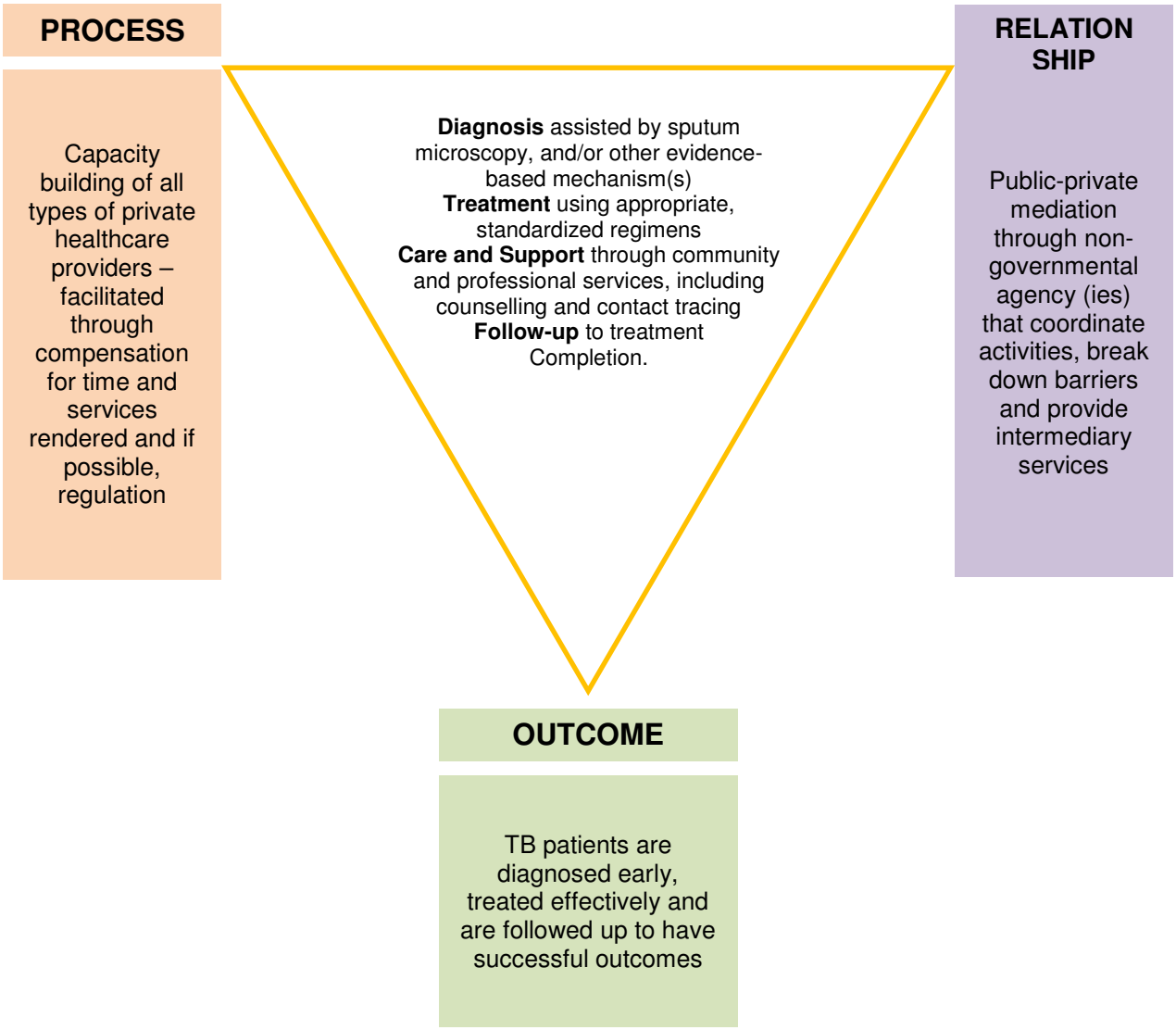
An important lesson from the past five years is, to achieve the goals of the NSP-RNTCP, requires changes in both the public and private sector. These changes include the need for a better understanding of incentive structures by both sides, clarity on managerial and financial structures, flexibility (without compromising core principles) and mechanisms to scale up successful pilot programmes. Central to the coming years will be a mindset in which the public sector clearly sets the goals and metrics but leaves it to the private sector to define the specific path for reaching them. Operations to achieve the same will be the major challenge over the next five years of TB control.

Strategic Vision for 2012-17

The intent of the NSP-RNTCP is to extend the umbrella of quality TB care and control to include those provided by the private sector, so as to reduce the costs

of morbidity and mortality and to reduce the risk of drug resistance. This will require extending RNTCP services to the private sector, increased flexibility for acceptable protocols, appropriate level of incentives to motivate private providers and a decreased reliance on schemes that have largely failed to work in the past.

Because the specific activities are not known, this plan will focus on large-scale pilot projects at the state level, with ambitions of going to national level by the end of the five-year plan. These projects will be structured to encourage genuine collaboration between the private and public sectors from the outset. These will be informed by the enormous body of evidence that has been accumulated in the past five years and guided by a **National Technical Working Group (NTWG).** However, this must be open to ideas from the complete range of potential contributors. The projects will be facilitated by the **PPM Technical Support Group (PPM-TSG)** skilled in the logistics, which will make the NTWG projects operational. The actual implementation of projects may be conducted by a **Private Provider Interface Agency (PPIA**) that has the capacity to bring together different players and enable operations through incentives. This exercise is aimed at enhancing the quality and pace of diagnosis and treatment in the private sector based on RNTCP guidelines, other acceptable practices or through referrals to the public sector.



To succeed, the strategy will need to be based on a realistic cost estimate and include a built in margin to attract the private sector to participate and also provide information through notification to the programme. Getting these cost estimates correct would be through an iterative process of 'learning by doing', but will be critical to implementation and meeting the expectations of the private sector.

It is important to demonstrate success and hence the attempt will be to stratify the providers and plan their engagements according to what they can best offer. Further, the roll out will focus on a few states initially and will be scaled up to cover at least 15-20 states over the five-year period. This will allow the plan for national roll out to be developed during the period 2012-17.

Activities

Achieving the goals of earlier diagnosis of more TB patients and higher quality treatment will require effective engagement of the private sector at a scale similar to that achieved in India for reproductive health / family planning. Each private service delivery unit - be it practitioners of modern medicine or indigenous systems of medicine, pharmacies and local laboratories - are important sources of referrals, and need to be covered in any initiative. Services of less-than-fully-qualified health providers are to be meticulously enrolled as they, despite their largely illegal status, tend to be first carers for many urban and rural base-of-pyramid populations and thereby, are again important sources of referral.

The following table categorizes providers against the potential function of each provider type *vis-à-vis* TB control and care. The functions are also categorized into 'provider-client services, 'programme management services' and 'partnership management services':

Type of Service Provider	Referral	Lab Services	Clinical Eval. – Diagnosis	Rational use of ATT	DOT or Facilitation of DOT	Counselling	Patient Tracking	Reporting	Higher Med. Services	Planning	Capacity Building	Communication	Research	Resource Mobilization	Laboratory QA	Supervision, Monitoring, QA	Documentation	Accreditation-Certification	Pub-Pvt Coordination	Donor Coordination	Pvt-Pvt Coordination
1ai. Primary Medical Service Providers – stand-alone clinics of practitioners of modern medicine	Y	-	Y	Y	Y	Y	Y	Y	-	-	-	-	-	-	-	-	-	-	-	-	-
1aii. Primary Medical Service Providers – stand-alone clinics of practitioners of indigenous systems of medicine and homeopathy, pharmacists and less-than-fully-qualified providers (the latter a.k.a quacks)	Y	-	-	-	Y	Y	Y	Y	-	-	-	-	-	-	-	-	-	-	-	-	-

Type of Service Provider	Referral	Lab Services	Clinical Eval. – Diagnosis	Rational use of ATT	DOT or Facilitation of DOT	Counselling	Patient Tracking	Reporting	Higher Med. Services	Planning	Capacity Building	Communication	Research	Resource Mobilization	Laboratory QA	Supervision, Monitoring, QA	Documentation	Accreditation-Certification	Pub-Pvt Coordination	Donor Coordination	Pvt-Pvt Coordination
1b. Secondary Medical Service Providers – with specialty services, laboratories and pharmacies	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	Y	-	Y	-	-	-	-	-	-	-	-
1c. Tertiary Medical Service Providers – with higher specialties and function; some may be medical colleges	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	-	Y	-	Y	-	-	Y	-	-	-
2. Implementing Agencies – may be NGO/INGO, CSO, CBO, FBO, Other	Y	-	-	-	Y	Y	Y	Y	-	Y	Y	Y	Y	Y	-	Y	Y	-	Y	Y	Y
3. Laboratories – large, networked (chain) or small	Y	Y	-	-	-	Y	-	Y	-	-	-	-	-	-	Y	-	-	-	-	-	-
4. Pharmacies – large, networked (chain) or small	Y	-	-	Y	Y	Y	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Listed below are some of the key initiatives that will be explored in the coming years involving these service providers However, it is important to emphasize that none of these can be initiated in seclusion and impact is likely to be seen through their interactions. It should be clearly understood that these are not intended as stand-alone initiatives. Though, programmes are expected to vary from one state to another, each is expected to involve a variety of activities in some form and combination.

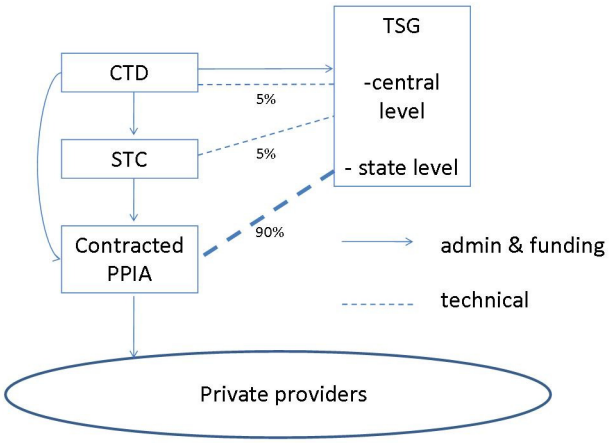
Establish mechanisms for PPM

Create a National Technical Working Group (NTWG): NSP-RNTCP would establish a National Technical Working Group on fostering engagement with the private sector. The purpose of this group would be to provide a forum for dialogue, to ensure sustained attention on the issue, and guide innovation and learning. The group will provide guidance on technical aspects such as the appropriate diagnostic and treatment standards, guidance on the scope and geographic distribution of initial projects, and policy requirements for improved PPM. It is important that the group include members representing a range of perspectives.

Create a PPM Technical Support Group (PPM-TSG) for the national and state Level: A TSG will be established at the national and state level (with presence in both) with the requisite skills and mandate to systematically improve and scale-up contracting of intermediaries to engage the private sector. This PPM-TSG will operate much as the NACO TSG for social marketing organizations, and be outsourced to a suitable qualified agency but designed to report to and work on behalf of RNTCP. The PPM-TSG will utilize national guidelines and wider public

health schemes and programmes to structure the implementation of the private sector engagement in TB control.

The PPM-TSG would operate as the figure below. A minority of the TSG support would go to the Central and State level.



Flexible funds for States can be used to contract professional intermediary organizations to engage private providers to scale. The tendering and contracting process can be managed by the PPM Technical Support Group. Contracts will become increasingly performance-based over time, as the TSG and PPIA gain experience. This initiative will be designed and monitored by the PPM-TSG.

Contracting will become performance-based as experience is gained over time. NSP-RNTCP may draw on lessons learnt by NACO as well as the reproductive health and contraceptive social marketing programmes. A core principle of this group is to clearly specify the desired outcomes without micro-managing the pathways to achieving them.

Create Private Provider Interface Agencies (PPIA): The TSG will facilitate to PPIA for PPM activities. These agencies will comprise of state-level entities designed and monitored by the PPM-TSG. The responsibilities of the interface agencies will focus on notification of TB cases by the private sector, verification of adherence to ISTC-compliant regimens, and deployment of innovative mechanisms to realign provider incentives. The approach/partner-type in each state may vary depending on the existing approach for faster referrals. The availability of quality Civil Society Organization (CSO) and/or private entities willing to play this interface function will be key to ensuring success. To reach these, NSP-RNTCP will need to move beyond the medical college and professional association routes.

The objectives of the PPIA would be to

- Improve case-finding, appropriate treatment and notification of cases in the private sector
- Ensure notification of cases diagnosed & treated cases in the private sector
- Ensure minimum quality standards as per the ISTC
- Provide or reimburse drugs for privately-treated patients for regimens that meet the ISTC standards and government quality requirements
- Voucher/conditional cash transfer to patients (to use to purchase drugs that meet govt quality standards)
- *And/or:* social marketing of anti-TB drugs following agreed procedures and quality standards (analogous to GoI oral contraceptive social marketing pgm)
- Innovate and adapt to meet these objectives
- Design and deploy financing mechanisms to meet objectives

This PPIA initiative will focus on urban India, given that there is strong existing capacity in the shape of many private practitioners (of differing size and coverage) operating sub-optimally (in terms of quality) in these settings. Incorporating them would immediately enhance capacity in a geography that is relatively under-served by public health.

Functions of the Private Provider Interface Agency

- Develop a thorough understanding of local health markets, including mapping of all providers.
- Establish productive relationships with providers, labs and chemists as necessary to capture large numbers of TB cases early.
- Develop a compelling value proposition for private providers to conform to the spirit of ISTC.
- Design and deploy appropriate financial mechanisms for providers and patients, which will seek to reduce overall costs to patients.
- Ensure convenient and attractive linkages between labs and providers (such as sputum collection and transportation, referral incentives, mobile phone applications, etc.) and explore alternative case finding strategies to achieve objectives in local context
- Manage communication campaigns directed at consumers and providers as appropriate
- Ensure case notification and monitoring to RNTCP.
- Maintain close coordination with RNTCP at all levels to ensure program supports their objectives
- Develop and deploy ICT applications to ensure accountability and efficient data-based management to scale
- Continually innovate, test, adapt approaches, in joint problem-solving mode with TSG

Certification will unlock existing TB control capacity by ensuring quality assurance. Monitoring will be outsourced to a third party monitoring agency (to allow objectivity and flexibility of cost and delivery). There would be participation from various types of private providers including stand-alone clinics, nursing homes, small and large hospitals as well as pharmacies and laboratories. To increase participation, certification must accept the use of all internationally accepted treatment regimens while remaining true to the core principles of established DOTS therapy. In principle, the non-negotiable components of accreditation should take into consideration the provider's willingness to investigate chest symptomatics

and treat TB patients using nationally/ internationally accepted standards of care, to notify TB and to follow-up, or agree for follow-up, on their TB patients to ensure treatment compliance until an appropriate outcome has been reached.

Innovative financing: Performance-based PPM contracts (i.e. results-based financing) is expected, where PPIA are reimbursed based on results. RNTCP will also explore innovative ways to strengthen TB diagnosis and treatment through demand-side health financing mechanisms, such as health insurance, pre-paid benefit schemes and market-based initiatives.

Further expand provision of TB control services via PPP contracts, via private laboratories and hospitals: Via the PPIA or via other mechanisms, RNTCP will seek to purchase or reimburse services at scale, using for example unit-based, results-based financing (e.g. per TB suspect, or per lab confirmed case) for at least some part of the reimbursement. The initiative will be designed and monitored by the PPM-TSG, and could be implemented by a PPIA. Some of the areas that can be supported via this route include new diagnostic equipment based facilities and urban TB clinics. The PPM-TSG will develop the overarching design and details, which will include: area(s) of focus (diagnosis and/or treatment), choice of technology to be deployed, basis for contracting and mode of financing. PPP initiatives are more likely to be the vehicle of delivery because these initiatives will be delivered on a large scale, will require reasonable private capital investment and will (also) cater to patients who can afford to pay (which will be critical/useful in a setting where high capital costs will be incurred).

This initiative will also focus on urban areas because the greater population density will allow for more effective utilization rates on new diagnostic equipment. Labs, nursing homes and small hospitals will be targeted first as prospective partners for the PPP. This is because these stakeholders are typically already delivering TB diagnosis and treatment, albeit outside the purview of and without accountability to the RNTCP.

Targeted outreach to private labs: RNTCP will increase efforts to engage private laboratories in TB diagnosis. This could be achieved by subsidizing (or by exploring client payment options) quality-assured diagnostic services, to the extent that it is cost-effective, and actively discourages the use of serological tests for TB diagnosis (see Chapter 2).

Involving DNB Training and PG Institutes in RNTCP

The success of involving Medical Colleges and organizing it under the task force mechanism, encourages the program to extend this to institutes offering Diplomate of National Board (DNB) training and also exclusive post graduate institutes not attached to a medical college. A total of 1105 hospitals are currently offering DNB training in the country. These facilities are available both in public and private sector. Supporting these structures with enablers similar to Medical Collages will help RNTCP extending its services and achieve universal access.

Involving Corporate Hospitals in RNTCP:

There has been a steady growth in the corporate hospitals throughout India since the 1970s. Corporate hospitals and clinics do not reach the majority of the poor

population, but they do play an important role in providing the best hospital services in urban areas of India, wherein public health care infrastructure is suboptimal. The growing popularity of such hospitals requires RNTCP to partner them. This partnership will aim at promoting International Standards of TB care (ISTC) and there by popularising rational Anti-TB prescription. The program will work out the mechanism of notifying TB cases, developing case definitions and validating TB diagnosis. This phase will be piloting the partnership with corporate hospitals and based on the experience with the pilots, further expansion of the collaboration will be planned.

Integration with enhanced surveillance: As described in depth in the surveillance section, the RNTCP will establish mechanisms to facilitate reporting of cases diagnosed and treated in the private sector. This includes collating all information in a central nominal registry of TB cases.

Increase control of TB drugs: RNTCP will continue to use a variety of mechanisms (including market based efforts) to strengthen control on the sale and distribution of anti-TB drugs, working alongside the Drug Controller General of India. A comprehensive approach is likely to involve systematic engagement of pharmacists and chemists, working with their associations, training and possibly accreditation, as well as enforcement. A systematic review of published prescription audits needs to be undertaken and a working paper will be developed for use in designing future strategy.

Continuation with scheme based approach: The schemes that have already been developed by the programme will be revisited to evaluate their continued need, content and attractiveness to the private sector providers. The PPIA can also roll out the schemes as part of their role in bringing about private sector participation. But the mandate will not be limited only to the roll out of the schemes, as earlier. The exercise of rationalizing the schemes - with clearly defined results and performance-based incentives needs to be carried out through a consultation and finalized. Further, efforts to market the schemes to the prospective stakeholders need to be provided certain flexible funding for carrying out such activities.

The requirement of advocacy with the private sector stakeholders has already been built-in as part of the Chapter on ACSM.

5

Scale-up of Programmatic Management of Drug Resistant TB

Key Messages

- MDR is deadly, difficult to diagnose and expensive to treat.
- Early diagnosis of drug resistance is critical to save lives and stop its spread.
- Treatment can be successful if decentralized and well supervised.
- The scale up of PMDT will require more labs, drugs and staff.

Abstract

Multi Drug Resistant TB (MDR-TB) is defined as resistance to Isoniazid (H) and Rifampicin (R) with or without resistance to other drugs. In 2008, WHO estimates indicated over 99,000 MDR-TB cases in India, which was second only to China. MDR-TB is exceptionally complicated and expensive to diagnose and treat. MDR-TB treatment requires specialized care, requires patients to endure 2 years of toxic and difficult to tolerate second-line anti-TB drugs, and even under the best circumstances cure is uncertain – especially if additional resistance exists to second-line drugs. A high prevalence of MDR-TB intensifies the challenge of controlling the TB epidemic, as it requires improved and advanced diagnostic tools and second-line treatment options both of which have higher resource implications.

Internationally, management of DR-TB is informed primarily by the WHO Guidelines for Programmatic Management of Drug Resistant TB (PMDT), earlier named as 'DOTS-plus'. India initiated PMDT service in 2007 and is in the process of scaling up nationwide. As of December 2011, basic PMDT services cover 260 /659 districts across 35 states, a cumulative total of 38,187 MDR TB suspects have been tested at RNTCP accredited culture and drug susceptibility testing (C-DST) labs for diagnosis; 10,267 MDR TB cases have been confirmed and 6994 MDR TB cases have been initiated on treatment with the help of 50 collaborating treatment centres.

Despite these efforts, large numbers of MDR-TB cases don't have access to services. MDR-TB poses a grave threat to the success of basic TB control activities, and failure to address MDR-TB early can have serious public health and economic consequences. Confronting MDR-TB requires intensified action under this five-year plan. The programme plans to accelerate the shift to earlier diagnosis of MDR-TB using rapid diagnostics (LPA, Liquid Culture, automated nucleic acid amplification test), putting such patients on the correct standardized regimen from the very beginning of their TB treatment, thereby reducing MDR-TB transmission. There exists a robust, national PMDT scale up plan developed through active engagement with all 35 states with the ambition to achieve nationwide access to quality PMDT services by 2012-13.

Key strategies articulated by this plan includes development of district-level diagnostic and treatment services nationwide, with a backup network of specialized diagnostic and treatment services. This will require the expedited upgradation of existing diagnostic and treatment infrastructure, drug stores in all states and districts across the country, developing district-level MDR diagnostic and treatment capacity, completing development and enhancing the capacity of the national network of reference laboratories and PMDT sites, seeking out public-private partnerships, building transport capacity for ensuring efficient system of sputum sample collection and transport and better enforcement of drug regulations. The programme will also require strengthening of capacity for programme management, supervision and monitoring, data management and research for simpler and more effective tools and strategies.

Introduction

Multi Drug Resistant TB (MDR-TB) is defined as resistance to Isoniazid (H) and Rifampicin (R) with or without resistance to other drugs. In 2008, WHO estimates indicated over 99,000 MDR-TB cases in India, which was second only to China (1). The emergence of multi-drug resistant TB (MDR-TB), poses a major challenge for TB control. For standard 6-month first-line anti-TB treatment to be effective, the M. tuberculosis organism must be susceptible to rifampicin, and to a lesser extent isoniazid. Tuberculosis caused by isolates resistance to both isoniazid and rifampicin (MDR-TB) is difficult to detect, complex to treat, and very expensive to manage. Detection requires laboratory testing in specialized facilities where highly-trained laboratory personnel have to be protected against accidental spread of the airborne pathogen; previously this has taken months for slowly-growing bacteria to give results. Treatment requires the use of weak, toxic second-line anti-TB drugs, which include daily injections for 6–9 months and multiple poorly-tolerated oral drugs for more than two years. Diagnosing and treating a single case of MDR-TB costs more than one lakh rupees on average, and can be much more expensive. After all of those efforts, death frequently occurs en-route to diagnosis and treatment. For those lucky few who make it to treatment, cure rates for MDR-TB are much worse than for drug-susceptible TB.

Successful control of MDR-TB requires prevention through effective TB control and private sector engagement, to prevent the generation of MDR-TB in the first place. But the large number of MDR-TB patients currently present must be found and treated effectively as early as possible, to prevent airborne transmission of resistant organisms. In countries which have failed to implement effective MDR-TB prevention and management, such as those of the former Soviet Union, MDR-TB has become entrenched as serious and highly costly public health threat.

The data available from three state representative drug resistance surveillance (DRS) surveys shows that the levels of MDR-TB are around 2-3%, amongst new patients, but range from 12-17% in retreatment (RT) cases (39). Given the large number of retreatment case notifications in India, these relatively low percentages translate into large absolute number of MDR-TB cases.

India has also reported cases of extensively drug-resistant TB (XDR-TB) to WHO. XDR-TB is defined as MDR-TB resistant to both fluoroquinolones and second-line injectable drugs, and is even more difficult and costly to treat than MDR-TB. The state representative DRS survey of Gujarat state showed 3.2% prevalence of XDR-TB among MDR-TB isolates (39). A precise estimate of the number of XDR-TB cases in the country is not available. Alarmingly, surveillance in Andhra Pradesh and Gujarat also showed a very high prevalence of fluoroquinolone resistance (24%).

Currently, efforts to identify drug resistance are based on the patient's treatment history and response to therapy. Patients who have been previously treated for TB are statistically at a higher risk of harbouring drug resistant bacteria and those who fail to respond to therapy frequently do so because they are infected with bacteria resistant to the antibiotics they are consuming. This approach was a compromise strictly based on laboratory testing and MDR treatment constraints in the country.

However, in the next five years, RNTCP will expand its target to "achieving 'early and complete' detection of all TB cases including drug-resistant TB and provision of quality treatment". The availability of highly accurate rapid molecular TB diagnostics suitable for sub-district implementation offers the opportunity to deploy drug susceptibility testing services for increasing numbers of TB patients at the initiation of therapy and ensure they are treated appropriately from the outset. Early diagnosis, early initiation of treatment and provision of appropriate treatment guided by drug susceptibility results will lead to decreased transmission and spread of both drug-sensitive and drug-resistant TB.

This chapter will address the response of the programme to this problem in terms of the organization and management of services, the provision of diagnostic services, and the delivery of treatment as well as programme monitoring, evaluation and research.

Achievements

The main achievement till date has been to develop and optimize systems for programme-based diagnosis and treatment of MDR TB that can be scaled up nationwide.

Planning Organisation, management and co-ordination for PMDT

In order to establish, organize, manage and coordinate the services for PMDT, efforts have been made at the national, state, and district level. PMDT services are being included as part of RNTCP services at the district level, and fully integrated into general health services in close coordination with the MDR-TB specialist services required from PMDT sites and C-DST labs.

At the national level, an expert RNTCP National PMDT Committee was formed in April 2005. The RNTCP guidelines for PMDT and training modules were developed and are regularly updated (latest revision in December 2011). State level PMDT Committees have been formed in all the states with responsibility to plan, implement, expand, maintain and periodically review PMDT services.

PMDT sites are being established and site committees are being formed (preferably at tertiary health care facilities) in the states for clinical management of individual patients during the initial, short in-patient period and address programme management challenges during ambulatory care. As on March 2012, 59 such sites are functional. C-DST labs are also being established and accredited under RNTCP for quality assured diagnosis of DR-TB. As on March 2012, 37 labs are accredited. State drug stores (SDS) are being upgraded with temperature and humidity controls. A robust supply chain management system of quality assured 2nd line anti-TB drugs (SLDs) up to the community level has been set up.

A clear strategy to meet the demands for trainings required for PMDT scale-up has been developed by CTD with support of a core team of experts from national institutes, states and experienced consultants. At the national level, Trainings of Trainers (ToTs) from various states are conducted in the 'RNTCP Guidelines for PMDT' at four identified national training centres. The national trainings of state

level trainers and first phase districts were accomplished in February 2011 and PMDT services are currently being rolled-out in all states. Training material for medical officers and paramedical staff has been updated and is being undertaken concurrently for other RNTCP staff. Similarly, the laboratory staffs are trained in C-DST at the National Reference Laboratories.

Co-ordination mechanisms between the PMDT committees at various levels and between various service delivery points like C-DST labs, PMDT Sites, SDS and the districts linked have been clearly laid down and are being established as the services are scaled up.

Scale up of PMDT services

Laboratory capacity and MDR-TB diagnosis

A RNTCP National laboratory scale-up plan calls for establishment of 43 labs & strengthening them with rapid molecular tests and enhanced sputum processing capacity sufficient to ultimately test ~144,000 MDR TB suspects annually. National Training Centre (International Centre for Excellence in laboratory training) has been established at the National Tuberculosis Institute, Bangalore to meet some of the training needs of laboratory staff.

As of December 2011, 35 C-DST labs were accredited under RNTCP to provide services for the diagnosis and follow up of MDR TB patients. 18 of the 35 accredited C-DST Labs are also accredited under RNTCP to provide services for diagnosis of MDR-TB using a rapid molecular test – the Line Probe Assay (LPA) that has a turnaround time of 48–72 hrs as compared to 3–4 months in conventional testing. A total of 38,187 MDR-TB suspects have been tested for C-DST since inception; 10267 patients have been confirmed to have MDR-TB or rifampicin resistance[2].

New rapid tests for MDR-TB diagnosis have been endorsed by WHO and are being introduced globally. Use of rapid MDR TB diagnostics are crucial to reduce diagnostic delay, minimize MDR TB transmission, and reduce the excess mortality associated with the months-long process of conventional phenotypic MDR TB diagnosis on solid media. RNTCP has initiated projects to validate & demonstrate these technologies under the EXPAND TB project (WHO, GLI, UNITAID and FIND) and Global Fund Round 9. The LPA was an example of a technology validated and demonstrated in India before nationwide scale-up. Another project recently initiated is a multi-site programme-based demonstration of cartridge-based nucleic acid amplification test (NAAT) (eg, Xpert MTB/RIF®) for the diagnosis of tuberculosis and multi-drug resistant tuberculosis.

During the initial phases of PMDT service establishment, only a limited number of patients could be offered testing and treatment due to constraints in laboratory capacity and drug availability, and a deliberately cautious approach was undertaken by RNTCP to introducing new services. Scale-up has been phased both by geography (i.e. starting districts after preparation and central appraisal) and by patient eligibility for DST to larger groups of persons, earlier in care. Patient eligibility was grouped into three categories:

i. Suspect Criteria A: This includes
    a. New PTB cases who had failed a RNTCP regimen

b. Retreatment PTB cases that remain smear positive at the end of 4th month of treatment or later.
c. Smear positive PTB cases that were contacts of MDR-TB cases.

ii. Suspect Criteria B: This includes the above and further includes
a. All retreatment smear positive PTB cases at diagnosis
b. All new or RT case with smear positive result at any follow up smear examination during treatment.

iii. Suspect Criteria C: This included the above and further includes
a. Retreatment PTB smear negative cases at diagnosis
b. All HIV-infected TB patients not captured earlier

As of December 2011, the RNTCP PMDT services have been scaled up to cover 260 / 659 districts across 35 states in India. Of the 260 implementing districts, 65 districts had advanced to implement "Criteria B", offering DST to a greater proportion of TB patients.

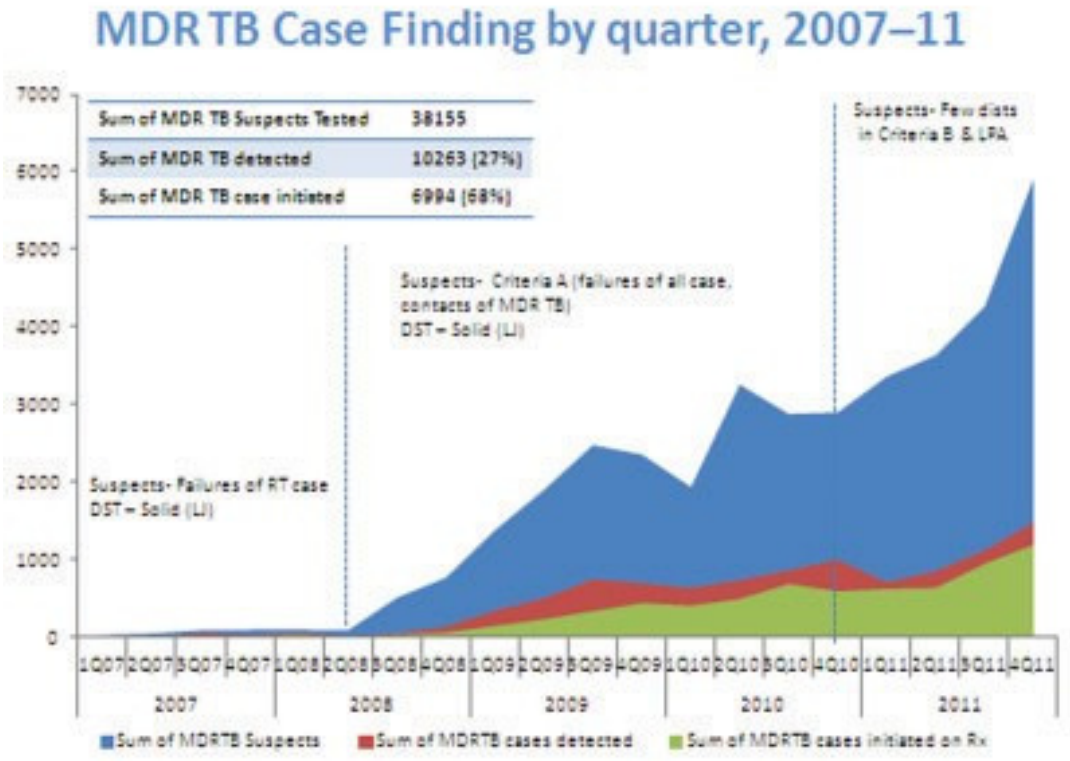
Currently those MDR-TB patients who are failing the second line therapy are tested by NRL for resistance to some second-line anti-TB drugs. Through this limited mechanism, some cases of XDR-TB have been diagnosed.

Treatment

After MDR-TB diagnosis, patients are hospitalized in designated PMDT sites for initial weeks and start of treatment and after 1-2 weeks of inpatient care the patient is returned back to his district for two years of decentralized ambulatory treatment. MDR TB wards require a management team of clinical specialists, laboratory services, and attention to airborne infection control as per national guidelines. Standardized second-line drug regimen is given under daily direct observation of (DOT) and standardized follow-up protocols are followed throughout the course of treatment for every patient. The districts have systems in place to deliver ambulatory DOT, a drug logistics system and standardized recording and reporting.

RNTCP is using a standardized treatment regimen (STR) for treatment of MDR-TB cases under the programme comprising of 6 drugs (kanamycin, high dose levofloxacin, ethionamide, pyrazinamide, ethambutol and cycloserine) during 6-9 months of the intensive phase and 4 drugs (high dose levofloxacin, ethionamide, ethambutol and cycloserine) during the 18 months of the continuation phase. *P-aminosalicylic* acid (PAS) is included in the regimen as a substitute drug in case of intolerance i.e. severe ADR leading to discontinuation of any drug in the MDR-TB Regimen. All drugs are given in a single daily dosage under DOT by a DOT provider.

Since inception, (figure 5.1), 10263 MDR-TB cases have been confirmed and



6995 MDR-TB cases have been initiated on RNTCP Category IV treatment through 50 PMDT sites with the rest of them lost to follow up or died while awaiting the DST results due to long turnaround time of 3 ½ - 4 months in conventional C-DST in solid LJ medium.

Education and Adherence

MDR-TB patients and their families receive education about MDR-TB, its nature and duration of treatment, potential adverse drug reactions, need for adherence with therapy and the consequences of irregular treatment or pre-mature cessation of treatment. Few pilot studies are evaluating the role of enablers & incentives to promote treatment adherence.

Procurement and Supply Chain Management of Second Line Anti-TB Drugs for DR-TB under RNTCP

Under RNTCP, the second-line anti-TB drugs are procured at the national level annually via GoI procurement mechanisms or via the GLC mechanism, with 6 monthly tranches delivered directly to states. RNTCP has issued guidelines for storage of 2nd line anti-TB drugs and the state and district drug stores are now being upgraded accordingly. Drug logistics have been supported by an outsourced agency, and systems have been developed and put in place to ensure uninterrupted supply for patients.

Supervision and monitoring

Supervision and monitoring for MDR TB patients has been integrated into the routine RNTCP systems. Laboratories keep records of all tested specimens, and report on activities. Treatment sites maintain special MDR TB treatment registers, and field workers use treatment cards and other tools to help them provide standardized high-quality services and supervision. Reporting is also integrated. All registered MDR-TB patients are included in quarterly cohorts and their treatment outcomes are analysed. A set of standard monitoring indicators for PMDT implementation status, coverage, case finding, interim and final outcomes by states have been developed and published routinely in all quarterly and annual programme reports.

Challenges

The current efforts are nascent; there are still large gaps between the burden of MDR TB and the actual number diagnosed and treated till date. The vast majority of MDR TB remains undiagnosed, and substantial numbers of MDR TB patients are mis-treated in the private sector, leading to additional drug resistance and XDR TB. Enormous operational challenges will need to be addressed in the coming years to achieve MDR TB control.

Infrastructure gaps

Although there has been significant progress towards establishment, up-gradation and accreditation/appraisal of the infrastructure required for PMDT services viz. C-DST laboratories for solid, liquid culture (Bio-Safety Level III) and LPA, PMDT Sites, state and district drug stores, the programme has yet to complete these activities for all the proposed labs, sites and stores in the country.

Need for greater administrative commitment

State PMDT Committee meetings are held infrequently and the time allotted for the review is insufficient. This is because the funding provisions for state level review meetings are all clubbed together with the review of the overall programme, state task force for medical colleges, state PMDT committee meeting, state OR committee meeting etc. The PMDT Site Committee meetings are not held regularly in many states because there is no separate funding available to cover organizational expenses of PMDT Site Committee meetings.

Human resources and capacity insufficient to supervise MDR TB services

The additional efforts to successfully treat complex cases of drug resistant TB with longer duration of treatment, greater probability of adverse drug reactions and treatment interruptions and high mortality, demands additional human resources to organization, manage and coordination to deliver quality services.

A treatment supervisor in RNTCP (i.e. STS) may already have to oversee 400-600 TB patients at any one time; the addition of 50 MDR TB patients, with much higher intensity of services required, would nearly double the staff workload. Training is critically important to deliver and sustain high quality of services to DR-TB cases. There have been consistent delays in conducting trainings at the state and district level due to lack of funds and poor facilities. Also, additional training needs have still to be met for lab personnel in Solid Culture, Liquid Culture, LPA and in conducting 2nd line drug susceptibility testing. Ices.

Need for expansion of specimen transportation services

Whether for diagnosis of M/XDR or for follow-up monitoring of M/XDR TB treatment, there needs to be systems to move sputum to district or reference laboratories. The public sector does not have an existing specimen transportation system. Operational research conducted in four districts of Andhra Pradesh showed that among patients registered for first line treatment during October 2008 to December 2009, 307 (55%) out of 559 MDR TB eligible suspects underwent diagnosis (40). Operational challenges include the distance for transport of specimen in cold chain from remote inaccessible areas to the C-DST lab poses a serious challenge, leading eventually to delays in case finding and high attrition rates during treatment initiation. There exists no formal scheme for sample collection and transport for C-DST. The current RNTCP NGO-PP scheme for sample collection and transport is meant for transporting samples from a remote collection centre to the nearby Designated Microscopy Centre (DMC) for sputum smear microscopy.

Need for expansion of rapid M/XDR diagnostic services

The currently planned capacity of C/DST will be insufficient to meet the challenge of universal access to C/DST services for those who are eligible to receive those services. Laboratory services will require dramatic expansion, either with centralized services and sputum transportation or decentralization of the initial testing for MDR TB. Out of the 43 reference labs planned, as on Dec 2011 35 labs have been accredited for solid C/DST, 18 for LPA ,29 solid culture and 5 for liquid culture. Even when this network is completed, the annual DST capacity (144,000) will be insufficient to achieve universal access to DST for those eligible to receive these services.

As the programme prepares for universal access to quality diagnosis and treatment, decentralizing the diagnostic services to district and sub-district levels by introducing the newer technologies like automated NAAT is urgently required till the time a reliable point of care diagnostic test is available.

Few reference C/DST labs are certified to conduct quality-assured DST for Second Line drugs, which is needed for MDR TB patients to rule out XDR TB. Private laboratories can fill some of the capacity gap, but till date few have been willing to engage with RNTCP under the current reimbursement structure provided in RNTCP schemes.

Challenges in delivery of DR-TB treatment services

Loss of patients prior to treatment

High turnaround time for diagnosis in solid C/DST (3 ½ - 4 months) leads to attrition of diagnosed MDR TB cases to the tune of ~30%. In operational research from AP, Of 169 patients found to be MDR-TB and only 112/169 (66%) were successfully initiated on treatment. Diagnostic delays, death, and lack of patient support were implicated as contributing to patient loss. The attrition is largely attributed to pre-treatment deaths, initiation of treatment in private sector and migration of the patients.

Funding and procurement: MDR-TB drugs being very costly, there is a need to secure long term commitment from all stakeholders (donors & government). Procurement support and drug logistics management of second-line anti-TB drugs will require strengthening of the procurement and logistics capacity of the central level. Currently, given the small number of patients diagnosed with XDR-TB, states have been empowered to procure the additional drugs required for these cases; however these "Category V" drugs are exceptionally expensive and not easily procured in small quantities across all states. The lack of a secure drug supply for these XDR-TB drugs is increasingly problematic for the programme, as the number of patients who needs this treatment is accumulating.

Unregulated private prescription of anti-TB drugs: Irrational use of anti-TB drugs including MDR-TB drugs have been widely reported. This has the potential to generate additional drug resistance and already there are few reports of additional resistance beyond XDR-TB . This would lead to a grave public health emergency. The sale and prescription of 2nd line TB drugs needs to be regulated.

Poor treatment outcomes: The treatment outcomes in the initial pilot sites in Gujarat and Maharashtra patients showed that 46% of cases successfully completed treatment, 20% died, 11% failed and 21% defaulted treatment. These results may be affected by the inclusion of large numbers of chronic TB cases who failed a re-treatment regimen in the initial cohorts. The initial cohorts had heavy pre-treatment experience and high prevalence of fluoroquinolone resistance, so outcomes are expected to improve as PMDT services become routine. Nevertheless, these findings are extremely concerning.

High level of fluoroquinolone resistance: There are documented high levels of Ofloxacin resistance at baseline in the initial cohort of MDR-TB patients treated under PMDT in Gujarat correlating with similar levels of Ofloxacin resistance in the DRS survey.

Inadequate patient support systems: The current provisions for travel support for patients to service delivery points and the honorarium to the DOT providers is inadequate. Patient counselling through a professional counsellor is a missing link in the programme. This is a critical intervention that can enhance the adherence of patients to these long regimens and has the potential to improve treatment outcomes.

Lack of mechanisms to involve private hospitals: In some states identifying government tertiary care institutes at the districts that are geographically accessible to multiple districts to serve as appropriate locations for PMDT Sites is a challenge. However, in spite of having tertiary care institutes in private hospitals, NGOs and private medical colleges, there exists no mechanism to engage them as PMDT sites under the RNTCP NGO-PP Guidelines.

Information management, Supervision, Monitoring and Evaluation

Complex and cumbersome paper based recording and lack of systems to share information between multiple levels of care: Enormous amount of information is generated through a paper based recording and reporting system posing a challenge to effectively use the available information promptly for better patient care and decision making about the policy and processes under the PMDT. Patients are cared for at the field, by local medical officers, by district officers, and by the reference laboratory, all under the supervision of clinical experts at the PMDT site, but all spread out over large distances. Sharing of information at every point in the chain of care is required to coordinate care; such sharing is exceptionally complex in a paper-based systems.

Human resources for supervision and monitoring of PMDT services: The supervisory staff currently is working at its peak capacity & any further demand would result in poor supervision and detoriation in service quality. MDR-TB patients are fewer in number than general TB patients but require far more attention and time, and with 2–2.5 years of treatment these patients accumulate. Human resources analysis has shown that existing supervision capacity is stretched, as each programme management unit is caring for approximately 300–600 TB patients at any given time. Current provision for supervisory visits by various cadres of staff will need to be enhanced. The management challenges posed by PMDT also apply at the State and National levels, and these units accordingly require strengthening.

Knowledge and practice gaps for DR-TB

There still exist unaddressed operational challenges and gaps in knowledge to further improve the quality of PMDT services. Key questions include:

1. Demonstration of decentralized rapid diagnostics and DST in field conditions
2. Reasons for patient attrition during case finding activities.
3. Reasons for interruptions/defaults and interventions to reduce default and improve adherence.
4. Best regimen and approach for programmatic treatment of poly-drug resistant cases, without rifampicin resistance
5. Best regimen and approach for programmatic treatment of MDR-TB with Fluoroquinolone and/or ethionamide resistance
6. Diagnosis and management of MDR-TB in extra-pulmonary disease sites
7. Averting delay in treatment initiation by decentralized pre-treatment Initiation
8. Effectiveness of standardized regimen for CAT V to improve treatment outcomes in XDR-TB cases.

Strategic Vision for 2012-17

The vision of the NSP-RNTCP is to promptly diagnose and effectively treat all TB patients with drug-resistant TB, through decentralized DST and PMDT treatment services integrated into RNTCP. Given the complexity, scale and cost, a phased approach has been developed, focusing first on those most likely to have drug-

resistant TB. RNTCP expects to treat about 1,60,000 MDR-TB and 4,100 XDR-TB cases over the next 5 years (2012-2017). Realizing this vision will require more laboratory capacity, more second-line drugs, infrastructure and manpower.

Activities

The nationwide scale-up of PMDT services has been included in the M/XDR-TB related resolution endorsed by the 62nd World Health Assembly in May 2009. Key milestones include:

- By 2010-11, basic RNTCP Category IV services for MDR-TB cases introduced in all states;
- By 2012, access to laboratory based quality assured MDR-TB diagnosis and treatment for:
  - All smear positive re-treatment TB cases, and
  - New cases who have failed an initial first-line drug treatment;
- By 2015, access to MDR-TB diagnosis and treatment for all smear-positive TB (new and re-treatment) cases registered under RNTCP early during their treatment.

Scaling up establishment of infrastructure for diagnosis, treatment and storage of second line drugs

Establishment and up gradation of reference diagnostic facilities: The programme will fast-track all preparatory activities to complete the civil work up gradation for Solid Culture, Negative Pressure area (Bio-safety level III) for Liquid cultures and 3 clean rooms for the LPA processes for all proposed 43 labs by 2013. Another 30 C-DST reference laboratories will be established in government and other sectors by 2015. This will be required to increase capacity to confirm MDR TB when required, monitor patients, and conduct testing for second-line drug resistance.

The programme plans to decentralize MDR-TB screening in the infrastructure up-gradation of at least 950 laboratories at district level and in tertiary care settings for introduction of the rapid automated TB and MDR TB diagnostics, such as cartridge-based NAAT (Xpert MTB/RIF®), after demonstration of operational feasibility and cost-effectiveness.

Airborne infection control and up gradation of PMDT Sites: To scale up treatment services PMDT sites have been planned as of 1 site per 10 million population wise for up-gradation for airborne infection control measure for rolling out of services. In those geographic areas where there is no PMDT site in public sector could be identified, option to engage with private tertiary care hospitals to serve as PMDT sites will be explored. A suitable package for reimbursing cost to such PMDT sites will be ruled out.

Improve drug storage conditions and capacity at state and district level: With increasing number of patient courses planned to be procured and managed from 2012-17, the state and district drug stores will upgrade additional space over and above the storage capacity that was largely developed considering the first

line drugs and up-gradation of the storage conditions as per the guidelines for storage of second line anti-TB drugs.

Maintenance: The programme will also consider the regular maintenance of all of the above facilities over the period from 2012-17.

Organization, management and co-ordination of PMDT (PMDT)

Increase funding for PMDT Committee meetings: Regularize and intensify the review of progress towards universal access and quality of implementation of PMDT services at national, state and PMDT site level in all states through enhanced overall funding for conducting meetings. This will also provide for additional cost to cover for state PMDT Committee meetings (at least 1 per quarter) and PMDT site committee meetings (at least 1 per month).

Human resource restructuring: Further strengthening of the human resources will be considered by provision of additional staff at various levels based on case load and need as follows:

- C-DST laboratories: Microbiologist, Senior LT and DEO at each lab
- PMDT sites: Provision of Senior Medical Officer, Statistical Assistant and a Counsellor at each site
- States: DR-TB Coordinator and Technical Officer for Procurement & Logistic for every state.
- Districts: Senior PMDT/TBHIV Coordinator for every district and additional coordinator for districts with >3.5 million population with mobility support, TA/DA as per RNTCP norm.
- State Drug Stores: Provision of a Pharmacist cum Storekeeper, store assistant is made for every State Drug Store with additional store assistant for every 1800 CAT IV monthly boxes prepared at the SDS per month.

The processes for recruitment, retaining trained staff and their performance assessment will be an integral function of the HRD cell proposed at CTD.

Enhanced training budget: Enhance financial allocation to conduct trainings at national, state and district levels regularly. This will help to meet the timelines of the state PMDT scale up plan till the vision of universal access to quality services is achieved.

Improving Access of quality DR TB diagnostic services

Up-gradation of diagnostic facilities in reference laboratories: The programme will fast-track all preparatory activities to complete the equipment installation with maintenance, human resource development, laboratory consumables and accreditation in Solid, Liquid and LPA for all proposed 43 labs by 2013 and another 30 C-DST laboratories through public-private partnerships by 2015. This will increase capacity to screen all the TB patients for drug resistance by 2017. Additionally, the provision of additional HR and lab consumables for LPA and Liquid Culture labs under the Global Fund Round 9 and Expand TB project will last till 2015; the program will also make provisions for sustaining this through 2016-17. This needs to be supplemented by rapid introduction of newer rapid molecular

diagnostic techniques like LPA in the 43 labs, as well as the establishment of second-line DST for diagnosis of fluoroquinolone-resistant or XDR TB.

Decentralising diagnosis of MDR TB: Ultimately every district will require DST services to rapidly screen all TB patients at the outset of treatment; the existing and planned referral laboratory cannot handle that enormous load. Decentralized DST is possible with automated cartridge-based NAAT or equivalent technology. After the demonstration of operational feasibility and cost effectiveness this will gradually be scaled up to every district and major medical colleges from 2012–17. It will improve the capacity to conduct decentralized diagnosis and ensure early and maximum enrolments of diagnosed MDR-TB (Rifampicin resistant) cases.

Revising guidelines for engaging NGO & PPs to improve access to diagnosis of DRTB: The RNTCP will revise its NGO-PP scheme on C-DST for engaging services in private and NGO sector to include revised costing for 2nd line DST, Liquid Culture and LPA to make private sector engagement sustainable and economically viable. Similarly the scheme for collection and transport of sputum samples to C-DST Labs would be upgraded.

Strengthening transport mechanism: Capacity building of the states and districts to establish an efficient system of sputum sample collection and transport in cold chain to C-DST laboratories in remote areas is critical. The costing for refrigerator at district TB centres, sample transport box with gel packs; falcon tubes, packing materials and cost for transport through courier or speed post or person need to be built in to the provisions of patient support and transport charges. In areas where this is not possible, the patient's travel expenses for visit to DMC for providing sputum sample will be reimbursed under the same head.

Capacity building for second line DST: Capacity building of NRLs and accredited C-DST labs to conduct second line DST through trainings at NRLs and proficiency testing will be undertaken from 2012-15.

Improving delivery of DR-TB treatment services and outcomes

Central procurement of drugs: Central procurement of Second line Category V drugs for management of XDR-TB cases will be considered with gradual scaling up of drug quantities from 2012-17 as mentioned earlier. The technical specifications for new drugs needed, such as Amikacin, will be developed as required.

Improving treatment outcomes: The programme plans to accelerate the shift to earlier diagnosis of MDR TB (Criteria A to B to C) and use of rapid diagnostics (LPA, Liquid Culture) to treat patients earlier, reducing morbidity and death. Patient support will be addressed as described. The programme will be vigilant to review developments worldwide to search for better drug regimens, and seek to rapidly evaluate any new more effective regimens for application in India.

Improve controls against inappropriate use of anti-TB drugs: The programme will proactively advocate with DCGI and relevant stakeholders to develop stringent

and effective mechanisms to avoid irrational and inappropriate use of anti-TB drugs and prevent further development of resistance.

Management of second-line drug resistance: For management of fluoroquinolone resistance, all MDR TB patients would be subject to baseline second-line DST upon diagnosis of MDR TB. Management strategies of patients with second-line drug resistance have been incorporated into treatment guidelines, and will be refined by the relevant technical committee as additional evidence and experience accumulates.

Enhancing patient support systems: Enhancement of patient support mechanisms for travel to service delivery points and the honorarium to DOT providers has been considered. The provision of a counsellor at every PMDT site is proposed to enhance the care, support and motivation of the patient to adhere to treatment and address any adversities faced by the patient from psycho-social and treatment perspective.

Programmatic Management of XDR-TB: As a more severe form of MDR TB, XDR TB management will be integrated along with MDR TB management. All MDR TB patients would also get second-line DST from a certified reference laboratory. Treatment regimens are centrally procured, and the regimen will evolve with the accumulation of additional evidence and experience.

Provision for packing material: Additional provisions for meeting the cost of packing material for creating patient wise boxes for Category IV at SDS will be made along with the procurement of drugs as the quantity of such boxes to be prepared will escalate with increasing number of patient enrolments over the next 5 years.

Information management, Supervision, Monitoring and Evaluation

Online data management: RNTCP will expedite development of an online data management system for PMDT for M/XDR TB case and drug management, pursue its pilot implementation, and scale up to all implementing states. This will facilitate information sharing among patient care levels and improve patient care, enable real-time monitoring of activities, improve safety and drug tracking, minimize risk of drug loss through expiration, and improve accountability of the national investment. This will require strengthening the existing IT and Data management Cell at CTD and building capacity of the statistical assistants and DEOs at the state and district level to operate the online data management system. Development of this online web-based data management system will be pursued immediately. To enable deployment, computer will be provided to all C-DST Labs, PMDT sites and State Drug Stores along with provision for their maintenance. Also, to strengthen drug and logistics supply chain management systems, provision will be made for equipment & software for Bar-Code reading at the state and district drug stores.

PMDT Support Unit at CTD: To have a PMDT support unit at CTD to strengthen the overall programme management, supervision, monitoring and evaluation related activities from CTD with support from partners.

Enhanced provision for supervisory activities: To enhance the provision for conducting supervisory visits, appraisals and evaluations of PMDT activities, within the overall budget of the programme.

Intensified monitoring through Video Conferencing with States: It is anticipated that implementing the ambitious scale up plans drawn up by the states will open up many operational challenges and will require frequent interaction with the state level teams. To enable this, video conference equipments and peripherals available with the Ministry of Health and Family Welfare (MOHFW) will be leveraged for intensified monitoring. This will also open up opportunities for CTD to interact frequently with the state teams to address challenges in TB control at large apart from reviewing progress on PMDT.

Conduct drug resistance surveys: Additional drug resistance surveys are planned in subsequent years in Rajasthan, Madhya Pradesh and West Bengal. Preferably prevalence surveys will be replaced by routine testing of all patients. If required, drug resistance surveys would be repeated after a gap of 5 years from the initial survey to observe the time trends in DR-TB.

6

Scale –up of Joint TB-HIV Collaborative Activities

Key Messages

- TB is the most common opportunistic infection and the most common cause of death for people living with HIV.
- There has been tremendous progress in scale-up of collaboration between TB and HIV programs; challenges however, remain.
- Earlier diagnosis of HIV-associated TB and linkage to care through intensified screening for TB and MDR-TB among PLHIV using newer, rapid diagnostics and further decentralization of HIV diagnosis and treatment would be the major focus in the next five years.

Abstract

TB and HIV act in deadly synergy. HIV infection increases the risk of exposure to TB, progression from latent to active TB, risk of death if not timely treated for both TB and HIV and risk of recurrence even if successfully treated. Correspondingly, TB is the most common opportunistic infection and cause of mortality among PLHIV, difficult to diagnose and treat owing to challenges related to co-morbidity, pill burden, co-toxicity and drug interactions. Though only 5% of TB patients are HIV-infected, in absolute terms it means more than 100,000 cases annually, ranks 2nd in the world and accounts for about 10% of the global burden of HIV-associated TB. This coupled with heterogenous distribution within country is a challenge for delivery of services. National and international studies indicate that an integrated approach to TB and HIV services can be extremely effective in managing the epidemic. A modelling study by Williams et al predicts that RNTCP should be able to reverse the increase in TB burden due to HIV, but to reduce mortality due to TB by 50% or more by 2015, universal access to coordinated TB and HIV care is essential. Studies also indicate that emphasis needs to be on early diagnosis linked to TB and HIV treatment.

Since the advent of the collaborative efforts in 2001, TB-HIV activities have evolved to cover most of the WHO recommendations. In 2007, the first National Framework for Joint TB-HIV Collaborative Activities was developed which endorsed a differential strategy reflective of the heterogeneity of TB-HIV epidemic. Coordinated TB-HIV interventions were implemented including establishment of a coordinating body at national and state level, designated human resources, integration of surveillance, joint monitoring and evaluation, capacity building and operational research. Interventions have focused on improving services for HIV-infected patients, with intensified TB case finding and linking with TB treatment; and for TB patients with provider initiated HIV testing and counselling, provision of ART and decentralised CPT and nationwide coverage is expected by 2012.

However, challenges remain. Only about 50% of TB patients know their HIV status and of those identified as HIV positive, only 50% are linked to ART as the majority are poor and unable to reach centralized ART centres. As compared to TB services, which are mostly decentralized and integrated into the general health system, HIV services remain largely centralized. Thus, this gap between RNTCP and NACP infrastructure results in suboptimal linkages.

Sputum smear microscopy is not a sensitive tool to diagnose TB among PLHIV, and access to a culture based diagnosis (or equivalent technology) is lacking. Implementation of airborne infection control measures in health care settings is also limited. The INH preventive therapy is not yet a policy; but is being tested for operational feasibility for further decision.

The vision is to achieve universal access to TB/HIV care in the next five years. Given the need to strengthen collaborative efforts, the next five-years would focus on reinforcing mechanisms for ensuring effective implementation and improving service delivery for TB and HIV infected patients. Early and improved diagnosis of TB and Rifampicin resistance, through rapid diagnostic technology for PLHIV is envisaged. For all HIV-infected TB patients, strategies to address the infrastructure gap including establishing facility integrated ICTC at all RNTCP microscopy centres without ICTC and providing travel support to HIV-infected TB patients to

reach ART centres are planned. Operational research to test improved methods of early diagnosis of HIV-infected TB patients (HIV testing among chest symptomatics and contacts of HIV-TB patients), to assess barriers in linkage to care and to assess feasibility of IPT implementation has also been planned.

Introduction

HIV-infection is the strongest known risk factor for progression of latent TB infection to active TB disease (1). Acquisition of HIV infection by individuals already infected with Mycobacterium Tuberculosis is associated with a massive increase in risk of TB from an approximately 10% lifetime risk to 10% annual risk. HIV-infected TB patients are at an increased risk of mortality as compared to HIV-negative TB patients and at higher risk of developing recurrent TB even if successfully treated (41). On the other hand, PLHIV are highly susceptible to TB infection and develop rapidly progressive disease following exogenous exposure. TB infection further increases the progression of HIV (42).

Though only 5% of TB patients are HIV-infected (43), in absolute terms it means more than 100,000 cases annually, ranks 2nd in the world and accounts for about 10% of the global burden of HIV-associated TB (1). This coupled with heterogenous distribution within country is a challenge for delivery of services. Effective interventions exist and there are clear policy recommendations from a variety of sources (44). For example, programmatic integration can help reduce barriers to getting care and treatment; intensified case finding can identify TB cases earlier thus decreasing transmission and improving clinical outcomes; ART can both prevent TB and improve its treatment outcome and prevention can also be achieved with infection control and IPT. Furthermore, there is data from India and elsewhere that such interventions can be done at scale and be cost effective.

Thus, TB-HIV activities are an area in which there is good evidence that investments yield clear benefits. For example, a modelling study by Williams et al predicts that RNTCP should be able to reverse the increase in TB burden due to HIV, and reduce mortality by 50% or more by 2015 by universal access to coordinated TB and HIV care (45).

In this chapter, we will discuss how to achieve the vision by improving the provision of TB care to those infected with HIV and HIV care to TB patients. This chapter focuses on achievements, challenges and future activities addressing the three main issues; i.e. coordination mechanisms, service delivery for PLHIV and services for TB patients.

Achievements

History of TB-HIV collaboration

TB-HIV activity coordination started relatively early in India in 2001, in the states of Maharashtra, Manipur, Nagaland, Karnataka, Tamil Nadu and Andhra Pradesh. The early activities were primarily joint training of health staff in TB-HIV and cross-

referrals. Expansion of these activities was then extended to eight additional states (Delhi, Gujarat, Himachal Pradesh, Kerala, Orissa, Punjab, Rajasthan and West Bengal) in the year 2004 (15).

In 2007, the first National Framework for Joint TB-HIV Collaborative Activities was developed that endorsed a differential strategy reflective of the heterogeneity of TB-HIV epidemic (46). A package of essential TB-HIV interventions was implemented in all states including:

1. Establishment of a mechanism for coordination of committees and technical working groups, both at the national as well as state level.
2. Training of programme officials and field staff on TB-HIV.
3. Intensified TB case findings at ICTCs, ART Centres, and care and support centres.
4. Risk-based referral of TB patients for voluntary HIV counselling and testing.
5. Referral of HIV-infected TB patients to NACP for additional care and support, including antiretroviral treatment.

Concurrently an "Intensified TB-HIV package of services", implemented in states with high burden of TB-HIV, comprised of:

1. Routine referral of all TB patients for HIV counselling and testing.
2. Provision of decentralized co-trimoxazole preventive therapy (CPT) to HIV-infected TB patients.
3. Referral of HIV-infected TB patients to ART centres for initiation of ART.
4. Expanded recording and reporting, including recording HIV status in the TB treatment cards and TB registers.

In 2009, it was decided to implement the full spectrum of "Intensified TB-HIV activities" nationwide with a goal of reaching all states by, 2012 (47). This expansion was accompanied by strengthening of joint monitoring and evaluation, with specified national TB-HIV programme indicators and performance targets.

TB and HIV activities are increasingly coordinated

At National level, National Technical Working Group (NTWG) is in place, comprising of key officials from NACO and CTD dealing with TB-HIV Collaborative activities and experts from WHO. The purpose of the TWG, which meets quarterly, is to review, optimize and plan, monitor and evaluate TB-HIV coordination activities.

At the state level, State Coordination Committees (SCC) are in place to ensure smooth implementation and regular review of TB-HIV Collaborative activities; State Coordination committees, chaired by Principal Health Secretary are established at the State level. State Working Group (SWG) is another body at state level, composed of key officials from SACS (PD and APD) and State TB Cell (STO, second MO if present), along with other officials dealing with TB-HIV collaborative activities and consultants involved in TB-HIV collaborative activities.

At the district level, District Coordination Committees (DCC), chaired by the District Magistrate have been formed in most districts of the country. In addition, monthly joint co-ordination meetings are held between RNTCP and NACP staff. Currently, about 60-65% of the districts report having conducted a DCC meeting every quarter.

Coordination is facilitated by appropriate Human Resources: TB-HIV collaboration is a part of the Revised National TB control Programme and hence, all staff involved in the programme are involved in TB-HIV activities as well. In addition, a few dedicated staff are present for improved supervision and monitoring.

- A full-time regular government officer is in-charge of TB-HIV collaborative activities in the programmes at the National and State level in NACP and RNTCP.
- National Consultants for TB-HIV (NACP & RNTCP) are available through WHO technical assistance.
- Technical officers at SACS for basic services (including TB-HIV) are available across the country (1-2 per state).
- State TB-HIV Coordinators initially sanctioned by RNTCP in 15 States (Assam, Bihar, Chhattisgarh, Delhi, Gujarat, Himachal Pradesh, Jharkhand, Kerala, Madhya Pradesh, Orissa, Punjab, Rajasthan, Uttar Pradesh, Uttaranchal and West Bengal) has now been extended to all the states.
- District level: TB-HIV and DOTS-Plus supervisors have been sanctioned for all districts by RNTCP.

Conduct surveillance of HIV prevalence among TB patients and TB prevalence among PLHIV: Another key coordination activity is integration of surveillance. Currently, this is part of the routine surveillance system and HIV status of TB patients, is being routinely reported in the quarterly reports of RNTCP. Similarly TB surveillance among HIV infected individuals attending ART centres is routinely reported.

Monitor and evaluate activities: Joint planning, supervision, monitoring and review are conducted through joint TB-HIV visits to states/districts and joint programme reviews conducted at national and state level. National targets for assessing TB-HIV collaborative activities have been defined (47). The performance of TB-HIV collaborative activities is analysed and indicators are published in the PERF reports of RNTCP every quarter. RNTCP conducts regular programme reviews at the national and state levels. It is planned that at one of these reviews at the national level, an annual review of the TB-HIV collaborative activities is held with the participation of state programme managers of both programmes. Similar annual reviews are held at the state level by adding an additional day to one of the quarterly RNTCP review meetings and inviting the District Nodal Officers for HIV/AIDS and SACS officials.

Capacity building: All the training modules for training various cadres of staff have been jointly prepared by CTD and NACO. These may be accessed from www.tbcindia.nic.in. Staff of RNTCP and NACP conducts all the trainings jointly.

Operational Research: Many operational researches have been conducted jointly, which have shaped the policy of TBHIV collaborative activities in the country. These have been published in international peer-reviewed journals and are accessible from www.tbcindia.nic.in. Some of the examples are provided in the chapter on Research priorities.

Improvements in delivery of TB care for PLHIV

Intensified TB case finding activities have been established in ICTC across the country with standardized recording and reporting. This activity has contributed to about 5-6% of total TB case detection in many states. Since 2010, these activities have been extended to all the ART centres in the country.

Substantial increases in the absolute number of clients referred from ICTC have been recorded over the past 5 years. The best data is available from the high HIV prevalence states, where a more detailed reporting system from the ICTC level has been in place since 2005 (Table 6.1). With the expansion of the ICTC network in these states, the number of ICTC clients has increased substantially, as have TB suspect referrals. TB suspect referrals have also increased as a proportion of all ICTC clients, from 3.5% in 2007, to 7.4% in 2010, suggesting improved implementation of intensified case finding activities. The number of TB cases diagnosed and put on DOTS has increased as well; the proportion of diagnosed TB patients put on DOTS has increased over these years, from 81% to 91%. Over the same time period, the total TB case notification rate has remained quite stable. Encouragingly, the proportion of total TB case notification in these 6 states that was found through ICF is also increasing, from 4.5% in 2007, to 7.9% in 2010.

Table 6.1 Annual results of Intensified TB Case Finding at ICTCs, 2007–2011, High HIV prevalence states*

	2007	2008	2009	2010	2011	Total
Number of ICTC clients	3,534,061	3,608,940	5,183,875	5,309,934	9,774,522	27,411,332
Chest symptomatics referred	125,091	185,411	315,111	393,110	579,258	1,597,981
Proportion referred as chest symptomatics	3.5%	5.1%	6.1%	7.4%	5.9%	5.8%
Total TB cases diagnosed	23,444	26,632	33,509	35,547	37865	1,56,997
Proportion of TB diagnosed	19%	14%	11%	9%	9%	12%
Diagnosed TB cases put on DOTS	18,993	21,729	28,040	32,356	34,355	1,35,473
Proportion placed on DOTS	81%	82%	84%	91%	91%	86%
Total TB registered	417,980	414,869	412,548	411,533	480,752	21,37,682
Proportion of	4.5%	5.2%	6.8%	7.9%	7.1%	6.3%

registered TB cases diagnosed by ICF						

Source: NACO ICTC monthly reports

* Andhra Pradesh, Karnataka, Maharashtra, Manipur, Mizoram, Nagaland, and Tamil Nadu

RNTCP and the Avahan Network, a large-scale HIV prevention project, partnered to deliver enhanced TB screening services for high risks groups across 6 states using a PPM based model for ICF. Between July 2007, – September 2008, 134 NGOs, operating 412 clinics and community-based outreach services, screened 124,371 HRG individuals and referred 3,749 (3.01%) for TB diagnosis. Of these, 849 (23%) were diagnosed with TB. RNTCP translated this model into national policy through a public sector funded TB-HIV PPM scheme for any non-governmental organizations serving HRG (48).

TB infection control in health care and congregate settings: The National Airborne Infection Control Committee (NAICC) with representations from Medical Colleges, NCDC, NACO, CTD, WHO, Architects and PWD Engineers was established in 2008. National guidelines on airborne infection control in all health settings including HIV care settings were developed that included a combination of simple managerial, administrative, environmental and personal protection measures. Pilot testing of operational feasibility and effectiveness of the guidelines have been conducted in the states of West Bengal, Gujarat and Andhra Pradesh and baseline assessments have been conducted in 35 health facilities. The plans for national scale up of this have not yet been set.

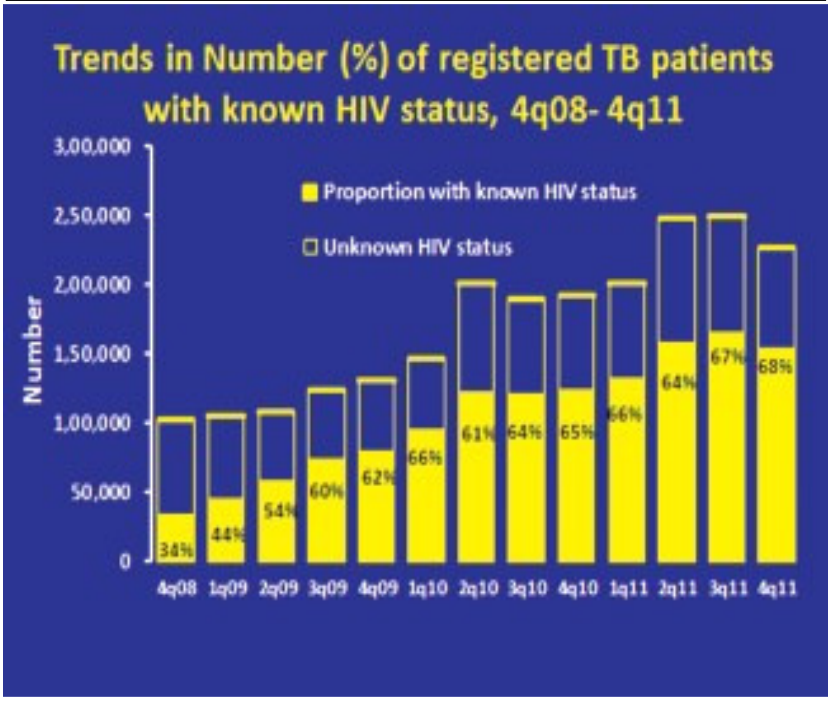
HIV care for TB patients

Provider initiated HIV testing and counselling to all chest symptomatics, TB patients and their contacts: To reduce mortality among HIV-infected TB patients, the first step is to detect HIV infection. Prior to 2008, the national policy was 'selective referral' - physicians to conduct HIV risk assessment of TB patients and to refer those with HIV risk factors for anonymous voluntary HIV counselling and testing. This policy reflected the limited availability of HIV testing services at that time, concerns for the privacy of HIV-related health information, and the lack of operational data on the impact of provider-initiated HIV testing and counselling for TB patients. The National TB Institute Bangalore and TRC Chennai conducted an operations research project, in order to evaluate Provider Initiated HIV Counselling and Testing for TB patients in Mysore and Trichy districts. This project demonstrated that through the routine referral of TB patients to ICTC for voluntary HIV counselling and testing, HIV status could be successfully ascertained for more than 70% of TB patients (49).

On the basis of international recommendations, Indian operational research, and the growing availability of HIV diagnostic and treatment services, routine referral of all TB patients for HIV testing was incorporated into the national policy. TB programme records and reports were changed to collect basic HIV status and treatment information. Complete and systematic reporting of data from these 9 states implementing the Intensified TB-HIV package was started from 4th quarter 2008 and by the end of 2010, data from 19 states were available. The number and proportion of TB patients with known HIV status has progressively increased from

34% in 4th quarter 2008 to 65% in 4th quarter 2010 (Figure 6.1). This has been facilitated by the scale-up of HIV testing centres in the country including the introduction of Facility integrated ICTC and Whole-blood HIV screening test in many PHIs.

Figure 6.1 – Number and proportion of registered TB patients with known HIV status, 4q08-4q11



HIV testing of TB patients has been an exceptional source of HIV case finding for NACO; HIV prevalence among TB patients has been consistently higher than HIV prevalence among ICTC clients (7 to 8% compared to 3% among ICTC clients at national level) and in some states as much as 15% of HIV cases detected were via referrals of TB patients for HIV testing. Operational research study has supported this finding, with at-least 50% of HIV infections detected among TB patients with not known prior HIV positive result i.e. being newly detected as HIV positive (49). These observations have spawned efforts to co-located HIV testing/Screening centre in every DMC.

Provision of ART to all HIV-infected TB patients: ART has been consistently effective in India and around the world against mortality during TB treatment. In analysis adjusted for baseline patient characteristics, the mortality risk is reduced by 64-95% by use of concurrent ART. Recent evidence (SAPIT trial, CAMELIA trial and STRIDE study) indicates the value of immediate/early ART in HIV-infected TB patients in reducing the risk of death, especially in severely immune-compromised individuals (50-52). NACO now recommends that 'ART be initiated as soon as possible, within 2 weeks to 2 months of initiation of anti-TB treatment for all HIV-infected TB patients'. The initial 2 weeks of anti-TB treatment is to allow for some reduction in infectiousness (especially for smear positive TB) before seeking care in HIV care settings.

Prevention of TB by early initiation of ART: In addition to improving treatment outcome, ART has a potent TB preventive effect. Data from multiple cohorts

including high TB burden and resource-limited settings report TB risk reduction of 54-92% in adjusted analyses (53). In a meta-analysis of these studies, summary estimate of this reduction was 67% (95% CI 61%-73%). Reductions in TB risk were similar among patients with either positive or negative TST suggesting an impact on risks of both endogenous reactivation disease and disease arising due to exogenous re-infection. ART also halves the risk of TB recurrence (41).

Case fatality rates are several-fold higher among HIV-infected TB patients as compared to HIV-negative TB patients and are strongly related to degree of immunodeficiency. TB treatment outcomes disaggregated by HIV status are now routinely reported under the programme and reconfirms this finding. To prevent death, WHO recommends PITC of TB patients and provision of CPT and ART to all HIV-infected TB patients. These set of activities are implemented in India as "Intensified TB-HIV package of services". This was initiated in October 2008 in 9 high-HIV prevalent states of the country. This has been expanded to 29 states in 2010-11 with a vision to achieve nationwide coverage by 2012.

Decentralized CPT for all HIV-infected TB patients: Evidence from randomized controlled trials has shown that CPT reduces mortality, morbidity and hospitalization stay with no significant increase in adverse events among HIV-positive smear-positive TB patients regardless of CD4 count including in areas of high levels of antibiotic resistance (54-55). Other non-randomized and operational studies showed that decentralized CPT is feasible, safe, cost-effective (56) and reduces mortality rates in TB patients (57-59).

CPT for HIV-infected persons has always been NACP policy, but previously cotrimoxazole was only available at the limited number of NACP ART centres. At the local level, cotrimoxazole was widely available through the general health system, but local public clinics only provided a maximum 3–5 days of drugs. The decentralized delivery of CPT in monthly dosing pouches was successfully pilot-tested in 3 districts in Andhra Pradesh in 2007, which paved the way for national policy (57). The reported performance from the states implementing intensified TB-HIV package has been excellent with more than 90% of HIV-infected TB patients receiving CPT during TB treatment. Surveillance data shows that >80% HIV-infected TB patients are presently initiated on CPT in high prevalent states. But the activity needs to be strengthened in other states where the programme was launched in later phases.

Challenges

The challenges currently faced by India for controlling the epidemics of TB and HIV can be best summarized in terms of coordination of activities, provision of TB care to those with HIV and provision of HIV care to those with TB.

Coordination of TB and HIV Services

Establishing a coordinating body for TB-HIV collaborative activities at all levels of health system has proved challenging: Ensuring complete geographic coverage has been difficult. Some districts do not have a functional District Co-ordination committee, especially those without a full time nodal officer for

HIV/AIDS. Many SCC and DCC do not have adequate representation of other stakeholders like representatives of PLHIV networks, representatives of other line ministries (Ministry of Labour and Home Affairs for prison health services and harm reduction services), private health sector etc. Also, information on establishment of DCC is not accurate in the Programme Management report of RNTCP. Many RNTCP reporting units are not separate revenue districts by themselves (e.g., Municipal corporations of Maharashtra, Chest Clinics of Delhi) and hence are not eligible to have a DCC.

Surveillance of HIV prevalence among TB patients and TB prevalence among PLHIV has not been comprehensive: Currently, HIV testing is not incorporated routinely as part of TB prevalence surveys and anti-TB drug resistance surveillance. This is important as it helps to understand the relationship between HIV and TB drug resistance at population level. Furthermore, HIV testing among chest symptomatics and contacts of TB patients is yet to be tested in India.

Inadequate joint programme management: There are inadequacies in joint TB and HIV planning for resources, capacity building, communication, community participation and operational research. For example, currently there are no TB-HIV consultants at SACS. This is required especially in the face of national scale-up of collaborative activities. There is also no mobility support for the district Dots-Plus and TB-HIV supervisor.

Administrative guidelines for organizing training of staff are not uniform under NACP and RNTCP and are frequently a source of conflict in programme implementation. This needs to be aligned. Joint planning at state level is also lacking. This is extremely crucial as we try to integrate the delivery of TB and HIV services at the same facility.

The efforts for joint communication have been patchy and not coordinated. The help line for HIV does not provide adequate information on TB. Currently there is no systematic approach to involve PLHIV networks in advocacy, communication and social mobilization activities. This requires attention.

The national programme in India does not address the special needs of IDUs who are at high risk of HIV, TB and Hepatitis systematically.

Monitoring and evaluating activities: Joint visits are not regularly conducted by the states to the districts, primarily due to lack of dedicated supervisory staff at state level. Additionally, the existing recording and reporting systems needs to be modified to allow for real-time monitoring of TB-HIV collaborative activities, especially information on linking HIV-infected TB patients to ART.

Improving TB care for those with HIV

Early diagnosis and therapy is critical for interrupting transmission and improving outcome of TB amongst those living with HIV. Progress has been made but more needs to be done, particularly:

Establishing Intensified TB Case Finding and linkage to TB treatment:

Though a lot of success has been achieved, there are many challenges as well.

- Data from the low-HIV states on ICF at ICTC show that the proportion of ICTC clients referred is much lower as compared to high-HIV states, suggesting that the implementation of intensified case finding is uneven, perhaps reflecting the low level of TB-HIV training for ICTC counsellors.
- The implementation of ICF at ART centres is uneven. Not all centres are reporting regularly and even the quality of data reported is poor.
- There is a need to extend ICF to other high-risk settings like LAC, CCC and TI sites. A concerted effort was made to partner with NGOs to deliver TB services to HIV high risk groups (HRG), including commercial sex workers, IDUs, men who have sex with men, and other marginalized populations who may face access barriers in the general health system. While the effort is ongoing to enhance uptake, as a long-term measure it is beneficial if the TB-HIV co-ordination activities are a part of complete package of interventions provided by TI NGOs.
- Changing the definition of TB suspect in PLHIV from “any cough” to “any of the four – cough, fever, weight loss and night sweats” needs to be disseminated.
- For patients receiving protease inhibitor (PI) containing ART, Rifampicin in TB treatment can lead to sub-therapeutic concentrations of PIs even with Ritonavir boosting. Hence, such patients are provided with Rifabutin under the National Programme. However, the effectiveness of such a change on Tb treatment outcomes has to be studied further.
- While widely assumed to have value, the absolute and comparative value of ICF in improving care and control of TB needs to be better studied.

Appropriate utilization of optimal regimens and technologies: Current tools like sputum smear microscopy used for diagnosing TB have limited sensitivity (under 50% in most of the series), especially in HIV-infected individuals where a large proportion of TB cases tend to be smear-negative TB or extra-pulmonary TB (42). Current capacity to diagnose smear-negative and MDR-TB among PLHIV is limited at decentralized level. Optimization of smear microscopy (like use of LED-based Fluorescent microscopy and concentration methods) improves performance only modestly in comparison to conventional microscopy using ZN staining. Hence, there is a need to deploy newer and rapid diagnostics like Xpert MTB/RIF (MTB integrated cartridge based automated nucleic acid amplification test (CB-NAAT) that uses a common platform to diagnose both TB and Rifampicin resistance), which has a sensitivity and specificity equivalent to that of solid culture, while providing the results rapidly within 2 hours. WHO has strongly recommended the use of Xpert MTB/RIF as the initial diagnostic test in individuals suspected of having MDR-TB or HIV-associated TB (60).

High mortality rates among HIV infected TB patients, have raised concerns about current policies and practices such as the adequacy of intermittent regimens in HIV-infected TB patients, the use of Rifabutin and the timing of initiation of ART therapy. Specifically, RNTCP uses a thrice-weekly rifampicin-containing regimen for all TB patients including HIV-infected; whereas, WHO recommends daily TB treatment at least during the intensive phase based on the results of the meta-analysis which showed that there was an increased risk of recurrence and failures among HIV-infected TB patients receiving intermittent TB treatment as compared

to daily regimen (61). However, review of the primary evidence indicates very limited, low-quality information on intermittency, mostly from observational studies in the pre-ART/early ART era which did not use standardized TB treatment. DNA finger printing studies in India indicate that most of the recurrences (88%) and many of the failures were a result of exogenous re-infection and not endogenous reactivation (62). This suggests that in the presence of immunodeficiency, poor infection control and high background prevalence of TB contribute to continuing transmission, rather than poor efficacy of the treatment regimen used. Recent evidence (from TB research centre, India) indicates excellent treatment outcomes among HIV-infected TB patients receiving intermittent regimens with concomitant Efavirenz-containing ART (63). Examination of reported treatment outcomes among HIV-infected TB patients treated under RNTCP indicates low failure rates, but high case-fatality rates associated with lack of ART. Hence, the highest priority is to reduce mortality by linking all HIV-infected TB patients to ART (15). In a national consultation held at National AIDS Research Institute (NARI), Pune, in February 2011, a group of national HIV and TB experts, researchers, civil society representatives, and programme representatives considered the primary evidence and deliberated extensively (32). The consensus was that the evidence for change was inadequate, hence RNTCP should continue using the current regimen and further prioritize early linkage of HIV-infected TB patients to ART; at the same time, the consultation recommended that the process of collecting direct evidence from randomized controlled trials to inform this question of dosing frequency in HIV-infected TB patients be expedited. Overall, though concerning, given the poor evidence for change and operational advantages (lesser side effects and being amenable for DOT) of intermittent regimen, RNTCP intends to collect additional evidence before national policy change.

Prevention of TB by introduction of INH Preventive therapy: The National Technical Working Group (NTWG) acknowledges the evidence and value of TB preventive therapy (IPT) among HIV-infected individuals but has been concerned about efficiency of health systems in excluding active TB with certainty due to lack of decentralized availability of culture facilities (especially newer rapid diagnostics; RNTCP is validating the use of Xpert MTB/RIF in diagnosing TB and Rifampicin resistance). However, recent evidence indicates the value of symptom screen with a group of symptoms like cough of any duration, fever of any duration, night sweats for 3-4 weeks and weight loss (64). This has a very high negative predictive value for excluding TB. Hence, HIV-infected patients with none of these symptoms have a very low probability (1-2%) of having TB and can be candidates for IPT. The NTWG accepted the evidence available globally and in India regarding efficacy of Isoniazid in preventing TB among HIV infected individuals. Clinical research by TRC Chennai indicated that 6 months of INH+Ethambutol is as effective as 36 months of INH alone in preventing TB and the protective effect lasted for 3 years (unpublished). The group also recognized the need for generating evidence to answer questions on operational feasibility of adoption of IPT strategy in NACP settings. Since NACO has revised ART guidelines and changed for the criteria for ART initiation for all HIV infected individuals and given the well established potential of ART in preventing TB, information on additional effectiveness of IPT would also need to be captured as part of the activity.

Improving HIV care among those diagnosed with TB

Evidence continues to accumulate that prompt identification and comprehensive therapy of HIV prevents TB and improves the outcome of anti-tubercular therapy. Progress has been made but more needs to be done, particularly for the following listed below:

Provider initiated HIV testing and counselling:

- Geographic: There are wide variations in the availability of services between geographic regions that will likely require different solutions. There is a mismatch between number of designated microscopy centres (DMC) and number of HIV testing services. Dramatic scale up of HIV services will be required in those areas where HIV prevalence is lower.
- In some areas there are other issues like delays in programme implementation. In district level trainings, printing and CPT procurement, poor supervision and monitoring, non-co-location of HIV testing services etc.
- Interrupted supply of HIV testing kits has been partially responsible for slowing down the achievements and is reflective of suboptimal procurement and supply chain management systems. This has a vicious effect as providers will stop referring and patients stop going even if referred and hence needs to be addressed on priority.
- HIV testing of chest symptomatics is currently not a national policy. WHO and ISTC recommend moving HIV testing upstream by testing all chest symptomatics as a measure of early detection of HIV-infected TB cases. Evidence of observational studies from sub-Saharan Africa shows that testing for HIV in patients with presumptive TB yields a high number of new diagnoses of HIV infection as prevalence of HIV is higher than among the general adult population; this however cannot be generalized to Indian situation. Initial studies from a couple of districts from South India have shown a HIV prevalence of 7-10% among chest symptomatics (65). Considering a HIV positivity of 3% among ICTC clients at national level, HIV testing of chest symptomatic appears to be a high-yield method of HIV case finding at-least in settings of high HIV prevalence. Though, broader surveillance across the country and greater HIV testing capacity is required before national policy decision.
- HIV testing of contacts of HIV-infected TB patients is not a policy in India. Studies from other settings (e.g., Thailand) have shown that this is a productive strategy and has the potential of early diagnosis of HIV-infected TB patients (66).
- Currently, TB patients are linked to HIV prevention services provided by NACP through the network of ICTC.

Inadequate provision of ART to all HIV-infected TB patients:

- All HIV infected TB patients should be linked to ART: At present only about 50% HIV infected TB patients are linked to ART care and support. It is observed that case fatality rate among HIV infected TB patients not on ART or having delayed initiation of ART is very high. International guidelines recommend initiation of ART in all HIV infected TB patients irrespective of the CD4 counts. NACO has accepted this as a strategy but its timely and effective implementation is important.

- Operational research has shown that many patients do not reach ART centre due to geographic and financial barriers. Linking all HIV-infected TB patients diagnosed throughout the country to about 300 ART centres is a huge challenge. Efforts are on to decentralize ART services through a network of Link ART centres (LAC) in the country, though this would only help adherence of stable HIV-infected patients on ART and would not affect the access issue that exists. Social welfare measures like provision of travel subsidies; nutritional support and others have been state specific and patchy. Hence more systematic and formal programmatic measures are required to enhance access of HIV-infected TB patients to ART centre including travel support to reach ART centres and co-ordination with the existing NGOs are required.
- One of the reasons ascribed to low proportion of HIV-TB on ART is that not all HIV-infected TB patients are eligible for ART. Many studies from India and abroad indicate that more than 80% of the HIV-infected TB patients were eligible for ART as per 2006 guidelines and hence as a public health approach, strongly justifies the adoption of 2010 guidelines(all HIV-infected TB patients eligible for ART irrespective of CD4 count) with modest resource implications to the national ART programme (67). NACO has agreed to adopt this strategy, which is likely to ease operational issues involved in linking HIV-infected TB patients on ART.
- The potential of ART in preventing TB has not been fully exploited. This can be done only if the ART is initiated in HIV positive patients at an early stage. The latest WHO ART guidelines (July 2010) to initiate ART for all PLHIV if CD4 count is less than 350/mm^3 is a welcome change in this regard (68). NACO has adopted this strategy (November 2011).
- Emerging evidence from various trials (CAMELIA, SAPIT, STRIDE) conducted across the globe regarding timing of initiation of ART indicates that ART should be started as a matter of emergency (even before 2 weeks) in TB patients with CD4 less than 50 cells/mm^3 and as early as possible in the remaining cases. This needs to be incorporated in the national guidelines.

Strategic Vision for 2012-17

The overall goal of joint TB-HIV collaboration is to reduce the mortality among HIV-infected TB patients. This will be achieved through coordinated and universal access to TB and HIV care.

The programme envisions expanded diagnosis to ensure that 1) all HIV-infected should have their TB promptly diagnosed, 2) that all TB patients should have their HIV promptly diagnosed.

In addition there will be an emphasis on treatment such that 1) all HIV-infected TB patients are initiated on ART promptly irrespective of CD4 count, that 2) all HIV-infected TB patients are initiated on Cotrimoxazole Preventive Therapy.

Finally there will be an expansion of prevention of TB among PLHIV through 1) early ART, 2) infection control and 3) IPT for those who are eligible.

Activities

Establish mechanisms of Co-ordination

- **Strengthen coordination mechanisms at districts and state level**
- **Increase Human resources for supervision and monitoring**
  - TB-HIV consultant position for all states (1 per state in high prevalence states and 1 per 2-3 states in the rest of the states). This would be budgeted under NACP-IV
  - Ensuring RNTCP TB-HIV co-ordinator and district supervisor posts are filled and functional in all states and districts with additional positions sanctioned in large states and districts
  - Strengthen mobility support to state and district level supervisors
  - Proposal in RCC-2 (NACO) for strengthening of national institutes for strengthening of HIV-TB activities to be executed at the earliest. This would be budgeted under NACP-IV.
- **Improve surveillance**
  - Implement a case-based, web-based electronic surveillance system to enable real time monitoring of inter-programme linkages.
  - Changes in RNTCP recording and reporting to reflect changing needs of TB-HIV collaborative activities.
- **Training of RNTCP staff in TB-HIV**
  - This is covered in detail in Chapter 9, Human Resource Development. In principle, all the staff would be trained using budgets under the respective programmes.
- **Other**
  - Incorporate TB related information in the existing helpline of NACO.

Reduce the burden of TB among People living with HIV/AIDS

Early and improved diagnosis: The focus would be on expanding locations for ICF, expanding patient profile (whom to test) and introducing newer, rapid diagnostic technologies.

- ICF at all HIV care settings and those with a concentration of PLHIV
  - Strengthen ICF activities at ART centres and expand the same to all HIV care settings.
  - ICF at the time of HIV diagnosis and at HIV care facilities is high TB yield activity.
  - Also, ICF in NACO targeted intervention projects (e.g. Avahan project) shows high value. Therefore all clients attending HIV diagnostic and care facilities should be screened for TB symptoms and TB-HIV activities should be instituted in NACO targeted intervention projects

- Use of Newer, rapid diagnostics for diagnosing TB
  - Symptoms are good, but the availability of rapid technology like Xpert MTB/RIF has the potential to further increase confidence of clinicians in excluding active TB and initiate IPT. More research is

required to establish the role of Xpert MTB/RIF as part of the screening strategy to rule out TB.
    - All HIV care settings should have access to Xpert MTB/RIF as the initial diagnostic test for diagnosing TB and Rifampicin resistance.
    - In addition, all HIV-infected individuals should be prioritized for accessing culture and DST to diagnose DR-TB.

TB preventive therapy: In addition to treatment of active disease, its prevention must be an increasing focus in the coming years as an effective intervention to reduce mortality and morbidity in PLHIV. The use of IPT will become increasingly relevant as the ability to exclude disease become greater through services and technologies described above. The recently published WHO guidelines for "Intensified TB case finding and IPT for PLHIV in resource constraint settings" (2011) categorically endorses the use of IPT for all PLHIV to prevent TB in all age groups based on clinical screening of TB symptoms (69). It is generally agreed by both NACP and RNTCP that evidence regarding efficacy of IPT to significantly reduce TB incidence in PLHIV is clear. Also trials conducted in India at TRC, Chennai has demonstrated efficacy of IPT in patients attending ART centres. ART is also known to prevent development of TB. Randomized controlled trials like - CIPRA HD 01 have demonstrated role of ART in reduction of TB incidence by about 50% among patients with CD4 between 250 and 350. Considering rapid scale up of ART services in the country and the change in guideline to initiate ART early (at CD4 count less than 350/mm3), more evidence is required on added benefit of IPT. Therefore NACO is planning a quick operational research to generate evidence for programme decisions. RNTCP needs to plan for resources to procure the additional INH and pyridoxine required for implementing IPT in case it becomes a national policy.

Implementation of National Airborne Infection Control policy at ART centres:

- Baseline assessment of all existing ART centres
- Implementation of administrative, environmental and personal protection measures.
- Resources should be planned to modify the existing structure of ART centres to implement environmental measures for airborne infection control.
- Future establishment of ART centres should be preceded for airborne infection control assessment.

Role of BCG in preventing TB among HIV-infected infants and children:
BCG vaccination greatly reduces the risk of severe forms of TB in infants and children. However, BCG can also cause local and disseminated disease in HIV-infected infants with risk as high as 1% leading to revision of WHO guidelines to make HIV infection in infants a full contraindication to BCG vaccination. In India, however, BCG vaccination is done at birth (for institutional deliveries) or within the first 6 weeks in India. Unfortunately serological testing cannot differentiate 'HIV-infected' and 'HIV-exposed but uninfected' infants because of passage of maternal antibodies until 18 months of age. Unless Early Infant Diagnosis (EID) based on PCR is widely available, implementation of this WHO recommendation is not feasible as that would deprive the majority of HIV-exposed but uninfected infants of the protective effect of BCG in high endemic country like India. Hence, India in the

coming years needs to collect evidence about the risk and benefits of BCG in the context of its evolving capacity to diagnose neonatal HIV so as to set policy on the appropriate use of BCG and other vaccines.

Reduce the impact of HIV among TB patients

TB patients know their HIV status:

- Scale-up of establishing facility integrated ICTC preferentially at all RNTCP DMC without co-located ICTC as these facilities are located strategically and equipped with basic infrastructure and HR required for implementing HIV testing services.
- DMC with no ICTC/F-ICTC may be upgraded to an HIV screening centre using Whole Blood Finger prick test (WBT). These screening centres may offer comprehensive screening facility beyond TB patients including STI, HRG and ANC clients.
- Contracting a professional agency at NACO to manage procurement and supply chain management to ensure uninterrupted supply of HIV diagnostic kits to all DMC.
- A new NGO-PP scheme to increase HIV testing uptake – NGO to visit DMC without ICTC and test the TB patients/collect blood sample and transport to ICTC for HIV testing.
- Expand vision of whom to test
    - Recent WHO TB-HIV policy guidelines recommend that HIV test be offered routinely to all chest symptomatics in addition to TB patients. Operational studies conducted by RNTCP in two districts in Andhra Pradesh and Karnataka have suggested the potential utility of this intervention. Hence the programme should promote further research to generate wider evidence so that it may be adopted as a national strategy.
    - Another strategy recommended is to offer HIV testing routinely among contacts of HIV-infected TB patients. This needs to be studied further before national policy decision.

All HIV infected TB patients should be linked to ART:

- Systematic measures to extend financial support to the HIV-infected TB patient for travel to ART centre for evaluation and treatment initiation. There would be a provision for travel support for HIV-infected TB patients to visit ART centre.
- Efforts would be made to optimize outreach activity undertaken by different categories of NACP outreach workers.

7
Pediatric tuberculosis

Key Messages

- Pediatric TB poses special challenges for which little evidence is available to guide policy and practice, both for diagnosis and management.
- RNTCP will seek to improve the quality of pediatric TB diagnosis, more effectively engage private providers and pediatricians, and incorporate more flexible, child-friendly treatment regimens and practices
- Over the next 5 years, RNTCP will expand engagement with pediatricians, improve diagnosis through expanded radiology access treatment regimens and practices in line with emerging evidence.

Abstract

Pediatric TB differs markedly from adult TB in both disease characteristics and management. These differences require a tailored approach. Because of the lower burden and infectiousness of pediatric TB, the issue has been accorded substantially less priority during the initial stages of RNTCP.

Universal access requires that the gap between pediatric and adult services be closed. RNTCP has established the vision that no child should die of TB in India. Progress towards this vision will require the strengthening of relationships and engagement with private pediatricians, improving access to existing radiology and microbiologic diagnosis, deployment of new diagnostic tools and case-finding approaches, development of more child-friendly treatment approaches and regimens.

Introduction

Pediatric tuberculosis (i.e., TB among the population aged less than 15 years) has traditionally received a lower priority than adult TB in National TB programmes because it is largely non-infectious, difficult to diagnose, misplaced faith on BCG, cases have been thought to be few and the assumption that effective control of adult TB could prevent childhood TB. The actual burden of disease is not known due to diagnostic difficulties but has been assumed that 10% of total TB load is found in children. Globally, about 1 million cases of pediatric TB are estimated to occur every year accounting for 10-15% of all TB; with more than 100,000 estimated deaths every year, it is one of the top 10 causes of childhood mortality. Though MDR-TB and XDR-TB is documented among pediatric age group, there are no estimates of overall burden, chiefly because of diagnostic difficulties and exclusion of children from most of the drug resistance surveys.

Achievements

Considering that children are highly susceptible to TB infection and are at a high risk of progression when infected at young age; considering childhood TB can account for 10-15% of all TB in high-incidence settings and can be a major cause of under-5 mortality, RNTCP has always accorded high priority to the diagnosis and treatment of TB in children since the inception of the programme. In order to simplify the management of pediatric TB, RNTCP in association with Indian Academy of Pediatrics (IAP) has described criteria for suspecting TB among children, has separate algorithms for diagnosing pulmonary TB and peripheral TB lymphadenitis and a strategy for treatment and monitoring patients who are on treatment. In brief, TB diagnosis is based on clinical features, smear examination of sputum where this is available, positive family history, tuberculin skin testing, chest radiography and histopathological examination as appropriate. The treatment strategy comprises the following key components.

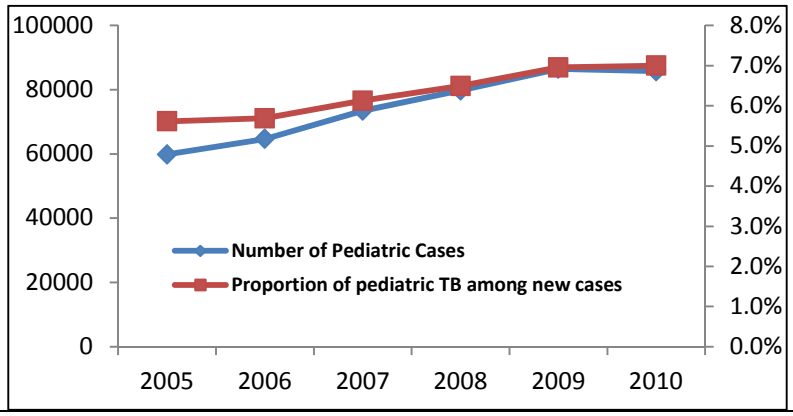
1. First, as in adults, children with TB are classified, categorised, registered and treated with intermittent short-course chemotherapy (thrice-weekly

therapy from treatment initiation to completion), given under direct observation of a treatment provider (DOT provider) and the disease status is monitored during the course of treatment.

2. Second, based on their pre- treatment weight, children are assigned to one of 6 pre-treatment weight bands (<6kgs; 6–10 Kg; 11–17 Kg; 18–25Kg; 26–30Kg and >30Kgs). Patients with pre-treatment weight within the range of these individual weight bands are treated with a corresponding pre-fixed weight band dosage made available in individual patient-wise boxes. Patients weighing less than 6Kg are treated with individualized dosages, and those weighing more than 30 Kg are treated using adult dosages.

3. Third, uninterrupted good quality anti-TB drugs through ‘‘ready-to-use’’ patient wise boxes containing the patients’ complete course of anti-TB drugs are made available to every registered TB patient according to programme guidelines. It is to be noted that India was the first country to introduce paediatric patient wise boxes. The number of paediatric TB cases registered under RNTCP has shown an increasing trend in the past five years and for 2010, about 90,190 cases were notified accounting for 7% of all cases. Expectedly, smear negative and EP cases predominate. (Tables and graph)

4. Treatment for MDR-TB for children is now available under the program and a new weight band (<16kg) has been created.



Pediatric TB cases registered in India, 2011

Type of case	No. of Pediatric TB cases	No. of Total TB Cases	Proportion of pediatric TB
NSP	12981	642321	2%
NSN	36673	340203	11%
NEP	34026	226965	15%
New Others	384	1952	20%
Relapse	1024	112508	1%
Treatment after Failure	249	17304	1%
Treatment after Default	453	72787	1%

Retreatment Others	2563	101832	3%
Total New Cases	**84064**	**1211441**	**7%**
Total Retreatment Cases	**4289**	**304431**	**1%**
Total TB cases	**88353**	**1515872**	**6%**

The treatment outcomes of pediatric TB cases, though not reported routinely under the programme, have been studied in operational research settings. **A study conducted in Delhi reported very high treatment success rates (about 95% among new TB cases)** among pediatric TB patients indicating the effectiveness of RNTCP regimens and management guidelines.

Active tracing of child contacts of smear positive TB patients and screening for TB is recommended by RNTCP. Since it is difficult to diagnose latent TB infection in a highly BCG-vaccinated population, prevention of TB is done through INH chemoprophylaxis (5mg/kg/day for 6 months) for all contacts (<6 years) of smear positive TB patients after ruling out active TB. BCG provided at birth through the general health system is proven to prevent serious forms (TB meningitis and miliary TB) of TB in children, though not effective in preventing adult TB.

Challenges

There is little understanding about how much pediatric TB there really is. The case definitions for pediatric TB are not yet agreed upon globally, and are subject to evolution. No disease burden study has been conducted for pediatric TB. Case-finding of pediatric TB is limited by the inability of many field providers to recognize the disease in time, and conversely is also challenged by an equal tendency of other providers to over-diagnose TB based on little evidence.

Collaborations with pediatricians: Engagement with pediatricians has been incomplete. Efforts to develop the initial approaches to pediatric TB diagnosis have not been followed through with sustained collaboration. Most private pediatricians still do not notify pediatric TB cases, and prescribe self-administered and unsupervised daily treatment on the basis of beliefs of higher effectiveness.

Diagnostic challenges: Pediatric tuberculosis is a complicated clinical entity, with a spectrum of disease ranging from low-burden “primary complex” disease which may spontaneously heal, and severe forms of extrapulmonary TB. The disease tends to involve different anatomical compartments – especially lymphatics, and sputum-based diagnosis is hence quite challenging. Even in pulmonary disease, establishing an accurate diagnosis is challenged by the collection of a good sputum specimen, making clinicians reliant on other poor-specificity tools like radiographs, Mantoux testing, and clinical decision making to make a diagnosis. Under programme conditions, such low quality diagnostic tests are frequently not available, and the skill of interpretation is limited. An enormous installed base of radiograph and digital radiograph services can be found in the private sector of every major and minor town, frequently linked up with tele-radiology interpretation by qualified radiologists; but RNTCP has no mechanism to reimburse radiologic testing done in the private sector, even for pediatric

diagnosis where it is essential in nearly all TB suspects. New diagnostic tools are usually only validated in children long after validation in adults. With little opportunity for microbiologic confirmation, confirmation of drug-susceptibility is not usually possible.

Treatment challenges: The proper dosing of pediatric TB remains a moving target. There are several issues regarding treatment of TB in children including dosage, formulations, schedule of administration etc, RCTs have been difficult to conduct due to problems in defining a case and objective endpoints. Since 2004, there have been changes in global and national guidelines in management of pediatric TB. Specifically, novel evidence has become available regarding the correct dosages of medicines for treating pediatric TB. WHO has issued a rapid advice in 2010 detailing the key recommendations. The guidelines of the International Union against TB and Lung disease have also been revised in 2010. The Indian Academy of Pediatrics has also revised its recommendations in 2010.

Issues in prevention of TB: The uptake of INH chemoprophylaxis has been suboptimal and needs to be strengthened. However the issue of preventive therapy among contacts of MDR-TB remains unresolved.

Strategic Vision for 2012-17

No child should die of tuberculosis in India. All children with TB should be diagnosed promptly and effectively, notified to RNTCP, and accountably treated with high-quality child-friendly formulations and approaches. To achieve this goal, RNTCP will seek to improve the quality of pediatric TB diagnosis, more effectively engage private providers and pediatricians, and incorporate more flexible, child-friendly treatment regimens and practices.

To improve access to high-quality pediatric TB diagnosis, RNTCP will apply the following principles.

- Use radiology capacity in the private sector, taking advantage of private service availability and reimbursing for pediatric radiographs.
- Improved quality of sputum specimens through introduction of standardized induced sputum and gastric aspiration procedures.
- Early validation of new diagnostic tools and case finding strategies and incorporation into the diagnostic algorithms.

To improve pediatric TB treatment, the same basic principles as planned for adult TB treatment apply:

- Prompt appropriate treatment, increasingly guided by drug susceptibility testing
- Making DOTS more patient friendly
- Improve treatment partnerships between the public and private sectors
- Research to guide improved regimens and delivery systems

Activities

Better engagement of private providers and pediatricians

A National Technical Working group for pediatric TB will be established to ensure that the latest evidence is considered and incorporated into national guidelines.

Use of existing tools – radiology and improved specimen collection

Radiology is essential to pediatric TB diagnosis, and public sector radiology is frequently insufficient or is not preferred. RNTCP will develop mechanisms to reimburse private diagnostic centres for x-ray of pediatric TB suspects. Such reimbursements would be budgeted as private sector engagement and diagnostic testing.

Microbiologic diagnosis can be improved with better specimen collection and processing. RNTCP will prepare standard normative guidance, develop district and medical college capacity to conduct gastric aspiration and safe sputum induction, and train microscopy centers in specimen processing from gastric aspirates.

Improve pediatric TB case finding through better diagnostic tools and case finding strategies

Diagnosis of pediatric tuberculosis will require validation of case definitions, and ongoing revision of the diagnostic algorithm to incorporate new tools and strategies. As new diagnostic tests become available, their use in pediatric TB diagnosis will be evaluated on priority. Engagement of private providers (described in detail elsewhere) will include pediatricians as a priority target group, along with chest physicians and internal medicine providers.

Improve treatment through child-friendly formulations, flexible supervision.

More child-friendly regimens are being developed, in line with global recommendations, national expert opinion, and emerging evidence. RNTCP has committed to seek better pediatric formulations, including dispersible tablets where possible for small children. RNTCP may explore and pilot test the feasibility and effectiveness of alternate approaches like “Mother or care giver at home as DOT provider” in selected areas and if found useful can be accepted as strategy and scaled up. For seriously ill patients, special ‘daily’ treatment pouches will be made available for intensive phase treatment.

Improved and more accountable prophylaxis

While today only pediatric TB contacts are eligible for TB prophylaxis, guidelines will be revised to include other risk groups such as immunocompromised children, irrespective of contact. More importantly, systems for some accountability for completion of prophylaxis will be developed and deployed.

Strengthen evidence base for pediatric TB management

As with all pediatric conditions, research is challenging and evidence is limited for pediatric TB. RNTCP will develop and actively pursue priority pediatric research, and seek to include pediatrics into as many programme OR as possible. For example, there is a striking paucity of data on pediatric tuberculosis dosing and pharmacokinetics. While RCT’s are preferred, a more pragmatic approach may be to follow a cohort of children being treated with the standard regimen, perform pharmacokinetic studies at multiple time points, ensure adherence to treatment and assess cure and relapses over 18-24 months.

8
Special Populations

Key Messages

- Enhanced outreach by RNTCP to poor and disadvantaged populations belonging to SC/ST and economically backward districts is critical to universal access.
- Increased coverage can be achieved by focusing on at risk and clinically, socially and occupationally vulnerable populations.
- Effective monitoring of services for special populations will be greatly facilitated by transition to electronic case-based reporting.

Abstract

To achieve the goal of universal access, it is the necessary to ensure access to all sections of population, including vulnerable and at risk groups. In context of TB control the special populations can be segmented into two categories: socially and clinically vulnerable. Socially vulnerable are those that have a higher risk of succumbing to TB due to the social inequalities that lead to exclusion and limit access to quality services. These include schedule castes and tribes, urban slums, migrants and prisoners among others. The clinically vulnerable category includes people who due to existing health issues, habits, or occupational hazards are predisposed to contracting TB and therefore are at a higher risk.

Special population groups are highly dispersed and developing appropriate strategies for inclusion poses a huge challenge. The concerns range from lack of physical access to public health services and poor health seeking behaviour, to core issues of poverty, communication barriers and socio-cultural differences.

The NSP-RNTCP vision articulates the need to strengthen the programme to better serve these marginalised groups and ensure equitable delivery of services. In the proposed five-year plan the focus would be on developing inter-sectoral linkages with concerned departments to provide impetus to the programme. These would include developing a National framework on TB and diabetes collaborative activities, a strategy for integrating TB and tobacco control, extending TB services to prisons, screening of malnourished children in *Anganwadi* centres, building linkages with RCH to target women, flexible treatment services for urban slums and workplace interventions. In order to ensure access in poor and backward areas financial norms and benefits of the tribal areas would be extended to the specific districts identified by the programme. Operational research would be conducted to design suitable interventions to ensure evidence-based decision-making.

Introduction

There is considerable evidence that social conditions decisively influence community health. Therefore action is required across all sectors to promote wellbeing, specifically in tuberculosis control. Tuberculosis affects some populations disproportionately and a major cause of the inequities in access to TB diagnostic and treatment services as well as in treatment outcomes arise from the conditions in which people are born, live, work and age—also referred to as social determinants of health. Many social factors influence people's health, but not all determinants are equally important. The most important are those that produce stratification within society - "structural" determinants - such as the distribution of income or discrimination according to gender and ethnicity. Special populations or communities created through this stratification require targeted attention during this plan period for TB control.

Though the programme has made substantial efforts in reaching out to the specialized populations considerable challenges still remain. Special populations that will be targeted during this plan period include:

PLHIV: The TB/HIV collaborative activities have been detailed in a separate chapter.

Diabetes Mellitus (DM): As a consequence of urbanization as well as social economic development in India, there has been an escalating epidemic of diabetes mellitus (70-71). Available data suggest that an estimated 11% of urban people and 3% of rural people above the age of 15 years have diabetes mellitus, with about half of those in rural areas and one third in urban areas being unaware of the problem. Most recent estimates put the number of persons with diabetes mellitus at 62 million (10% of the adult population), with a further 77 million having impaired glucose tolerance (71). Epidemiological surveys and studies have been completed and published or are currently being conducted in India on the association between diabetes and tuberculosis, but country-wide collaborative control activities are not yet formalized or being implemented.

On-going work, which was presented at the National Stakeholders' Meeting in Delhi in October 2011, includes that being done at the MV Diabetes Center in Chennai, Tamil Nadu (Dr V. Vishwanathan, personal communication), and through the state TB officer in Kerala (Dr J. Shankar, personal communication). In Tamil Nadu, crude prevalence rates of diabetes and pre-diabetes in TB patients were found to be 25% and 24 % respectively with rates in the general population being 10% diabetes and 8% pre-diabetes. A comparison of different methods of screening for diabetes (fasting blood glucose, oral glucose tolerance test and HBA_{1C}) showed the fasting blood glucose to be the more cost-efficient. In Kerala, 23% of the TB patients self-reported diabetes, and 27% of those denying a history of diabetes were found to have diabetes on measurement of HBA_{1C} (> 6.5%). Altogether, 44% of the 552 TB patients were found to have diabetes (comparisons with the general population were 16%-20% diabetes). This work suggests high levels of co-morbid diabetes in patients with TB in the states of Tamil Nadu and Kerala. This may have an important effect on TB treatment outcomes by lengthening the time to sputum culture conversion, increasing death

rates and increasing the risk of recurrent TB after successful completion of TB treatment (33). This association may also theoretically lead to the development of multi-drug resistant TB (TB resistant to rifampicin and isoniazid).

Diabetes is a well known risk factor for the development of active TB, and is estimated to increase the risk by a factor of 2 – 3 (72-73). In high HIV-TB burden areas, it is recommended that HIV-infected persons are actively screened for TB, and those identified and diagnosed are given treatment as soon as possible. In a similar vein, it is recommended that persons with diabetes are actively screened for TB (74), although how this is best done most efficiently and with the least expense is not yet known.

The World Health Organization (WHO) and the Union have just launched a new "Collaborative Framework for the care and control of Diabetes and Tuberculosis" with one of the important activities being the routine implementation of bi-directional screening of the two diseases (73). The ways of screening, recording and reporting for the two diseases in routine health care settings are not well determined, and these knowledge gaps need to be addressed (72, 75).

Tobacco users: There is strong evidence to show that tobacco use, particularly smoked tobacco use, increases risk of infection, disease and death from TB. While data on the prevalence of tobacco use among TB patients in India is limited, small studies have shown that up to two-thirds of adult male TB patients could be using tobacco with the potential to worsen their TB treatment outcomes.

Geriatric population: The 2001 census has shown that the elderly population of India is 77 million (76). The age structure of RNTCP case notification suggests that substantial cases being missed by the programme are in the elderly >65 year age groups. Age of 65 years and over has also been shown to be independently associated with unfavourable outcomes to TB treatment.

Malnourished Children: The prevalence of malnutrition among children varies across states, with Madhya Pradesh recording the highest rate (55 per cent) and Kerala among the lowest (27 per cent). This is a high-risk group that needs to be focused upon as they have a high propensity to contracting TB.

Migrants: While data on internal migration and TB in India are limited and a subject for operational research, delays in diagnosis and provision of uninterrupted treatment of tuberculosis have been a challenge. This vulnerable group of people often cannot provide proof of residence and their inability to stay in one-place limits their access to TB diagnosis and treatment.

Occupational high-risk group: Although reliable statistics are not available in India, it is known that thousands of workers and local residents are exposed to hazardous silica levels during stone crushing operations. Studies have shown increased morbidity and mortality rates among stone crushing mill workers from silicosis, lung cancer, and other lung diseases. Several other occupations also increase risk for tuberculosis including coal and other mining, tobacco (bidi rolling) and carpet weaving. Vulnerable and socially marginalised groups including tribal

communities, children and migrant population are often used in these industries and do not have access to routine health services.

Tribal population: According to the 2001 census, about 8.10 percent of India's total populations tribal. This population lives in concentrations in various parts of the country, some of them being Chhattisgarh, Jharkhand, Uttar Pradesh, Assam, Rajasthan, Orissa and Maharashtra. Tribal communities continue to face multiple challenges in accessing TB diagnostic and treatment services despite the implementation of the Tribal Action Plan in Phase II.

Prisons: There are 1336 prisons across the country, with Maharashtra having the maximum number (210). Overcrowding in prisons is a common problem and enhances transmission of TB.

Achievements

Tribal Action Plan

The RNTCP has prioritized special populations and 'hard to reach' groups in both the earlier phases (I and II). Groups that were specifically identified included tribal populations for whom a specific Tribal Action Plan was developed with clear guidelines and interventions for tribal communities. The programme has sustained focus to provide effective and quality services for the tribal population; it has made several special norms and guidelines for better implementation in the tribal areas which includes more incentives, human resources and decreased population size for designated microscopy centres when compared to the norms for plain areas.

Urban Slum Population

Urban slum-dwellers require intensive focus and support from the tuberculosis programme, as these populations often are not able to access timely diagnosis or complete the full duration of anti TB treatment, and hence are at risk of unfavorable treatment outcomes. The programme has also identified marginalized populations in urban slums and 'other marginalized and vulnerable sections of the community'. Special slum schemes to improve TB control in urban slums has been devised under the programme. About 50 NGOs have taken up such scheme across the country. Based on local evidences generated through operational research and field experiences, the activities to reach these special populations have been implemented across the country.

Prisons

The majority of prisons in India have DOTS centres on the premises, and a large number also have microscopy centres. Prisons DOTS centres are included in the RNTCP referral for treatment and transfer system.

Challenges

The challenges faced by these special population groups are many and include access to public health services, secondary effects on health seeking behaviour and resulting utilization of TB services as well as issues of poverty and the constraints imposed by out-of-pocket expenditure on already poor patients.

The communication barriers at various levels of the health services as well as the cultural differences in ethnic tribal groups, migrant communities and others limit even a basic understanding of the needs of these communities needs to be addressed.

Some of these challenges may be summarized as below:

Problems with health service: Inadequate staff and infrastructure at the local level. Inadequate public transport facilities inhibit access to the available health facilities.

Poverty and inability to afford any out-of-pocket expenditure: Transport costs and loss of work time and wages remains a barrier to accessing services and delay diagnosis and treatment.

Communication barriers: Social distances and attitudes create barriers to understanding the needs and requirements of the tribal and other vulnerable population. Knowledge about the disease and related risks among communities is limited and often not addressed by the health care providers. Language and dialect differences compound the issue as health care providers in the public health services are seldom from the communities that they serve.

Lack of accountability of referral for treatment: As patients diagnosed with TB are not notified, a referral for treatment is not accounted for in the current RNTCP system. Paper-based postal feedback has largely failed, and in particular has not served the needs of the migrant population of the country. Similarly, transfers are more accountable, but are sabotaged by the local RNTCP unit reluctance to register patients who will be shortly transferred, such as migrants diagnosed in cities.

Absence of workplace interventions: Significant proportion of workforce in the occupationally high-risk environment is from the unorganized sector and hence cannot access services at the work place.

Incarcerated Population: The category of population in the prisons varies and the turnaround is also high, affecting the continuity of provision of services. For example, in Tihar jail daily turnover is over 3,000 prisoners and detainees. Prison referrals and transfers, like all referrals and transfers, are not sufficiently accountable to the system as discussed above.

Strategic Vision for 2012-17

The programme will systematically identify vulnerable and at risk populations and communities during this phase and invest resources to make TB services accessible and available to them. This investment will include a range of interventions targeting policy change, strengthening health services at the primary care level, supporting patient and attendant transport for diagnosis and during the course of treatment. It will also include identifying and empowering volunteers from

the local community to support patient treatment adherence, hiring of contractual staff from vulnerable communities, instituting mechanisms for patient referral and follow-up when they move to another area.

Developing local and contextual Information Education and Communication (IEC), to increase community awareness of TB and related risks will be undertaken. Increasing access to testing for co-morbidities such as HIV, diabetes or identifying tobacco use and supporting them to give up such habits will also be another priority.

The RNTCP transition to an electronic case-based reporting system is necessary to improve management of special populations. With individual level information on key population risk factors, it will become possible to understand weaknesses in programme services for special populations. With electronic case-based notification comes electronic referral for treatment and transfers, which are expected to greatly improve the efficiency and accountability of services for migrants and other mobile populations.

Activities

Activities to promote universal access of TB services equitably across special populations can be broadly categorized as 1) those that target specific geographies, populations and co-morbidities and 2) those that focus on processes such as integration with other programs.

Targeted Activities

Focus on districts with large tribal population

Engaging contractual staff from community: The RNTCP will increasingly recruit contractual staff from the tribal communities in districts with large tribal populations .This staff will be trained and empowered to function adequately through NGO support where necessary.

Filling up of staff vacancies: The RNTCP will fill staff vacancies in these districts on priority, funding it from resources available for contractual appointments. These districts will also be encouraged to identify volunteers from the tribal communities to support patients on treatment. Programme support will be provided to actively implement the Tribal Action Plan already developed in Phase II and with regular monitoring.

Development of locally relevant IEC: Priority will be accorded to the development of cultural and context specific IEC materials by engaging the local population in their development.

Focus on poor and backward districts

Using already available data: The Planning Commission has identified 144 districts, with a population of nearly 266.4 million, as ‘poor and backward’. The health infrastructure in these districts is poor and the programme will empower

these districts by extending the financial norms and benefits of the tribal areas to these districts. This will, in particular, be extended to patients/attendants who are below poverty line.

Allowance of enhanced norms: Financial norms and programme support will be reviewed and enhanced to empower and engage special populations in the poor and backward districts. Appropriate incentives will be considered to increase access to diagnosis and complete treatment services.

Transport mechanisms: Sputum transport will be encouraged through NGO collaborative schemes and patients / attendants will be provided travel support where necessary.

Increased involvement of civil society: Civil society and NGOs will be progressively involved to expand the reach of the RNTCP in these districts. Lessons learned from the ongoing Global Fund Round 9 grant will be extended to all districts in the country in a phased manner so that access of special populations to TB services is increased. NGO schemes will be reviewed to incorporate additional needs of special population groups during the plan period.

Implementation of collaborative framework for TB/Diabetes

In first year of the plan, Central TB Division in collaboration with the Union will be pilot testing bidirectional screening at selected sites in the country and other interventions recommended in the WHO-Union collaborative framework (73) for care and control of tuberculosis and diabetes before decisions on nationwide scale-up. Drawing the lessons from TB/HIV collaboration, efforts will be made in the next five years to collaborate closely with the National programme for prevention and control of Cancer, Diabetes, Cardiovascular disease and Stroke (NPCDCS) (77). Hence, these pilot efforts assume great significance and have the potential of shaping future national policy. NPCDCS is also planning ambitiously to cover the entire country with its services in the next five years. The collaboration would evolve closely in line with developments in NPCDCS.

Develop and implement collaborative framework with Tobacco Control

The RNTCP will pilot the development and implementation of a collaborative framework, with the National Tobacco Control Programme. This framework will identify tobacco users among TB patients and support them to quit tobacco use as well as provide screening for TB among tobacco users visiting public health facilities across the country.

This information will be systematically collected through routine programme surveillance and data will be shared with the National Tobacco Control Programme. Additionally, tobacco using TB patients requiring higher levels of counselling or pharmacotherapy will be referred to the appropriate support services in the National Tobacco Control Programme.

Training and involving Prison Medical Personnel

RNTCP will engage, at the state level, with the department of prisons and develop and implement a framework to identify and treat TB in prisons. It will also provide health check ups on the TB patients upon their release. This will include the screening all prisoners on entry and programme support to prisoners when they are transferred between prisons. This will be carried out by training of prisons' medical personnel.

Provision of work place interventions

The RNTCP will engage with the Ministry of Labour and Mining to identify high priority districts with stone crushing units / mining industry. They will develop specific guidelines to support persons with an occupational risk for TB and provide access, diagnosis and treatment services from the programme.

Improving the management of Paediatric TB under RNTCP

In order to address the several challenges detailed, a "National consultation on diagnosis and treatment of Paediatric TB" with representation from leading paediatricians in the country, members of Indian Academy of Paediatricians, WHO experts and programme managers has been done with the objective of reviewing evidence base and advances in Paediatric TB diagnosis and treatment, updating the RNTCP guidelines on Paediatric TB management in line with the evolving global and national guidelines and developing a revised RNTCP-IAP consensus position on management of Paediatric TB. The revised Paediatric TB guidelines have been developed and will be disseminated very soon.

Provision of services for malnourished children

The RNTCP will engage with Nutritional Rehabilitation Centres set up in states to identify malnourished children and screen them for TB and link them to appropriate TB treatment services. The programme will also engage with the Ministry / Department of Women and Social Welfare at the national and state levels to screen children at the Anganwadis. The engagement will include the development of guidelines for routine screening of children, who are undernourished, for TB and referral to TB services.

Provision of services for the old

Districts will identify old age and pension homes in their jurisdiction and implement active screening for TB among the aged. This will also be extended to the old visiting public health facilities after appropriate operational research.

Urban Slum Population

People living in urban slums will be prioritized during this plan period. House to house surveys will be carried out to actively screen for TB and services will be provided close to the patient's homes through local volunteers. Peer education groups will be capacitated through collaboration with civil society and NGOs working in these slums.

Process Activities

Engagement with other programs

Non-formal providers: The RNTCP will engage with rural health care providers and traditional healers as well as local pharmacies who are often the first point of contact for TB patients and symptomatic and also their 'trusted' provider.

Collaboration with RCH: Research has shown that women are more likely to experience diagnostic delays due to difficulties in freely access diagnostic facilities. The programme will emphasise universal access to all the sections particularly women by linking the TB screening activities with reproductive and child health programme, which specifically targets women in the reproductive age group.

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

Strengthening referral and follow up for mobile population: Referral and follow-up mechanisms will be strengthened to support mobile patients to move without interrupting TB treatment. This will include strengthening the surveillance system for TB to capture patient wise information electronically and link this to the ongoing unique identity programme of the Government of India.

Communication strategy to address local needs: Communication strategies and campaigns will systematically include local elements incorporating the culture and ethos of the local tribal, migrant, and other communities. Wherever possible, local members of the community will be involved in peer education programs to increase acceptability and awareness of the local population.

Soft skills training for health workers, piloted and expanded through the Global Fund Round 9 project will also prioritize districts with higher proportions of special populations.

9
Integration with Health Systems

Key Message

- Integrating the RNTCP with the health system will increase effectiveness and efficiency of TB care and control.
- In rural areas the RNTCP can focus integration through the National Rural Health Mission (NRHM).
- In urban areas the RNTCP can integrate through the private sector and the evolving National Urban Health Mission (NUHM).
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Abstract

The last decade has high rates of case detection and cure rates, which are proof of the success of intensive and extensive efforts to control the spread of TB. The Programme has been vertical in nature with limited involvement of other components of the health system. A vertical programme has the ability to ensure the relevant thrust to programme activities which is sometimes crucial in achieving efficient results. However, with the changes in the health system in India, the need is to mainstream the TB Control Programme into the overall health system. The NSP-RNTCP envisages strengthening the health system by developing an integrated approach to TB and leveraging on the existing capacity of the health system to further TB control goals.

The health systems in India have evolved based on the geographical dispersion of the population and in context of the specific needs of the rural and urban areas. There are separate programmes catering to the rural areas under the NRHM and equivalent urban initiatives are within the purview of NUHM. The TB Control Programme would focus on developing strong linkages with both the NRHM and NUHM to improve access to diagnostic and treatment services. Though in rural areas the tremendous success of the NRHM has facilitated the delivery of quality diagnostic and treatment services closer to the community, the urban areas remain a challenge.

At the rural initiative level convergence with the NRHM programme management structures at the ground level would translate into improved efficiency of human resource allocation. It is envisaged that administrative and financial management functions would be transferred to the NRHM programme management structures. This integration would allow technical staff to focus on technical support functions, such as supervision and monitoring. At the Block level, it would translate into reducing the population addressed by a Tuberculosis Unit (TU) from 500,000 to 200,000.

The urban area strategy would focus on developing strong public private partnerships and integrating with the NUHM. The private sector initiatives are separately addressed in the chapter on PPM. As the NUHM has not yet been operational, NSP-RNTCP plans to develop suitable structures aligned to the NUHM structures as the latter evolves to ensure an integrated approach.

Additionally, given the widespread and adverse impact of TB on the economic development of a country (as it impacts the economically productive population) inter-sector coordination will be adopted as a strategy for mainstreaming TB into the activities of the identified ministries and departments.

Introduction

The health systems in India can be broadly segmented into those serving rural and those serving urban populations. Rural healthcare has been significantly strengthened in the past six years since the launch of the NRHM. A similar intervention at the national level is envisaged with the advent of the NUHM, which is not yet operational. Over the last decade, the RNTCP has been functioning as a vertical programme within the health department. Its focus includes providing TB

services in a decentralised manner with efforts to ensure close alignment with the country's overall health system. The programme has developed an extensive nation-wide programme management structure for improving TB related service delivery starting from the block to the national level.

In the next five years, the TB control programme aims to reinforce its activities and continue to provide decentralised services. However, the distinguishing factor of the NSP-RNTCP is the integrated approach adopted for service delivery. The programme will converge with both NRHM and NUHM so as to leverage on the strengths and build a synergised response to control the epidemic.

Approximately 60% of TB patients live in rural areas. NRHM was launched to provide accessible, affordable and accountable quality health services including the poorest households in the remote inaccessible rural regions and tribal population. The thrust of the mission was on establishing a fully functional, community owned, decentralized health delivery system with inter-sector convergence at all levels. Since its advent, NRHM has made significant achievements in partnership with states. It has created an institutional platform of Village Health and Sanitation committees, the Rogi Kalyan Samitis and the Panchayati Raj committees at various levels, which provide a rare opportunity for convergent action on all determinants of health.

A group of local resident, Accredited Social Health Activists (ASHA), with strong referral links has been created to support the existing health structure. About 800,000 ASHAs are currently fully trained. The NRHM has strengthened the public health facilities by establishing 24 X 7 health facilities with additional manpower and mobile medical units to provide diagnostic and outpatient care closer to hamlets and villages in remote areas. The district programme management unit and block programme management unit have been established to manage the national health programme. NRHM has identified, flexible financing, innovations in human resource management, monitoring against Indian public health standards and building capacities at all levels as the principal approaches to ensure quality of service and efficient utilization of scarce resources. This is to ensure the availability of health services at the local level. These activities are likely to be scaled up to form the basis of rural health care strengthening.

The remaining 40% of patients reside in urban areas. Urban health care is more complex consisting of divided segments of slums and re-settlement areas. Some of these are part of the municipal corporation area and the rest are outside it. Furthermore, the nature of NUHM is yet to be defined. However, all have a relatively high coverage of a variety of non-governmental health providers.

Given the differences of the health systems in rural and urban areas, in the coming years the TB programme will have to use different approaches to achieve health system strengthening in these areas. In rural areas it will strengthen engagement through the NRHM. In urban areas it will continue its current efforts to integrate with general health services and augment these efforts by partnering with the urban private sector.

This chapter focuses on mechanisms for strengthening the health systems for an improved response to the epidemic. It describes the achievements of the last five-year plan and the associated challenges. This is followed by a description of the activities planned for the next five-year plan.

Achievements

During the past five years, RNTCP had developed a structure of programme management. The basic field unit designated as the Tuberculosis Unit (TU) is expected to cover a population of 500,000. The unit structure consists of a Medical Officer – Tuberculosis Control (MOTC), Senior Treatment Supervisor (STS) and Senior TB Laboratory Supervisor (STLS) at the sub-district level. At the district level, District TB Centre serves as an administrative unit comprising of a District Tuberculosis Officer (DTO) and support staff. At the state level, the State TB Cell serves as the programme management unit. The state TB officer monitors the programme at the district level with the support of a team.

There are about 2,600 TUs and 13,000 Designated Microscopy Centres (DMC) to provide the diagnostic services for every 100,000 population. Majority of the DMCs are located in the public health facilities with RNTCP trained laboratory technicians. The TUs are evenly distributed in both urban and rural areas. A component of an additional Tuberculosis Health Visitor (TBHV) is provided in urban areas where the population is in excess of 100,000. The programme has also effectively engaged the community in creating awareness and providing DOTS treatment through community volunteers.

The programme has strengthened the Intermediate Reference Laboratories (IRLs) at the state level. The main function of an IRL is to supervise and monitor the DMC and efficiently achieve the external quality assurance function (EQA) by providing human resource support and establishing culture and drug susceptibility testing laboratories with a capacity to diagnose drug resistant bacilli using different technologies including solid culture, liquid culture and line probe assay (LPA).

Challenges

Though, the RNTCP has integrated the service provision with the public health systems the TB control programme is perceived as a vertical health programme. This has led to states not taking responsibility and expects the programme to cover all aspects of its implementation.

Access to services

Insufficient access for clinically vulnerable and remote area population: Currently under the programme, the DMCs are situated at public health facilities for every 100,000 population that comprises of nearly 20-30 villages in the rural areas. The symptomatic suspects for TB residing in remote areas and population that do not have access to diagnostic services are deprived of the opportunity of getting screened for TB. The focus on accessibility has remained poor especially for the socially vulnerable and clinically at risk population. This might significantly impact the proposed Universal Access objective.

Lack of transportation systems adversely impacting quality of service: The diagnosis of DR-TB is done at the accredited culture and DST laboratories that are usually located at the state capital. The sputum samples for diagnosis or follow-up are transported to the laboratory either by the programme staff, a special messenger from the health system or by a courier agency. This dependence of programme managers on the staff for transportation of samples has critically impacted the performance of the other basic functions of the programme staff, in turn affecting the delivery of quality services.

Inadequate use of NRHM platforms for advocacy and communication: The programme has substantially underutilized the impetus generated by NRHM in creating awareness at the grassroots.

Untapped inter-sector coordination: The programme has not actively sought inter-sector coordination within the various ministries/departments of the Government, to either utilize their services or create awareness or provide other support.

Diagnostic and treatment services

Lack of proper guidelines for management of patients screened for TB: The programme annually screens nearly 70-80 Lakhs chest symptomatic cases for TB. Only those who are found to be sputum smear positive are put on treatment and the suggested an antibiotic trial. If the symptoms persist even after the trial they are subjected to chest X-ray examination. If the chest X ray is indicative of TB, then the patient starts anti-TB treatment. In many cases the patients seek private sector providers, who prescribe non-rational treatment resulting in the patient returning to the public health system. This is either at the stage of re-treatment of TB or MDR- TB. The health system lacks guidelines for the management of this sub-section of population who were screened for TB.

Increased workload of programme staff adversely affecting quality: Apart from managing the programme at the block levels the TU team also oversees the operational and administrative functions. The additional responsibility of TB-HIV,DOTS Plus and ACSM/PPM has considerably increased the workload. The combination of technical and operational/administrative functions to be performed by the field units has affected the quality of programme implementation adversely.

Complexity of financial disbursement for DOT providers: A majority of DOT providers are community volunteers, who are provided an honorarium by the programme. The quantum of honorarium as well as the complexity involved in determining the eligibility and disbursement increase the workload of the programme staff. There is a need to simplify this in learning from procedures followed by other health programs.

Utilization of new communication technology: The programme has failed to harness potential opportunities provided by the advancement in communication technology through gadgets like the mobile phone.

Insufficient mechanisms for airborne infection control: There has been limited progress in installing airborne infection control mechanisms especially at ART centres, C&DST laboratory, and DMC and hospital wards. Unfortunately this is where there exists an increased susceptibility of infection for both the staff and the patients.

Strategic Vision for 2012-17

The vision of the TB programme for the next five years is to strengthen the decentralised programme structure and ensure integration with mainstream public health systems.

- In the rural areas, this will be focused on convergence with NRHM and leveraging on the structures and systems that have been established.
- In the urban areas the programme will focus on establishing appropriate structure for implementation at the field levels with flexibility to integrate with the urban health systems as they evolve through the implementation of NUHM and also utilize the potential available through partnerships with the private sector.

Activities

Improving accessibility of services

Establish diagnostic centres in greater proximity to the community: To further decentralize the diagnostic services and improve accessibility of services, the sputum collection centres will be established at the Primary Health Centres (PHCs), sub-centres, private practitioners, private hospitals, aanganwadis, schools, pharmacies and any other location as identified by the programme. This is expected to decrease the delay in accessing diagnostic facilities. It will also contribute towards achieving early diagnosis and initiating treatment. The cost of the transportation of sputum samples may be derived from the untied funds available with the PHCs or Rogi Kalyana Samitis (RKS).

Improving access for poor and backward districts: The population based norms adopted for programme delivery structure for tribal districts will be extended to the poor and backward districts. The Central TB Division will identify the districts annually and the norms will be included in the annual action plan. This will empower the districts to improve the implementation of the programme.

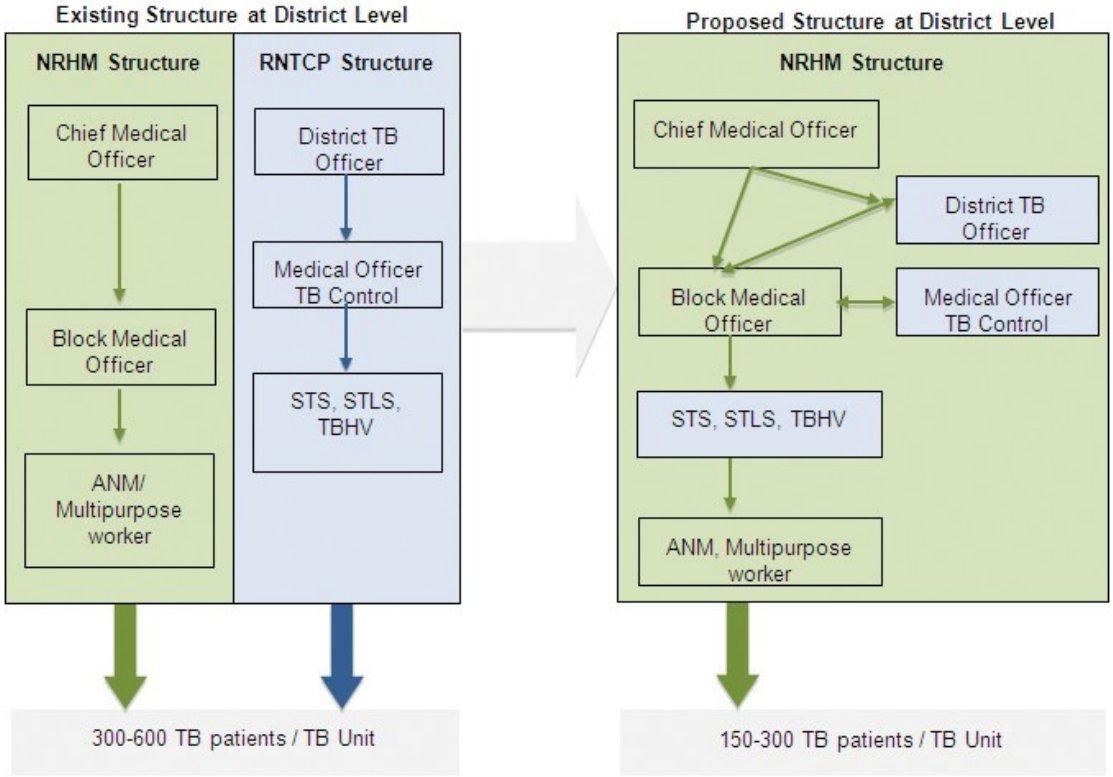
Designated transportation agency to improve efficiency of sample transportation: For optimal implementation of programmatic management of DR-TB- it is vital for districts to instil a sustainable sputum transportation mechanism. This will enable transportation of the samples to the culture and DST laboratories, which are located at various distances from the districts. The samples also need to be transported in a controlled temperature condition and reach the labs within 48 hours. The programme has made the provision of contracting a courier or transportation agency at state or district level to provide these services. Budgetary

allocation for the same will be created under a separate head of transportation within the current budget systems.

Outreach through village health and nutrition days: The village health and nutrition days would be utilized for advocacy and communication to disseminate information regarding TB with an aim to increase knowledge and awareness amongst the community. This may generate demand for correct diagnosis and treatment of TB within the community and promote early health seeking behaviour. Through this outreach pattern the topics around TB will be discussed monthly.

Strengthening diagnostic and treatment services

Integrating programme management structures of NRHM and RNTCP:
To address the operational and administrative issues of supervision and monitoring at sub-district level, the programme has planned to align the TU to the block level administrative structure of NRHM. The existing TU for a population of 500,000 is planned to cover a reduced population of 200,000 when aligned with the block administrative structure of NRHM. The block level medical officer will function as medical officer –TB control supported by a STS. However, the STLS will cover a population of 500,000. As a result of these changes improvement in the areas of diagnosis, supervision, involvement of nursing homes, pharmacists, easy flow of funds and MDR-TB care will be witnessed leading to quality implementation of all components of the programme. The vision of this change is depicted in the figure below:



Capacity building of Medical Officers on PAL methodology: The programme has planned to emphasize Practical Approach to Lung Health (PAL) for the management of chest symptomatic patients who are found to be symptomatic

even after the antibiotic trial management. This includes the capacity building of the medical officers on PAL during the modular training of the Medical officers.

Establish National Reference Laboratories: To strengthen the supervision of Intermediate reference laboratories at the state level, the programme is planning to establish two National Reference Laboratories, one each in the North East Zone and the West Zone in addition to the existing NRL.

Improved mechanisms for fund transfer: In order to bring about a smooth disbursement of honorarium to the eligible DOT providers a mechanism for transfer of funds to Block Programme Management Unit (BPMU) of NRHM from the District TB centre will be developed. This will facilitate transfer of funds to the DOT providers by cash, cheque or e-transfer.

Mobile phone allowance to improve communication: To adapt with the newer information technologies and to decrease the communication gaps which cause delay in initiating the treatment for diagnosed TB patients, the programme has made the decision to provide allowance for use of mobile phones for the programme staff under Common User Group (CUG) facility. The STS/STLS will be provided Rs.300 per month and Rs.150 for TBHV/RNTCP laboratory technicians.

Strengthening urban health systems

In the interim period pending clarity on the NUHM structure, programme will continue to operate with its own delivery structure based on population norms. The PPM component will involve a combination of insurance, vouchers and incentives for appropriate and quality assured private laboratory diagnostic services and patient care.

Opportunities to further strengthen integration

Inter-sector coordination in the government departments: To further strengthen the integration of various ministries at Central and State level, a mechanism will be developed with the respective ministries to implement specific activities.

- Ministry of Women and Child Development
  - To strengthen the involvement of Aanganwadi workers as DOT providers
  - Regular screening of malnourished children at the Aanganwadis and nutritional rehabilitation centres for TB
  - To register chest symptomatics in their area
- Ministry of Labour
  - To promote workplace interventions
- Ministry of Consumer Affairs
  - To promote rational prescription of anti-TB drugs
- Ministry of Public Distribution System
  - To provide extra ration for TB patients on treatment
- Ministry of Telecommunication
  - To spread the message on TB during World TB day

- Ministry of Education
  - To conduct quiz or essay competitions in schools during World TB day
  - Screening of school children and provide information about TB. Also suggest ways by which TB discussions can be a part of the school health programme.

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

Increasing emphasis of RNTCP in quarterly review meetings: Currently BPMU conducts quarterly review meetings of all disease control programs along with paramedical and medical officers. The major focus of these review meetings is on RCH activities and RNTCP is provided only a limited focus. A quarterly review meeting with greater focus on the RNTCP during the review of National Disease Control Programs might be an option to strengthen implementation at the block level.

Leveraging NRHM linkages with private sector providers: NRHM has engaged the private sector for service provision in the reproductive child health services. The private practitioners/nursing homes could be utilized for all components of RNTCP in cases where facilities in the public health institutions are inadequate.

Facilitating private sector participation: The programme can pilot a voucher scheme. The vouchers will be given to the Medical officers of Primary Health Centre/Community Health Centres/Urban Health Centres/Urban Family Welfare Centres who in turn will provide these vouchers to patients who might require services at private facilities. The private facility will be reimbursed on production of these vouchers on a periodic basis through the BPMU.

Linking to social welfare scheme - Public distribution system: The MO-TC/DTO will submit a list of TB/MDR-TB patients below poverty line to the Block Development Officer on regular basis. This will enable linking these patients to receive additional nutrition through additional ration above the basic eligibilities.

Develop linkages with Integrated Disease Surveillance Programme **(IDSP):** The IDSP has IT enabled services located at the PHI level and daily reports to the district/state. The RNTCP may explore this idea to utilize these services.

10
Human Resource Development

Key Messages

- TB care and control services are becoming more complex and demanding, with multiple new tasks for MDR-TB management and TB-HIV care.
- An adequately staffed, trained, and motivated health workforce is required to achieve the ambitious TB control objective of Universal Access.
- The goal of RNTCP's HRD strategy is to optimally utilize available health system staff to deliver quality TB services, and to strengthen the supervisory and managerial capacity of programme staff overseeing these services.
- RNTCP will align more effectively with health system under NRHM to leverage field supervisory staff more effectively, and increase capacity building of the staff to equip them to handle multiple tasks of DOTS, MDR-TB, TB/HIV
- Support cells at states and district levels will be strengthened to increase administrative and managerial capacity, creating space for local programme mangers to focus on supervision and quality of services.

Abstract

Committed, qualified and trained health care providers equitably distributed at all levels are the foundation of an effective health system. In the context of TB it is important to remember that DOTS is human resource intensive which is premised on a strong patient-provider bond and extensive supervision and monitoring. The RNTCP established a separate HRD policy and HRD unit at CTD that has enabled it to function at optimal capacity. The programme has created standardized training modules for each component and customized it for each category of staff. As a consequence, several lakh of health care providers in the general health system have been trained in various initiatives of the RNTCP.

The main thrust of the RNTCP Phase II was the provision of diagnostic and treatment facilities at the peripheries of the district and the creation of a sub-district level supervisory unit, which would also provide diagnostic and treatment services. Accordingly, and based on the TB epidemiology of the country, Designated Microscopy Centres (DMC) were set-up for every 100,000 population (for every 50,000 population in tribal and hilly areas) and TB units were set up at every 500,000 population (at every 250,000 population for hilly and tribal areas).

Unprecedented programme expansion in the last five years has outpaced capacity at central, state and district level to ensure quality of services. A workload analysis highlighted the human resource gaps and categories of personnel working over capacity. Members of the staff at state and district levels have to perform multiple functions leading to increased workload and being overburdened. As a result training is often neglected.

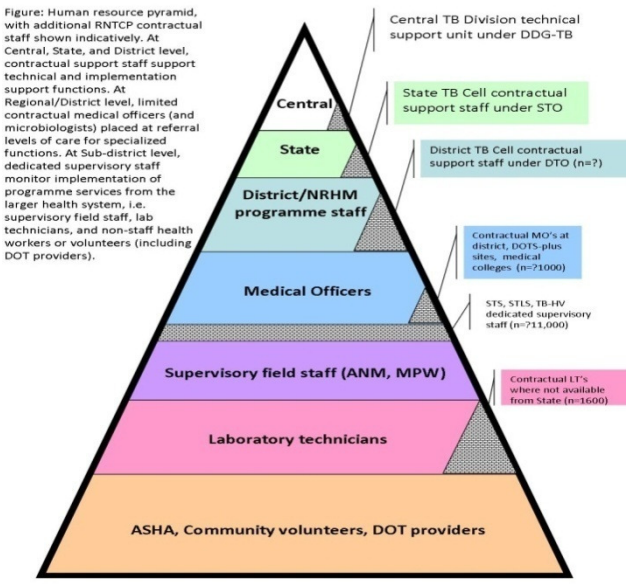
Not only that, new case finding, treatment, MDR, TBHIV, PPM, and ASCM activities required to achieve Universal Access over the next 5 years necessarily need a better approach to human resource development. Hence, there is an urgent need for national HRD planning that strategically and comprehensively addresses the overall staffing issues related to recruitment, capacity development, performance and retention.

The key strategies under the NSP-RNTCP are: to develop a comprehensive HRD plan based on needs assessment; strengthening programme management units at central, state and district level; leveraging NRHM structures for supervisory functions; engage the state general health system to address HRD issues; initiating comprehensive personnel management strategies; building strategic partnerships with stakeholders and strengthening capacity building. Ultimately, by aligning with the health system and strengthening programme management capacity to leverage and supervise the health system, the programme expects that Universal Access may become a reality.

Introduction

Health care providers, who are trained, competent, committed and, sufficient in numbers, equitably distributed geographically at all levels of health system are essential for the successful implementation of any programme. They determine how health resources are translated into effective health outcomes. Not surprisingly, they account for nearly two thirds of all recurrent health expenditure.

The diagram alongside is illustrative of the human resources available for TB control from the grassroots to the national level, both government and contractual.



Despite the importance of human resources in achieving programme outcomes, insufficient attention has been given to this area beyond training and personnel management.

Given the ambitious vision of achieving Universal Access to TB care, comprehensive development and management of human resources in RNTCP becomes critical. This chapter will detail the achievements, challenges and the proposed way ahead.

Achievements

The RNTCP structure for capacity building for DOTS implementation has allowed the programme to expand to full coverage and improved programme performance. This structure includes a HRD policy that envisages "having at all times adequate number of staff at different levels of the health system, who have the skills, knowledge and attitude necessary to successfully implement and sustain TB control activities based on the DOTS strategy, including the implementation of new and revised strategies and tools".

A clear HRD Approach: HRD for DOTS implementation is well reflected in the RNTCP guidelines. There is a separate unit at the CTD that looks at HRD with a separate national consultant. Functions of the State TB Cell, State TB Demonstration Centre, and TB Unit team, national and intermediate reference laboratories, the Medical College Task Forces and core committees are well spelled out. The responsibilities of State TB Cell staff, district-level staff and PHI staff are clearly defined. Over years many initiatives has been taken to ensure adequate contractual manpower to support the general health system in managing TB control activities. Remunerations have been revised from time to time also increment policy is implemented. Non financial incentives like awards on World TB Day have created a motivated workforce. Preference for candidates with experience of working for TB Control for higher positions has further motivated the peripheral hired staff giving them career pathways.

Extensive Capacity Building: Standardized materials and schedules for initial training in DOTS in RNTCP, EQA, TB/HIV, Culture and DST, and initial training for medical college staff, as well as schedules for retraining, have been developed. Skill development appropriate for the task matrix of different cadres of staff has been the central theme while developing training curriculums. There is ongoing work to develop training materials for new initiatives including MDR-TB modules and training modules. These training modules have undergone periodic revision based on need to reflect revised policies and recommended practices. RNTCP has been appreciated by several joint-monitoring missions for its attention to creating standardized training modules for each programme component and customized for each category of staff. It's to the credit of RNTCP that several lakh of health care providers in the general health system have been trained in various initiatives.

Challenges

Unprecedented and exponential programme expansion in the last five years has outpaced capacity at central, state and district level to ensure quality of services. Implementation of all components of the Stop TB Strategy has posed major challenges to all aspects of HRD. This is particularly the case for management of MDR-TB. The same rigorous framework that was used earlier during the expansion of RNTCP to new districts (e.g. listing of functions of all staff categories involved, training material with standard schedules for the respective staff categories, standard procedures for appraisal etc.) is being developed and deployed to achieve nationwide scale up of the management of MDR-TB. However, this has led to increased workload for existing staff and shifting of attention from the quality implementation of basic DOTS services. This is not desirable and needs to be addressed carefully. It calls for a major strengthening of the programme management units at central, state and district levels both in terms of increased staff and increased capacity.

Need for increased integration with NRHM

Service delivery for TB care has been integrated with General Health System from the beginning. However due to certain aspects of programme like independent financial and supervisory structure of RNTCP has resulted in perception of vertical programme by some. The general health system staff at times does not take ownership of TB service responsibilities. Hence, it is left to the insufficient number of contractual supervisory staff who is overburdened with health system responsibilities.

A major part of the problem with integration has been separate programme structures at sub-district level, especially the TB Unit system of basic programme management units. These discrete systems were acceptable when RNTCP started off. This is because there was no functional alternative, but in the current context the TU structure of RNTCP has hindered the progress of integration with the growing NRHM. The Block Medical Officer today has the responsibility for effective local implementation of all national disease control programmes – except for TB.

Alignment with NRHM Block Programme Management Units (BPMU) and its supervisory structures has the potential of leading to greater ownership and review of RNTCP by the general health system.

Staffing Challenges

Staff shortages at all levels remain a major concern, which will be accentuated, with the scaling up of the management of MDR TB. There are vacancies and high turnover and problems related to retention at all levels, in both RNTCP contractual staff positions and the general health system persist. Staff motivation is variable, and health system deficiencies are affecting motivation.

Staff at state and district levels often performs multiple functions that increase their workload. Achieving Universal Access means an increased attention to PPM and ACSM activities that are currently not within terms of reference of existing staff. Adding responsibilities would further stretch the already fragile work force. A detailed workload analysis done by an independent agency through a variety of methods like time-task analyses, time utilization observations, record review and interviews confirmed this concern and quantified the burden for some categories of staff. The study found that STS were already working over capacity and to achieve Universal Access objectives, nearly three STSs (or full time equivalents) would be required. The part-time accountant was almost working full time and study recommended a full time accountant in every district.

Further, there is no formal system for performance evaluation, particularly for contractual staff, with a linked incentive system. The salaries are low and those of the contractual staff have not been increased following the recommendations of the 6th Pay Commission. Allowances for training differ between programmes (NRHM and HIV/AIDS in particular). The incentive packages for staff working in tribal and other difficult areas (recruitment and retention) are insufficient.

Training challenges

The managerial capacity at district and state levels (including training, planning and implementation) is insufficient. Training activities are included in the state and district plans; however, they are rarely linked to the needs based on the data from routine reporting. They also lack priority setting and long-term planning. Training activities are always the first to be postponed and/or modified when staff with training responsibilities, are overburdened. In most states, there are no plans for update/refresher training, i.e., training on new issues and training for staff that were trained a long time ago in districts that implemented RNTCP early. The quality of training is not routinely assessed, with poor adherence to recommended methodologies, schedules, batch size, ratio of facilitators to trainees, and limited evaluation. Supervision is rarely linked to follow-up training, or is used for identification of retraining needs. The training needs are only going to grow with new initiatives being proposed for implementation.

Need for comprehensive HRD planning

The failure to address HRD comprehensively now seriously threatens the gains made so far, and are proving to be serious bottlenecks in effective programme

implementation. These must be addressed in order to successfully deploy more complex MDR-TB services nationwide. It is unrealistic to expect progress towards Universal Access unless HRD-related issues are addressed with deserved urgency. Long-term management issues related to recruitment, performance, retention, reducing vacancies and rotation, as well as capacity building, all require strategic and comprehensive planning and vigorous efforts to implement and increase resources.

Strategic Vision for 2012-17

RNTCP is now entering a new, more complex phase as it tries to achieve Universal Access and aim for nationwide scale-up of MDR-TB services and improved engagement of the private sector. In line with the Universal Access objective, the HRD vision for the next five years is to move to a situation where every person in India has access to a motivated and supported health care worker who is skilled in TB control.

The ultimate goal of HRD for comprehensive TB control is to have the right number of people, with the right competencies (knowledge, skills and attitudes), in the right place, at the right time, who are motivated and supported to provide the right services to the right people.

To this end, RNTCP will align more effectively with health system under NRHM to leverage its staff effectively, and focus on building its capacity to equip it to handle multiple new services related to Universal Access. In turn, the programme support cells at states and district levels will be strengthened to increase managerial and technical capacity, which will be better equipped to guide health system staff in their implementation of TB control services.

The key activities are:

1. To develop a comprehensive HRD plan based on needs assessment to achieve Universal Access;
2. Strengthening of programme management units at central, state and district levels;
3. Engaging state general health systems to address HRD issues;
4. Evidence based realignment of human resources under RNTCP with the supervisory structures under NRHM;
5. Moving towards comprehensive personnel management (including retention strategies, performance appraisal management systems with incentives linked to performance);
6. Building strategic partnerships with all stakeholders for health workforce development;
7. Continue to strengthen existing capacity building initiatives.

Activities

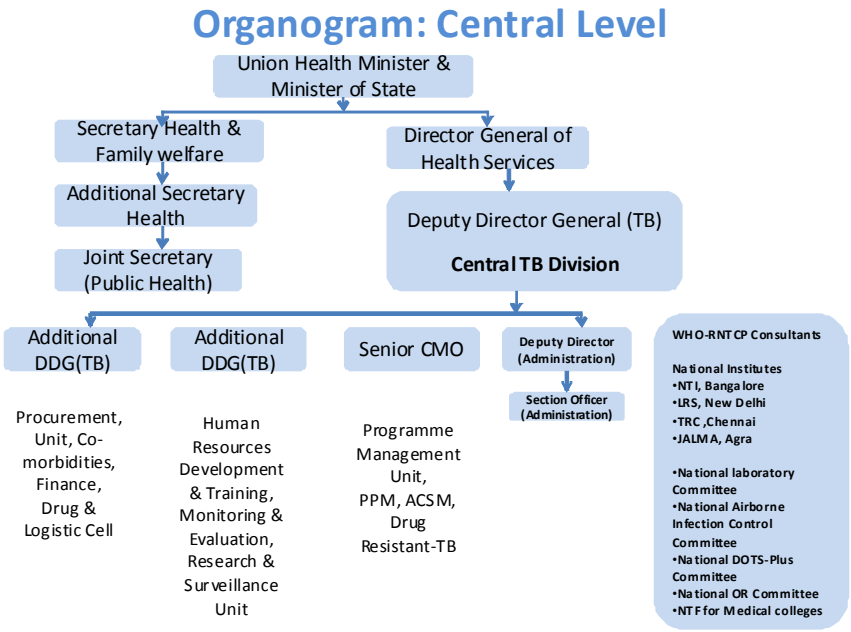
To develop a comprehensive HRD plan

A medium to long term strategic plan for all aspects of HRD for the implementation of the Stop TB Strategy with subsequent annual implementation plans would be developed. This plan would be based on evidence generated by an independent assessment of HR needs in order to implement the strategy to achieve Universal Access. The HRD consultant along with the nodal officer for HRD at CTD would be leading this process. This would guide all further reforms envisaged under HRD.

Strengthening programme management units

A phased, progressive decentralization taking into account the preparedness of individual states was initiated under RNTCP II and will continue in the next five years. The objective is to enhance the capacity of the states to take full ownership through planning, executing and supervising RNTCP activities. Decentralization will cover the planning, programmatic, financial, and logistics management and will assign the state a greater role in these areas. The strengthening of the State TB Control Unit and the District TB Control Unit or their equivalent has been initiated to prepare them for increased responsibilities.

Strengthening CTD:
Central unit (CTD) continues to focus on capacity building of states, technical expertise, policy formation, lesson sharing, monitoring and evaluation.



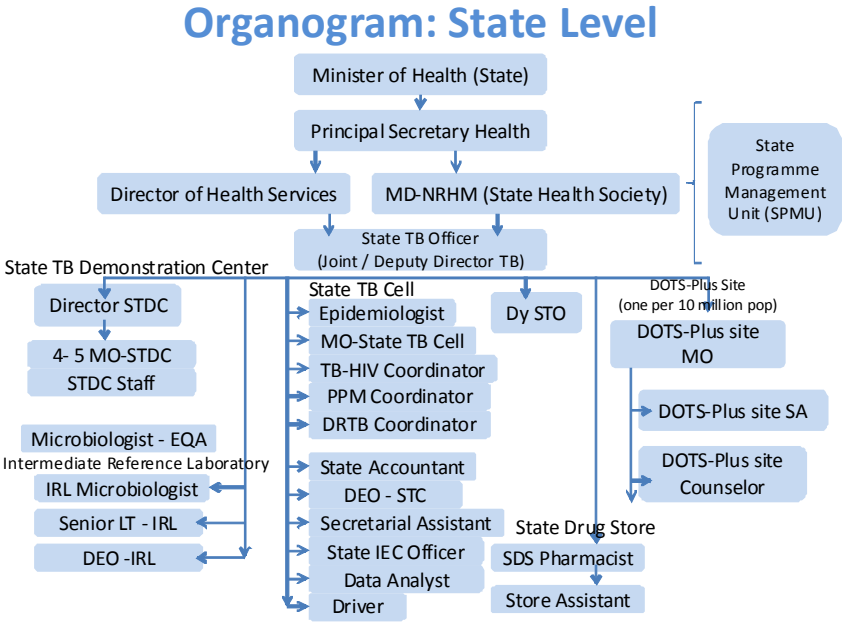
Reorganization: Under the RNTCP Phase II, the following 5 functional units were created – Monitoring & Surveillance Unit, Procurement & Supply Management Unit, Advocacy & IEC Unit, Finance Unit, and HRD/Training Unit. These will be re-organized into 3 divisions – Procurement & Supply Management, Finance and Contractual Manpower Management Division, Programme Management Division, and Division for supervision, monitoring, evaluation and HRD.

Human Resource: Besides the Programme Manager and 3 Deputy program managers, the central unit is supported by 10-12 RNTCP Technical Consultants (supported by WHO and the Union). In addition, under the World Bank project and

the earlier GFATM projects contractual Finance Consultants, Accounts Officers and Secretarial staff/DEOs have also been recruited to support the programme. Even with this, the capacity is stretched and grossly insufficient. JMM has repeatedly recommended establishing at least six new regular posts of zonal medical officers in CTD for supervision and support, or the Government of India to contract staff for this purpose. Since establishing regular positions takes a long time, efforts will be made to contract staff as a short-term solution. Considering the scale of activities in the next five years and need for efficient financial and programmatic management and reporting, the staff under earlier grants would be continued and would be strengthened by recruitment of additional technical officers for each programme component. Considering the uncertainties in continued funding of the RNTCP technical consultants by WHO and the Union, it is proposed to appoint contractual technical consultants for each of the above described programme components.

Strengthening State TB Cell: State TB Cells within the State Health Societies have been provided with equipment, infrastructure, contractual staff and training, to support these activities under the earlier project.

Increased Responsibilities: With an increase in scope of RNTCP and introduction of PMDT services, expansion of TB/HIV activities, invigorated PPM activities with revised schemes and IMA and CBCI sub-project, and need for improved programme monitoring and surveillance, it was considered essential to further strengthen the State TB Cell. The JMM also suggested that similar functional units as the ones created at the national level be created within State TB cell.



Strengthening State TB Training and Demonstration Centres: Provisions had been made in the earlier phase for up-gradation of the State TB Training and Demonstration Centres (STDCs) to enable them to support the State TB Cell (STC) in programme management. Not all states currently have STDCs and many of the already existing STDCs are unable to carry out all the expected activities because of staff vacancies and/or non-utilization of funds. Therefore, an alternate concept has been considered to ensure that the functions of the STDCs are

available to the STCs. If the states identify monitoring and training units, and a laboratory in an already existing institution/facility in the state, then these could be considered as alternatives to having an STDC. The idea is to utilize the entire existing state-level infrastructure in support of the RNTCP, which may also have advantages of easier maintenance and more flexibility in planning and implementation of the various activities.

Capacity building of the State TB Training & Demonstration Centres (STDC) will be undertaken. The state will post epidemiologist, microbiologist, training coordinator, statistician and lab technicians as specified under the 'STDC guidelines' of RNTCP and conduct activities related to training, monitoring and evaluation, operational research, sputum microscopy external quality assurance, drug resistance surveillance and operational research.

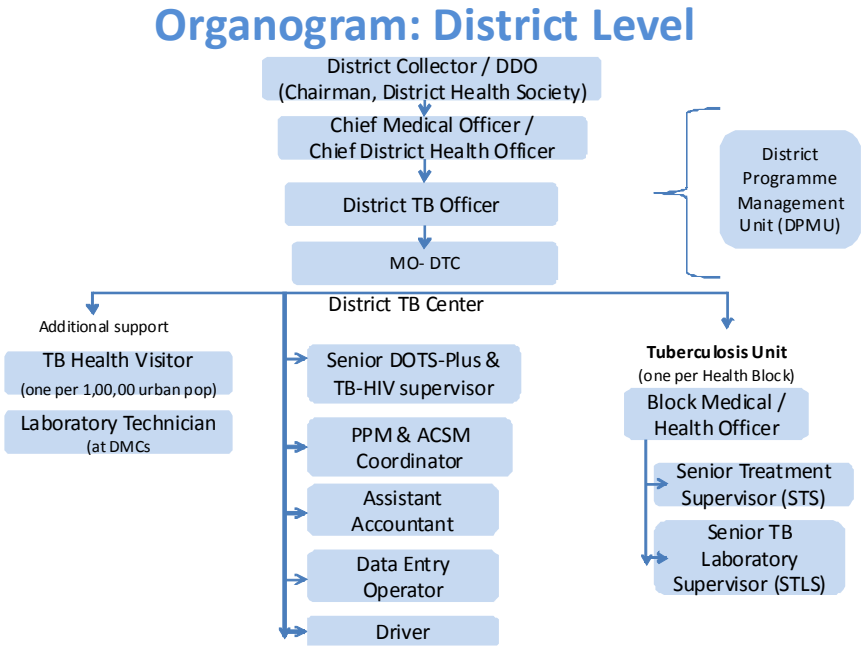
Additional Staff: In the next phase, in addition to the existing contractual staff[1] each state would be provided a DR-TB co-ordinator to monitor the scale-up of DR-TB services. With discontinuation of the special position of WHO TB-HIV field consultant in high prevalent states, it is proposed to provide all states with a TB-HIV coordinator. The post of TB/HIV coordinator is proposed to be improved to a 'Specialist' rank (MD – Community Medicine/Public Health/Medicine) to ensure highest level of technical support to the states. Another position to lead the PPM initiatives in the state, called 'PPM co-ordinator' would be created.

The states will continue to be entirely responsible for financial management of the project. Funds will be released through State Health/TB Control societies. States will continue to have the authority to reallocate 100% funds amongst districts and heads based on requirement. State will continue to have flexibility to start up to 10% additional TU/MC as required and justified by local and regional demand.

District Strengthening:
The setting up of District Health Societies has ensured that the district administrative leadership is fully aware of the functions of the DTC and its activities. Since, the health system is already stretched due to shortage of staff, District TB Officers are expected to take up multiple roles reducing dedicated attention to RNTCP. Districts without dedicated full-time programme managers would not be able to cope with planned scale-up of existing and proposed activities. Hence, it is proposed to provide a district programme co-coordinator to assist the DTO, freeing the DTO to focus on the technical supervision and monitoring for the RNTCP.

[1] (Assistant Programme Manager/Epidemiologist, Medical officer at State TB Cell, TB-HIV Coordinators, Urban TB Coordinators for million plus cities, Microbiologist for IRLs, IEC Officer, DEO, Accounts Officer/ Accountant, Secretarial Assistant, Pharmacist/Storekeeper for State Drug Store and Driver)

District contractual staff provision includes: STS/STLS; 1 TB Health Visitor for every 100,000 urban population; 1 DEO per DTC; 1 full-time accountant per district; senior DOTS-Plus and co-ordinator drivers for those limited areas that have vehicles procured under RNTCP. To ensure



continuous staffing of critical positions at district and sub-district levels, additional contractual appointment is allowed (from state) for up to 20% laboratory technicians (up to 40% in Bihar, 30% in Orissa and 50% in Uttar Pradesh, as approved under RNTCP Phase II) and 20-40% medical officers at District TB Centre without seeking approval from the centre.

To strengthen and address the challenges mentioned above, it is proposed to align TB units under RNTCP with the supervisory structure of BPMU under NRHM, with the programme officer at BPMU in-charge of supervising RNTCP activities as well. This would require scaling up of the number of treatment supervisors (STS) at the rate of 1 per 1.5 to 2.0 lakh population and realigning their terms of reference to visit private sector health facilities and register cases diagnosed and treated in private sector. This would reduce the number of patients to be monitored per supervisor and is expected to improve treatment outcomes. Keeping in view the increased focus on PPM activities, it has been proposed to create an additional position of PPM/ACSM co-ordinator at district level.

Revision of remunerations for contractual staff: In addition to the staff positions, the programme proposes to raise the contractual staff salaries in line with recent increase in salaries in the government sector, to ensure parity of pay structure across all programmes (NRHM, HIV, Malaria etc.), and more importantly to attract and retain good staff in key positions. This is critical to maintain the morale of the staff and avoid movement of critical staff across programmes/projects. JMM 2009 recommended that, the salaries of contractual staff should be at par with the increases made in the 6th Pay Commission for other staff. Though not to that scale, the details of the revisions proposed are specified in Finance chapter. Also given the fact that most of the staff have been in their positions since 2005-06 and had been receiving a performance based annual increment of 5%, their consolidated salaries have been revised. Proposed changes

in salary and new staff positions would be applicable across the country irrespective of source of funding.

Performance management system: A system would be developed to systematically assess performance for all contractual staff against pre-decided deliverables. This is expected to provide objective criteria for contract renewal and enable linking incentives and allowances to performance. This process would also enable identification of non-performance at an early stage that can lead to early corrective actions and need-based capacity building.

Engaging the state health systems

Since RNTCP is implemented through the state health systems, the states contribute significantly to RNTCP in terms of human resources and man-hours. Hence, it is crucial for the RNTCP to monitor and assist states in optimizing HR management. To overcome the multiple human resource constraints (rapid turnover, lack of training, unfilled contractual vacancies staff not being posted at the required stations, and of lack of information on availability and training status of staff, the CTD would adopt the following strategies to ensure optimal utilisation of available staff:

- **Advocacy:** CTD will advocate with state authorities to support TB control as a critical health priority focusing on issues related to recruitment and retention in remote areas as well as additional HRD needs for MDR-TB management. CTD will request states to increase regular staffing of the State TB Cells and STDCs.
- **Monitoring:** CTD will discourage multiple assignments and frequent transfers of key staff such as STO, DTO and MO-TC. The centre would regularly take up the issue of filling of vacant posts with the states ensuring less than 10% of vacancy in key posts. Similarly, trained DTOs/MOTCs would be advised to be transferred, if required, to similar posts in other districts so that their training and technical skills in RNTCP are not wasted. Such advocacy with states would be continuous and ongoing.
- **Planning:** It will be incorporated in the recruitment guidelines that the health societies should maintain “waiting lists” for a period of at least one year for contractual posts after selection for any given post. This will facilitate speedy filling up of a post if it gets vacant.
- **Retention:** Strategies for staff retention and increased motivation would be explored and implemented including performance based reward system, non-monetary incentives linked to better performance, differential remuneration and incentives for staff working in rural and remote areas.

Leveraging the resources under NRHM

As described earlier, the existing TB units would be realigned to the existing health blocks under NRHM which envisages that the supervisory structure existing under NRHM in the form of a BPMU with the programme officer would be used to supervise RNTCP implementation at sub-district level. The BPMU programme officer (BMO/BHO) would replace the MO-TC and all the RNTCP staff would work under his/her guidance. Further coordination with NRHM would be strengthened

for training, motivation and retention of peripheral Health workers. NRHM mechanisms would also facilitate further capacity building of ASHAs and Community Health Volunteers in delivering TB services in remote areas.

Building strategic partnerships for health workforce development

External technical support to RNTCP is currently provided by WHO through a team of RNTCP consultants both at the central and field level throughout the country. Currently, a network of 100 medical consultants of which 10 are located at CTD while 90 are field consultants support RNTCP. At the field level the WHO external technical assistance facilitates the smooth implementation of the programme and helps in improving the quality of services through assistance in training, planning, monitoring and surveillance. In addition, the monitoring provided by WHO team is an external validation mechanism at the field level for CTD.

Technical support would continue to be required as the programme scales up new initiatives and sustains the quality of existing initiatives in the coming years. The WHO team will continue to provide external technical support without getting involved in the direct implementation of the programme. Technical assistance will be focused on state-level planning and operations, especially MDR-TB service scale-up, planning for new interventions, operational research, improving surveillance, and support for supervision and monitoring of district activities. The national technical assistance team will work closely with the CTD and the local programme officers, and will be accountable to DDG-TB and WHO-India. The direct reporting of the team to the central level will ensure their independent technical advisory role at the state and district levels.

CTD would assess the need and explore opportunities with all stakeholders to strengthen technical support to RNTCP. Other organizations like The Union, FIND, and PATH etc. are also providing technical support in various new initiatives. The role of the WHO and other partners in providing support would be constantly evaluated depending upon the need and stage of the programme.

Strengthened capacity building

The training plan would ensure ongoing timely, need-based, training for new and existing staff. The trainings planned include: initial training of all newly placed staff; re-training of some health staff, when major performance problems are identified based on assessments and training on new initiatives. It is envisaged that at least 5% of the staff would need to be retrained every year. This also includes ongoing training of staff, resulting in sustained proficiency by the end of 5 years. Update training would involve training (when required) key staff on new initiatives that are being incorporated.

Strengthening of training institutes:

Currently, there are three central level institutions involved in imparting training to the master trainers - National TB Institute (NTI), Bangalore, Lala Ram Sarup Institute of TB & Respiratory Diseases, New Delhi, and the TB Research Centre (TRC), Chennai. In addition to strengthening these institutes, the RNTCP will explore opportunities to involve other public health institutes, medical colleges and

training institutions, which can be used as training centres. To strengthen the existing institutes, it is proposed to provide two additional staff members who would function as full time trainers for RNTCP. Also, regular training assessments would be conducted for continuous improvements. CTD will continue to support and further strengthen the activities of STDCs (including advocating with the states to have a nodal HRD person at the state level as a focal point accountable for all HRD related activities.

Revision of modules: Training materials for both induction and in-service training, maintaining the existing standardization of training materials, with detailed instructions will be provided to the states/districts. The financial guidelines for organizing such trainings have been altered and revised norms are proposed in the Finance chapter.

With possible introduction of new drug regimens, novel diagnostic tests, improved use of communication technology in delivering treatment services the need for revision of technical and operational guidelines and training manuals would happen continuously. Once the nationwide scale-up of the special activities has been achieved, the training modules need to be integrated so that the need for stand-alone and component specific trainings is eliminated.

11

Advocacy, Communication and Social Mobilization

Key Messages

- Advocacy and communication initiatives can generate demand leading to earlier diagnosis and correct treatment.
- Community ownership, participation and involvement are essential to achieve the goal of universal access.
- Enhancing the ACSM capacity of service providers will improve the quality of service delivery.
- ACSM can reduce stigma which is critical for universal access.

Abstract

The overarching goal of the programme in the next five years is universal access to TB care. To achieve the same, ACSM will be used to increase demand for early diagnosis and treatment and simultaneously improve standards of care. The demand will be created by focusing on audience based targeted interventions and community mobilisation. Existing community structures will be empowered to identify suspects, facilitate referrals, provide patient support and effectively supervise DOTS provision in order to increase adherence and treatment completion. On the supply side the focus of ACSM will be on the provision of quality care through multiple-stakeholders such as all care providers, media/journalists, policy-makers, NGOs, community based and faith-based-organizations. Partnership with civil society is crucial and will be enhanced based on already established models to all districts in the country. These initiatives will increase community support for TB care, reduce stigma and augment demand for quality services there by playing a significant role in achieving universal access.

An evidence-based and focused communication strategy will be adopted with an aim to increase the demand for TB control services through synchronized communication at the mass media, mid-media and the inter personal communication levels. The underlying strategic approach of the NSP will lead to changes based on audience segmentation. The periodic review of the ACSM strategy will identify areas that require strengthening.

Introduction

Advocacy, Communication and Social Mobilization (ACSM) is an important component of the TB control strategy to ensure long-term and sustained impact. Advocacy seeks to ensure that there is strong commitment for TB control; while policy advocacy informs politicians and administrators how an issue will affect the country and outlines actions to take to improve laws and policies, programme advocacy targets opinion leaders at the community level on the need for local action and media advocacy validates the relevance of the subject, puts issues on the public agenda, and encourages the media to cover TB-related topics regularly and in a responsible manner so as to raise awareness of problems and possible solutions. Communication aims to favourably change knowledge, attitudes and practices among various groups of people. Social mobilization brings together community members and other stakeholders to strengthen community participation for sustainability and self-reliance. Although distinct from one another, advocacy, communication and social mobilization (ACSM) are most effective when used together. ACSM is a supportive strategy that focuses on all aspects of TB care for ensuring quality in diagnosis and treatment interventions, strengthening social support systems for TB care and community interventions to reduce stigma. Major challenges in TB care and control in the country include delay in diagnosis-both patient and system delay, lack of awareness on diagnostic services, social stigma leading to further delay in reaching RNTCP

facilities for TB care and challenges in treatment adherence due to lack of patient counselling and social support. Universal access to TB care calls for early and complete case detection. Thus ACSM activities should focus on improvement in early identification of symptoms of TB and referrals from community aiding in early case detection, support for treatment adherence; combating stigma and discrimination; people's empowerment; mobilizing political commitment and capacity building for decentralised planning.

The potential of ACSM has not been realized

Though modest achievements have been made in TB ACSM, the full potential of the initiative remains to be explored. The visibility and the gravity of the TB epidemic is not grasped beyond RNTCP. The lack of prioritization of TB adversely affects potential private sector involvement in the programme, as well as commitment of funds to NGOs and other RNTCP ACSM activities at the national, state and district levels.

This chapter begins with a discussion on the achievements made under RNTCPII, followed by the articulation of the key challenges that still remain. Following this the strategic vision for 2012-2017 is discussed. The chapter concludes with an activities section, given that there still remains a lot of ground work to be done in regard to ACSM. The activities section enlists the priorities as well as the mechanisms to be developed and strengthened to realise them. Finally the key initiatives necessary to achieve this vision are outlined.

- Increase demand for early diagnosis and treatment.
- Improve referral from communities for case detection, community support for case holding.
- Increase ownership by the community.
- Combat stigma and discrimination and empower people affected by TB
- Increase capacity of health providers and front line workers to deliver ACSM messages
- Mobilize political commitment and resources for TB
- Increase capacity for prioritizing TB in health planning, at the grass root level of Panchayati Raj

Achievements

1. RNTCP has a well-conceived ACSM strategy in place. From the beginning of the programme ACSM had a place in the planning and monitoring process under the programme. There is a dedicated IEC resource center in the programme website with relevant communication materials in various languages for local use. The programme commissioned a number of studies on knowledge, attitude and practices (KAP studies) and social and environmental assessment studies such as impact Assessment of

RNTCP II communication campaign on KAP of target Audience, Social Assessment Study done by ORG Centre for Social Research (ORG), Environmental Assessment Study, Study on Accessibility and Utilization of RNTCP by SC/ST, conducted by IIHMR, Study on Accessibility and Utilization of RNTCP by women conducted by Administrative staff College of India (ASCI), Study on Accessibility and Utilization of RNTCP by PLWHA conducted by ORG, http://www.tbcindia.nic.in/pdfs/Baseline KAP Study under RNTCP Project - CMS.pdf and Mid term and End term KAP studies, Centre for Media Studies. The reports of these studies are available in http://www.tbcindia.nic.in/documents.html#

2. Having succeeded in establishing DOTS as sure cure for TB , the current extension branding of the logo –"Pura Course Pakka Ilaaj" takes communication to next higher level – focussing on treatment adherence.

3. RNTCP has dedicated human resources at State and district levels; there are State IEC Officers assisting programme officers in planning, implementation and monitoring of ACSM activities, while a cadre of Communication facilitators from NGOs have been provided to districts for supporting district programme managers in ACSM activities.
4. RNTCP annual action plan incorporates sections on ACSM and has separate state level quarterly reports on ACSM activities apart from reports on patient provider interaction meetings and community meetings in the quarterly programme management report.
5. Substantial efforts have been made towards capacity building of programme managers, state IEC officers and communication facilitators in ACSM with dedicated national, regional and state level ACSM trainings and workshops. Module on interpersonal communication skill have been developed and used for training peripheral health workers on IPC skills. ACSM module is incorporated in all health workers training on basic DOTS. To update the technical and operational aspects of the programme a revised training module has been prepared for the private practitioners. A patient information booklet (PIB), in simple terminology, has been developed to help patients learn about TB. This is also provided to the private practitioners.
6. Dedicated media management agencies have been hired by GOI for developing mass media campaigns and various mass media tools such as TV spots were developed and used.
7. A large ACSM project under GFRound-9 is being implemented in the country in a phased manner to cover 374 districts called Project Axshya, with an overall objective to increase the reach and visibility of RNTCP. Under the dual track financing mechanism available in the Global Fund, the RNTCP was awarded a grant in Round 9 along with two other principal recipients – the International Union Against Tuberculosis and Lung Disease (The Union) and World Vision India. While the Government of India component of this grant addresses expansion of diagnostic and treatment services for drug resistant TB, the component managed by the two civil society principal recipients address advocacy, communication and social mobilization in 374 districts across 23 states and union territories in India. A wide variety of interventions have been implemented through this

project since 2010 and show promise to expand the reach of RNTCP to all sections of the population. This grant will cover the period from 2010 to 2015.

Challenges

1. Though there have been various efforts from the programme to expand visibility to RNTCP, the threat of TB to the community is not yet effectively understood by public at large and decision makers. The reasons include suboptimal advocacy at all levels, lack of brand ambassador, minimal social mobilization activities etc.
2. One of the major challenges is poor implementation of existing strategy at field level, both for communication and social mobilization. States are not adapting generic material to local language and in apt cultural context. There are also issues with printing sufficient quantity of these materials for use in the field.
3. Community institutions and FBO/NGO's not engaged enough in awareness generation or case-finding or TB service demand creation.
4. At implementation level there is inadequate audience segmentation, particularly for special populations at high risk for TB. The RNTCP ACSM strategy has limited understanding of the appropriate communication strategies for specific populations such as tribal, urban slums dwellers, migrants and other special populations. This is a critical challenge since access to RNTCP and other health facilities is limited for many of these populations. These marginalised populations are poor and access to healthcare is often through unqualified village doctors or 'quacks'. Daily labourers are unable to access state provided health services because of fixed timings of health facilities. In the urban context stigma could be one factor inhibiting access and treatment in large workplaces.
5. Most of ACSM activities are limited to special events like World TB day. ACSM activities are often conducted on an ad-hoc basis without proper planning and participation of all required stakeholders and are currently focused on World TB day activities.
6. Existing partner-driven ACSM activities are missing out on half the country as project Axshya will cover only about half of the districts.
7. Lack of involvement in TB ACSM by cadres of general health staff dealing with ACSM is another reason for non-alignment with general ACSM structure in the health system. Peripheral health staff who deals with all programmes at field level tends to give less attention to TB ACSM due to priority issues. The auxiliary health workers are the health care providers - mainly female health workers operating within different national health programmes. Their workload is broad; their lack of interest and involvement in TB ACSM may also be due to smaller budgets for ACSM related training and lack of any IEC materials for patient-provider inter personnel communication (IPC). Other auxiliary workers operating within different departments of the health and social welfare system are Anganwadi workers (AWW) and Accredited Social Health Activists (ASHA). Although coverage by these auxiliary workers is considerable, their involvement in TB ACSM is relatively limited as a result of competing priorities such as maternal and child health, nutrition, malaria and other social issues.
8. There is a general lack of in depth understanding on strategic planning in relation to ACSM and currently there is general lack of direction in ACSM

planning, development, implementation and evaluation. This makes it difficult to show the impact of ACSM on the programme and return on investment.

Strategic Vision for 2012-17

Key vision for TB control is for achieving universal access, ie all TB patients in the community to have access to early and good quality diagnosis and treatment services in a manner that is affordable and convenient to the patient in time, place and person. All affected communities must have full access to TB prevention, care and treatment including women and children, elderly, migrants, homeless people, alcohol and other drug users, prison inmates, people living with HIV and other clinical risk factors. (ref. htpp://www.tbcindia.nic.in/pdfs/Universal_accessto_TB_Care.pdf). In order to achieve the universal access, ACSM strategies will complement every other programme initiatives. ACSM strategies will be used for better demand generation for early diagnosis and treatment as well as for improved supply of quality care. Major components of the strategy are:

1. Advocacy for administrative and political commitment, and to keep TB control high on health and development agenda
2. Communication for demand generation and stigma reduction. Audience-segmentation, targeted behaviour-change interventions and community mobilization will be focused to increase demand
3. Community ownership and mobilization for case finding and support of TB patients. On the supply side, multiple-stakeholders including various groups of health care providers, media, policy-makers, NGOs, CBOs, FBO, other vibrant community groups, local self-governments etc, will be targeted for improved provision of care

Activities

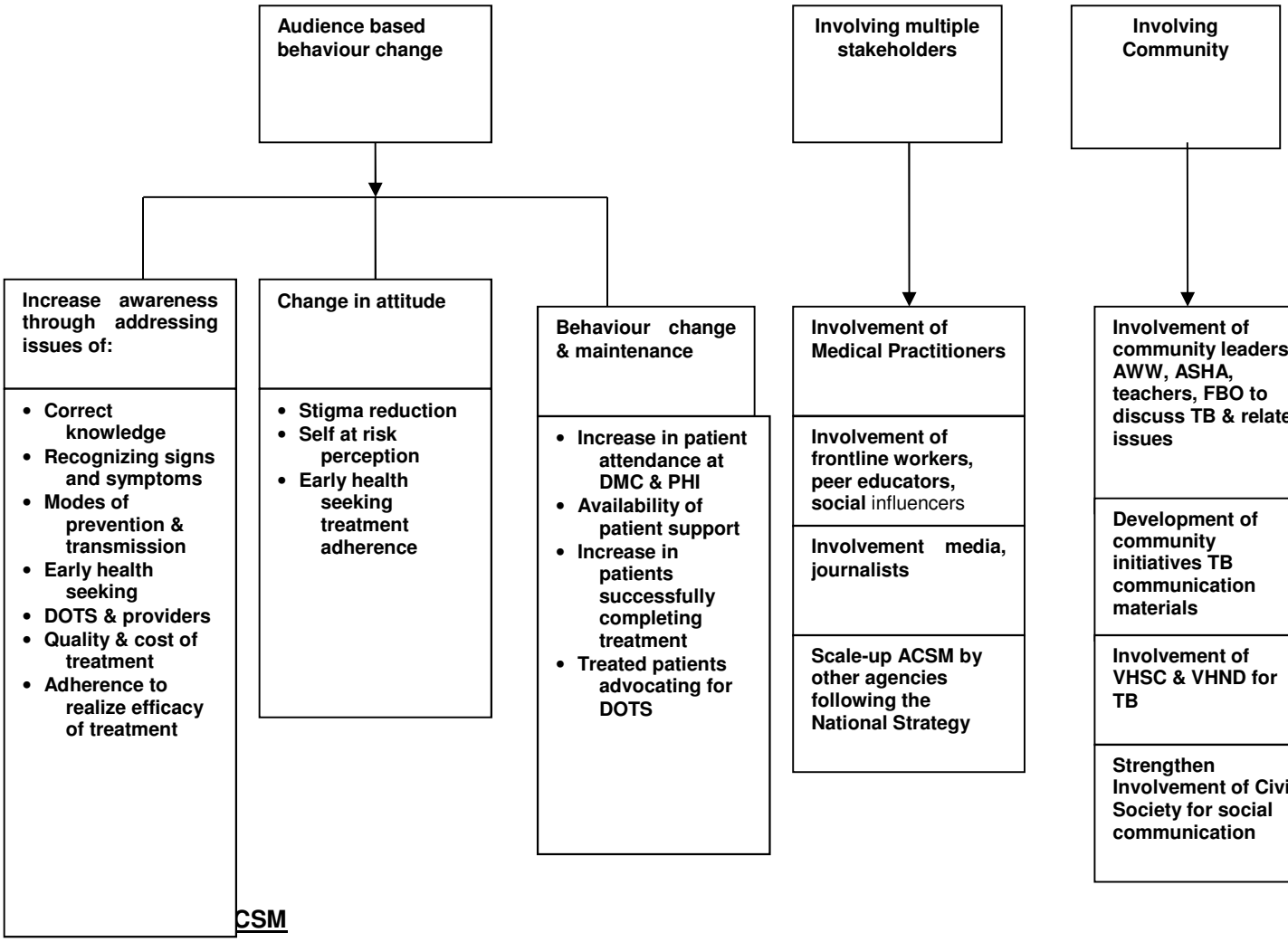
Activities are broadly classified in to two groups

1. For greater demand for early diagnosis and treatment, improvement in the health seeking behaviour through empowered community structures and other stakeholders, using evidence based BCC strategies will be adopted.

2. For ensuring supply of quality assured diagnosis and treatment, enhancement of political will and commitment of policy makers at national, state and community level will be focussed. This will be achieved by effectively engaging with other stakeholders including media, NGOs, patient support groups etc to support advocacy and communication.

The diagram below is an illustration of the broad strategy that would be adopted for designing activities.

Strategic Approach to plan activities



This will follow the planning cycle of RNTCP with need assessment - designing specific interventions, implementation, monitoring, evaluation and remodelling based on evidence as and when required.

Stage 1 – Planning

- Conduct participatory stakeholder consultations with donors, government, civil society and the private sector.
- Conduct formative research with target groups and rapid assessments to identify risk settings for a comprehensive situational analysis.
- At State and district level utilise ACSM sub-committee and district ACSM staff for coordination of ACSM campaign planning, development, implementation and review.
- Develop ACSM planning documents – creative communication and market research briefs.
- Produce inclusive, participatory district implementation work-plans that include need assessment, work plan, delegated agencies, timing/phasing considerations and adequate budget.

Stage 2 – Development

- Conduct relevant training programmes and capacity building to ensure effective community based ACSM programme delivery. Out-sourcing of

services as required for training, capacity building, community based advocacy, media production and dissemination, monitoring and evaluation need to be explored where ever required
- At National level develop creative communication messages and creative concepts for activities and materials.

Stage 3 - Implementation
- Amend and produce ACSM tools in accordance with ACSM sub-Committee recommendations and disseminate these through District, NGO and community networks.
- Execute supporting multi-media umbrella, media advocacy and integrated range of community-based activities
- Link with health system ACSM personnel for supervision of implementation.

Stage 4 - Monitoring Evaluation
- Integrate ACSM Monitoring and Evaluation system with specific input, process, output, outcome and impact indicators in RNTCP M&E system
- Develop market research brief for tendering of qualitative (focus group) and quantitative (pre and post intervention) research and integrate within Monitoring and Evaluation Framework.
- Measure behavioural determinants through KAP (knowledge, attitudes and perceptions) studies.
- Conduct operational research in the areas of ACSM to generate data for problem solving and decision-making.

Implementation Priorities and maximising impact

Priority1 - Adopt targeted interventions: Adopting the 80/20 rule, i.e. 80% of ACSM efforts diverted to 20% of the poorest performing TU in every district.
- Advocacy through PRI, SHG and other community groups to strengthen community commitment for TB care and control
- Community meetings with various vibrant groups in the community during World TB Month (March- April) to create community support groups for TB care.
- Advocating with the community to support contact tracing and tracking family contacts of smear positive TB in the community.
- Advocacy with the private sector to adhere to the International Standards for TB care and notify all TB patients treated in the private sector
- Strengthen sputum collection and transportation system using community support groups to address accessibility issues.

Priority 2- ACSM programme management: The establishment of a participatory ACSM programme management is critical to the long-term success of the programme. Once an effective management structure is in place and functions effectively at the state level, the structure can be replicated at the district and eventually, sub-district level. This will require organizational development to integrate the range of ACSM and IEC personnel currently operating within RNTCP and the health and social welfare departments.

- Establish an ACSM sub-committee, at state level, with representation from staff with core competencies in capacity building and institutional strengthening, community advocacy and events, mass media production and distribution as well as monitoring and evaluation.
- Meet with relevant ACSM and IEC management to establish a cohesive and integrated management structure to coordinate programme activities.
- Involve relevant district health staff in state level ACSM planning.
- Endorse the state level ACSM strategy at high-level meetings to ensure buy-in across sectors.

Priority 3 - Training and Supervision: Build capacity in RNTCP staff for effective patient education through IPC approaches and include refresher training for sustained commitment in implementation of ACSM. Also, enhance capacity of the RNTCP staff for effective supervision of ACSM activities as part of routine programme supervision.

- Incorporate the ACSM component within training modules for MOs and other clinical providers to instil a culture of 'customer focus', enhanced service delivery and effective inter-personal communication.
- Support field-staff and DOT providers with greater ACSM training opportunities and an enhanced component of TB ACSM within other health priorities.
- Conduct state-level media training workshop during the World TB Day campaign and involve district-level media and local NGOs in ACSM trainings
- Identify training needs for ACSM staff operating within NGOs, RNTCP, health and social welfare departments and provide training support to ensure coordinated, integrated, district and state level ACSM priorities and planning approaches - problem identification, audience segmentation, behavioural objectives, development of interventions, selection of channels for delivery and performance monitoring.
- Conduct ACSM training of trainers (TOT) to leverage activities.

Priority 4 - IEC Materials Production and Logistics: Review existing TB IEC resources and coordinate the development of new resources including a simple resource to provide key messages to DOT providers. Adequate supply of IEC materials will be provided to support front-line field workers in education through IPC approaches.

- Create DOT providers IPC resource - To impart key TB knowledge over 42-56 contact points during the treatment cycle; through soft skills training already available in the Round 9 Global Fund grant.
- The 'patient charter' which outlines the rights and responsibilities of people with Tuberculosis can empower people with the disease and their communities and this need to be widely publicized. Patient Charter– placed in the IEC resource centre of RNTCP website (www.tbcindia.nic.in) in many regional languages to be printed and distributed broadly
- Refresh the RNTCP brand (strap-line only) to support specific campaign themes and apply uniformly.
- Establish Communication Resource Information System (CRIS) - for effective and continuous IEC materials distribution.

Priority 5 - Establish Monitoring, Evaluation and Research Framework: Coordinate with stakeholders and develop formative, evaluative, impact and outcome research methods and tools.

Delivery of ACSM

Two *Tiers of ACSM* activities are proposed to address the overarching objectives of the programme, targeting most vulnerable and marginalized population groups.

- *Tier 1 ACSM* – Targeting general population segments of males and females including field staff - Health Workers (female and male), AWWs, ASHA, village doctors, and other opinion leaders with messages to increase TB knowledge and change attitudes and perceptions toward treatment and care.

- *Tier 2 ACSM* – Targeted interventions focusing on vulnerable population segments and districts, which are not achieving targets. Use messages emphasizing the need for greater involvement and support within these groups and geographic settings.

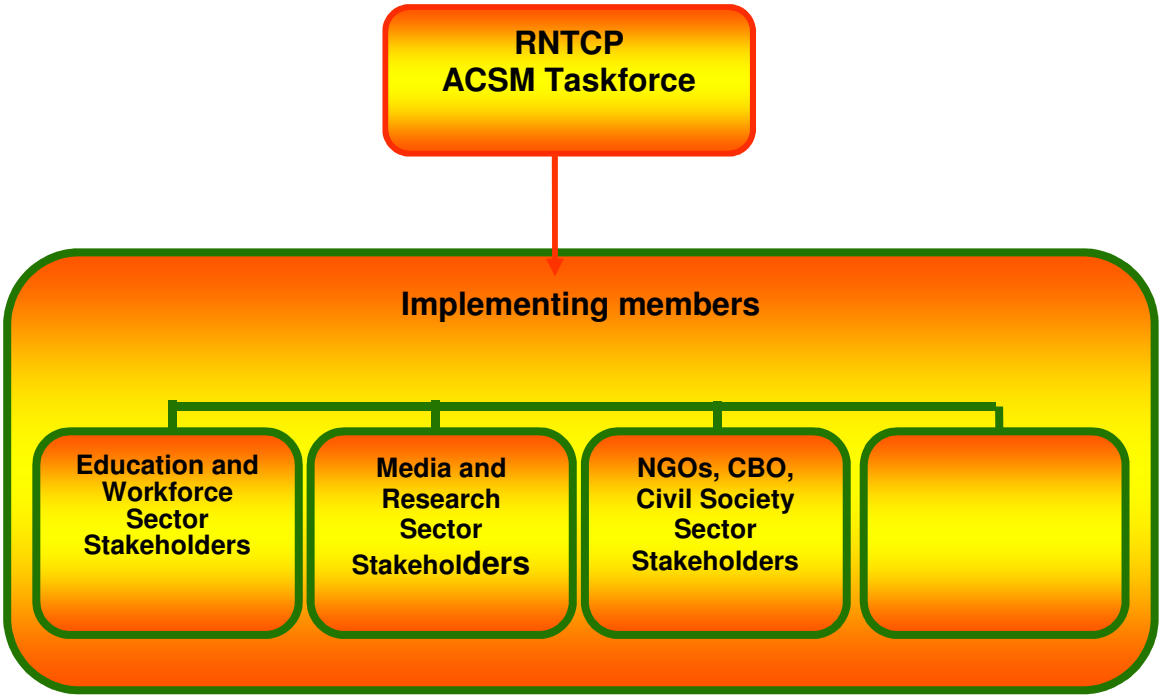
The ACSM strategy will be managed by the RNTCP through a co-ordinated multi-stakeholder approach. Partners would include other government ministries / state health departments, the educational sector, youth sector, armed forces, correctional and rehabilitation services, faith-based sector, rural sector, and the private sector including advertising and market research agencies, workplaces, media proprietors as well as coalitions of patients, former patients and vulnerable groups. Building alliances with these sectors will also facilitate the development of guidelines, policies and ACSM programmes to create community environments that are more conducive to social change.

The RNTCP will require competencies in the following areas to expand / scale up ACSM within the programme – these competencies could be developed through partnerships with public / private agencies. The areas include:

- Capacity building and technical transfer.
- Community advocacy and events.
- Media materials production and distribution.
- Monitoring, evaluation and research.

Institutional arrangements

The ACSM technical taskforce needs to be established at the national level to manage the programme rollout. The sub-committee will comprise of stakeholders from the RNTCP and NGO partner specialists in the core competency areas, who will in turn liaise with the State TB Cell. The ACSM sub-committee will primarily be responsible for coordinating the range of policy and implementation aspects of the programme. This will ensure integration and capacity building opportunities for all programme partners.



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Monitoring, Evaluation, Surveillance and Impact Assessment

Key Messages

- Each level of the programme and the overall health system requires relevant, timely and accurate data collection. Analysis of data is critical for ensuring continual programmatic improvement.
- Surveillance system will shift from current paper based recording and aggregate reporting to case-based web-based system in order to capture individual patient data from all health providers, in real time, for improved individual case management and programme action.
- Efforts will be made to strengthen routine surveillance and use it for measuring impact rather than periodic surveys.

Abstract

The existing RNTCP surveillance system provides high-quality aggregate data from the sub-district level for patients diagnosed and treated in the public sector. Analysis of this data has been central to improving DOTS and monitoring progress in the fight against TB. However, the data collected at present does not adequately reflect some of the major focus areas of the coming years, in particular that of reaching out to all TB patients and addressing the challenge of MDR-TB. Thus, improvements in monitoring, evaluation, surveillance and impact assessment will be a major thrust area of NSP-RNTCP.

From 2012,for the next five years, RTNCP plans to substantially augment the reach and quality of routinely collected information on incident TB cases and drug-resistant TB. The fundamental approach to assessing disease burden will change from “guestimating” the approximate amount of disease to simply counting cases and deaths, as is done for all diseases of public health importance around the world. A strengthened routine case-based reporting and surveillance system, which includes patients diagnosed and treated in private sector, will be used for improved case management, better local programme monitoring, and better disease burden estimation. We should move away from the complex, expensive and imprecise disease-specific surveys, which was the norm in the past.

The program aims at achieving the following milestones in the surveillance system by 2017:

- Comprehensive information on TB incidence and drug-resistant TB detection at district, state, and national level, that is immediately accessible for local monitoring and feedback to support programme action,

- Improved TB burden and trend assessment, and
- Improved TB case-management support for physicians and other health care providers.

Introduction

India suffers from a very high absolute burden of TB. While the burden of disease has been substantially reduced under RNTCP, TB continues to exert a striking health and economic toll on the country, with an estimated 2.0 million cases of TB and 280,000 deaths in 2009 alone. For example, in an on going community survey area in Haryana, about 1 in every 6 deaths among male adults aged 15 - 49 years, and 1 in 8 deaths among female adults, was attributable to TB. Nearly 100,000 people emerge with MDR-TB annually, creating an enormous future for TB control liability that requires immediate action. Nearly 100,000 people with TB also suffer from HIV, adding significantly to the burden of both diseases in the country.

Monitoring processes in RNTCP includes supervisory visits, review meetings, and regular programme evaluation activities at each level of the health system and programme operations. Monitoring is the routine tracking and reporting of high-priority information on the indicators set in RNTCP, its inputs and intended outputs, outcomes and impact. Data is obtained through recordkeeping, regular reporting and surveillance systems as well as observation and surveys. It provides the information needed to make evidence-based decisions for programme management and improvement, policy formulation, and advocacy. It also generates good-quality data to satisfy accountability requirements. Investing in strengthening of the RNTCP, national monitoring and evaluation system is crucial as it will eventually save resources that may otherwise be spent in inefficient programs or overlapping activities supported by different partners.

Monitoring and evaluation is intrinsic to the RNTCP system and decisions are based on transparent assessment of results against time-bound targets. The direct output of activities related to the programme are linked directly to the programme objectives of 85% cure and 70% case detection of new smear positive pulmonary (NSP) TB cases. Examples of indicators include number of patients started on RNTCP DOTS treatment; percentage of “initial defaulters” amongst the diagnosed NSP; percentage of diagnosed NSP cases placed on non-DOTS treatment; NSP case detection rates; number of patients who completed treatment and are cured etc. It is crucial that information is presented as time trends to measure not just a one-point snapshot, but also performance / progress over time. These indicators should be measured at the central, state, district, TB Units (TU) and Designated Microscopy Centre (DMC).

This chapter highlights the achievements till date in monitoring and evaluation and surveillance of the TB programme. It then follows some of the key challenges as posed especially in context of the new wider mandate of the NSP-RNTCP. The last section provides a list of interventions to be undertaken in the next five-year plan. Details of review activities, review meeting protocol and supervision activities are illustrated in tabular form in the annexure.

Achievements

Enhanced TB programme monitoring

From 1997 to 2008, RNTCP used a DOS-based computer programme for districts to enter aggregate quarterly reports and send it to respective states, which were then sent to the central level. In 2008, RNTCP made minor improvements to the recording and reporting system by including HIV, allowing for local monitoring of TB-HIV collaborative activities. In 2010, RNTCP transitioned to sub-district aggregate reporting using the Windows-based "Epi-Centre" programme, putting limited automated analysis of aggregate information in the hands of the local programme managers. Over the last 5 years, more than 99% of reports have been completed on time. Routine standard internal evaluations, where state and central teams conduct detailed field reviews of district activities and study of reports, have strengthened the quality of data.

Improved disease burden estimation

Between 2007 and 2011, RNTCP improved its disease burden estimation through large surveys and made incremental enhancements to the routine surveillance system for patients diagnosed and treated in the public sector.

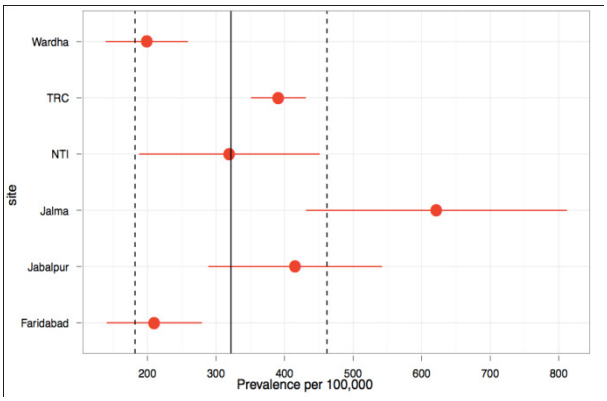
The second National Annual Risk of Tuberculosis Infection (ARTI) survey was completed in 2011. The ARTI survey estimates the proportion of people newly infected by TB annually over the survey period. New infections result from transmission and reducing TB transmission is universally recognized as the most important step to reduce future disease burden. The ARTI survey required an enormous effort to conduct tuberculin testing of over 200,000 school children in more than 40 sites nationwide. The results indicated a positive trend by showing a significant reduction in TB transmission over the project period. State-level surveys in Andhra Pradesh and Kerala conducted over the project period showed similar findings. (Previously, RNTCP and WHO used ARTI to estimate TB incidence in India). This methodological approach, in recent years, has been considered unacceptable due to the high uncertainty around key estimation parameters. Hence, for the past few years no other country globally has sought to estimate incidence using the ARTI survey.

Table 11.1: Annual risk of tuberculosis infection, 2000-2003 and 2007–2009, and percent annual change. Source: Chadha, NTI

Zone	North	West	East	South	National
Survey	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**	**% (95% CI)**
I. 2000–2003	1.9 (1.7, 2.1)	1.7 (1.5, 1.9)	1.2 (1.0, 1.3)	1.1 (1.0, 1.2)	1.4 (1.3, 1.5)
II. 2007–2009	0.9 (0.7, 1.1)	0.7 (0.6, 0.9)	1.1 (0.8, 1.4)	1.2 (1.0, 1.3)	1.0 (0.9, 1.1)
% Annual change	-8.4 (-11.1, -5.7)	-9.9 (-12.6, -7.3)	-1.1 (-4.4, +2.1)	1.0 (-0.7, +2.6)	-3.7 (-5.1, -2.4)

TB prevalence surveys from 6 selected districts between 2007 and 2009 showed wide range of TB prevalence; results of which were used to help estimate national TB prevalence with substantial uncertainty due to the small number of districts.

Figure 11.1: Bacteriologically confirmed TB from district prevalence surveys (2006 – 2009). Red dot shows point estimate, and the lines show confidence limits.



Several large community-based mortality surveys have been conducted over the last 5 years, including Andhra Pradesh (state-wide), Andhra Pradesh (rural areas only), Orissa (state-wide), Tiruvallur (Tamil Nadu, sub-district), Kolkata (West Bengal; sub-district and slum area), and Ballabhgarh (Haryana, sub-district). These household surveys, used verbal autopsy to ascertain cause of death from a defined recent time interval and found TB mortality ranging between 28 and 76 per 100,000 population.

Challenges

The current approach to TB surveillance, although simple, robust , firmly established and produces quality data for programme management, but is not structured enough to yield timely local feedback (at the point of service delivery) for programme or case management improvement. The current surveillance system produces feedback for peripheral health facilities, where it is most needed, with significant time lag thus reducing its usefulness for individual case management and patient-wise monitoring, in real time by the peripheral health facilities and the programme.

In the current system, paper-based records of patients diagnosed and treated under RNTCP at the local level are seen by a programme officer anywhere from a week to a month after treatment initiation, and entered into a sub-district TB register. Feedback on the patient's treatment, monitoring and completion occurs within this local loop only and is not readily available for programme managers to monitor, and is subject to substantial delays. At some point between 1 to 4 months after treatment initiation, subset of information from TB registers is aggregated into a sub-district report, which is transmitted to the district and then to the central level over a period of 2 to 4 weeks. This process of aggregate reporting is repeated once during the course of treatment, and again approximately 1 year after starting the treatment. In this system of reporting information on treatment non-adherence comes to the notice of the programme only after a substantial duration of time into the treatment by which time the problem has already set in. More than half of patients who default do so before the start of their continuation phase of treatment. By the time the state even receives the report of these patient registration, the program would have already lost them to follow up.

A vast amount of information is generated at all levels from supervision, monitoring and evaluation of the program activities. Most of this information is poorly organized, and not effectively utilized for programme monitoring, feedback, or to

assess if program activities are achieving their targets or not. Indicative examples include routine reporting on external quality assurance from every microscopy centre nationwide, monthly financial reporting from Statements of Expenditures, and detailed state internal evaluations (nearly 100 annually nationwide).

Patients reported by the RNTCP represent only those diagnosed and treated in the public sector or by a very limited number of NGO or private providers working with RNTCP. An unknown proportion of all incident TB cases remain entirely outside the existing surveillance system. Hence, the current approach is insufficient to inform disease burden estimation. Instead, the country has had to rely on poorly informed assumptions and indirect estimation procedures to generate imprecise measures of disease burden.

Strategic Vision for 2012-17

For 2012–2017, the TB programme will continue to improve the existing supervision, monitoring and evaluation systems, augmenting them to measure indicators from the new challenges and programme priorities. The NSP-RNTCP will fully transition from recording TB cases treated under the programme in locally-held paper TB registers' aggregate paper-based reporting to a national electronic TB register that registers all TB patients irrespective of the source of their TB diagnosis or treatment, and extends to the private sector. This will strengthen the routine case-based reporting and surveillance system and will be used for improved case management, better local programme monitoring, and improved disease burden estimation.

The programme requires improved information on disease burden and impact to assess the effectiveness of the overall implementation and to justify the expanded national investment in TB. The fundamental approach to assessing disease burden will change from "guestimating" the approximate amount of disease to simply counting cases and deaths, as is done for all diseases of public health importance around the world. The information from counting TB patients, instances of drug-resistant TB, and deaths would inform disease burden estimation with far greater precision and reliability than today's survey based-estimates. Information routinely collected would directly inform incidence and drug-resistant TB.

Strategic vision of NSP-RNTCP in this domain takes into account three broad trends in the health and technology spheres of the country. First, India has embraced the concept of Universal Health Care for the population, and is seeking to increase its national expenditure on health care and improve both preventative and curative services. Second, the outlook paper on the 12th National Five Year Plan indicates that to achieve Universal Health Care, the government is boldly moving towards utilizing the large private sector installed base of providers and health care facilities for public health care purposes, most notably in urban areas. Third, there is dramatic improvement in the available infrastructure of information technology at all levels, from mobiles held by patients and health care workers, to internet-connected devices in all health care facilities under NRHM, to large data centres – including those operated by the Government of India for national advancement. This creates enormous opportunity for improved monitoring and accountability, and improved case management services.

Activities

The monitoring, evaluation, surveillance and impact evaluation assessment activities can be broadly categorized as those related to a) data collection, b) data analysis and c) data reporting.

Data Collection

Strengthening routine surveillance:

Surveillance would be strengthened through expansion of case finding and reporting to private sector providers, labs, and pharmacies, and by development of a case-based electronic reporting system.

Over 2012–2017, NSP-RNTCP will fully transition from aggregate paper-based reporting to a case-based electronic reporting system, i.e. a national electronic TB register that registers all TB patients irrespective of the source of their TB diagnosis or treatment, and extends to the private sector. This information would be available for local case management improvement, through innovations such as automated reminders and notifications to patients and providers alike.

In 2012, NSP-RNTCP will seek to expand the existing surveillance system to include patients who may be diagnosed and treated in the private sector. This can include reporting directly from private providers, private pharmacies (e.g. from schedule HX related documentation), and private laboratories on patients with positive test results (e.g. from smear microscopy, culture, validated molecular test). From these regular lists of possible TB cases, the District TB programme management unit will be responsible for case validation and final registration. This system will require normative development, district-level pilot testing, and subsequent national deployment of the final approach. The system is not expected to be complete in the beginning, but to offer a platform to monitor the success of future engagement of the private sector. Key inputs for this activity will be dedicated human resources and, technical assistance. The success of this strategy will primarily be driven by development of platforms for successful engagement of the private sector.
In 2012, the programme will seek to develop an electronic case-based surveillance system, involving a web-based database and local data entry primarily at the block level, with mobile facility for both data inputs (registration, monitoring information) and outputs (results, reminders) which will be tested in 2013. Key inputs for this activity will be human resources, project funds for co-development with the appropriate agency and pilot testing, hardware costs for block programme management units and providers (e.g. mobile facility for STS), system maintenance costs, and transition costs of training.
The quality of this system will be primarily driven by effectiveness of efforts to engage the private sector and register patients diagnosed and treated outside the reach of the RNTCP. Further, an effective system for case based reporting can support efforts to engage the private sector, especially if linked to case management improvements and timely and accountable reimbursements to private providers. To monitor the effectiveness of the deployment of this system

and also broader efforts to extend services to patients diagnosed in the private sector, the programme will use district-level inventory surveys, and capture-recapture analysis. This would enable estimation of case detection as well as guide efforts to optimize systems and approaches, especially for private sector engagement.

Disease prevalence surveys

Limited repeat disease prevalence surveys in 6 sentinel districts will be conducted after 2016 to establish trends in prevalence of TB. This is expected to be a one-time activity, and will offer further refinement of both prevalence and incidence estimation.

Strengthening mortality estimation

Mortality estimation would be strengthened through survey participation and vital registration. NSP-RNTCP will engage the Registrar General of India to ensure that TB is appropriately represented in community-based mortality surveys.

Conduct inventory surveys

The programme will also conduct inventory surveys with a capture-recapture analysis to estimate the proportion of un-reported cases under the RNTCP. The primary activity will be the deployment of a national disease burden survey utilizing the capture-recapture analysis to reliably quantify the proportion of under-reporting in the current surveillance system. This approach will yield improved incidence estimates, period prevalence, and useful information on the existence of patients who have yet not been approached within the health system. To improve incidence estimation immediately, a survey of the burden of un-reported TB will commence by 2012. This would involve a national sample that will be used to collect information from other data sources outside RNTCP, such as patient records from non-public health care facilities, pharmacies, and laboratories. This activity will be designed and coordinated by National TB Institute, Bangalore.

Data Analysis

Programme supervision, monitoring, and evaluation:

In 2011, the RNTCP has developed a detailed supervision and monitoring strategy. This will be finalized, incorporated into policy and trainings and made operational. The summary of programme-wide supervision and monitoring activities is detailed in Annex 3.
RNTCP has developed a detailed system of programme evaluation, consisting of regular quarterly and annual performance reports, state-level internal evaluations of districts, and central internal evaluations. This system will be further strengthened through the expansion of the state-level internal evaluation teams by inclusion of neighbouring states, partners, and community members. Findings from the state level internal evaluation reports will be included in the routine RNTCP electronic reporting in order to make data readily available for immediate and periodic evaluation and feedback.

Review meetings:

NSP-RNTCP will continue the system of periodic review at all levels, with increasing emphasis on inclusion of the TB programme in general health system review activities. Regular reviews will be conducted on a pre determined schedule by teams with specified compositions. The details of the schedule focus and composition of reviews is provided in the annex 3. In addition, a mid-term programme review mission (formerly known as Joint-Monitoring mission), led by GOI but independently conducted with the support and participation of technical partners and donors, will be conducted in early 2015.

Data Reporting

Five key reporting outputs are planned to strengthen programme accountability, management, learning, and planning aspects. These include:

- Programme reports will be produced on a quarterly schedule at the national and state levels, using information from the national reporting system. Programme managers at the national, state and district level will be the key users of these reports. This will also include the "RNTCP Scorecard" results.
- A "RNTCP Scorecard" with information on key indicators will be prepared which will serve as a quarterly monitoring tool of districts and local programme management units. It will be automatically generated by the information system and primarily based on data from the national reporting system. The "RNTCP scorecard" includes extensive programme management inputs such as HR, financial expenditure, and programme activities. These will inform administrators and programme managers on the programme implementation status and provide early warnings of weaknesses or processes that are failing. It will also help states and the CTD in identifying districts performing sub-optimally and in need of more intensive support and supervision. Efforts will be made to enhance the use of RNTCP Scorecards not only as management tools but also for rewarding good performance, local innovations and perhaps even for performance-based financing.
- Annual reports will be published by CTD and states, highlighting the state and Nation's status, challenges, and plans towards achievement of the overall goal of Universal access.
- Special annual research/learning reports will be generated by the National Research Cell highlighting new knowledge and experiences developed for programme application.
- Reports from external programme evaluations at mid-term and at the end of 5 year period will be generated at the national level. These reports will be based on information from the field, annual reports, special surveys, and evaluation processes.

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Research to inform TB control, policy and practice

Key Messages

- Operation research is essential to optimize TB control.
- Programme needs to prioritize research agenda.
- Conduct or commission priority research.
- Rapidly translate lessons into innovative policy and practice.

Abstract

Research plays an important role in the design of new strategies to ensure optimal utilization of resources and maximise programme outcomes. Programme implementation when supported with action-oriented research has the ability to innovate and develop most useful interventions. Recognising the importance of research, RNTCP-II established normative guidelines for research under which research projects for disease burden were undertaken. However, due to weak implementation of guidelines and limited accomplishment of research topics, the research potential has not been realised.

The NSP-RNTCP has established a new programme goal of universal access and defined several others for improved TB detection and management. Action-

oriented research is required to better the service and delivery mechanisms in order to achieve the goal of universal access. The plan for 2012–2017 envisions large-scale operations experiment with innovative approaches to TB control. This is to be followed by a cycle of evaluation, optimization, and implementation of innovation on a large scale. Regular periodic review of implementation results and new evidence will inform and direct revisions of policies and approaches.

To achieve these goals, a dedicated research officer at CTD will manage a process whereby the programme's research needs are prioritized and articulated. A National Research Cell will be established for this purpose. The cell will develop normative guidance, commission relevant and priority research, synthesize evidence, review and recommend approval of research proposals, fund research institutions, manage and monitor research activities and conduct research dissemination and capacity building. Coordinated efforts will be pursued to foster research capacity. Commissioned research is important for the programme to develop the required evidence to inform evaluation at regular intervals.

For improving RNTCP performance, medical colleges remain key partners. The colleges are required to conduct prioritized and decentralized research projects of both local and national interest, as well as engage new professionals by supporting postgraduate research. The role of state and zonal OR committees is to provide a detailed outline of streamlined procedures for research approval and funding.

Introduction

Indian research has generated various core strategies used in global TB control today, including home-based outpatient treatment, short course chemotherapy with rifampicin-based regimens, and decentralized diagnostic and treatment services. These advances were organized with a public health management approach in the form of the DOTS strategy. Over the past ten years, this strategy was applied not only globally in the 1980's and 1990's but in India as well. Basic DOTS services and core elements of the subsequent WHO Stop TB Strategy are now well established in India.

These services are based on global scientific and operational guidelines as well as evidence that, continues to evolve over time. To generate the evidence needed to guide policy makers and programme managers, the programme encourages operational research. In accordance with new evidence, the RNTCP has made the necessary changes in its policies and programme management practices.

The new ambition of universal access of RNTCP articulated in this plan is attached to the question of 'how' to achieve the same. The questions related to 'how' are manifested in the box below and will influence the strategic thinking as well as related activities undertaken by the RNTCP in the next phase.

Question of "How"

- DOTS is established nationwide and case notification has plateaued since the past five years. The question of how to increase the same remains. How to take advantage of the impending pipeline of new diagnostics?
- How to balance the ability to diagnose and capacity to treat MDR-TB?
- How to choose between tests and applying the same to achieve maximum health impact on TB?
- How to diagnose patients earlier, especially for those not within the public health system?
- How to stratify suspects for DST in order to refer correct treatment from the outset to reduce TB transmission? How to reduce TB mortality further, particularly among HIV co-infected individuals?
- How to intensify or modify TB treatment and control in context of co-morbidities such as DM and smoking?
- How to optimize currently available therapies, evaluation and incorporation of new drugs and therapeutic advances?
- How to maintain and improve treatment success in the light of stable results over the past decade as, the number of detections continue to rise?
- How to achieve any of the above in a health system that is and will continue to be dominated by the for-profit sector?
- How to increase notification from the private sector?
- How to achieve all of the above in the most cost effective manner possible?

The answers to most of these questions are not known today, but solutions can be developed, evaluated, and optimized. A critical component over the next five years will be integration of quality research with responsive and adaptive policy as well as improved practices.

This chapter begins with a discussion on the achievements of RNTCP II, followed by the articulation of the challenges and gaps that still remain to be addressed. Finally, it proposes and outlines better mechanisms for effective and efficient research production, knowledge management, and utilization for action.

Achievements

Normative guidance for research

The 2006 – 2011 RNTCP Project Implementation Plan established basic operational research guidelines, which were formalized in 2008. The guidelines outlined the structure, human resources, responsibilities, and processes to promote, review, approve, and fund research activities. A "RNTCP priority operational research agenda" was also developed which, aimed at specifying operational research activities that RNTCP felt necessary to inform programme policy and practice. The agenda also included detailed concept notes for priority areas to enable prospective researchers to commence protocol design and development from start. Standard protocol formats were developed to facilitate submissions of proposals for programme funding.

Research activities

All commissioned research by RNTCP specified in the Project Implementation Plan for 2006 – 2011 was successfully completed. This included disease burden studies for measurement of TB transmission (1 nationwide survey and 2 state surveys), limited district disease prevalence surveys (8), state TB mortality surveys (2), and state anti TB drug resistance surveys (3), where success is defined as research that informs policy and practice. Additional, research successes are summarized in Annexure 6 .

Research capacity development efforts were negligible from 2006–2010, and minimally productive in terms of generating completed projects. Capacity development efforts have increased dramatically in 2010 – 2011. Notable efforts have been made by the Union, WHO, NTI in collaboration with US-CDC, to organize a mentored year-long capacity development project oriented around programme requirements. Additional research capacity development workshops in India have been organized by PHFI.

Challenges

Growing need for evidence-based guidance

Initial implementation of DOTS was based on global research, with extensive pilot testing in country 1992-1997. DOTS has essentially been optimized, and the pathway to achieve universal access in India is not clarified by WHO or any international or national agency till date. The need is greater than ever to innovate, evaluate, and scale-up approaches to elevate TB care and control.

Limited Implementation of RNTCP OR guidelines

Implementation of the RNTCP OR guidelines, have been limited in practice. Although, the 2008 OR guidelines were designed to address many shortcomings of the existing approach to research, few of the recommended guidelines from 2008 were put into practice for the reasons listed below:

- The guidelines called for an OR agenda to define programme priorities, with periodic calls for proposals and streamlined review and approval process for priority OR. However, there was no procedure for promotion, regular review and revision or review on progress towards meeting

research needs. Furthermore, there were no calls for proposals issued and clinical research was not included.

- There was no procedure for prioritization, promotion, approval, or review of the specific clinical research that was needed to inform programme guidelines and policies. There was no policy for review and approval of 3rd party clinical research in programme settings. Thus, interested researchers were unclear about whom to approach to collaborate with RNTCP on research that may be relevant to programme.

- A "Research Cell" was developed in the CTD. However, there were no dedicated posts or consultants for research and the daily demands for programme management overwhelmed CTD's capacity to conduct research. Furthermore, planned approaches to increasing research capacity at this level did not occur.

- A 'National Standing Committee on Operational Research' was established, but they met infrequently resulting in long delays in protocol reviews. Their role became little more than as 'gatekeepers' for high-budget operational research.

- Zonal and State Operational Research Committees were established to promote decentralized interest and action on operational research by medical colleges and other local bodies. However, they too met infrequently, with resultant delays. Only a few proposals were actually developed and submitted to these committees and even those approved did not yield timely funds for small projects. Referrals of more expensive research to the central level were not promptly acted on, reviewed or funded.

- The flow of funds via state health societies under the 'research' heading were delayed or not released, particularly in times when capital flow was limited. Furthermore, the timing of research submission and funding needs was not aligned with the annual planning cycle of RNTCP.

- There was no overarching and coordinated programme to develop research capacity development and activities were limited to ad hoc workshops and uncoordinated activities from many partners. Furthermore, the capacity development not necessarily aligned with needs.

Limited accomplishments and results of OR

Weaknesses in normative guidance implementation described above were mirrored by limited accomplishment and results. Review of both the 2005 research agenda from the Project Implementation Plan and the revised 2008 RNTCP Priority Operational Research Agenda showed that, a limited number of proposed priority research questions were successfully addressed in any form. Most of what was completed was either (a) commissioned by CTD from national institutes or led directly by national partners, (b) included in the TRCF-WHO MDP project and driven by a separate research funding and promotion process, (c) driven by partners of RNTCP as part of project implementation, or (d) completed as part of

operational research training projects. Research from medical colleges was oriented towards relatively low-impact clinical research questions, e.g. duration of treatment for specific forms of extra-pulmonary TB.

Translation of research into policy has till date been largely ad hoc, driven by the availability of research or changes in global guidelines. The health impact of the issue has not been closely associated with prioritization for either production or translation of research findings.

Strategic Vision for 2012-17

Implementing science research will be critical in driving the programme service and delivery optimizations required to achieve universal access. Thus, in the coming years, the programme will embark on phased experimentation with innovative approaches to TB control, followed by a cycle of evaluation and optimization.

The strategic vision with regard to operations research is as follows:

- Operations research is essential in optimizing TB control and achieving the overarching goal of universal access.
- The programme will establish and fund mechanisms to prioritize those research projects that are most likely to improve TB control.
- It is envisaged that the programme will both conduct and commission priority research. In the next 5 years RNTCP will allow greater flexibility to decentralized research.
- Periodic review of implementation results and new evidence will rapidly translate lessons into innovative policy and practice.

Activities

Establishment of National Research Cell

The Cell will include a senior researcher, technical officers, a statistician, and accounts officers. The terms of reference for the National Research Cell are included in Annexure 4.

Revise and regularly update the operational and clinical research agenda

The National OR Cell will have the responsibility to revise and update RNTCP operational and clinical research agenda. A new prioritization will be conducted annually, to finalise studies that need to be commissioned during the year to meet key challenges facing the programme. The high-level challenges that must be addressed are (1) extending essential services to patients diagnosed and managed in the private sector. (2) improving early case-finding, particularly among the HIV-infected and vulnerable, (3) improving surveillance systems, and (4) reducing TB morbidity and mortality, including putting patients on the correct treatment from the outset of therapy,

Commission rigorous, targeted and relevant research for programme priorities

For topics of immediate national importance, the RNTCP can directly commission research activities with agencies that have demonstrated the capacity to implement large-scale studies. These activities include clinical research, field evaluation of new diagnostic tests, new drug regimens or therapeutic advances, epidemiological research, drug resistance surveillance, disease burden surveys, and programme service delivery models for engaging all service providers.

To drive interest and to promote the development of high quality OR for RNTCP, the RNTCP will annually issue at least two priority topics for 'Calls for Proposals'. The intent of the 'Calls for Proposals' will be to engage researchers and stimulate interest in the priority issues, through broad dissemination of funding opportunities. These 'Calls for Proposals' will be open invitations to a broad audience of researchers and partners. 'Calls for Proposals' will be openly advertised on the RNTCP website, and further disseminated by direct mailing to medical colleges, institutes, as well as other researchers. The National Research Cell will select the topics for recommendation to the DDG. To promote the likelihood of proposals meeting a minimum technical standard, an 'OR Concept Note' will be disseminated along with each 'Call for Proposals', detailing the research question of interest to RNTCP and suggesting appropriate research methodology.

Promoting partnerships for clinical and applied research in the country

The next several years will see the development and availability of new diagnostics, drugs regimens, vaccines, and service delivery approaches. These new tools and approaches must be tested within the country, so that they can be applied for the benefit of the population as quickly as possible. RNTCP and current partners do not have the capacity alone to achieve this goal. RNTCP will in principle seek to cooperate with researchers to evaluate new tools and approaches. In particular, RNTCP will seek partners for implementation research to support the National Research Cell and it's activities.

State and Zonal Operational Research Committees

Promotion of research from medical colleges and local partners would be through state and zonal research committees.

Membership of State and Zonal OR committees: The zonal committee will comprise at-least 5 members, formed by the Zonal Task Force (ZTF) Chairman and Member Secretary. The 5 members will include members of the State Task Force from the zone, one member from the Central TB Institutions (LRS for North zone, TRC for South and North- east zone, NTI for East and West zone), and experts including a statistician, social scientist or other experts for review and ensuring quality of the proposals.

At the state level, the committee will comprise at least 5 members, formed by the State Task Force Chairman and medical college representatives.

Tasks: Zonal and State OR committees

- Identify priority areas for research as relevant to their zone/state, based on the national research agenda.
- Review all OR proposals/PG thesis submitted as per guidelines below, assess technical quality and programme relevance, and approve or deny proposals within 3 months of submission. Approved proposals will then be directed to the National Research Cell for final approval and funding.
- Advocate for the uptake of RNTCP operational research within the zone/state with medical colleges, institutions, and other researchers.
- Facilitate documentation and dissemination of findings of research undertaken within the zone/state.
- Monitor the progress of approved studies at state and zonal level.
- Submit minutes of meetings to Zonal Committee / National Research Cell.

Administrative considerations: Medical colleges have been provided funds through concerned STCS/ DTCS for activities related to referral of cases and treatment, operational research, sensitization and advocacy among the staff, faculty and medical students. The OR committees at the zonal/state level are formed through the Zonal/State Task forces that have been formed for medical college involvement under the RNTCP. The cost for travel and per-diem for the chairmen and members of these OR committees for attending OR meetings and follow-up/monitoring visits to the OR sites in their jurisdiction would be borne by the respective STCS/ DTCS. The organizational cost for such meetings would also be borne by the respective societies. Similarly, the provisions made for support to conferences, symposiums, panel discussions and workshops organized at state levels (at state level - Rs. 1,00,000/- per conference for 4 conferences annually) and at level of medical college (support to plenary session on RNTCP in seminars / CME /workshops up to Rs. 10,000 once in a year, for a medical college) may be utilized for OR dissemination at the state/medical college level.

Activities to increase OR awareness and capacity at medical colleges

- The Nodal Officer of the Core Committee in the medical college shall disseminate the information about the OR activities and opportunities at the institutional level in the form of meetings/display on notice boards/inserts in institutional publications/intranet/website.
- RNTCP research priorities agenda, brief outlines or concept notes on OR issues and approved well written 'model proposals' should be made available at the CTD website for public viewing to serve as guidance to applicants.
- STF Chairperson to sensitize state officials, medical colleges, institutions, and other researchers regarding the RNTCP research agenda and funding opportunities of RNTCP, and disseminate information regarding the same to all in the state.
- The STF agenda shall include a 2-hour research methodology training for the STF meeting/workshop/CME.
- ZTF agenda shall include a half-day research methodology workshop in the ZTF meeting, with the assistance of national institutes and/or CTD research cell.
- One of the four RNTCP supported state-level CMEs may be conducted as an OR workshop.

- ICMR guidelines on constitution of ethical committee and ethical issues to be provided at CTD website (http://www.icmr.nic.in/ethical.pdf)

14
Procurement and Supply Management

Key Messages

- Procurement and supply management is particularly important for TB control.
- RNTCP has strong systems that can be expanded to encompass the increased complexity of the coming years.
- An uninterrupted supply of quality drugs is critical to ensure successful clinical outcomes and prevent drug resistance.

Abstract

Given the complexities of diagnosing and the protracted nature of its treatment, having uninterrupted access to quality commodities is particularly important to TB control programs. Thus, one of the most significant achievements of RNTCP has been the establishment and continual improvement of procurement and supply management systems for the full spectrum of civil works, laboratory and treatment services.

RNTCP is now well positioned for the increased size and complexity required for achieving the goals of universal access. The challenges in the coming years will be partly set by the need to increase the scope of established efforts. These include procuring and distributing increasing quantities of quality assured first and second line drugs. Furthermore, there will be unanticipated challenges such as increased need for contractual services with the private sector and procuring novel diagnostic technologies.

Introduction

Procurement and supply management function covers the most important aspect of the programme by ensuring uninterrupted supply of drugs. First line and second

line Anti-TB drugs are procured under RNTCP and the logistics function ensures its seamless availability at the different levels of the programme to be provided to the patients. The determination of the requirement of the drugs is based upon stocking norms established by the programme. The additional feature is the concept of Patient-wise Boxes (PWB), which has been viewed as the brand equity of RNTCP.
The procurement of drugs continues to be done centrally through International Competitive Bidding by a procurement agent contracted by the MoHFW. Central procurement of drugs ensures →

- ∞ availability of good quality drugs,
- ∞ competitive costs of procurement as a result of economies of scale,
- ∞ homogeneous drug quality standards throughout the whole country
- ∞ Monitoring of drug stocks and logistics becomes easier for the Central TB Division
- ∞ Central level procurement is cost effective
- ∞ The States are able to concentrate on the other important aspects of RNTCP implementation

State and District level will procure consumables & other items for miscellaneous use. Alternatively, states may undertake procurement at their level only on behalf of districts, provided advantages of cost, quality and timeliness are obtained.

The procurement function also covers the contracting of civil works by adopting appropriate processes depending upon the value of the work. This will cover establishment of new facilities such as DMCs, Drug Stores and civil works necessary for the housing of equipments.

The procurement of equipments for laboratory diagnostic facilities is part of the procurement function. The procurement of microscopes (all types), procurement of newer diagnostic technologies such as Automated NAAT (Xpert MTB/RIF test on GeneXpert platform) will also be carried out under procurement function.

Consultancy services, hiring of media agency for ACSM activities, hiring of laboratory for testing of Anti-TB drugs, large scale research/studies such as surveys, printing services, contractual staff, and office equipment are critical component of the function. Logistic and supply chain management also plays a vital role and is included as part of procurement function.

The methodology to ensure better competition and transparency in procurement and in the delivery of quality services is well established and the same will be followed during planning period 2012-17. The additional requirements arising out of the shift in strategies that have been spelt out in the different areas have also been taken into account.

This chapter will highlight the achievements in drug procurement and distribution in the current phase of the programme, followed by the challenges that remain and that can be expected to arise in light of the new goal of NSP-RNTCP The last section addresses these challenges by proposing activities to improve drug management including: procurement, storage, distribution and quality of drugs.

Achievements

Procurement

Established Units: The programme has been able to successfully procure and supply the drugs required for treatment of patients seamlessly in the past. The procurement of Anti-TB drugs will be done at the level of Ministry of Health & Family Welfare (MOHFW), Govt. of India through International Competitive Bidding by the procurement agency selected by MoHFW. Procurement, Supply & Logistics Unit has been established in Central TB Division (CTD) for procurement and logistics functions at the Central level. The unit is under the supervision of a Additional DDG and is supported by a Procurement & Supply Management Consultant and an agency, outsourced with the support of WHO. The sustenance of this agency within the programme is important.

Established Systems: Special attention has been given by RNTCP to the procurement of Anti-TB Drugs since the inception of the programme. During Phase I of RNTCP, drug procurement was made via a "Procurement Support Agency".

The Ministry has established an Empowered Procurement Wing (EPW), to carry out procurement activities without the support of a Procurement Support agency. The Ministry is in the process of strengthening this wing. Until the time that the EPW is fully strengthened, a procurement agent, with independent decision making capacity is being engaged to carry out all the procurement following World Bank procedures.

Supply of quality Assured Drugs: Due to the adoption of ICB process and Central level procurement of drugs under RNTCP, the programme has been able to ensure supply of quality drugs to patients.

Procurement capacity building of states: The state level officials (STO & State TB Cell Staff) of almost all the states have been imparted training during the workshops conducted by CTD at the central level After the workshops, trainings of the district level officials (DTO & DTC staff) has been conducted by the respective states.

Transparent Processes: As per the Governance & Accountability Action Plan (GAAP) agreed between the World Bank and the Government of India, Annual Procurement Plans for the Central level procurements are made available on RNTCP website i.e. www.tbcindia.nic.in, which is linked to the website of Ministry of Health & Family Welfare i.e. www.mohfw.nic.in. The Bid documents, information regarding Contracts awarded, reasons for rejection of bids and other related information are also uploaded on RNTCP website, which is updated regularly.

Distribution

Procurement Management Information System (ProMIS) Software:
Empowered procurement Wing (EPW) of the MOHFW has developed web-based software (ProMIS) to streamline procurement systems and it 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. RNTCP has been selected for pilot testing of the software.

Logistics of 2nd Line Drugs:
Drug Logistics of 2nd Line drugs has emerged as the new challenge under DOTS-Plus in RNTCP, considering that the influx of patients into the programme is slow, treatment is spread over 24 months and 2nd line drugs have shorter shelf life than 1st line drugs.

The management cycle of second-line anti-TB drugs comprises six elements: drug selection; quantitative assessment of drug requirements; management of procurement and distribution; assurance of drug quality; and ensuring rational drug use. Accurate demand forecasting of second-line anti-TB drugs, i.e. correct quantification of the drug needs for a specific period of time, is one of the elements that guarantees an uninterrupted drug supply.

Challenges

Increasing number of TU: The increase in number of TU anticipated due to the decision taken by the programme to align with the NRHM block and reduction in population norms for TU to 200,000 will have its impact in logistics management at the district level.

Increase in requirement of contractual staff: There will be a substantial increase in the number of contractual staff to be engaged by the programme arising out of the revision in norms. Further, since functional focus is being brought about in the district, state and central level structures this will also add to the number of contractual staff.

Surveillance: The programme will be slowly moving towards a case based surveillance system and also electronic reporting of notification and treatment by making the case registers and the treatment registers electronic. This will require acquisition of required technology as well as training of human resources in using these systems

PPM Thrust: In order to increase the participation of the private sector providers as well as increasing information flow from them contractual institutional arrangements are being proposed under the NSPTB. This is expected to be scaled up gradually over the plan period in order to be rolled out nationally by 2017. This will pose a challenge in terms of effective contract management.

Research: Research will be intensified in order to strengthen the surveillance in terms of estimating the under reporting of TB using the capture-re-capture methodology. Further, research required to inform the programme on policies and strategic directions will also be strengthened. This may increase the requirement of number of competent agencies to be hired for carrying out research work.

Strategic Vision for 2012-17

The strategic vision for 2012-17 is to ensure availability of quality assured diagnosis and treatment for all TB patients, through adoption of improved diagnostic technology, quality assured drugs of first and second line, strengthening supervision and monitoring and gathering evidence for better programme design. Having an effective and efficient mechanism for procurement and supply chain management will be essential in the coming years.

Activities

Procurement of drugs

First Line Anti TB Drugs: The entire country has been covered under RNTCP from March, 2006. The procurement of these drugs will be done at the level of Ministry of Health& Family Welfare (MOHFW), Government of India through International Bidding by the procurement agency selected by MOHFW, following the World Bank procurement guidelines. Measures taken by the programme to procure good quality drugs include: ensuring WHO-GMP certification, careful supplier selection, pre-dispatch inspection, batch certification, proper storage and transportation, product defect reporting mechanism, quality assurance at the most peripheral level of utilization by randomized testing by a quality assured laboratory.

RNTCP procurement of 1st Line Anti TB Drugs for the 2008-09 was limited to 'Prequalified Suppliers' defined as GMP compliant manufacturers as assessed by WHO Pre-qualification Programme. The advantages of such stringent quality assurance standards are threefold:-

i. Ensures that only Anti-TB Drugs of the highest quality are available through RNTCP
ii. Reduces procurement lead times by a) reducing the bidding period through Limited International Bidding (LIB), which is one of the agreed method of procurement as per the Development Credit Agreement (DCA) between Govt. of India and IDA (World Bank) for the Second National Tuberculosis Control Project, b) revalidation of GMP certificates by Joint Inspection team of DCG (I) not required.
iii. Enables higher degree of harmonization of quality assurance standards with those of major international donors and organizations involved in financing and procurement of anti-TB drugs.

Sufficient competition among manufacturers meeting stringent quality assurance requirements is however a mandatory requirement in order to ensure that the increased cost due to limited competition does not become onerous for the Programme. If this condition is ensured, the procurement process through application of stringent quality assurance standards would provide quality assured drugs and competitive prices with a shorter lead time.

Second Line Anti TB Drugs: The procurement of 2nd Line Anti TB Drugs is being done through International Competitive Bidding (ICB) by the procurement agency of MOHFW. RNTCP has taken measures to procure good quality 2nd Line Anti TB Drugs such as WHO GMP is a requirement for the bidding process, GMP compliance of the bidders is assessed by a Joint Inspection team constituted by Drug Controller General (India), pre-dispatch inspection & batch certification etc. For the states funded by GFATM, these drugs are procured through Green Light Committee (GLC) of Stop TB Partnership. The list of drugs is provided in Annex 5.

Drug Distribution

First Line Drugs

Drugs are released by CTD from the Government Medical Supply Depots (GMSD) every quarter to the States, after receipt of the quarterly programme management reports from the districts.

Analysis at CTD is made of closing drug stocks at the end of quarter in the entire State (including the closing stock of the districts), consumption of drugs during the quarter, and drug requirement of the districts for a quarter, with a reserve stock of 7 months for the entire State. The State Drug Stores (SDS) subsequently releases drugs to the respective districts for one quarter's consumption, with a reserve stock of 4 months. From the districts, the drugs are released to each TB unit every quarter to maintain a reserve stock of two months, and from the TU drugs are released to the PHI with one month stock for consumption and one month's stock as reserve after receipt of the monthly report from the PHI at the TU. A transport mechanism is developed at State level to transfer drugs from SDS to DTC and DTC to other subordinate units on the basis of yearly contract with transport agency.

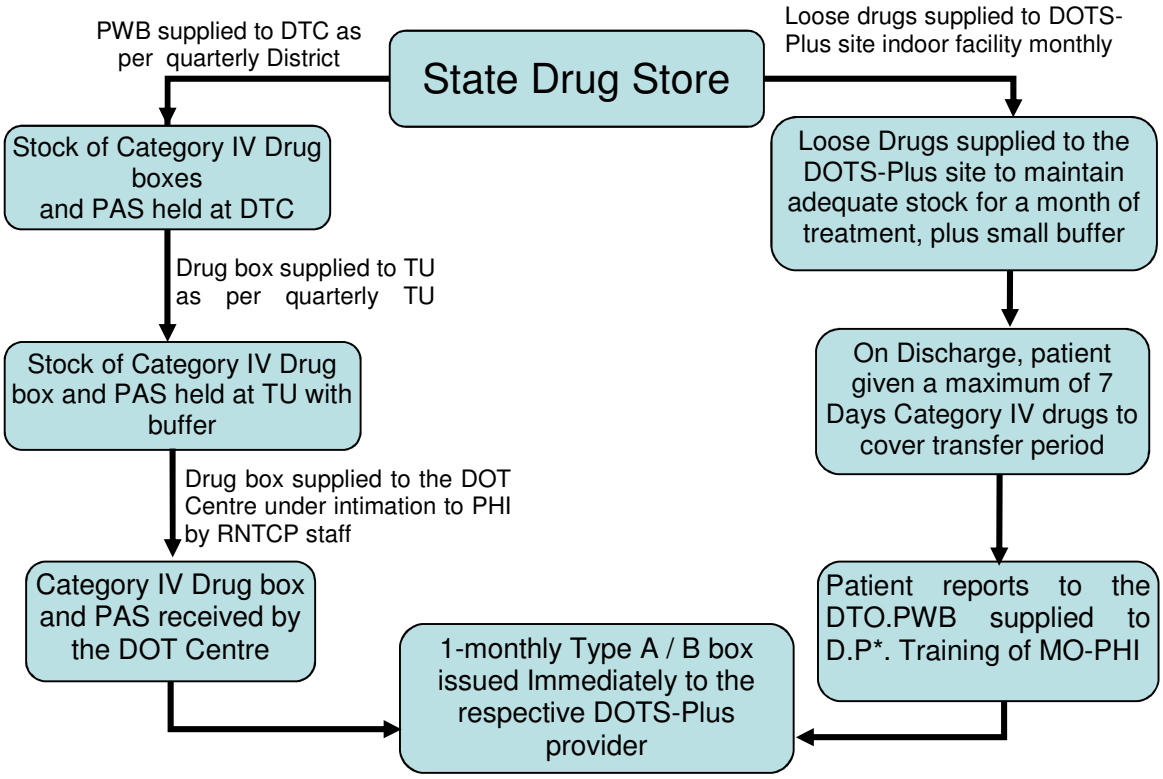
In addition, drugs are also released any time during the month or quarter, from all levels in the event of an increase in consumption or extra requirement of drugs due to other reasons, after submission of an "Additional Drug Request" (ADR).

Second Line Drugs

Loose drugs, being procured by Central TB Division through a Procurement Agency, are dispatched to the State Drug Stores (SDS) directly by the suppliers. The States need to ensure that drugs are as per Technical Specifications with special regard to their DOM & DOE. These Loose drugs are to be supplied to DOTS Plus site indoor patient facility by the concerned SDS. Further, these drugs are to be packaged into 1-monthly drug boxes as Type A & Type B to be used for both Intensive Phase (IP) & Continuation Phase (CP) at the SDS only. For the first time, SDS shall send drug boxes to the implementing DTC as per requirement. Subsequently, the flow of drug boxes shall be monitored through the District Quarterly PMR. DTC shall send the drug boxes to its implementing TU in a similar manner & then monitor through the TU Quarterly PMR. Buffer stocks of

both Type A & B will be held only at DTC & the concerned TU, equivalent to one Type A/B box for each patient undergoing IP/CP.

Figure 1 Proposed Movement of 2nd Line Anti TB drugs



Management of Stocks

First Line Drugs

The stocks at the various levels are monitored via the submission of the following reports:

1. **PHI Monthly Report:** The PHI submits their monthly report to its TB Unit (TU). The TU monitor the stocks in all its PHIs and release drugs based on the stocks reported in the monthly reports.
2. **District/TU Quarterly Report**: The TU compiles the monthly reports of the PHI and submits a consolidated quarterly report to the District. The Districts submit their consolidated report to the concerned State and Central TB Division.
3. **GMSD/SDS Monthly Report:** The SDS and the GMSD report their monthly stock to CTD, which monitors the stock levels on an on-going basis.
4. **Drug Briefing**: CTD also prepares a drug briefing for "Adequacy of Drug Stocks", every quarter after release of drugs to the SDS and Districts. The drug briefing includes projections for the coming year based on the stocks available in the entire country, expected consumption of drugs and the expected supplies of drugs during the coming year.

Second Line Drugs:

The stocks at the various levels are monitored through the submission of the following reports:

1. **DTC/TU Quarterly Report** – TU submits their Quarterly PMR for stocking & indenting of Cat IV drugs to respective DTC. DTC consolidates the report of all its TUs and submit their Quarterly PMR to SDS and Central TB Division.
2. **DOTS-Plus site Monthly Report**– DOTS Plus site submits Monthly Stock Report for stocks & indenting of Cat IV drugs STO /SDS.
3. **SDS Monthly Report** – SDS reports their Stock position to CTD, which monitors the stock levels on an on-going basis.

Management of excess stocks and/or shortage: A stock analysis is prepared every quarter by CTD for all the districts of the State. If excess stocks are available in the districts, directions are given to the State for making inter-district transfers. If there are excess stocks at the State levels, then drugs are transferred to other States. The Districts monitor excess stocks of drugs at lower levels. **"First Expiry First OUT" (FEFO)** is followed at all levels to prevent expiry of drugs and the date of expiry of drugs is also monitored at all levels to take suitable corrective actions. However, short expiry drugs will be evenly distributed to all the consumption units.

Potential shortages are addressed through submission of Additional Drug Request (ADR) and emergency release of drugs is done from various levels of drug stores based on the submission of ADR.

Management of State Drug Stores

For management of State Drug Stores, a number of new activities will need to be taken up which will ensure implementation of the SDS procedures and the effective institution of drug management systems in the state. These activities are as follows:

- Staffing requirement: For effective discharge of storage and logistics function, a pharmacist and a helper/watchman shall be provided on contractual basis at the SDS, once it is established.
- Communication and information technology infrastructure: Effective transmission of information comprises the backbone of efficient functioning of the programme. A computer and a telephone will be provided at the SDS, as these infrastructure facilities are important for communication, coordination and follow-up activities.
- Arrangements for transportation of drugs: Arrangements will be required to be made for the transportation of drugs from the SDS to the various stocking units in the state. To facilitate movement of drugs, the STO shall enter into an agreement with a transport organization, with provision for onward distribution to the TU and possibly PHI levels.
- Miscellaneous expenses: Any expense for day-to-day activities will be met by the STCS from the "Miscellaneous" budget head. Would want to add helper at SDS for loading, unloading etc. Budget provision for SDS should have manpower (Pharmacist, Asst store-keeper, helper), computers with internet, transportation of drugs from SDS to Districts & beyond, if possible,

improvement/ up gradation of stores including provision for ACs, exhaust fans, fire fighting equipment, etc,

- Training: The STO, DTO, pharmacist, store-keepers and data entry operators will be given training in the Standard Operating Procedures prepared for the SDS and the district stores.
- Software for drugs and logistics: It is envisaged that during the period, web-based software will be developed for drug logistics and management, which will be able to assist drug management down to the district level. Provision for bar-code readers with requisite software.

As per norms, for each 50 million population, one SDS is to be established. Hence, with the existing SDS & the population in the states, additional SDS will be required in some states and it is estimated that approximately 10 more SDS will be required.

Quality assurance of drugs

Apart from the quality assurance at the procurement levels RNTCP Quality Assurance (QA) system has been developed and implemented for the RNTCP supplies post-dispatch. The MOHFW has district & state drug inspectors along with central drug inspectors who are at liberty to pick up samples of drugs from any drug stores and get them tested. In addition the Central TB Division has hired the services of an independent testing laboratory, which tests samples selected at random from the DTC, GMSD and SDS.

All implementing districts, GMSDs and SDSs have been arranged on a zone-wise basis i.e. North, South, East and West. Zone-wise random collection of drug samples is conducted during each quarter. For the respective zone selected for the quarter, drug samples are selected from the following sites:

- For 1st Line Anti TB Drugs -
  - 1 GMSD (2 batches)
  - 1 SDS
  - 5 DTC
- For 2nd Line Anti TB Drugs –
  - 2 SDS

CTD issues directions every quarter to the concerned offices to collect the required number of drug samples as per the RNTCP drug QA protocol, and send them to the contracted testing laboratory. The contracted laboratory shall send the drug testing reports to the sender, with a copy to CTD, within 15 days of receipt of the drug samples. Based upon the report, a Committee headed by the DCG (I) will recommend the required action to be taken.

New Initiatives

Diagnostic Technology: Procurement of LED fluorescent microscopes will be conducted in a phased manner in high load centres and the binocular microscopes in these centres will be moved to the other centres where the microscopes have served their life and are due for phasing out from the system.

It is proposed that CBNAAT machines will be procured for installing them at the district levels. It is proposed that 950 machines will be procured in a phased

manner over the project period. The support structures required such as power back up, air-conditioning will also be provided. The recurring cost for procurement of cartridges will also be provided assuming that the machines will operate to full capacity.

Upgrading Storage system of drugs: Upgrading activities for improving storage condition of drugs at GMSD, SDS, and district drug store will be undertaken. Provision of bar coding and provision of necessary bar code readers and associated software will be procured.

Increased management of contracts: Due to the emphasis on private sector participation in the programme as well as increased involvement of NGO/FBO/Civil Society it will be required to manage contracts effectively. Institutional arrangements for carrying out this intensified activity will be required.

Increased level of ACSM activities: The thrust that will be provided for ACSM right from its development to implementation it will be required to manage outsourcing of these activities and managing them.

Increased volume of research: One of the strategies of the programme will be to increase the evidence base to improve the design of the programme and improve its delivery there will be considerable effort in developing evidence through research and surveys the procurement needs to be able to manage the increased volume.

Surveillance: Shift to case based reporting and using it for surveillance will require considerable investment in technology and this would have to be managed by the procurement.

Purified Protein Derivative (PPD): Provisions have been made pertaining to the procurement of PPD for diagnose of paediatric TB, surveillance etc. Necessary arrangements for ensuring cold chain will be required to be made under the programme**.**

Adverse Drug Reaction (ADR): Patients experiencing higher rates of adverse drug reactions should be at increased risk of non-adherence. Therefore early and effective management of ADR should be part of adherence-promotion strategies in the management of MDR-TB under RNTCP.

15
Budget and Financial Management

Key Messages

- Previous financial norms and guidelines had fallen behind NRHM norms, making implementation of the programme difficult towards the final years of the 5-year plan.
- RNTCP has approached TB control with substantially more ambition than the past; finding additional cases and treating them more effectively will require substantially more money. Detailed budget justification and what those additional funds are expected to achieve are summarized here.
- To maximize access to quality TB diagnosis and treatment, RNTCP will be moving from a pure public service model towards a combination public service and private reimbursement model, where in a given area services would also be purchased through private providers and laboratories.

RNTCP will be implemented in line with National Strategic Plan with effect from 1st April 2012 with the proposed allocation as given in Annexures. The implementing agency will continue to be the Central TB Division (CTD), Ministry of Health and Family Welfare (MOHF&W), Government of India (GOI). The Controller Aid, Audit and Accounts of Department of Economic Affairs (DEA), Ministry of Finance, Government of India would maintain a Special Account in the Reserve Bank of India that would be operated This would be a centrally sponsored scheme with the State Health Societies, District Health Societies /Municipal Corporation Health Societies with a separate sub-account for TB Control Activities from the funds from the Ministry of Health and Family Welfare and implementation of the project activities within the concerned State/ District/ Municipal Corporation. All State Governments who have agreed to implement the project as per RNTCP Guidelines have signed Memorandum of Understanding.

There is adequate experience at the Central and State level for the disbursement and financial management of the project funds. The project has provided training to the finance staff at State level in maintenance of the records and forwarding the necessary reports. The Finance staff at central level has also provided training to staff at district level during their visits to the states. The states have sufficient capacity to plan and utilize the funds for project activities as also maintain requisite records and generate the required reports to be provided to the CTD, MOHF&W and other agencies. The project at the central level has a Finance Unit (staffed by Finance consultants, Finance Manager, Accountants, Assistant Accountants, Accounts Officer, and Data Entry Operator) at the Central TB Division. At the State level, there is an Accounts Officer, Accountant (Two accountants in larger states) and the districts to have a full time accountant. The CTD will continue to make efforts to enhance the capacity for financial management at state and district level by visits by central staff for internal reviews, identifying training needs and providing the necessary training.

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

Budgeting and flow of funds

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

The budgets will be prepared by the states. These will be compiled from the district budgets that have been examined and consolidated at State level. Budgetary norms have been specified for planning of activities. The budgets will be supported by State and District annual action plans. These will be approved by the Central TB Division and should form the basis of release of funds and monitoring project implementation by State and CTD.

Accounting, Internal Controls and Finance Indicators

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

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

		within 30 days of end of quarter	

Internal control system would include the following:

(a) Establishment of appropriate budgeting systems and regular monitoring of actual financial performance with budgets and targets;
(b) Adoption of simple, clear and transparent financial and accounting policies. These policies would include identification of expenditures that can be charged to the project and the categories under which it can be charged; policies and procedures for transfer of funds and accounting of expenditures
(c) Establishment of standard controls such as verification of expenditures, levels of authorization, reconciliation and physical verification.

Financial reporting

The financial reporting would commence at districts that would provide SOE to the state with an electronic copy to CTD. The state in turn would consolidate the SOE and forward to CTD. CTD will compile the SOEs from all entities and claim reimbursement, if any from the World Bank / external funding. After audited statements are received the balances at STCS and DTCS will be revised. The reports would include comparison of budgeted and actual expenditures and analysis of major variances. The release of first installment will be based on consolidated SOEs of state for QE December. The second and third installment will be released on receipt of consolidated audit report, Utilisation certificate and SOE of the latest quarter.

Auditing arrangements

The Comptroller and Auditor General (CAG) will audit the accounts of CTD. Local Chartered Accountant firms on the panel of CAG/State AG appointed by state/NRHM will audit the State and district societies on an annual basis. The STCS/NRHM will contract the firm for audit of all State and district societies. The Auditors will carry out such tests and controls as deemed necessary by them. This may include visits to districts, verification of Bank accounts, physical inspection etc. as per the Terms of Reference which will be forwarded by CTD as per Operational Policies of World Bank/NRHM. The Audit reports will be forwarded to CTD within six months of close of financial year (as per World Bank's / External funding agencies, if any, Operational Policies). CTD will compile these and forward to appropriate authorities in Government/World Bank/External funding agencies, if any.

Financial requirements for RNTCP:

1. Finding more cases earlier:

Early case detection which is crucial for effective TB control has been envisaged as a major component in the proposed plan with a 32 % of the budgetary provisions. This includes

a. Improved Diagnosis of TB including MDR-TB and XDR-TB
b. Public-private mix (PPM)
c. Advocacy, Communication & Social-mobilization

The details of all these components are as follows:

a. Improved Diagnostics of TB:

Quality assured diagnostics which can provide the results with minimal turn-around time at a decentralized level for patient convenience is very important for early case detection. This is being planned in the program with proposed provision for diagnosis of TB is as follows:

Sr. no.	Early TB Diagnosis	2012-13	2 013-14	2014-15	2015-16	2016-17
1	Number of NRLs for supervision & monitoring	5	6	6	6	6
2	No. of Culture & DST Lab with					
	Solid	43	43	43	43	43
	Liquid	33	33	33	33	33
	LPA	43	43	43	43	43
3	No. of DMC with up-gradation for rapid diagnostics	13164	13373	13559	13745	13931
4	No. of Designated Microscopy Centre with	2902	3037	3549	3820	4096
	• Binocular Microscope	2639	2239	2480	2476	2473
	• LED Florescent Microscope	263	798	1069	1344	1623
5	Expected sputum smear examination by ZN Staining for diagnosis	17657491	17958147	18225926	18493704	18761483
6	Expected sputum smear examination by ZN staining for follow-ups	4767522	4848700	4921000	5363174	5440830
7	Expected tests in DMC with Rapid diagnostics	288,000	864,000	1,440,000	2,016,000	2,736,000

The culture & DST services for diagnosis of drug resistant tuberculosis will be available by solid, liquid and LPA methods across the country. The DMCs with rapid diagnostics will be available at 950 centres which can diagnose TB early in co-infected group of patients as well as R-resistant TB in re-treatment group of patients even at DMC level. The diagnosis of TB at most peripheral level is to be improved with LED based florescent microscopy with phasing out the Binocular microscopy with newer technology. The budgetary provisions for the same will be as follows:

Amount in lakh

Sr. no.	Particulars	2012-13	2013-14	2014-15	2015-16	2016-17	Total
1	Improved diagnosis of TB and MDR TB	14959	22162	21426	24857	30,008	113411

b. PPM:

Public private mix is an essential component for the early diagnosis and improved notification of TB cases. Improved notification of tuberculosis is envisaged with pro-active involvement of all the health care providers. The involvement of Private practitioners, NGO health facilities and medical college, PG teaching institutes and corporate hospitals is crucial. The program has planned for following activities:

Medical colleges & hospital involvement:

Particulars	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL
National Conference	8	8	8	8	8	40
State level conferences	140	140	140	140	140	700
No. of Medical college involved	307	310	313	316	319	319
No. of PG teaching / Corporate hospitals involved	50	60	65	65	70	70
No. of NTF / ZTF meetings	6	6	6	6	6	30
No. of STF meetings	70	84	91	91	98	434
CMEs at medical college	307	310	313	316	319	1565
No. of doctors undergoing Training/Sensitization at medical colleges	7675	9300	10173	10270	11165	48583
No. of PG students supported for research on TB	307	310	313	316	319	1565

Considering the experience of uptake of NGO-PP schemes in previous years, the coordinator for PPM activities at State and District level was included in the proposed budgets and the presence of most of the private providers in urban areas, the Tuberculosis Health visitors were made more responsible for PPM activities with the inclusion of them under this head. The scheme needs revision with norms of costing at par with the program and current situation as well as inclusion of the new schemes for upcoming needs of the program. The budgetary provision for the activities promoting and effectively managing the PPM activities has been also included in this head.

The budgetary provision in the budget is as follows:

Amount in lakhs

	2012-13	2013-14	2014-15	2015-16	2016-17	Total
NGO & PP Support	8801	12688	13769	13448	15272	63978
Medical colleges	2532	2975	3211	3449	3691	15858

c. Advocacy, Communication & Social Mobilization:

Advocacy, Communication & Social mobilization at different levels has been proposed. The central level activity will include and target mainly the advocacy component and nation-wide communication with print and electronic media. The

state level activities will include a major component for communication for service demand generation and effectively utilizing the available ACSM agencies with a focal point at state level. The district level activities will include and target more on social mobilization and actual participation of the community in TB control.
The IEC campaign would be for all the stakeholders including the different target groups i.e., medical professionals, paramedicals, patients, relatives of patients and community. This includes various activities undertaken during World TB Day week, patient provider meeting, community meeting, CME, communication facilitator cost, print media, electronic media, school activities, activities targeting universal access, TBHIV, MDR-TB, etc. The urban area and groups with high risk for TB has also been targeted with additional allocation for the activities for this population within the budget head. The program proposed the following activities under ACSM:

No. of Activities / facilities involved	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**TOTAL**
No. of places where World TB Day observation done	30203	30590	30972	31350	31724	154839
Patient provider meeting	113166	110122	111500	112862	114206	561856
Community meeting	15291	24472	24778	25080	25379	115000
CME for PP/NGO	654	654	654	654	654	3270
Focused TBHIV / MDR TB	3823	6118	6194	6270	6345	28750
Print & electronic media activity	654	654	654	654	654	3270
School / Education institute involvement	7646	12236	12389	12540	12690	57500
Innovative activity as per local needs	2238	3386	3424	3462	3499	16010

The program budget the exclusive budget for ACSM as follows:

Amount in lakhs

	2012-13	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**Total**	%
ACSM	1,495	1,627	2,434	2,985	3,175	11,715	1,495

2. Improving patient friendly treatment:

a. Anti-tuberculosis drugs:

Provision of quality assured free treatment for each and every TB patient under the program has been further strengthened with provision for the MDR, XDR & Co-infected TB patients on 2nd line ART. The TB drug cost contributes to almost 26% of the total proposed budget of TB Control program. (First line 11% & Second line 15%).

The program targets to provide treatment to 88 lakh TB patients including 6.13 lakh paediatric patients. Similarly program targets to treat another 1.65 lakh drug resistant TB patients over a period of five years.

Number of TB patients to be treated under program:

Patients to	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**TOTAL**

be treated						
Total TB Cases on first line drugs	1655390	1683576	1708681	1862213	1889177	8799037
Total Paediatric cases	115877	117850	119608	130355	132242	615933
MDR TB cases	25400	29000	30000	36000	40000	160400
XDR TB cases	100	1000	1000	1000	1000	4100
Co-infected on 2nd Line ART requiring Rifabutine	5437	5506	5575	5643	5710	27871

The anti-tuberculosis drugs budgeted under the program is as follows:

Amount in lakhs

Anti-tuberculosis drugs	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**TOTAL**
1st Line Drugs	**9,115**	**10,256**	**12,566**	**13,784**	**14,135**	**59,857**
2nd Line Drugs	**7,425**	**17,258**	**20,832**	**12,380**	**13,415**	**71,310**

b. Patient support and transportation & counselling charges:

Patient support and counselling has been experienced as crucial for the treatment adherence and completion of the treatment by the TB patients. Provision of transportation cost to the patients, co-infected for ART visit, collection and transportation of sputum samples to the laboratories plays an important role in early treatment initiation as well as proper monitoring of the patients. Additional assistance to the TB patients in tribal / hilly / difficult areas to cover up the cost of transportation for treatment and follow-up has been proposed. MDR suspect and patients' needs frequent long distance transportation for specialized services of accredited laboratories and DRTB centres and hence the budgetary provisions have been included with an intention of early treatment initiation and prevent further transmission and spread of infection.

Amount in lakh

	2012-13	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**TOTAL**
Honorarium – to non-salaried DOT provider	**1,055**	**1,241**	**4,345**	**5,209**	**5,593**	**17,443**
Patient support & transportation charges	**(0)**	**320**	**2,614**	**3,135**	**3,166**	**9,234**

Decentralized DOT with non-salaried community dot provider for patient convenience is promoted for treatment adherence. The honorarium/counseling charges for provision of DOT for TB treatment will be paid only to such workers who are not salaried employees of the Central/State

Government. This would include among others Anganwadi workers, trained dais, village health guides, community volunteers, ASHA, link-workers etc. Around 30 lakh patients over 5 years will be provided DOT provision from the non-salaried DOT providers.

3. **Human Resource Development & Capacity Building:**
Program envisages incorporating a strong policy on human resource development. The program management units at Central, State and District level units are being strengthened in proposed plan. The plan also includes the required expertise for the culture & DST laboratories which will be crucial for early diagnosis of drug resistant tuberculosis. The alignment of the tuberculosis units with the NRHM block level program management units for improving and integrating the TB program at sub-district unit level with NRHM. Similarly the financial management has been planned to strengthen with conversion of part time accountant post to full time accountant under the program. Areas of Procurement and logistics management have been also strengthened by making provision of experts under the project. Counseling of drug resistant TB patients at very initial stage of treatment initiation at DRTB centres has been planned with a full time counsellor at DRTB centres across the country. Similarly an operation research cell at national institute is being supported with required experts.

Amount in lakh

Particulars	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL
Human Resource Development and Capacity building	172.27	238.29	303.54	301.59	303.57	1,319.26

Capacity building of medical, para-medical and program managers have been a key activity for sustainable quality service delivery. Around 5.33 lakh manpower is proposed to be trained in 30422 batches for various areas of the program over 5 year period. This includes more than 1.9 lakh manpower in 14900 batches for newer areas of management of MDR TB and co-infected TB. Around 15800 batches for retraining of more than 3 lakh manpower is expected over next 5 years. The training to be undertaken as per the RNTCP guidelines developed as per the program needs and approved by CTD from time to time.

4. **Programme operations, supervision, monitoring and research:**
Miscellaneous head of the RNTCP-II has been clearly divided based on the activities into the Supervision & Monitoring head and Office operations. The program has planned to include the two wheelers for improved mobility and patients visits for counseling, retrieval, tracing the suspects and patients for early diagnosis and complete treatment. Provision of vehicle for laboratory supervisors improves the supervision and monitoring of the laboratories, specially required with change in the technology from binocular microscopy to LED based fluorescent microscopy, decentralized rapid diagnostics and decentralized collection centres. The central, state and district level program management units have provision of hired vehicles for supervision and monitoring. The tribal / hilly / difficult areas with problems for hiring a vehicle will be provided with four wheelers

Few of the major components under this head are described below:

a. **Provision for the mobility support with for the central, state, district and sub-district level:**

Supervision and monitoring has been a crucial component in the TB Control program. Mobility support has been kept at all levels central, state, district and sub-district level.

Amount in lakh

Particulars	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL
Vehicle procurement cost	226	328	1,369	234	328	2,484
Vehicle Operation	892	1,000	2,166	2,427	2,444	8,928
Vehicle hiring	575	789	2,062	2,299	2,305	8,030
TOTAL	1693	2117	5597	4960	5077	19442

b. **Central level and State level Internal Evaluations:**

Quality ensured program implementation is being ensured by regular evaluations of the states and districts by central level and state level respectively. All the states and districts are to be covered at least once in 3 to 4 years. The numbers of evaluations to be undertaken by central and state level are as follows:

Particulars	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL
Central evaluations to cover states	12	12	12	12	12	60
State level evaluations for districts	218	218	218	218	218	1090

The cost budgeted in the plan is as follows:

Particulars	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL	% to total budget
Programme operations, supervision, monitoring and research	5,204	6,145	12,794	12,160	12,754	49,057	11%

c. Web-based Case-based monitoring of TB patients:

Another major change proposed is applying the technology for the web-based case-based monitoring of the program. The first year will plan to develop, pilot and finalize the system and software and the phase wise expansion to cover the complete coverage of the country.

Phase-wise Expansion of web-based case-based monitoring of TB patients across the Tuberculosis units:

	2012-13	2013-14	2014-15	2015-16	2016-17
Number of TUs with web-based case-based monitoring of the program	0	612	1858	3762	6345

Expected number of TB cases to be enrolled under web-based case-based system under the program in phase wise expansion:

Type of TB cases in web-based case-based system	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL
TB Cases (Cat I/II)	1655390	1683576	1708681	1862213	1889177	8799037
MDR TB cases	25400	29000	30000	36000	40000	160400
XDR TB Cases	100	1000	1000	1000	1000	4,100
Total TB Cases	**1680890**	**1713576**	**1739681**	**1899213**	**1930177**	**8963537**

The budgetary provision under the program is as follows:

Budgetary provisions under the program

Amount in lakh

Particulars	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL
Hiring of Agency for for developing, piloting & upgradation of web based DOTS R&R software	281	281	0	0	0	562
Software Maintenance cost with full time DBA with updation and upgradation of software for new changes and requirements	0	67	112	114	117	410
Support to end users with Helpdesk technical and program support & application hosting charges and its maintenance	14	76	83	90	99	362
Cost of the PDA to be procurement	0	94	191	293	399	977
Cost of maintenance of the PDA	0	19	57	116	195	387
Communication cost for each TU for data transfer	0	37	114	194	277	622
HR						

Network administrator 1	6	6	6	6	6	30
Data analyst -2	4	7	7	7	7	32
TOTAL	**305**	**587**	**570**	**820**	**1100**	3382

This will benefit in improved monitoring of the patients and the program.

Proposed budget heads & norms:

All the expenditures on various activities under RNTCP are to be booked under one of the following budget heads. The proposed budget heads are as follows:

Sr. no.	Norms
1.	**Civil Works**
2.	**Procurement of Equipment**
3.	**Procurement of Vehicles**
4.	**Procurement of Drugs**
5.	**Printing**
6.	**Laboratory materials**
7.	**Training**
8.	**ACSM**
9.	**Medical Colleges**
10.	**Contractual Services**
11.	**Honorarium/Counseling charges**
12.	**Patient support & transportation charges:**
13.	**PPM (NGO/PP support)**
14.	**Research & Studies & Consultancy**
15.	**Vehicle operation (POL & maintenance)**
16.	**Vehicle hiring**
17.	**Office Operation**
18.	**Equipment Maintenance**
19.	**Supervision & Monitoring**

The details of the various activities to be considered while booking the expenditure under each budget is as follows:

1. **Civil Work:** All expenditure on construction / renovation / improvements /other structural modifications / building and necessary furniture and fixtures of RNTCP establishments including STDC, IRL, SDS, State TB Cell office, DTC, Drug stores, TU, lab of DMC – all these will be incurred as per the RNTCP guidelines. Expenditure on maintenance of civil works / structures used for program is also to be booked under this head. This includes minor repairs, plumbing, white-wash, electrical and other fixtures etc., requiring no structural modifications, and to be incurred within the RNTCP norms. Expenditure done under this head towards refurbishment and repair will not be capitalized in books of accounts. During next five year plan, it is proposed to further decentralize the monitoring and notification units for patient friendly and complete notification of all the cases and to manage the MDR TB.

Sr. no.	Up gradation	2012-13	2013-14	2014-15	2015-16	2016-17	TOTAL

1	NRL	1	1	0	0	0	2
2	STDC	5	0	0	0	0	5
3	SDS	0	3	5	5	0	13
4	IRLLPA	6	4	2	0	0	12
5	IRLLIQUID	2	2	2	0	0	6
6	DR TB Centre	47	25	21	0	0	93
7	DDS to be upgraded for 2nd line anti-tb drugs storage	66	196	196	0	0	458
8	Tuberculosis Units	1204	2413	93	93	93	3895
9	Designated Microscopy Centre	337	209	186	186	186	1104
10	DMC to be upgraded for rapid diagnostics	100	200	200	200	250	950

These will provide improved accessibility with decentralization of the services maintaining the quality and alignment with the NRHM supervisory and monitoring units.

2. **Procurement of Equipment:** Provision of essential equipments for quality service delivery has been included in the plan.
   Laboratory equipments for Designated microscopy centres has been planned with replacing the Binocular microscope with LED based fluorescent microscopes in phased wise manner and equip 1623 DMCs with improved and early case detections. Similarly 950 diagnostic centres are to be upgraded with automated NAAT facilities for decentralized and improved early diagnosis of TB in specialized groups and including the drug-resistant TB to a great extent.
   Every DTC, SDS, DRTB Centres, STDC, IRL, C&DST lab, SDS (DRTB section), State (type A/B/C=3/2/1), STF (with more than 15 colleges involved), ZTF are eligible for computer system (desktop with essential software, printer, scanner, UPS etc) and to be provided if needed. Every STC, STDC & DTC will be eligible for photocopier. Every SDS & DDS is eligible for equipment and software for the Bar-code reading. Every TU who is under web-based case-based notification system will be eligible for a PDA hand held devise. Every state Type A /B/C will be eligible for LCD with laptop system 2/1/1 respectively to be placed in STC/STDC. Urban districts with more than 40 lakh population are eligible for LCD with laptop.
   Thus office equipments includes the provision of the 982 computer systems, 754 photocopiers, 64 LCD sysetm with laptops, for district, state and central level facilities including the DRTB centres and labs for improved and efficient communication and reporting. These also include replacing the existing computer systems (>5 years), LCD & Photocopier (>7 years) as and when they get condemned over a specified period. 6345 PDA hand-held devices proposed for web-based case-based notification of the TB cases. 42 Video conferencing equipments for central and state level offices proposed for

improved communication and reviews. Provision for equipping the central level offices has been made. 654 refrigerators for district level storage of the paediatric and diagnostic materials. All state and district level drug stores to be equipped with 682 bar-code systems for efficient drug logistic management.

3. **Procurement of Vehicles:** Seventy-eight four-wheelers has been planned to be provided / replaced in the tribal / difficult districts where the vehicle hiring problems limits the mobility of the program managers for supervision and monitoring. Four-wheeler procurement needs to be done only after written approval from Central TB Division. Every STS, STLS, district level PPM coordinator, district level DRTBHIV coordinator are eligible for the two-wheeler vehicle. STLS will be provided with the existing two-wheelers of the STS with phase-wise expansion of the TUs for population of 1.5 to 2 lakh. Thus thirteen thousand three hundred ninety four 2 wheelers planned for the mobility of these staff in the field. This includes additional created structure as well as replacing the existing vehicles due to condemnation over a period of time.
4. **Procurement of Drugs:** All the TB patients are provided anti-TB drugs free of cost. The provision has been made for managing 88 lakh TB patients including around 6.1 lakh paediatric TB patients over 5 years. Similarly 1.6 lakh MDR TB patients and 4100 XDR TB patients provision for anti-tuberculosis drugs have been made. The budget for the 1 lakh MDR TB courses have been budgeted at low cost with procurement to be undertaken by the GoI. The provision for the Rifabutine drug for the co-infected on 2nd line ART for 27800 patients has been made in the program over 5 years. All the drugs are to be procured by central level for competitive and quality purposes. Drug procurement by state / district level is to be undertaken only in exceptional situation with clear written permission from central level in case of emergency or out of stock due to unavoidable circumstances.
5. **Printing:** Provision for the printing of the RNTCP material has been kept at central, state and district level. The material includes program guidelines, modules, registers, booklets, forms, reporting formats, treatment cards, etc. The state level should undertake the printing of the guidelines, modules, registers etc for maintaining the uniformity and competitive costing. Usually the budgetary provision ratio is of 66% at state and 34% at district level, but may vary based on the requirements and level of printing of the RNTCP material.
6. **Laboratory materials:** Laboratory material for the early quality diagnosis of TB includes lab materials for the DMCs, IRL, Culture & DST laboratories. Over 502 lakh TB suspects will be examined and 88 lakh patients put on TB treatment will be subjected for follow-up sputum examination over the 5 year period. Similarly the 29 IRLs, 43 Culture & DST laboratories will be provided lab material for the EQA and for culture and drug susceptibility testing to put on treatment around 1.6 lakh MDR TB patients and to undertake their follow-up cultures during the course of 2 years of treatment for each patient. Similarly provision for the kits of the automated NAAT has been made for examining over 73 lakh suspects for early and decentralized diagnosis of TB including R-resistance. The laboratory material for sputum smear microscopy by ZN staining is to be done at district level. The laboratory material for IRL, Culture & DST laboratories, DMC with rapid diagnostics can be done by central / state / STDC / IRL / Culture & DST laboratories / District in such a way that

competitive quality assured with specific technical specifications reagents and materials are available with minimum turn-around time following program financial guidelines.

7. **Training:** This head covers the cost of all trainings organized at Central, State & District level. The specific trainings are to be carried out at specified levels to maintain the quality and operational issues. Trainings to be carried out at lower level needs prior approval for each batch from appropriate authority i.e. where the training is expected to be done. The course organization cost should cover all the activities related to organization of such trainings like communication, venue cost, audio-visual / equipment hire cost, transport cost, inaugural / closing ceremony, additional allowance to the staff involved in organization of training etc. The organization cost may also be given to the institute for aggregate expenses undertaken by them for training. The course material cost should include the folder, pen, pad, pencil, eraser etc or a kit containing all these material, addendum, presentation, CDs, certificates, print-outs etc. provided during the training to the trainees. The refreshment cost includes two teas, breakfast and working lunch for the trainees, trainers, facilitators and staff involved in organization of training. The refreshment cost to be reduced to 50% for sensitization / training of half day (4 hours). Honorarium to the facilitators is to be provided as per the prescribed norm. External facilitators are eligible for honorarium @ 1.25% of the norm. Visiting experts coming for a short lecture or presentation are also eligible for 50% of the norm of honorarium. Organizers should ensure that the total cost of honorarium for specified training remains within the prescribed cost limit for the batch. The central and state level trainings should be preferably organized with stay arrangements for residential trainings. Institutes where the residential arrangements are not available, but has been done by the training organizers by local hiring, then the participant will be provided DA at a norm of "DA with stay facility" the cost of the residential arrangement can be expended from this head at the rate of difference between the two norms of DA i.e. DA with stay facility and DA without stay facility. The TA/DA cost for all central / state / district level trainings to be given at the venue as per guidelines from this head.
8. **ACSM:** ACSM activities is to be planned at Central, State, District, Sub-district and PHI level. The norm for central level activities includes GoI initiated Advocacy and advertisement through the media agencies. GoI other IEC activity has also been budgeted.

   The norm for the state level activity includes a fixed annual budget of 20, 14 and 10 lakhs for the large, medium and small states. Apart from this population based budgetary norm @ Rs. 0.4 lakh per million population has been kept to carry out the other IEC activities either through agencies or directly and includes the activity cost also. This will balance between the less populous and high populace states with adequate availability of funds for ACSM activities.

   All the District level activities have been budgeted @ Rs.1.88 lakh per million population for various activities. This includes various activities like World TB Day observation at DTC, TU, DMC, PHI level (e.g. budgetary provision of Rs. 5000 to 10000 for DTC, Rs. 2000-3000 for TU, Rs. 1000 for DMC and Rs. 500 per PHI); Patient provider meeting @ Rs. 250-500 (base on participants) per patient provider meeting per PHI per quarter, Community meeting @ Rs. 1000

per meeting with 2 meetings per TU per quarter, CME for PPs / NGOs @ Rs. 20000 per CME; 2 CMEs per district; Focused activity for TBHIV, MDR TB @ Rs. 2500 per TU, Print & electronic media @ Rs.10000-30000 (Type A/B/C district=10/20/30) per district; School activities Rs. 500 per school to cover 8 schools/education institute per TU annually, Other innovative activities as per local need @ Rs.10000- 30000 per district (Type A/B/C=10/20/30) and Rs. 1000 per TU per year. These are tentative activities and norms which may be applied based on local need and local cost for the activity. Activities need to be prioritized so as to accommodate in the district level population norm budgetary provision. Communication facilitator is budgeted for all districts, with average 1 visit per month with a norm of Rs. 1000 per day provision (Max Rs. 2000 per visit) which includes all the cost of CF as well as TA/DA.

Similarly higher norm has been kept for urban areas considering the higher cost and more focused activity. Urban areas will get @ 3.33 lakh per million population while the million plus cities will get @ 3.78 lakh per million population. Urban areas to focus their additional activities on the vulnerable population like slums, and to involve the private health care providers. ACSM Officer for state level budgeted to ensure proper implementation and monitoring of the ACSM activities. The bigger states to get 2 ACSM officers.

9. **Medical Colleges:** Medical college involvement has been crucial for the TB control. The mechanism of National Task Force, Zonal Task Force, State Task Force and Core-committee is proposed to be continued. The periodic meetings of these task forces were supported from external agency is now budgeted from the program. The advocacy among the health care providers by promoting the session in the various national and state level conferences has been included. Promotion of research towards priority areas of the program by supporting to 975 PG thesis has been planned.

   Considering the high load of patients the contractual medical officer, laboratory technician and TB health visitors have been continued in the present plan. Considering the variability of the case load, additional laboratory technicians and TB health visitors have also been budgeted.

   Similarly the NTF, ZTF, STF mechanisms have been proposed to be strengthened with provision of the organizational expenses, contractual data entry operator, additional allowance of (10% of contractual renumeration) to respective MO-medical colleges where the NTF, ZTF and STF is located. Miscellaneous, communication and stationary cost has been budgeted at the annual rate of Rs. 250, Rs. 500 and Rs. 1000 per involved medical college for NTF, ZTF and STF respectively. Similarly a monthly allowance of Rs. 2000, 1000 and 500 to be provided to the available clerical staff of the NTF, ZTF and STF respectively.
10. **Contractual Services:** Central level monitoring unit strengthening is to include Technical officer and Technical assistants to each function of the technical unit, five data entry operators and four secretarial assistants and one statistician. The administrative section is to have one post of administrative officer and two administrative assistant. Finance section is to have three Consultant finance, one Finance manager, four accountants and one account officer. The procurement and logistics management section is to have one consultant, one logistic manager, one supply chain manager and ten assistants. Each NRL can be provided upto three microbiologists and four senior LTs for EQA. The national institute for tuberculosis to have one HR

officer, two training facilitators, two epi-centre experts (one field expert and one computer expert), one epidemiologist, two research officers, one librarian and one documentation assistant with a view to strengthen and promote research and its dissemination.

The state level units strengthening includes one post of each of Epidemiologist (assistant program officer), Medical officer – STC, TBHIV coordinator, Drug resistant TB coordinator. For bigger states (>30 million), there will be two posts for all these staff. State to have one post of Technical officer for procurement and logistic management. Every IRL is to have one contractual microbiologist for EQA. The culture & DST laboratory is to have one microbiologist, one Sr LT and one DEO from program. The SDS is to have one Pharmacist cum store-keeper and one store assistant. If the preparation of Cat IV / V drug monthly boxes from loose drugs is more than average of 1800 per month, then SDS will be eligible for additional store assistant.

The district and sub-district level units to have Medical officer-DTC in 20% of the DTCs. With phase wise expansion of criteria C of MDR TB suspect, this norm can be increased upto 50% in the last three years of the project. Every district is to have one post of DEO, Sr DRTBHIV coordinator; the bigger districts type C to have two posts. The District is to have one post of district program coordinator and full time accountant instead of part-time accountant. Every TU is to have one post of STS; if annual case load is more than 500, additional STS can be provided based on the need and after approval. STLS post will be for every 5 lakh population. Upto 30% of the DMCs can be provided with contractual laboratory technicians provided there is a vacancy or non-availability of the LT to manage the sputum smear microscopy load in such DMCs. The districts with RNTCP vehicles will only be eligible for the contractual driver post from program. Every DRTB center will be eligible for one post of each – Sr. MO DR TB Centre site, Counsellor and DRTB Statistical assistant. If the annual registration of Cat IV/V patients increases more than 250 cases in the DOTS plus site, then additional MO and SA can be given on approval from state.

The existing contractual staff posts and persons if in line with the above norms will continue as per the guidelines. The relocation of posts and person is to be undertaken as per the need and approval by appropriate authority. All the contractual staff will be appointed for 1 year at a time and annual renewal every year to be done till the project exists, except discontinued for non-performance / under-performance / abolish of the post / show-cause notice issued and satisfactory response not received during previous contract period. During transition from RNTCP II to RNTCP 2012-17, all the contractual staff shifts on the post on new salary norms and retaining all the actual increments amount received after last revision of salaries.

11. **Honorarium** / **Counselling charges:** For improving the treatment adherence, continuous motivation of non-salaried community DOT provider is essential. Program promotes to decentralize dot provision for maximum patients for convenience and improving the adherence. The non-salaried DOT provider to ensure collection and transportation of the sputum sample required for follow-up examination during the treatment. The honorarium can be paid in two installments – 40% on completion of IP and 60% on completion of CP provided the patient is treatment completed or cured. If the installment after

completion of IP is released and given to the non-salaried DOT provider before the patient defaults / dies / fail / does not complete treatment in CP, the already given amount should not be recovered. Similarly the honorarium can be divided into multiple non-salaried DOT providers on pro-rata basis of the doses provided by the respective DOT provider. In-case the non-salaried DOT provider is also giving the injection in IP, the injection prick charges of Rs. 10 per prick is to be given as additional honorarium to the non-salaried DOT provider. The amount to be provided as soon as the treatment outcome has been recorded on treatment card and TB register. The amount can be paid through the block level MO / PHI MO / STS / TBHV etc as per the local arrangement so as to ensure fastest disbursement with complete documentation.

12. **Patient support & transportation charges:**
    Enables for the patient and provision of transportation charges for early diagnosis and treatment adherence for focused group of patients.
    Tribal / Hilly / Difficult areas: Patients from tribal areas will be provided a support for travelling for the DOT and for follow-up during the treatment. An aggregate amount of Rs. 750 on completion of treatment to cover the travel costs of patient and attendant.
    Sputum collection and transportation: Incentive to the non-salaried DOT provider / government staff with no provision for TA from government fund for patient convenience from non-DMC PHI to DMC can be provided at the rate of Rs. 15 per patient (maximum Rs. 1000 per month). There should be atleast 5% positivity rate among suspects whose sputum has been transported for diagnosis and amount to be given on pro-rata basis if positivity rate is below 5%. Around 10 lakh sputum samples will be collected in this way for patient convenience and early diagnosis and proper management of the patient.
    Sputum samples collected and transported for culture and / or DST: MDR / XDR TB suspect samples collected and transported to the culture and / or DST charges can be paid as per the norm mentioned in document. The expenditure on required box, cold packs etc to be undertaken from this head as per local need and if not provided from state level. The most competitive and minimum turn-around time mechanism of transportation to be implemented as per local situation and expenditure done from this head.
    Travel Cost to MDR / XDR TB suspect and patient and Co-infected TB patient: Cost of travel by public transport to such patients to district level / DOTS plus site / IRL / Culture & DST laboratory / ART centre can be provided as per the norms. The travel cost can be provided for two (patient + one accompanying person). In case of non-availability or in-convenient public transport in the local situation, the norms approved by the local authority / state authority can be used for disbursement. All such travels must be as per the RNTCP technical guidelines.
13. **Public-private mix (PPM):** All the activities included in this head are payments of NGO/PP schemes grant-in-aid, activities undertaken for involvement of NGO/PPs, Cost of the state and district level PPM Coordinators and TBHVs, and costs for pilots / innovations for improving TB control at central / state / district / sub-district level. All the NGO registered under State Societies Act/ Societies Act/ Companies Act or Trusts Act with their Memorandum /Articles of Association expressly stating that the Company/Society has been formed for purpose of non□profit and has its

independent sources of funding and is not solely dependent on any programme funds. Private practitioner / clinic / dispensary / hospital / agency / individual / institute / organization should be registered with the appropriate authority. To intensify the PPM activities, PPM Coordinator provided at State level: 1 per state (additional 1 if population >30 million) and District level: 1 per district (additional 1 if population > 40 million) TBHV: 1 per lakh urban aggregate population in the district are to be provided from the program. Out of the total available budget under this head, upto 10% can be utilized for activities involving promotion of NGO / PP involvement, upto 30% can be utilized for piloting / innovations activities which are included in the action plan and approved from CTD. The coordination with NGO/PP can be done through either a PP/NGO cell or through a private Provider Engagement Agency which can undertake various functions of inviting, processing, evaluating and monitoring and disbursement at an agency fees approved by appropriate authority (not more than 10% aggregate disbursement amount). The National Technical Working Group (NTWG) to further provide guidance on implementation through the PPM technical support group at various levels. All expenses related to this can be done through this head.

14. **Research, Studies & Consultancy:** There are certain studies like disease burden studies, social assessment studies, IEC impact assessment studies, mortality surveys and drug resistance surveillance studies which will be undertaken by CTD and Central Institutes. Additionally operational research proposals on identified priority areas will be invited from State level and from the Medical Colleges. Capacity building programs for Operation research for stakeholders to be carried out. National Operational Research cell supported by HR as mentioned in contractual salary head. Proposals approved by State level OR committee / Zonal level OR committee / Central TB Division / National OR cell to be funded.

    Consultancy charges for procurement of drugs, lab testing charges for drug quality assurance, procurement & logistic supply chain management agency, agency fees for advocacy / media management campaigns, consultancy cost for agency developing, maintaining, upgrading the web based DOTS plus recording & reporting software, MIS system with web based case based reporting system.

15. **Vehicle operation (POL & maintenance):** Vehicles provided by RNTCP and used for supervisory visits by DTO, MOTC and contractual staff under RNTCP are covered under this head. The cost includes repairs, spare parts, service charges, insurance, vehicle essential accessories, fuel and oil. Insurance should cover the insurance of driver and pillion and passengers. In-case of non-RNTCP vehicles being used for RNTCP work by DTO, MOTC or contractual staff due to non-availability / non-working of RNTCP vehicles, then the actual fuel (petrol / diesel) cost can be provided under this head with appropriate documentation. Any other cost (other than petrol / diesel) for non-RNTCP vehicle cannot be reimbursed. The actual expenditure based on the fuel cost, distance travelled and other costs can be approved even beyond the norms. The norm is 1.20 times for the tribal / difficult / hilly areas. Every state type A and district of type A and B to have one four-wheeler (either RNTCP or hired); Type B states and district Type C to have 2 four-wheelers while type C states to have three four-wheelers vehicle provided full time officers are available for supervision and monitoring for each vehicle. MOTC who are not

hiring the four-wheeler can also be provided POL cost upto Rs. 0.5 lakh annually on appropriate travel and vehicle log-book documentation.

16. **Vehicle Hiring:** Vehicles are hired where RNTCP or State Government Vehicle are not available, for supervisory visits to be under taken by Officials from CTD, STO, DTO or MO□TC: Appropriate documentation for supervisory visits to be ensured. Officials having NRHM hired vehicle / govt vehicle / other program vehicle available for supervision & monitoring cannot hire additional vehicle from RNTCP. The vehicles can be hired only for the days when supervisory, monitoring or official visits are expected to be undertaken. In case the hiring is not possible in the norm, the norm can be increased by higher authority after verifying the facts for other vehicle hires from NRHM, other programs.
17. **Office Operation:** Office operation expenditure includes janitorial expenses, electricity, telephone bills, fax bills, postage, office stationery, office furniture for STCs/DTCs and TB Units, repair of furniture, hiring of daily wage labour for loading and unloading of drugs, sputum transportation box, drug boxes for Cat IV / V, recruitment advertisements, transportation of drugs from State drug store to district store, office rental, *etc.* Only costs not covered by State / institute routine budgets will be provided under project funds. Any other expenditure which does not fit in any of the other heads is to be booked under this head with proper documentation.
18. **Equipment maintenance:** This includes the maintenance cost and repair costs for all the equipments provided and/or utilized under the program. This includes consumables for these equipments like cartridges, toners, fax-machine rolls, annual maintenance contract cost, repairs for office equipment like computer, printer, photocopier, fax, LCD, Laptop, refrigerator, binocular microscope, LED based fluorescent microscopes, newer diagnostic equipments, Culture & DST equipments, PDA etc. The maintenance funds can be pooled at state or district level and arrangements made for responsive maintenance of equipment for least down time. Software up-gradation, anti-virus program cost is also included in equipment maintenance.
19. **Supervision & monitoring:** This head includes the expenditure related to review meetings, TA & DA of the staff, organization of team visits, internal evaluations, appraisals etc. The central level includes expenses for all the team visits, TA &DA of the staff at CTD and various central institutes. All TA & DA is to be borne from this head except for visits undertaken for training. The state level budget includes expenditure related to meetings, evaluations, appraisals, team visits, TA &DA of the staff from STC, STDC, SDS, IRLs etc.

The proposed budget estimate year wise is given at Annexures 10.1 to 10.4 The details of states, population category wise is provided in Annexure 9 The supporting sheets to each line item in the budget are given at Annexures 11.1 to 11.19. The Donor wise budget is given at Annexure 12.

Norms and Basis of Costing for RNTCP under NSP:

The norms may be used as a guide to prepare annual action plans and budgets. These may not be deemed to be limiting factors and States may provide justification to CTD in case they need to incur expenses over and above these norms. These norms once approved will be applicable to all States/UTs irrespective of the source of funding. For North-Eastern states

(Arunachal Pradesh, Assam, Nagaland, Mizoram, Meghalaya, Manipur, Tripura and Sikkim), these norms would be applicable at the rate of 1.3 times as compared to the rest of the country except for the expenditure under the head "Contractual Services". All the financial norms are base rate and will be automatically revised by 1.25 times Mid Term period i.e. April 2015 for the remaining project period.

20.6. Norms and Basis of Costing for RNTCP under NSP:

These are indicative norms and may be used as a guide to prepare annual action plans and budgets. These may not be deemed to be limiting factors and States may provide justification to CTD in case they need to incur expenses over and above these norms. For North-Eastern states (Arunachal Pradesh, Assam, Nagaland, Mizoram, Meghalaya, Manipur, Tripura and Sikkim), these norms would be applicable at the rate of 1.3 times as compared to the rest of the country except for the expenditure under the head "Contractual Services" or contractual staff in other heads. All the financial norms are base rate and will be automatically revised by 1.25 times Mid Term period i.e. April 2015 for the remaining project period.

Norms and Basis of Costing for RNTCP -2012-17

Sr. no.	Norms	Basis of Costing (Unit cost)
1	**Civil Works**	
	• **Designated Microscopy Centre (DMC)–** 1 DMC per 1 Lakh population. (In tribal/hilly/difficult areas 1/50,000 population). States can relax norms by 10% in case of additional requirement of DMC based on geographical or technical considerations. • **Tuberculosis Unit (TU)** – 1 per 200,000 (1.5 to 2.5 lakh range) population for rural and urban population and 1/100,000 (0.75 to 1.25 lakh) population in hilly/tribal/difficult areas with the overall aim to align with NRHM BPMU for optimum resource utilization and appropriate monitoring. • **DTC** 1 per revenue district / NRHM District Program Management Unit. • **DRTB Centre (DOTS plus site):** 1 per million population. • **State Drug Store (SDS):** 1 per 50 million population. For civil work, plumbing, electrical and other repairs for facilities/ structures under RNTCP like STC, STDC, SDS, IRL, C&DST lab, DRTB Centre, DTC, DDS, TU, DMC etc.	**Initial Establishment / Refurbishment costs:** **One Time Costs - Upgradation** • **DMC**- Up to Rs. 60,000 per DMC (Additional Rs. 50,000 to upgrade DMC for rapid diagnostics) • **TU** – Up to Rs 1,00,000 per TU • **DTC** – Up to Rs 10 lakhs per DTC. New DTC (where no DTC exists) upto Rs 25 lakhs per DTC which includes the above provision of Rs 10 lakhs per DTC • **STO Office** upto Rs 5 lakhs •**STDC:** upto Rs.5 lakhs • **State Drug Store** – upto Rs 20 Lakhs In addition, one time provision of Rs. 10 lakh per SDS and Rs. 60000 per District Drug store to improve storage capacity for 2nd line drugs for DOTS plus. • **IRL** – up to Rs 1 lakhs for Laboratory and Monitoring unit •**Culture DST Lab**: For Solid method: Rs. 10 lakh, for Liquid including Negative Pressure provisions: upto Rs.50 lakh, for LPA: upto Rs. 4 lakh • ***DRTB Centre (DOTS Plus Site)****-upto Rs. 15 Lakhs* **Maintenance of Civil works**: • **DMC:** Rs. 5000 per year • **TU:** Rs 10000 per year • **DTC including DDS:** Rs 50000 per DTC per year • ***State TB Office, ,STDC, SDS:*** *Rs. 100000 each per year* • ***IRL:*** *Rs. 50000 per year* • **DRTB Centre:** *Rs 150000 per year each* ***Culture & DST Lab:*** *Rs. 100000 per C&DST Lab; Rs. 25000 additional for each of the technology – Solid, Liquid & LPA*

		The maintenance amount for DMCs and TUs may be pooled at district level and repairs are undertaken where necessary.
2	**Laboratory materials**	
	Lab consumables for DMCs, Culture / DST laboratories, STDCs, NRLs and IRLs to be procured. The detailed list of laboratory material is given in the RNTCP laboratory QA protocol / program website.	**State Level:** Rs. 0.30 lakh/million population at State level for procurement of lab, material for states performing culture and DST activities. **District Level:** Rs. 3 Lakh/million Populations at district level. **Central level:** *Laboratory consumable kits for newer diagnostics like Automated NAAT and other consumables: Rs. 750 per test kit.* *The above costing is based on a suspect examination of 180 per lakh population per quarter. If the suspect examination rate is more, the consumption of laboratory consumables will be higher and the DTCS/District Health Society may have the flexibility of proportionately increasing the expenditure on laboratory consumables.*
3.	**Honorarium/ Counseling charges**	
	It is presumed that of all the TB patients put on treatment, approximately 25% in the district may not come to the public health facility for DOTS. This group of patients will need community volunteers to facilitate DOTS. • The honorarium/counseling charges for provision of DOT will be paid only to such workers who are not salaried employees of the Central/State Government. This would include among others Anganwadi workers, trained dais, village health guides, community volunteers, ASHA, etc. The honorarium/ counseling charges to be paid to volunteer supervising MDR-TB treatment. • Special provisions for Tribal areas under 'Tribal action plan'	Rs. 0.28 lakh/million based on actual expenditure at district level. Rs. 250 per patient upon completion or cure to each volunteer. This is expected to be within 25% of all the patients put on DOTS in the district. With more community volunteers, including ASHA being involved as DOT providers this can be more than 25%. Rs.2500/-(Rs.1000/- for IP and Rs.1500-for CP) to the individual volunteer for each MDR patient treatment completed to be disbursed in two instalments. As per the tribal action plan an aggregate amount of Rs 250 will be provided to patients on completion of treatment to cover travel costs of tribal patients and attendant(s) in tribal areas. As per the tribal action plan, volunteer for sputum collection in tribal areas may be paid an honorarium of Rs 100 per month for costs towards sputum collection and transport to DMC from tribal areas. If visit to health centre is more than one per week then Rs 200 per month may be given. .
4.	**ACSM**	
	The IEC campaign would be for all the stakeholders including the different target groups i.e., medical professionals, paramedicals, patients, relatives of patients and community. This includes various activities like patient provider meeting, community meeting, CME, communication facilitator cost, print media, electronic media, activities in school / educational institutions, advocacy meetings, cost for communication between stakeholders,	**State Level norms**: • Population up to 10 million: Rs. 10 Lakhs • Population of 10 to 30 million: Rs. 14 Lakhs. • Population of over 30 million: Rs. 20 Lakhs. IEC Agency and Activity cost (apart from above) for local need based ACSM state level initiatives: Rs. 0.40 lakh per million population <u>ACSM Officer:</u> 1 per state; Additional 1 per state if population is over 30 million ; **District Level norms**:

	campaign for intensified case finding, community radio, PRI involvement, involvement of FBOs, activities during World TB Day/ week, nukkad nataks, street plays, puppet shows, brand ambassadors, activities targeting universal access, special population like migrants, tribal and slums, TBHIV, MDR-TB, etc.	• Rs 1.88 lakh per million population per year. For more focused targeting already identified urban cities with more than 1 million population the norms is higher at Rs 3.38 lakh/million population per year. For all other urban areas with municipal corporations / councils Rs. 2.33 lakh per million population per year. **Central Level norms:** GoI initiated Advocacy and Advertisement upto Rs 5000 lakh over 5 years and GoI initiated other IEC activities upto Rs. 2500 lakh over 5 years.
5.	**Equipment Maintenance**	
	Maintenance/upgradation costs for Laboratory equipment and office equipment like computers, photocopier, fax, etc. are included under this head.	Maintenance costs for the equipment have been estimated on the basis of the current market cost as: • Office equipments including Computers/Photocopier /Fax – Rs 45,000/- • LCD system- Rs. 10000 per machine • Refrigerator- Rs. 1000 per machine • Binocular Microscope - Rs. 2000 per microscope • LED Fluoroscent Microscope - Rs. 5000 per microscope • Newer diagnostic Automated NAAT - Rs. 92000 per machine per Year • Culture and DST equipment - 6.81 lakh per lab (should be around 15% of cost of C&S equipment per Year). Any other equipment not mentioned above, maintenance can be budgeted at upto 15% of the cost of the equipment. The maintenance funds can be pooled at state or district level and arrangements made for responsive maintenance of equipment for least down time.
6.	**Training**	
	The training of STO/DTOs will be organised in coordination with central institutes / CTD. The other categories of staff will be trained at State/District/Sub-district level. It also includes sensitization. The training will be held in batches and cost for each batch of training for different category of staff is calculated applying the various approved norms. • The STOs/Dy STO/DTOs/ MO-STC / STDC faculty/Microbiologist/STC, STDC, IRL, SDS staff, RNTCP contractual staff, any personnels participating in any of the RNTCP activities will be allowed travel expenditure as per norm mentioned under this head. All travels involving distance more than 500 km are eligible for economy air-travel. If distance is upto 500 km, then State level staff and other Medical staff will be eligible to travel with 2AC while the para-medical staff will be eligible for travel with 3AC. Air-travels for distance less than 500 km or travel beyond these guidelines can be undertaken with prior approval of	Training to be planned as Initial Training, Retraining and Update training. **District level:** Annual costs for trainings at district level are Rs. 2.16 lakh per million population. **State Level:** Annual costs for trainings at state level are Rs.0.21 lakh per million population. In exceptional case higher amount can be sanctioned at district / state level based on the training load. **Central Level:** Annual costs for training at Central level are Rs. 0.23 lakh per million population. Norms guidance: The norms for trainings are as follows: Course material cost is central level Rs. 350, State level Rs. 300 and District level Rs. 150. Refreshment: Rs. 200 per day for central and state level and Rs. 175 per day for district / sub-district level trainings. Honorarium - faculty: Rs. 750 per day for central, Rs. 500 per day for state / district level trainings.

	appropriate authority. • The costs include hiring of venue, organization charges, honorarium for trainers, TA/DA, course material and refreshment or for any activity related to training. State level facilities includes State TB cell, STDC, SDS, IRL, C&DST lab, DRTB Centre for all the financial heads including training.	DA with stay facility: Rs. 500 for central level and Rs. 400 for state / district level for medical and Rs. 250 for central level and Rs. 200 for state / district level DA without stay facility: Provision for stay in hotel as per actual - maximum upto; Rs. 1000 for central level, Rs. 800 for state level and Rs. 500 for district level for medical staff and Rs.500 / 400/ 250 for central / state / district level trainings for paramedical. Institutes with hostel facility available cannot be given this option. All state level / central level trainings preferably should have hostel facility. TA: All travels involving distance more than 500 km are eligible for economy air-travel. If distance is less than 500 km, then Medical staff eligible to travel with 2AC while the para-medical staff eligible for travel with 3AC. Air-travels for distance less than 500 km or travel beyond these guidelines can be undertaken with prior approval of appropriate authority. *During training programmes the norms for lunch refreshment and TA/DA costs can be changed with proper justification after approval from NRHM/State Health Society.* *The norms for the size of the batch, duration and level of trainings are provided in Annexure I and can be changed by CTD from time to time based on the needs and requirements of the training.* *The population based budgetary norm for training can be changed based on the training load, additional trainings for newer initiatives and revision of guidelines.* Review meetings involving newer updates on program for state level is Rs. 4/2/1 lakh per year for Type A/B/C states.
7.	**Vehicle operation (POL & maintenance)**	
	Vehicles used for supervisory visits by DTO, MO-TC and contractual staff under RNTCP are budgeted on the basis of: • Kilometers traveled/day, number of days in a month and current cost of POL. • Total amount includes repairs, spare parts, insurance, tax, helmets, PUC, essential accessories, service charges, etc. which may be required for the maintenance of vehicles. Higher amount can be allowed based on fuel cost, distance travelled and fuel efficiency of vehicle. Appropriate travel documentation including ATP, tour dairy/report, vehicle log book etc as applicable is to be ensured. In case of increase in POL costs, corresponding increase in norms for vehicle operations & maintenance will be made at Central level from time to time.	Cost of POL and maintenance has been taken as: • 2 wheelers for STS – Rs. 45,000 per year • 2 wheelers for others– Rs. 35,000 per year • 4 wheelers – Rs. 2.10 lakh per year • 4 wheeler – MOTC upto Rs. 50000 per year, if available In case of 4 wheelers, funds for vehicle operation are only provided to districts which have four-wheelers from system/program rather than hired vehicles. Vehicle operation cost for two wheelers may be increased up to 20% in tribal/hilly/difficult areas.
8.	**Vehicle hiring**	
	Vehicles are hired where RNTCP or State Government Vehicle are not available for supervisory visits. Appropriate documentation for supervisory visits to be ensured.	Vehicle hire (inclusive of POL/driver and all costs except toll tax): four wheeler / jeep: Rs 1100/ day, (up to Rs 1250/day in Tribal / Hilly / difficult areas. *The above rates are for a distance of 80 km and duration of 8 hrs. Additional cost towards extra*

<table>
<tr><td></td><td>MOTC/ Officer /Staff having NRHM hired vehicle available for supervision & monitoring, cannot hire additional vehicle.
<table><tr><th>Staff</th><th>No of vehicles eligible</th></tr><tr><td>PPM Coordinators – state level</td><td>1 (upto 15 days a month)</td></tr><tr><td>HIV - TB Coordinators State level</td><td>1 (upto 15 days a month)</td></tr><tr><td>State TB Cell</td><td>1 (3 for state with population >30 million & 2 for states with population 10-30 million)</td></tr><tr><td>STDC</td><td>1 per month</td></tr><tr><td>DTO</td><td>1 per month (2 for type A districts)</td></tr><tr><td>MO-TC</td><td>1 (upto 7 days per month)</td></tr><tr><td>CTD</td><td>Upto 6 vehicles per month</td></tr></table>
Vehicle hire is allowed only for the days of supervision & monitoring or official visits. State level officers & Coordinators can hire vehicle for the days of supervision & monitoring visits.</td><td>mileage or duration would be on pro-rata basis of Rs.10 per every additional kilometer and Rs.40 for every extra hour.</td></tr>
<tr><td>9.</td><td>Public-private Mix: (PP/NGO Support)</td><td></td></tr>
<tr><td></td><td>Activities included in this head are payments of NGO/PP schemes grant-in-aid, activities undertaken for involvement of NGO/PPs, Cost of the state and district level PPM Coordinators and TBHVs, and costs for pilots / innovations for improving TB control at central / state / district / sub-district level.

NGO/Agencies/Institutes should be registered under State Societies Act/ Societies Act/ Companies Act or Trusts Act with their Memorandum /Articles of Association expressly stating that the Company/ Society has been formed for purpose of non-profit and has its independent sources of funding and is not solely dependent on any programme funds. Private practitioner / clinic / dispensary / hospital / agency / individual / institute / organization should be registered with the appropriate authority.
• NGOs/PP working for or planning to work for TB Control Programme are required to follow the NGO/PP guidelines of RNTCP.
To intensify the PPM activities, PPM Coordinator approved as follows:
20. State level: 1 per state (additional 1 if population >30 million)
21. District level: 1 per district (additional 1 if population > 0.40 million)
TBHV: 1 per lakh urban aggregate population in the district</td><td>Up to Rs. 5 lakh / million populations per year inclusive of central, state & district level.
Districts and state health societies may approve additional expenditure over and above the proposed norms.
Norms for various schemes are as provided in the revised NGO/PP Guidelines issued by RNTCP.
Contractual cost:
1. State level: PPM Coordinator: (Two for Type A and One for Type B/C states)
2. District level:
PPM Coordinator (at par with Sr DRTB-TBHIV supervisor):
TBHV: Rs

Support to Hospitals with only PG degree / DNB courses (other than those included in medical college task force mechanisms):
These hospitals / health facilities to be included in various NGO/PP schemes based on the functions like DMC, DOT Adherence, Notification etc.</td></tr>
</table>

<table>
<tr><td></td><td>Out of the total available budget under this head, upto 10% can be utilized for activities involving promotion of NGO / PP involvement, upto 30% can be utilized for piloting / innovations activities which are included in the action plan and approved from CTD.</td><td></td></tr>
<tr><td>10.</td><td>Medical Colleges</td><td></td></tr>
<tr><td></td><td>Medical colleges will be provided funds through concerned State/District Health-TB Control Societies for activities relating to referral of cases and treatment, operational research, sensitization and advocacy among the staff, faculty and medical students.
• National/ Zonal/State Task forces have been formed for medical college involvement under RNTCP. The cost for travel and per diem for the Chairmen and members of these task forces for attending task forces meetings and follow-up visits to the medical colleges in their jurisdiction would be borne by the respective health societies. The organizational cost for such meetings would also be borne by respective Societies.
• Meetings /Visits to be conducted by the Task forces will be as under:
o NTF - Whenever called for ZTF meetings
o ZTF- Quarterly meetings of ZTF and all STF within the zone will be visited once in six months
o STF- Quarterly meeting of STF and all medical colleges in the state will be visited once a year
Contractual staff i.e MO, LT, and TBHV to be hired at medical colleges for RNTCP work and follow up of cases put under RNTCP regimen.

Post-graduate teaching institutes hospitals (apart from medical college), TB or other hospitals etc. with high load of TB case load will be eligible for contractual MO, LT, TBHV from the program: MO-Hospital or TBHV if annual TB case notification of >800; Both if annual TB case load is more than 1200; LT-Hospital – Daily sputum examination > 60-80 slides a day; This needs prior approval from CTD.

<table>
<tr><th>Norms for NTF / ZTF</th><th>Norm</th><th>Per day cost in Rs.</th></tr>
<tr><td>Personal / Secretarial Assistance</td><td>1 per 30 participants</td><td>750</td></tr>
<tr><td colspan="3">Per-diem including residential arrangement</td></tr>
<tr><td>Outstation experts</td><td>1 per 30 participants</td><td>3000</td></tr>
<tr><td>Local expert</td><td>1 per 30</td><td>1000</td></tr>
</table>
</td><td>The Medical colleges to be provided with the contractual staff (MO, LT and TB HV each). No. of LTs can be increased if the average daily slide examination volume is more than 80-100 and TBHVs can be increased if no. of all TB patients diagnosed are more than 2000 annually or indoor TB patients are more than 1000 annually.
High case load PG teaching hospitals (other than Medical colleges), TB hospitals can also be provided staff, if eligible.
For Corporate hospitals: there will be one position named Treatment Monitor (at par with PPM Coordinator)based at State TB Cell.
Rates of contract, recruitment norms & annual increment are same as for similar staff at district level.
Provision has been made for need based training / sensitization of resident doctors / faculty / interns/ staff of all departments in RNTCP. It is expected that 50 residents/year/medical college would require this training. Rs. 60000 per medical college for trainings. May be changed based on the training load and change in training norms.
A thesis grant of Rs 30,000 for research on RNTCP priority areas will be approved by STF at an average of one thesis per medical college per year in the state. All post-graduate degree / diploma students undertaking thesis as a part of their MCI recognized studies will be eligible for thesis grant.
Provision is also available for support to Conferences, symposiums, panel discussions and workshops organized at National and state levels and at level of Medical college.
• At the National level- Rs. 4 lakhs per conference for 8 conferences annually;
• At the state level - Rs. 1 lakh/- per conference for 4 conferences annually.
• Sponsorship of plenary session on RNTCP in seminars / CME /Workshops up to Rs.10,000/ annually for a medical college.
Organizational cost for each meeting:
NTF: 4 lakh
ZTF: 4 lakh
STF: 0.5 lakh
Operational research committee meetings: 0.4 lakh per meeting on an average basis; 2 meetings per state / zone
Travel costs and per diems for participation in STF/ZTF/NTF, for attending the trainings, participation in meetings and internal / central level evaluations / appraisals will be borne under this head. TA/DA norms as per the training head.
STF Chairman – office and miscellaneous costs.</td></tr>
</table>

	participants		
Outstation participant	Metro / state capitals	2500	
	Non-metro	1500	
Local participant	15 per meeting	600	
Venue hiring	upto 80 participant	10000	
	>80 participant	20000	
Training material	per participant	750	
Refreshment	per participant	500	
Report writing, publication, documentation, photography, etc	upto 80 participant	15000	
	>80 participant	20000	
Contingency - inaugural, closing ceremony, local travel etc	upto 80 participant	15000	
	>80 participant	20000	

Norms used for guiding the budget are as follows:

Activity	Amount in Rs. (lakh)
TA/DA costs of NTF/ZTF/STF Chairman and Members to NTF	0.3
TA/DA costs of NTF/ZTF/STF Chairman and Members to ZTF	0.2
TA/DA costs of NTF/ZTF/STF Chairman and Members to STF	0.15
TA/DA costs for National Training of Medical College Faculty per medical college	0.3
STF Chairperson Travel Cost for supervisory visit per medical college	0.05
STF Chairperson Travel Cost for meetings and IE per state	0.7
Stationary and Misc Fund for STF office	0.02 per medical college
Stationary and Misc Fund for ZTF offices	0.01 per medical college
Miscellaneous – core committee expenses, postage, communication, fax, etc. per medical college	0.1
Operational Research Committee Meetings	0.4
Allowance to existing manpower with STF Chairperson for clerical assistance	Upto Rs. 500 per month

These are norms for budgeting purpose and travel cost will be as per the actual at the rates / norms as mentioned in training head. Accommodation to be done by organizers for residential meetings from this head as per the local cost and DA to be paid to the participant as per the norm of "with stay facility" as mentioned in training head except for ZTF / NTF for which norms are stated in this head itself.

11.	**Office Operation (Miscellaneous)**	
	Office operation expenditure includes janitorial expenses, electricity, telephone bills, data user charges, video conferencing charges, internet cost, fax bills, postage/courier, office stationery, office furniture for STCs/STDCs/DRTB Centers/C&DST laboratories/DTCs/ TB Units/DMCs, display boards, repair of furniture, hiring of daily wage labour for loading and unloading of drugs, sputum transportation box, drug boxes for Cat IV / V, recruitment /procurement/EOI/RFP advertisements, transportation of drugs from State drug store to district store, office rental, *etc.*	**Central level:** • Rs. 0.02 lakh per million population **State level:** Fixed component for states with population: • upto 20 million – Rs 3 lakhs • 20-30 million – Rs 5 lakhs • >30 million – Rs 7 lakhs And additional for each state: Rs. 0.15 lakh per million population. **District level:** •Fixed: Rs. 0.5 lakh per district •Additional Rs. 0.8 lakh per million population Norms for: a. Culture & DST Laboratories: Rs. 24000 annually b. DRTB Centre (DOTS plus site): Rs. 24000 annually Only costs not covered by State/Districts budgets will be provided under project funds.
12.	**Contractual Services**	
	Central Level **Technical section:** Technical Officers*, Assistant Technical Officer* Data Entry Operators , Secretarial Assistant Statistician, Data Analyst IT Officer*, Network administrator* **Administration section:** Administrative Officer, Administrative Assistant **Finances**	**Contractual Staff (State Level): These are the positions at each level. The annual unit cost is the maximum salary that is allowed under program. However this is up to states that how much the salary is fixed by state within the maximum limit.** Name of the staff category / **Central Level** — Annual Unit Cost in Rs lakh

	Consultant Finance, Finance Manager* Accountants, Accounts Officer **Procurement & Logistics** Consultant Procurement and Supply Management Logistic Manager*, Supply Chain Manager* Logistic & supply chain management Assistants* **NRLs:** Consultant Microbiologist , Senior Laboratory Technician(EQA) **NTI:*** HR Officer, Training Facilitator Epicentre Expert (1 computer & 1 field expert) Epidemiologist, Research officer, Librariarn Documentation Assistant **State Level:** Provision is available for Epidemiologist(Asst. Prog.Officer)^ Medical Officer (MO-STC) TB HIV Coordinators^ Accounts Officer / State Accountant^ Secretarial Assistant Data Entry Operator (STC)^ Driver (if RNTCP vehicle available) DR-TB Coordinator*^ State PPM Co-ordinator*^ DEO-STF chairman* Data Analyst*^ Technical Officer - Procurement & Logistic Personnel* ^ Additional posts for bigger states. **IRL** Microbiologist - EQA* **Culture & DST Lab (wherever approved)** Microbiologist Sr. Lab. Tech. for IRL Data Entry Operator for IRL **SDS** Pharmacist cum Storekeeper Store Assistant (Additional post if >1800 Cat IV/V monthly boxes preparation per month) **District level:** Medical Officer (MO-DTC) (upto 20-40% of DTCs in the state) Senior Treatment Supervisor (STS) (1 per 1.5 to 2.5 lakh to be aligned with blocks for optimum resource utilization and appropriate monitoring) (additional STS if >500 cases registration annually in a TU) In case of tribal/hilly/difficult areas 1 per 0.75 to 1.25 lakh population to be aligned with blocks and additional STS if >250 cases) Senior TB Laboratory Supervisor: 1 per 5 lakh population (1 per 2.5 lakh population for tribal/hilly/difficult areas). Laboratory Technician (upto 30% of the DMCs) Driver (only if RNTCP vehicle is available)	**Technical:**	
		Technical Officers*	
		Assistant Technical Officer*	
		Data Entry Operators	
		Secretarial Assistant	
		Statistician	
		Data Analyst	
		Network administrator*	
		Administration section:	
		Administrative Officer	
		Administrative Assistant	
		Finance section	
		Consultant Finance	
		Finance Manager*	
		Accountants	
		Assistant Accountant	
		Accounts Officer	
		Procurement & Logistics	
		Consultant PSM	
		Logistic Manager*	
		Supply Chain Manager*	
		Logistic & supply chain management Assistants*	
		NRLs:	
		Consultant Microbiologist	
		Senior Laboratory Technician(EQA)	
		National TB Institute:*	
		HR Officer	
		Training Facilitator	
		Epicentre Expert (1 computer & 1 field expert)	
		Epidemiologist	
		Research officer	
		Librariarn	
		Documentation Assistant	
		State Level	
		Epidemiologist(Asst. Prog.Officer)	
		Medical Officer (MO-STC)	
		TB HIV Coordinators	
		Accounts Officer / State Accountant	
		Secretarial Assistant	
		Data Entry Operator (STC)	
		Driver	
		DR-TB Coordinator*	
		DEO-STF chairman*	
		Data Analyst*	
		Technical Officer - Procurement & Logistic Personnel*	

	Data Entry Operator (2 for Type A districts) Senior DRTB TBHIV Supervisor (2 for Type A districts) DRTB Centre (DOTS plus site): Following staff 1 per DRTB Centre: Senior MO DRTB Centre (DOTS Plus Site)*** Counselor DRTB Centre Statistical Assitant DRTB Centre*** (***Additional 1 if annual enrollment is more than 250) Accountant (full time)* District Program Coordinator* **(* new positions)**	**IRL**	
		Microbiologist - EQA*	
		Culture & DST Lab	
		Microbiologist	
		Sr. Lab. Tech. for IRL	
		Data Entry Operator for IRL	
		SDS	
		Pharmacist cum Storekeeper	
		Store Assistant	
		District level:	
		Medical Officer (MO-DTC)	
		Senior Treatment Supervisor	
		Senior Laboratory Treatment Supervisor	
		Laboratory Technician	
		Driver	
		Data Entry Operator	
		Senior DOTS-plus & TBHIV Supervisor	
		DOTS Plus Site/DRTB Centre Senior MO	
		DOTS Plus Site/DRTB Centre Statistical Assistant	
		MO-Medical college	
		LT-Medical college	
		Counsellor for DOTS plus site*	
		Accountant*	
		District Program Coordinator*	
		A fixed allowance of Rs 1000 per month will be given to contractual STS/STLS/LT at TU/DMCs in notified tribal / hilly / difficult areas. Additional upto 10% to be paid in case of giving additional charge to the staff due to vacancy or leave or absence. Additional 10% of base salary to be given to MO-Medical college providing support to the NTF / ZTF / STF Chairperson. DA (daily allowance for travel) is only to be released against appropriate travel documentation. Where eligible such DA may be paid under State Government rules or as mentioned in supervision & monitoring head. All new recruits will commence at above basic rate of remuneration. All the existing staff will continue to get all the existing increments in addition to revised basic salary. All contracts will be for one year. Contracts will be renewed by the society based on satisfactory performance. On every renewed contract the remuneration would be enhanced by 10% or at the rate prescribed by NRHM (whichever is lower) for every one year of service in RNTCP. Enhancement will be calculated over the basic rate and not the remuneration in the previous year.	

13.	**Printing**	
	Printing of stationery items such as treatment cards, patient identity card, TB register, laboratory form, referral form, notification form, health establishment registration form, transfer form, training modules, quarterly report format, research reports, Action Plans and other formats required for Programme implementation at State/District level. Modules, registers, guidelines, etc needs to be undertaken at state level while the forms, identity cards, reporting formats etc to be district level printing. Printing of prototype materials, RNTCP materials, perf reports, quarterly / annual / bi-annual reports of performance and its dissemination	Rs.2.25 lakh/million population, including printing undertaken at State and District levels. State level budgets upto 66% and district level upto 34%. The norm for the central level is Rs. 50 lakh.
14.	**Research & Studies & Consultancy**	
	There are certain studies like disease burden studies including prevalence surveys, mortality surveys, inventory studies, ARTI surveys, social assessment studies, IEC impact assessment studies, and drug resistance surveillance studies which will be undertaken by CTD and Central Institutes or appropriate agencies / institutes. Additionally operational research proposals on identified priority areas will be invited from State level and from the Medical Colleges. Capacity building programs for Operation research for stakeholders to be carried out. National Operational Research cell supported by HR as mentioned in contractual salary head. Proposals approved by State level OR committee / Zonal level OR committee / Central TB Division / National OR cell to be funded. Consultancy charges for procurement of drugs, lab testing charges for drug quality assurance, agency fees for advocacy / media management campaigns, consultancy cost for agency developing web based DOTS plus recording & reporting software, MIS system with web based case based reporting system	The priority areas for operations research and formats for proposals are given in the website www.tbcindia.org. The research may be initiated at district, states or medical colleges. Proposed studies and their estimated costs may be included in the Annual Action Plans. Research proposals up to Rs 2 lakh may be approved by State OR Committee, upto Rs. 5 Lakhs may be approved by the ZTF (for medical colleges) or OR committee of the STCS. Proposal above Rs 5 lakhs will be forwarded to CTD. CTD may approve proposals upto Rs 15 lakhs and proposals above Rs 15 lakhs will be forwarded to the Central OR Committee.
15.	**Procurement of Drugs**	
	Drugs required during TB treatment are being procured centrally. They are not to be procured at the State and Districts levels except with written approval from CTD.	Drugs are procured centrally through a competitive process.
16.	**Procurement of Vehicles**	
	New Four Wheelers: All districts are expected to hire four wheeler except where procurement of four wheeler has been specifically approved in writing for hilly/ tribal/difficult districts or in special extra-ordinary situations. These are to be procured at DGS	• Jeep (petrol/diesel) - Rs. 6.5 lakh • Two-wheeler - Rs. 0.65 lakh

	& D rate contract. **Two Wheelers:** 1 Two wheeler vehicle for mobility for each STS, STLS, DOTS plus & TBHIV Supervisor, PPM Coordinator. Existing two-wheelers at TU will be retained by STLS after new two-wheelers are procured for STS, DOTS plus-TBHIV Supervisor and PPM Coordinator. • **Replacement:** Replacement of four wheeler vehicles will be permitted for notified tribal and hilly / difficult districts. Purchase of new four wheeler vehicles will be done in consultation with CTD. Vehicles due for replacement should have completed 6.5 years or 150,000 Kms whichever is later. • **Replacement for 2 wheelers** may be allowed if they have completed 6 years or 100,000 kms whichever is later. Condemnation rules of State Government will be followed, where applicable.	
17.	**Procurement of Equipment**	
	Lab Equipment: Binocular Microscopes & Fluorescent LED based microscope are being provided by CTD for training institution and for service delivery in RNTCP areas. **• Culture and Sensitivity Equipment:** Will be procured by CTD, wherever approved. **• Office Equipment:** Office equipment will be procured by States/districts for new units planned under the project (State TB cell, DTC, SDS, *IRL and DRTB Centre)* and for replacing them which are more than 5-7 years old and are not functional. Condemnation rules of State / Local self Government to be followed. Every district will be provided with photo-copier, if not already available. Computer system with internet, Fax machine for every DTC, IRL, Culture DST laboratory, SDS, STDC, DRTB Centre (DOTS plus site), NRLs, and all STCs. STCs will have computer system for Type A will have 3, STCs Type B will have 2 and Type C will have 1. Similarly bigger districts DTC Type A will have 2, while Type B & C will have 1 system. States with 15 or more medical colleges to have provision of one computer system for STF Chairperson office. Every state Type A /B/C will be eligible for LCD with laptop system 2/1/1 respectively to be placed in STC/STDC. Urban / districts with more than 40 lakh population are eligible for LCD with laptop. SDS and DDS/DTC level Refrigerator – 1 per district/SDS;	**Lab Equipment:** Light Binocular Microscope with LED: Rs. 20000 each unit Binocular Microscope: Rs. 12,000 each Fluorescent LED based microscope: Rs. 75000 Automated NAAT: Rs. 9.2 lakh per machine Culture & DST equipments: Rs. 45 lakh per set **Office Equipment:** Computer, Modem, Scanner, Printer, UPS, software and set-up-Rs. 60,000 per system Fax Machine Rs. 10000 Photo-copier: Rs. 1 lakh per unit LCD system with laptop: Rs. 1 lakh per unit Refrigerator: Rs. 20000-25000 per unit (depending on capacity) Equipment & software for Bar-code reading: Rs. 85000 per unit Bar-code printer: Rs. 1 lakh per unit PDA: upto Rs.15000 per unit Video-conferencing unit and arrangements: upto Rs. 5 lakh per unit CTD level office equipments: Rs. 15 lakh per year

<table>
<tr><td></td><td>Equipment & software for bar-code reading: 1 per SDS & 1 per DDS.
Barcode printer: 1 per SDS;
PDA (handheld devise): 1 per STS. Video-conferencing unit: 1 per CTD / NRL / STC;
Office equipments for CTD</td><td></td></tr>
<tr><td>18.</td><td colspan="2">Patient support & transportation charges:</td></tr>
<tr><td></td><td>Tribal/Hilly/Difficult areas : Patients from tribal / hilly/ difficult areas to be provided an aggregate amount of Rs. 250 on completion of treatment to cover travel costs of patient and attendant.
Sputum collection and transportation: Non-salaried dot provider / community volunteers / govt staff without provision of TA, to be provided an aggregate amount of Rs. 15 per patient (maximum Rs. 1000 per month) for sputum sample transportation non-DMC PHI to DMC.
Sputum sample transportation cost from DTC / DMC / Collection centre to Culture / DST lab by individual / courier agency / volunteer within the pre-decided time limit.
MDR TB suspect travel to DTC / Collection centre for Culture / DST: MDR TB suspect travel to DTC / Collection centre to be paid as per the actual with public transport.
Drug resistant TB patient travel: MDR / XDR TB patient travelling to DRTB Centre or to district for treatment initiation /follow-ups / adverse reaction management during the treatment along with one accompanying person / attendant. Travel cost to be reimbursed as per actuals maximum upto equivalent to travel cost with public transport or norms approved by society for such visits to be provided.</td><td></td></tr>
<tr><td>19</td><td>Supervision & Monitoring</td><td></td></tr>
<tr><td></td><td>Activities including component of supervision, monitoring, evaluations, appraisals, review meetings

Includes cost of TA/DA(except for training) for STOs, STDC staff, IRL Microbiologist, DTOs, MO-TC and all RNTCP contractual staff.

Internal Evaluations: All districts to be covered atleast once in 3-4 years and All states to be covered under CIE atleast once in 3 years.
Norms for SIE:
<table>
<tr><th>Population in million</th><th>Districts per quarter</th></tr>
<tr><td>Upto 30</td><td>2</td></tr>
<tr><td>>30 to 70</td><td>3</td></tr>
<tr><td>>70</td><td>4</td></tr>
</table></td><td>Central level:
• Rs. 0.08 lakh per million population
State level:
Fixed component:
• Population upto 20 million – Rs 3 lakhs
• Population of 20-30 million – Rs 5 lakhs
• Population of >30 million – Rs 7 lakhs
Additional component:
• Rs. 0.35 lakh per million population
District level:
• Rs. 0.8 lakh per district – fixed &
• Rs. 2.3 lakh/million population
Central / State level IE: Mobility support, Refreshment cost, external members residential accommodation, material cost etc:
Norm: Rs. 0.81 lakh per SIE & Rs. 1.05 lakh per CIE (the norms are for budgeting, but the actual expenditure on IE for mobility, refreshment, residential accommodation etc will be as per the financial norms applicable for RNTCP)
TA/DA would be as per approved norms mentioned in</td></tr>
</table>

		training head or as approved by NRHM. Only costs not covered by State/Districts budgets will be provided under RNTCP.

16
Results Framework

Results Framework for National Strategic Plan of RNTCP 2012-17							
Vision: A TB-free INDIA							
Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
Trend in estimated incidence of TB (per 100,000)	Estimates from notification and surveys	168/100,000 (2010)	↓↓ Declining trend	↓↓ Declining trend	↓↓ Declining trend	↓↓ Declining trend	↓↓ Declining trend
Percentage reduction of estimated TB mortality relative to 2010 level	Estimates from mortality surveillance	29/100,000 (2010)	5%	10%	15%	20%	≥30%
Overall objective: To ensure universal access to quality assured diagnosis and treatment for all TB cases in the community							
Outcome Indicators							
Proportion of estimated incident TB cases	Case Finding, Results of	65%	70%	75%	80%	85%	≥90%

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Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
diagnosed and treated as per nationally accepted protocols	Treatment reports, and estimates						
Objective 1: To ensure early and improved diagnosis of all TB patients							
Number of TB cases put on treatment (in lakhs)	Case Finding Reports	15.3	15.5	16.0	16.5	17.0	17.5
Proportion of estimated incident TB cases notified	Case Finding Reports	65%	70%	75%	80%	85%	≥90%
Time to diagnosis of TB patients from the onset of symptoms	Survey based/Internal Evaluation reports	NA	↓↓ Declining trend	↓↓ Declining trend	↓↓ Declining trend	↓↓ Declining trend	↓↓ Declining trend
Proportion of re-treatment microbiologically-confirmed cases receiving DST at the start of treatment	DOTS Plus / Case finding reports	NA	5%	20%	60%	75%	≥90%

Results Framework for National Strategic Plan of RNTCP 2012-17							
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Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
Proportion of new microbiologically-confirmed cases who received DST early in the course of treatment	MDR TB / Case finding reports	NA	1%	3%	5%	7%	≥10%
Objective 2: To provide access to high-quality treatment for all diagnosed cases of TB							
Treatment success rates among new TB cases treated under DOTS	Treatment Outcome Report	87%	87%	88%	88%	89%	≥90%
Treatment success rates among previously-treated TB cases treated under DOTS	Treatment Outcome Report	70%	70%	73%	76%	80%	≥85%
Objective 3: To scale-up access to effective treatment for drug-resistant TB							
Number of MDR-TB cases initiated on treatment	MDR TB / Case Finding Reports	2169 (2010)	15000	25500	30000	31000	37000

Results Framework for National Strategic Plan of RNTCP 2012-17							
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Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
Notified cases of MDR TB as % of all estimated MDR-TB cases among all notified pulmonary TB cases under DOTS	MDR TB / Case Finding Reports & Global TB Control Report	5%	10%	15%	25%	40%	≥50%
Objective 4: To reduce morbidity and mortality of HIV-associated TB							
Proportion of TB patients with known HIV status	Case Finding Reports	40%	50%	60%	70%	80%	≥90%
Proportion of HIV-infected TB patients who received ART during TB treatment	Results of Treatment Reports	50%	60%	70%	80%	85%	≥90%
Objective 5: Extend RNTCP services to patients diagnosed and treated in the private sector							
Proportion of districts and TUs notifying patients diagnosed and treated in the private sector	District PMR	NA	PILOT	PILOT	50%	100%	100%

Results Framework for National Strategic Plan of RNTCP 2012-17							
Vision: A TB-free INDIA							
Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
Objective 6: To strengthen health systems and achieve optimal integration with NRHM							
Proportion of districts with TUs aligned with health system structure the block levels	State PMR	0	PILOT	PILOT	50%	100%	100%
Proportion of districts with electronic case based notification and using it for quarterly reporting	CTD	0	DEVELOP & PILOT	DEVELOP & PILOT	50%	75%	100%
Programme level output indicators							
1. Case Finding							
Number of chest symptomatics examined (per 100,000 population)	Programme Management Report	160	163	167	172	175	>180/100,000 Population
Proportion of all estimated incident TB cases notified	Case Finding Report	65%	70%	75%	80%	85%	≥90%
Proportion of paediatric cases diagnosed out of new cases	Case Finding Report	7%	7%	8%	8%	9%	≥10%
Proportion of re-treatment microbiologically-confirmed cases receiving DST at start	DOTS Plus / Case finding reports	NA	5%	20%	60%	75%	≥90%

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Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
of treatment							
Proportion of new microbiologically-confirmed cases who received DST early in the course of treatment	MDR TB / Case finding reports	NA	1%	3%	5%	7%	≥10%
Proportion of microscopy centres using LED microscopes	Programme Management Report	NA	Procurement	9%	10%	15%	20%
2. Treatment							
Number of TB Patients put on treatment (in lakhs)	Case Finding Reports	15.3	15.5	16.0	16.5	17.0	17.5
Proportion of new TB cases who successfully completed treatment under RNTCP	Results of Treatment Reports	87%	87%	88%	88%	89%	≥90%
Proportion of re-treatment Tb cases who successfully completed treatment under RNTCP	Results of Treatment Reports	70%	70%	73%	76%	80%	≥85%
Default rate among new TB cases	Results of Treatment Reports	6%	5%	<5%	<5%	<5%	<5%
Default rate among re-	Results of	15%	14%	13%	12%	11%	≤10%

Results Framework for National Strategic Plan of RNTCP 2012-17							
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Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
treatment TB cases under RNTCP	Treatment Reports						
Case fatality among HIV-infected TB patients treated under RNTCP	Results of Treatment Report	15%	14%	13%	12%	11%	10%
Treatment success rates among MDR-TB patients treated under RNTCP	Results of Treatment Report	<50%	50%	52%	55%	57%	60%
3. Scale-up of programmatic management of drug resistant TB Cases							
Number of districts implementing DOTS-Plus with arrangements for sputum transportations	District PMR	139 (2010)	250	550	650	650	650
Number of MDR chest symptomatics tested	MDR TB / Case Finding Report	10,025 (2010)	95,000	144,000	160,000	170,000	200,000
Number of M/XDR-TB patients initiated on treatment	MDR TB / Case Finding Report	2169 (2010)	15000	25500	30000	31000	37000
Proportion of MDR TB patients alive, on treatment, and culture-negative after 12 months	MDR TB / Results of Treatment Report	57% (2010)	58%	58%	59%	59%	60%

Results Framework for National Strategic Plan of RNTCP 2012-17							
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Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
MDR-TB treatment success rate	MDR TB / Results of Treatment Report	43% (2010)	47%	50%	53%	56%	≥60%
Number of XDR-TB patients put on treatment	MDR TB / Case Finding Report	NA	100	300	500	1000	>1000
4. Scale-up of TB/HIV collaborative activities							
Proportion of states who have conducted SCC meetings at-least twice over 4 quarters	State PMR	50%	60%	70%	80%	90%	>90%
Proportion of Districts with at least 2 DCC Meetings over past 4 Quarters	District PMR	50%	60%	70%	80%	90%	>90%
Number of chest symptomatics identified at HIV care settings and referred to RNTCP	NACO MIS	400,000	Increasing trend ↑↑	Increasing trend ↑↑	Increasing trend ↑↑	Increasing trend ↑↑	Increasing trend ↑↑
Proportion of chest symptomatics among PLHIV screened using culture/molecular-based method	Operational Research	NA	5%	20%	50%	70%	≥90%

Results Framework for National Strategic Plan of RNTCP 2012-17							
Vision: A TB-free INDIA							
Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
Percentage of RNTCP registered TB patients with known HIV status	Case Finding Report	40%	50%	60%	75%	>90%	>90%
Percentage of HIV-infected TB patients receiving CPT during TB treatment	Case Finding Report	60%	70%	80%	90%	>90%	>90%
Percentage of HIV-infected TB patients receiving ART during TB treatment	Results of Treatment Report	50%	60%	70%	80%	>90%	>90%
Case fatality rate among HIV-infected TB patients	Results of Treatment Report	15%	14%	13%	12%	11%	≤10%
Private Sector participation							
Number of States with outsourced Technical Support Group for PPM	Contracts	NA	0	4	6	12	20
Number of states with Private Sector Interface Agencies Contracted for Urban areas	Contracts	NA	0	4	6	12	20

Results Framework for National Strategic Plan of RNTCP 2012-17							
Vision: A TB-free INDIA							
Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
Proportion of districts notifying patients diagnosed and treated in the private sector	District PMR	NA	PILOT	PILOT	50%	100%	100%
ACSM							
Number of patient forums working for TB	Reports	NA	25	50	100	200	300
Number of states with technical working group for ACSM	Reports	NA	5	10	20	35	35
Proportion of TB patients treated under RNTCP by a community DOT provider	PMR	30%	35%	40%	45%	50%	≥50%
Proportion of smear-positive TB patients started on treatment within 7 days of diagnosis	PMR	80%	85%	87%	89%	93%	≥95%
Proportion of people who are aware of TB symptoms and services	KAP survey		Increasing trend ↑↑	Increasing trend ↑↑	Increasing trend ↑↑	Increasing trend ↑↑	Increasing trend ↑↑
Research							

Results Framework for National Strategic Plan of RNTCP 2012-17							
Vision: A TB-free INDIA							
Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
National OR Cell Established	CTD	0	0	1	1	1	1
Operational research projects mentored through completion as part of capacity development efforts every year	National Research Cell report	NA	10	10	10	10	10
Inventory study completed to estimate un-reported TB case burden	CTD				Completed		
Disease burden survey based on capture-recapture approach	CTD				Completed		
Special Population							
Treatment success rates among new TB patients in poor and backward districts	Results of Treatment Report	87%	87%	88%	88%	89%	≥90%
Treatment success rates among new TB patients in tribal districts	Results of Treatment Report	87%	87%	88%	88%	89%	≥90%
Number of states	RNTCP	NA	PILOT	1	2	4	5

Results Framework for National Strategic Plan of RNTCP 2012-17							
Vision: A TB-free INDIA							
Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
implementing TB-DM collaborative activities							
Integration with health systems							
Proportion of districts with TB Unit (TU) aligned at block levels with health systems	State PMR	0	PILOT	25%	50%	100%	100%
Monitoring & Evaluation							
Proportion of districts with electronic case based notification and using it for quarterly reporting	CTD	0	DEVELOPMENT & PILOT	DEVELOPMENT & PILOT	50%	75%	100%
Proportion of districts providing timely reports on all programme quarterly reports (including CFR, RTR, SCR, PMR, SOE, Audit Report etc.)	CTD	85%	90%	95%	95%	95%	95%
Number of states reviewing the programme through quarterly review meetings as	State PMR	80%	90%	100%	100%	100%	100%

Results Framework for National Strategic Plan of RNTCP 2012-17							
Vision: A TB-free INDIA							
Goal: To decrease mortality and morbidity due to TB and stop transmission of infection until TB ceases to be a major public health problem in India in line with the Millennium Development Goals and Stop-TB partnership targets							
Impact Indicators	**Data source**	**Base line**	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**
per schedule							
Number of states completing their internal evaluation of districts as per schedule	State PMR	80%	90%	100%	100%	100%	80%
Human Resource Development							
Proportion of key RNTCP staff in place	PMR	80%	85%	90%	≥90%	≥90%	≥90%
Proportion of key RNTCP staff trained	PMR	80%	≥90%	≥90%	≥90%	≥90%	≥90%

Annexure

Annex 1
Training Schedule

Table : Initial RNTCP training

Category	Duration (working days)	Batch Size	Training Material	Venue
STO/STDC staff/District TB Officer/ TB-HIV coordinator/ DR-TB co-ordinator/ PPM co-ordinator	14	20	RNTCP MO Modules 1-9, STCS/ DTCS guidelines, Financial Management manual, Procurement + SDS Manual, Monitoring strategy	Central Institute
MO-TC or BPMU programme officer	12	20	RNTCP MO Modules 1-9	STDC
MO	5	20	RNTCP MO Modules 1-4	District
STS (2+6)	8	12	MPW Module, then STS Module	STDC
STLS (10+5)	15	6	LT Module, then STLS Module	STDC
LT	10	8	LT Module	District
State Drug Store Staff /Pharmacist in RNTCP	2	25	MPW Module/ Manual on Std. Operating Procedures for State Drug Store	District/TU
MPHS	3	25	MPW Module, sections of STS Module	District/TU
TB Health Visitor etc.	2	25	MPW Module	TU/PHI
MPW/HA etc.	2	25	MPW Module	TU/PHI
Anganwadi Worker/ Midwives/ Community Volunteers, etc.	2	25	DOT Provider Module	TU/PHI
Community based DOT providers, ASHA	1	25	DOT Provider Module	TU/PHI
Private/NGO/ other sector Medical Practitioners	6 hrs	20	Training Module for Medical Practitioners	DTC/IMA
TO / SA	6	12	STS Module	STDC/District
IEC Officer	6	Need based	IEC Module + MPW module	Central level
Data entry operator	2+2	12	MPW module, then Epicentre training	MPW module &Epicentre at state level
Accountants for district	1	Need based	Manual on Financial Management and Guidelines	State level

Category	Duration (working days)	Batch Size	Training Material	Venue
Accountant – state level	3	Need based	Manual on Financial Management and Guidelines, DTCS/ STCS guidelines	Central TB Division

Table: Initial Training on EQA

Category	Duration (days)	Batch Size	Training Material	Venue
EQA (Master Trainers/ Microbiologist)	5	10	EQA Manual	Central Institute
EQA IRL LTs	5	6	EQA Manual	Central Institute
EQA STDC Dir/ STO	2	15	EQA Manual	Central Institute
EQA DTO/MOTC	2	25	Sections from EQA Manual	State Level
EQA STLS	2	6	Sections from EQA Manual	District Level
EQA LTs	1	25	Sections from EQA Manual	District Level

Table: Initial RNTCP training on TB/HIV

Category	Duration (days)	Batch Size	Training Material	Venue
TB-HIV Master Trainers	5	10	TB HIV Modules	State level
STO/ DTO/ MO-DTC/ MOTC	2	10	Module for MOs on TB/HIV	State level
MO	1	30	Module for MOs on TB/HIV	District
STS/STLS	2	10	Module for STS STLS on TB/HIV	District
DOT Provider	1	30	Module for Health Workers on TB/HIV	TU/PHI

Table: Initial RNTCP training on DOTS Plus

Category	Duration (days)	Batch Size	Training Material	Venue
STO/ DTO/ DOTS Plus site faculty/ STDC/ IRL	5	25	DOTS Plus guidelines/ Module	Central level
MO-DTC/ MOTC/MO	3	20	Module for MOs on DOTS Plus	State level
STS/STLS/ Paramedical staff	3	10	Module for Paramedical workers on DOTS Plus	District
DOT Provider	1	30	Module for DOT Providers on DOTS Plus	TU/PHI

Table: Initial RNTCP training for Medical College staff

Category of staff to be trained	Type of training	Place of training	Trainers	Training material	Duration (in days)
Medical Staff					
STF Chairperson	Concise modular	National institute	Central institute staff	RNTCP – Key facts and concepts	1*
Faculty in charge of RNTCP	MO-TC modular	State-level	STC/STDC staff	1-9 modules	12
TOT's	MO-TC modular	National/ State-level	Central Institute/ STC/STDC staff	1-9 modules	12
HODs and Senior staff	Concise modular	State-level	STC/STDC staff	RNTCP – Key facts and concepts	1
Other faculty members (interested)	MO modules	Medical college	Faculty in charge of RNTCP	1-4 modules	5
PG students/ Residents/ Interns /UG's	Part of Curriculum + Sensitization	Medical College	Faculty in charge of RNTCP	Curriculum	2-3 hrs**
Paramedical staff					
Nurses	MPW training	Medical College	Faculty in charge of RNTCP	MPW module	2
Pharmacists	MPW training	Medical College	Faculty in charge of RNTCP	MPW module	2
Other paramedical staff	MPW training	Medical College	Faculty in charge of RNTCP	MPW module	2

* 5 days or 12 days modular training for those interested

** Consists of theory classes. Practical training will be imparted during posting to the Chest or Medicine Departments and the DOTS Cell.

Table: Retraining schedules

Category	Maximum duration (days)	Venue
STO/STDC	5	Central

		Institute
DTO/ MO-TC	3	STDC
STS	2	STDC
STLS	3	STDC
LT	2	District
MO/TO/ SA/ IEC Officer	2	District
Pharmacist/ Staff Drug Management (State/ District/ TU)	1	District/TU
MPHS	1	District/TU
TB Health Visitor etc.	1	TU/PHI
MPW/HA etc.	1	TU/PHI
Anganwadi Worker/ Midwives/ Community Volunteers, etc	1	TU/PHI
Community based DOT providers	1	TU/PHI
Accountant	1	State/District
EQA (Master Trs./ Microbiologist)	2	Central Institute
EQA-IRL LT	2	Central Institute
EQA (STDC Dir/ STO)	1	Central Institute
EQA (DTO/MOTC)	1	STDC
EQA (STLS)	1	District
TB-HIV (DTO/ MOTC)	1	STDC
TB-HIV (MO)	1	District
TB-HIV (STS/STLS)	1	District
DOTS Plus (STO/STDC)	2	Central level
DOTS Plus (DTO/MO-TC)	1	STDC
DOTS Plus (STS/STLS/Paramedical staff)	1	District

Annex 2
Illustrative List of ACSM Activities

Community Level Activities

The focus of ACSM activity should be centered on community, interpersonal, dialogue-based approaches, in conjunction with efficient service delivery. In order to achieve these ends in the 5-year term of this strategy, the following activities are recommended.

Capacity Building

There is a need to strengthen the capacity of a number of public and private sector partners to achieve a greater understanding of strategic ACSM approaches and the principles of behaviour change. Technical assistance and training is required to properly plan, develop, implement and evaluate the ACSM strategy at different levels. Financial resources will be required to technically support the RNTCP and to ensure that programme partners are properly trained in ACSM processes in order to build institutional capacity over the duration of the strategy.

Although RNTCP is involved at the state-level through STC in coordinating implementation, capacity building to re-energise the programme can be augmented with support from NGO technical specialists, as well as private sector partners who have currently not contributed significantly to the ACSM strategy. ACSM private sector communication and research partners should also be engaged in order to further build capacity with these and other potential partners to support ACSM programme implementation. Further focus on building skills and understanding of social marketing, BCC and other ACSM approaches is required. Capacity building and institutional strengthening will assist NTP in the efficient disbursement of programme funds to achieve greater programme impact.

ACSM Activities to support Capacity Building

- Support the establishment of an ACSM Sub-Committee comprised of multi-sectoral public and private sector partners including RNTCP staff, NGOs and other civil society organisations, private sector ACSM partners, research and clinical service providers.
- Provide additional specialized TA to support RNTCP and other programme stakeholders to further build ACSM capacity through strategic planning processes.
- Capacity building in some cases will need to include the establishment of infrastructure and equipment including human resources, computing hardware/software and audio-visual equipment.
- Once capacity is established at the state-level, the endeavour is to expand the capacity building process with public sector and NGO partners at District levels.
- Setting up of patient forums at district and sub-district levels
- Coordinating with the NRHM to build capacity for local health planning and prioritising TB within this through the Village Health and Sanitation Committee.

Training

Public health services in the country have an extensive human resource network of health and auxiliary workers, community DOT providers and health education personnel around the State. However the workforce is often provided with inadequate training in TB control, in relation to other health programme priorities, and no refresher training.

Training activities to support the ACSM strategy development, implementation and evaluation process, can build institutional capacity and a degree of sustainability with stakeholders involved in community-based DOTS provision and health promotion. Continuous feedback and on-going technical support will be required to enable the process of skills development and the effective utilization of skills that focus on IPC approaches. Another aspect of the training could incorporate specific agreed upon activities with NGOs and other stakeholders involved in training to ensure integration and participation in all state level ACSM campaigns.

ACSM training's desired outcomes could include the development of a range of local level activities, events and materials with work plans and activities agreed upon by NGO management, prior to the training. An aspect of the training should ensure that learning is translated into realistic and achievable interventions in-line with agreed upon deliverables, with monitoring and evaluation being an integral component of activities. Front-line workers should be provided with a broader training platform that includes building IPC skills, confidence and leadership development. It is also important to instil a greater understanding of the importance of IPC with MOs and other clinical staff as a necessary component of their clinical service delivery.

ACSM Activities to support Training

- Support field-staff/DOT providers in ACSM training – Service provider quality assurance training programmes to instil a culture of 'customer focus' enhanced service delivery and effective inter-personal communication skills.
- Conduct a media training workshop at State level during the World TB Day campaign and involve District level media and local NGOs in ACSM trainings.
- Identify ACSM training needs within NGOs, and provide training support to ensure coordinated, integrated, District and National ACSM priorities and planning approaches - problem identification, audience segmentation, behavioural objectives, achievable interventions and performance monitoring.
- Review existing training programmes and training capacity and conduct training of trainers (ToT) to leverage activities.

Peer Education

TB is often more prevalent in settings such as slum areas, tribal and remote rural areas which contain the most economically disadvantaged and marginalized population groups. These population segments represent some of the most difficult to reach groups due to their infrequent attendance to media communication channels and access to other forms of communication. For these reasons successfully treated TB patients who live in these communities can often be the most effective channels of communication with their peers. Lessons learned from peer education programmes have shown that the approach can reduce stigma, increase understanding, ownership and involvement toward important health problems. Peer-led communication

activities ensure that messages disseminated are more credible, and more likely to be heard and acted upon by other peers.

In addition to cured patients, peer educators could also include village heads, village doctors, schoolteachers, worksite representatives, and role models who are in an excellent position to discuss TB within their constituencies. Peers could be trained and given appropriate resource materials to equip them with the information they need in order to act as effective advocates for the ACSM strategy.

The participatory process of dialogue within targeted vulnerable and marginalized communities, coupled with moderation by peer leaders can be a powerful behaviour-changing tool. In order for these programmes to be successful, venues for peer led interventions will need to be identified, and moderators trained and supported with appropriate ACSM aids.

ACSM activities to support Peer Education

- Identify NGOs, and other civil society organisations working with cured patients and local leaders to review and scale-up peer to peer (PTP) training programmes in particular, with slum dwellers, fishermen, transient and street populations, and other vulnerable groups.
- Build capacity and support for peer education by including incentives within training formats, and resource materials support.

Advocacy

Advocacy is an important and integral aspect of the community sensitization process and is already well utilized through events and advocacy conducted by role models and other community leaders. These efforts should continue to add-value to the ACSM process through more purposive advocacy approaches through community social structure channels as well as media advocacy approaches.

Using role models such as local leaders, religious leaders, sporting icons, musicians and other members of the arts community can create opportunities for dialogue with young people, between health providers and communities, between community leaders and communities, between communities, among family members, neighbours and friends. The process can also be a key feature in any efforts to raise community awareness of TB risk and prevention approaches and reduce community stigma.

ACSM activities to support Advocacy

- Contract public relations and media private sector partners to provide support through media advocacy approaches by developing more media advocacy programming – TV panel discussions, reality TV and radio talkback programmes.
- Support NGO partners to identify and use community leaders, role models and opinion leaders when planning ACSM programmes, and integrate advocacy as a key element of strategic planning.
- Support advocacy through the identification and training of media sector partners, to regularly disseminate proactive, structured media releases, incorporating accurate programme information including relevant research findings and other points of interest.

Street Theatre

Mass communication approaches adopted in RNTCP are an appropriate mix of traditional and contemporary media. One such interesting media is the ‘Street Theatre’ that has been effectively adopted as powerful media to

communicate messages in RNTCP. It breaks through language and cultural barriers and is an extremely useful communication tool.

Street theatre does not require literary skills or clever speaking to be effective. Theatre communicates with the whole community - it appeals to community emotions, passions and prejudices. It is an entertaining way of sharing information. Both adults and children learn their best when they are entertained and interested. It is a form of play-acting in the open, before the general public. More often adopted as an innovative approach to propagate and support RNTCP, it is enacted by local boys and girls (NGOs) on the streets or roads. It portrays real life situations of patients that usually involve conflicts and emotions. It is a medium to expose injustice towards TB patients (especially women) in the social system and stimulates the audience to think hard about practical solutions. It communicates important messages/ideas and attitudes in a manner that easily captures people's attention. Some elements of humour, tragedy and intrigue are induced to sustain interest in the audience during the play. Throughout enacting, participation from the audience is encouraged.

More recent developments in Music, Dance and Drama (MDD) use sport and physical activities in the form of team games linked to health messages to further expand this interactive and entertaining media form. Enter-educate approaches utilise entertainment mediums such as these to also provide educational messages on TB and related health issues. These activities make use of idiomatic expressions, which vary from one ethnic community to another and are the basis for ACSM within and across generational and community leadership structures.

The integration of messages on TB into street theatre requires a degree of coordination to establish quality assured messages and programmes, and integration of activities, as well as the active involvement of participants in the development and implementation process. An important aspect of this creative media form is to establish a link with the audience and encourage participation through scenarios that enable community and individual problem solving, and exploration of pre-existing attitudes and beliefs.

ACSM Activities to support Street Theatre

- Integrate and expand on street theatre opportunities and promotional events with NGO partners and integrate activities within the wider ACSM framework of coordinated activities.
- Support the development of a coordinated street theatre roll-out in Districts by providing TA and infrastructural support to lead proponents including transport, audio-visual equipment and merchandise for distribution.
- Add value to street theatre by producing televised dramas and soap operas from MDD community productions for television transmission, as well as radio plays, CDs and audiocassettes for community distribution.
- Support the professional development of popular musicians and role models in the arts who can promote TB prevention and care by developing songs on TB, thus making them advocates for the programme.

State Level Activities

At the State level, the media has the undeniable power to inject changes into the society. Communication and communication media are important

components, as well as indicators, to support the development process. They are a means of teaching, sensitizing, carrying development messages, and channelling reactions between audiences and development workers.
In RNTCP however, it is a challenge to present the information in a manner that will be credible, understandable and acceptable, as well as ensuring that the information flow remains efficient. One major challenge is the large and scattered populations in remote areas where out-reach becomes difficult.
An effective approach is communication through various media and the integration of strategic communication. Strategic communication is a powerful tool that strives for behavioural change and not for just information dissemination, education, or raising awareness. In order to effect behavioural change, it is necessary to identify the root causes of non-compliance, its manifestations and the most effective communication channels for delivering messages to support population health approaches. The idea is to build consensus by raising public understanding and generating informed dialogue among stakeholders. Well-conceived, professionally implemented, strategic communication campaigns are of particular need in the future.

Television

Television ownership and coverage, especially in urban areas have been rapidly expanding and viewing of TV among youth is particularly high. The other aspect of television is its relatively novel appeal and high impact due to graphic imagery with rural population segments.
There has been a large growth in the number of cable TV channels and operators in India. Viewers have a choice of several entertainment channels, sports, news and other variety shows. The limited but rapidly expanding satellite broadcasts in India will surely increase viewing options and alter viewing patterns even further.

ACSM activities to support Television

- Provide public service announcements and paid media schedules featuring key influencers and successfully treated patients.
- Translate street theatre and other MDD (Music, dance and drama) approaches for television broadcast.
- Provide training to television journalists on advocacy approaches in support of TB prevention.
- Conduct televised activities such as TV panel discussions using advocates to raise TB risk perceptions, referral options, reduce TB stigma and promote early health seeking behaviour.
- Provide television current affairs and news opportunities on important TB issues.
- Develop campaign (generic) brand and campaign specific positioning (slogan) to provide a cohesive, integrated range of ACSM messages through state media and community based resourcing.

Radio and community radio networks

Although radio has the widest reach among the mass media the greater impact of television seems to have temporarily 'cannibalised' radio listenership in urban areas. However radio stations still have broad reach and listenership with approximately 50% coverage in rural areas where there is no electricity or population segments cannot afford television media. For these reasons radio is still an important medium with illiterate groups who depend on oral based communication for their health information.

More interesting health and social programming may renew interest in radio once the initial novelty of Television has waned. While the urban audiences are shifting to television and other media, there is still a need to strengthen radio reach to more inaccessible rural populations in remote rural and border areas.

ACSM activities to support Radio and community radio networks

- Provide public service announcements and paid media schedules featuring key influencers on radio, and provide radio talk- back opportunities on important TB issues.
- Establish linkages with existing popular radio soap opera productions for the provision of themes and storylines to support TB messaging to set the ACSM programme agendas and support community based IPC.
- Fund the translation of street theatre and other MDD approaches into radio treatments.
- Provide training to radio journalists and radio jockeys on advocacy approaches in support of TB prevention treatment and care.
- Use call in programmes and focussed discussions to emphasise messages already broadcast through radio / community radio networks

Newspapers

Newsprint media can provide ACSM opportunities through 'long copy,' informational approaches and topical news stories generated through media advocacy activities. Although access to daily newspapers in rural areas drops-off rapidly, as does the reading culture, the more remote the area. Print is an important medium for opinion leaders with readership far exceeding circulation.

There are a broad number of low-cost vernacular newspapers that are accessed and widely read by the literate population and inform discussion and debate in rural and slum communities. The mainstream daily newspaper's increasingly open editorial policies are appreciated by readers, and the medium's primary audience segments are policy makers and the educated elite. Opportunities arise through working closely with journalists, to stem the tide of 'anger stories' and generate more positive purposive coverage for RNTCP.

ACSM activities to support Print Media

- Support the focus of State newsprint media ACSM to political leaders and key influencers – health workers, head teachers, religious and cultural leaders, to influence TB advocacy behaviour within social structure channels.
- Support NGOs through capacity building and training to develop greater interest and involvement in print journalism with TB and other health stories focusing on vulnerable populations.
- Support NGOs and other partners through media training for the development of media events, launches, media releases and print based-stories to set the TB programme agenda with influential groups and support community based IPC programmes.

Outdoor Media

Outdoor media can provide ACSM campaign impact, memorability and longevity, and is accessible to large numbers of people in rural and urban areas. There are a number of opportunities for targeted approaches to billboards in higher risk areas such as slums and tribal communities. There is

somewhat limited experience with outdoor media through stand-alone signage, painted on roadside barrier walls, and vehicle stickers. Although potentially costly to implement, a relatively untapped outdoor media opportunity is the bus and taxi services with public transport vehicles ferrying large numbers of people around the country, daily. Buses, railways and taxis provide moving TB billboards on high-traffic routes, as well as providing 'captive audience' reminders, through TB messages placed inside of the vehicles. Given the fact that mobility is a characteristic of a number of vulnerable population groups, outdoor media should be fully explored as a potentially important means of message dissemination.

ACSM activities to support Outdoor Media

- Work with the Transport Authority, railway authority and large worksites, to identify potential, free, outdoor sites (factory entry points, truck-stops, bus-parks, hospitals and school-grounds) to be used exclusively for TB and other public health, social marketing activities, and contract an agency to erect hoardings at the sites.
- Develop high-quality billboard messages and contract an agency to implement a pilot programme of vehicle signage for buses and taxis in urban and rural areas.
- Develop an M&E programme to evaluate the outdoor strategy and make recommendations for possible future scaling up of activities.

Community Materials Development and Delivery

A critical feature of any TB prevention efforts is the need to build knowledge and change attitudes and perceptions of vulnerable groups; they are often fatalistic, and lacking in confidence and skills to make effective health decisions. Community-based ACSM materials in the form of publications, other print based materials and merchandise can assist key influencers in supporting behaviour change within these groups and mobilizing the call to action. This includes publications to increase knowledge on key modes of TB transmission and prevention, and the need for early health seeking behaviour, treatment adherence and referral options. Other community materials will need to be produced in more user friendly formats to support health service providers to be more aware of the range of issues related to TB prevention, treatment services, and referral options.

Due to lower literacy and vernacular issues in rural areas, more visually based messages such as flip charts should be scaled-up. Publications should be seen as predominantly supporting advocates and other influential groups in their understanding and dissemination of important health messages to their constituents through IPC approaches.

A key feature of any ACSM materials development programme is the timely and efficient delivery of materials, when and where they are needed. Therefore an ACSM Communication Resource Information System (CRIS) utilising logistics similar to that employed for TB drug distribution should be considered to minimize the current ad-hoc production and dissemination of these resources. A materials distribution database could be developed incorporating public sector distribution in non-traditional outlets, through pharmacies, schools, hospitals, health facilities, community centres and administrative offices in urban and rural networks.

The current drug distribution programme could also provide valuable distribution support through existing networks at District and Block levels. A

demand driven approach should be encouraged following establishment of the materials distribution network. TB stakeholders could be provided with resource order forms to monitor resource dissemination and minimize stockpiling.

ACSM activities to support Community Materials Production and Distribution

- Rationalise the existing broad range of resources produced by a number of NGO partners into a core set of quality assured publication materials.
- Design, pre-test, develop and distribute the core range of ACSM materials and merchandise to support community-based dialogue on TB.
- Seek support from private sector distributors to disseminate materials to reduce costs and improve delivery times, or integrate materials resourcing with medical resource supply to service providers.
- Monitor the system to identify current and future materials demand in all Districts.

Quality Assurance

Quality Assurance (QA) is a process of establishing policies and guidelines to ensure that programmes and products developed are of the highest standard. This ACSM strategy feature can utilize QA mechanisms for processes such as the International Standards Organization (ISO) standards for World's best practice, WHO standards for ACSM quality assurance, or develop continuous improvement mechanisms within the strategy to ensure that ACSM programmes, products and services are effectively delivered and continuously improved upon. QA processes could include ACSM message and materials pre-testing, prior to materials production and distribution, or quality-assured service delivery for the range of TB prevention programmes and activities currently being considered or scaled-up.

Effective monitoring and evaluation to assure programme quality is an essential component of any ACSM strategy, often overlooked in the desire to move to new and more stimulating ACSM initiatives.

ACSM activities to support Quality Assurance

- Increase ACSM programme efforts towards more 'customer focused' approaches by service providers and incorporate QA in all ACSM training activities.
- Incorporate customer satisfaction surveys within formative, qualitative and quantitative surveys and report findings to programme partners.
- Provide a patient charter in all RNTCP and Medical College facilities and develop an M&E programme to increase the levels of client entry, and assess involvement and satisfaction with health service delivery.

Incorporate QA policy guidelines into all programme activities and materials development to ensure ACSM strategy best practice.

Audience Segmentation

The main audience segments identified for this strategy are as follows:

Primary Audience Segments: These include TB patients, their families and communities with a history of TB and population belonging to lower-socio-economic categories including: slum dwellers, tribal populations, fishermen,

migratory mobile and street populations, prisoners in jails and correctional facilities as well as other marginalized groups.

Secondary Audience Segments: This segment would include the general population (both males and females)

Influencing Groups: This segment includes, health professionals including public and private practitioners, health workers, Anganwadi workers, ASHAs and other DOT providers, pharmacists, nurses and doctors; teachers, district and block level administrators; Panchayati Raj/village heads; religious leaders; traditional leaders and other rural health providers**;** successfully treated former TB patients and their families; scouting leaders and coaches**;** sporting heroes, musicians and other role models (shift to annex) .

Message Development for different result areas

Stigma Reduction:

- Building TB Brand Equity - to improve perceptions of TB generally in the community in order to make early detection and disclosure more acceptable in the community through the creation of a range of tangible and intangible benefits to health services user groups.
- Creating Transformational PPIAs – to stimulate interest, build personal risk perceptions, and graphically display treatment efficacy and subsequent reduction in debilitation. Thereby, reducing general community resistance and increasing community dialogue on TB.
-

Messages to encourage early health seeking behaviour and treatment adherence:

- Promote the benefits of early health seeking behaviour - following cough for more than 2 weeks as well as treatment efficacy – cost and cure if help is sought early.
- Promote improved and expanded service delivery network - through traditional service providers (public and private clinics) and non-traditional service providers (Community DOT and Fixed DOT providers).
- Provide complementary messaging – linking early detection, screening and treatment to reduction in debilitation of patient, spread of infection to other family and community members.
- Promoting the International Standards of TB Care - involving the private sector, encouraging and documenting notification of all TB patients treated in the private sector
- Promoting the use of the patient charter – ensuring the rights and responsibilities of patients as well as ensure delivery of patient centred TB services

Specific TB Messages (Generic)

- A complete cure from TB is available if you seek help early.
- If you have a cough for more than 2 weeks visit your local health centre.
- A sputum test is the best way to diagnose TB.

- A sputum test is more reliable that X-ray to diagnose TB.
- If you do have TB you will need to take treatment for a period of 6 - 8 months.
- The TB treatment is available free of cost at all PHCs and community DOT providers. The drugs available under the program are one of highest quality & are provided free of cost to all patients.
- Taking drugs under the direct supervision of a DOT provider helps in completion and regularity of treatment.
- A DOT provider within your community can support you in regular intake of medicines.
- Irregular or discontinuing treatment can lead to severe complications that are difficult to cure.
- Early detection, screening and treatment can cure TB and prevent spread of infection to others.

Annex 3
Monitoring, Evaluation, Surveillance and Impact Assessment

Schedule of Review/Technical meeting

Level	Type of Review	Chairperson	Participants	Frequency
National	RNTCP performance review	DDG (TB)	STOs	Biannual
	Medical College performance review	DDG (TB)	ZTF members	Annual
	TB-HIV collaborative activities	DDG-TB	Members of National Working Group for TB-HIV collaborative activities	Quarterly
	Laboratory Committee	Chairperson Laboratory Committee / DDG (TB)	Members of Laboratory Committee	Biannual
	National DOTS-Plus Committee	Chairperson National DOTS- Plus Committee / DDG (TB)	Members of National DOTS-Plus Committee	Biannual
	National Technical Working Group (NTWG) for PPM Activities	Chairperson NTWG for PPM Activities / DDG (TB)	NTWG for PPM Activities members	Biannual
	National Operational Research Committee	Chairperson National OR Committee / DDG (TB)	National OR Committee members	Biannual
	National Airborne Infection Control (AIC) Committee Members	National AIC Committee Chairperson / DDG (TB)	National AIC Committee members	Biannual
Zonal	Medical College performance review	ZTF Chairperson	STF members	Annual
	RNTCP Performance Review including one day exclusively for PMDT activities	DDG (TB)	Regional Directors, STOs, DTOs of selected districts	Annual
State	State Health Society Review (RNTCP included as an agenda item)	PS (Health), MD-NRHM	Director Health Services, CMHO , All programme heads in state,	Quarterly
	RNTCP performance review	STO	DTO	Quarterly
	Performance review of Under-performing districts	STO	DTO	Biannual

Level	Type of Review	Chairperson	Participants	Frequency
	Medical college performance review	STO/ STF Chairperson	Nodal Officers from all medical colleges	Quarterly
	State Operational Research Committee Meeting	STO/ STF Chairperson	State OR Committee Members	Quarterly
	State TB-HIV Co-ordination committee meeting	PS (Health)	Members of State TB-HIV Cordination Committee	Biannual
	State Working Group Meeting for HIV/TB collaborative activities	PD-SACS / STO	Members of State Working Group for HIV/TB collaborative activities	Quarterly
	State DOTS-Plus Committee meeting	PS (Health)	State DOTS-Plus Committee members	Quarterly
	Review of RNTCP Accounting	State Accountant	District level Accountant	Biannual Review and One for PIP
	Review of Drug management	State Drug Store Manager	District Drug Storekeepers	Biannual
	Review of data management	State epidemiologist and state Statistical Assistant	District DEO/Statistical assistant	Biannual
	Workshop for Other Sector Health Facilities such as Railways, ESI, CGHS, Mines, etc…	STO	Representatives from Other sector Health facilities	Annual
	Review Meeting of Partners	STO	All Partners	Biannual
District	District Health Society Review (RNTCP included as an agenda item)	District Magistrate / Chairman District Health Society.	CMHO, All programme heads in district, Block Medical Officers, MO-PHIs (infrequently)	Quarterly
	CMHO Monthly Meeting with Block Medical Officers and MO-In charge PHCs (RNTCP included as an agenda item)	CMHO	All Block Medical Officers, MO-In-charge PHC, and Superintendent CHC.	Monthly
	RNTCP performance review	DTO	MOTC, STS and STLS	Monthly
	Medical college performance review	Core Committee Chairman of the respective Medical College	Core Committee Members of the respective Medical College and DTO	Quarterly
	TB-HIV District Coordination Committee meeting	Chairperson of TB-HIV District Coordination Committee	Members of District TB-HIV Coordination Committee	Quarterly

Level	Type of Review	Chairperson	Participants	Frequency
	Review of Drugs and Logistics	DTO and DTC Pharmacist	Pharmacists/Incharge Storekeeper of all TUs and PHIs	Quarterly
	DOTS-Plus site committee meeting	Chairperson/Coordinator DOTS-Plus site	DOTS-Plus site committee members, DTOs / Sr.DOTS-Plus-TB-HIV Coordinator	Monthly
	Workshop with Partners and other sector hospitals such as Railways, ESI, CGHS, IMA, AYUSH, NGOs, External funded projects etc…	CMHO/DTO	Representative from Partners	Biannual
	Review of TB-HIV collaborative activities along with RNTCP monthly meeting	DAPCU/DTO	ICTC/CCC Counsellors, STS,__DOT-Plus-TB-HIV Coordinator	Monthly
Block	Block Level Meeting with MO-In-charge PHI and other staff. (RNTCP included as an agenda item)	Block Medical Officer	MO-I/C-PHC and other staff.	Monthly
PHI	Monthly Meetings with Staff (RNTCP included as an agenda item)	MOIC, PHC	MPHS/ANM/MPW/ASHA	Monthly

Supervision, Monitoring, and Evaluation activities under RNTCP

S.No.	Levels	Category of Supervisor	Field visits (No. of days/month)	Objective	Facilities to be visited	Patients visits *
1.	National	Officials from Ministry of Health and Family Welfare, GoI.	RNTCP inclusive as a supervisory agenda in their routine field visits for supervision.	Supervision of Programme.	State TB Cell, DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	As required.
2.	National	DDG (TB) and other officials from Central TB Division.	10 days/month (1-2 days per visit)	Supervision of Programme.	State TB Cell, DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	As required.
3.	National	Central Internal Evaluation	One per month	Evaluation of Programme Performance including all aspects such as data validation etc…	State TB Cell, DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	As per protocol
4.	National	National Reference Laboratory	All states assigned to be visited at least once in a year.	Supervision and Evaluation of External Quality Assurance activities	IRL, One district and a few DMCs.	As required.
5.	National	NACO and CTD	One state per quarter	Supervision of TB-HIV collaborative activities	State TB Cell, SACS Office, DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	At least 3 patients per visit
6.	State	Officials from Ministry of Health and Family Welfare, State and State Health Society.	RNTCP inclusive as a supervisory agenda in their routine field visits for supervision.	Supervision of Programme.	DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	As required.
7.	State	STO (Including visits by STC/STDC officers)	12-16 days/month (1-2 days per visit)	Supervision of Programme Performance. Cover all districts in the state every 6 month	DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	At least 3 patients per visit
8.	State	State Internal Evaluation	Upto 30 million – 2 districts per quarter; 30-100 million – 3 districts per quarter; >100 million – 3-4 districts per quarter. Aim to cover all districts	Evaluation of Programme Performance including all aspects such as data validation etc…	DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	As per protocol

S.No.	Levels	Category of Supervisor	Field visits (No. of days/month)	Objective	Facilities to be visited	Patients visits *
			at least once in 3-4 years.			
9.	State	Intermediate Reference Laboratory	All districts to be visited at least once a year	Supervision and Evaluation of External Quality Assurance activities	DTC and a few DMCs.	Not applicable.
10	State	Joint visit by SACS and STC officials	One district per quarter	Supervision of TB-HIV collaborative activities	District AIDS Control office, DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	At least 3 patients per visit
11	District	District Health Society Members (District Magistrate, CMHO and other District Officials).	RNTCP inclusive as a supervisory agenda in their routine field visits for supervision.	Supervision of Programme.	DTC, TUs, DMCs, PHIs, DOT Centre, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	As required.
12	District	DTO (including visits by MO-DTC)	20 days	Supervision of Programme, Cover all TU every month and all DMC every Quarter.	DOT Centre, DMC, PHI, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre, NGO and PP health facilities	At least 3 patients per visit
13	Sub-district	Block Medical Officer/MOTC	RNTCP inclusive as a supervisory agenda in their routine field visits for supervision; at least 7 days per month	Supervision of Programme, Cover all DMC every month all PHI every quarter	DOT Centre, DMC, Drug Store, DOTS Plus Site, ICTC Centre, CCC, ART Centre	At least 3 patients per visit
14	PHC level	MO-PHI	RNTCP inclusive as a supervisory agenda in their routine field visits for supervision.	Supervision of Programme, Cover all sub-centre every month	DMC, DOT Centre	At least 3 patients per visit

S.No.	Levels	Category of Supervisor	Field visits (No. of days/month)	Objective	Facilities to be visited	Patients visits *
15	District	Senior DOTS Plus- TB HIV Coordinator	18-20 days per month	Supervision of Programme, Visit DOTS Plus site in the district every week (if present) Cover all MDR –treatment providers every referable monthly. Cover all ICTC in a quarters, cover all ART centres and link ART centres every month, Cover all CCC/ DIC / NGO facilities every quarter	DOTS Plus Centre, ICTC Centre, CCC /DIC/NGO	2-3 patients every visits (co-infected or MDR-TB patient)
16	Sub-District	STS	18-20 days per month	Supervision of Programme, Cover all PHI at least every month, all DOT centres every quarter	DMC, Non-DMC PHI, ART centre (if present in TU) ICTC, DOT Centres, NGO and PP	All patients to be visited within one month of initiation of treatment; all patients interrupting treatment; all Category IV patients every month in IP and every quarter in CP
17	Sub-District	STLS	18-20 days per month	Supervision of Programme, Cover all DMC at least twice a month	DMC; All sputum collection centres; all diagnostic centres	All patients with contaminated samples or invalid results.
18	PHC level	PHI level supervisors (MPHS)	5-7 days	Supervision of Programme, Cover all sub-centre every month	DOT Centre	2-3 patients per visit
19	PHC level	MPW/ANM		Supervision of Programme, Cover all DOT providers every month	DOT Centre	All patients on treatment during the month.

* MDR, paediatric, co-infected patients should be prioritized for interview

Annex 4
Operations Research

Specific guidelines for review of research proposals by State and Zonal OR committees

- Proposals from medical colleges and local research proposals are to be initially sent to the State OR committees, for review and scoring as per the RNTCP National OR Guidelines.
- If the budget is up to 5 lakh the proposal is reviewed by the State OR Committee; if approved the proposal is forwarded to the National Research Cell for funding.
- If the budget is 5 – 10 lakh, the proposals are forwarded to the Zonal OR Committee for approval; if approved the proposal is forwarded to the National Research Cell for funding.
- Proposals beyond 10 lakhs are to be reviewed by the State OR committee, and if endorsed forwarded to the Zonal OR committee for information, and simultaneously National Research Cell for review and, if approved, funding.
- The National Research Cell is empowered to recommend to CTD for funding of proposals up to 25 lakhs without additional technical review. For projects beyond 25 lakhs, the additional endorsement of the National OR committee is required.
- Provision of Rs 20,000 grant to Post-Graduate students whose thesis topic is on RNTCP would be made. PG thesis requires ethical approval, endorsement of the institution, and can be submitted via the nodal officer of RNTCP core committee at the institution. The State OR committee itself will make the review and approval, within 3 months of submission. To meet this timeline, the State OR committee chairperson is empowered to seek approval of a PG thesis via email communication with 2 members of the committee.
- On approval of a proposal, the Principal Investigator will sign a Memorandum of Undertaking (MoU) with the TB programme manager on behalf of the society for the release of funds. The MoU will include the objects for which they will utilize the funds and the timeline for the study. It will also include a commitment from them to return the funds if the study cannot be taken up due to any reason, and other relevant clauses.
- Funds will be released in the name of the institution and not the individuals, so that the College/ Department can continue the study to its completion/return the funds in the event that the Principal Investigator or a Co-investigator is moved from the college during the course of the study.
- Funds for OR proposals will be released in three instalments – 50 % at the beginning of the study, 30% at mid point of the study when a particular milestone has been achieved and remaining 20% after the final report is made available.

- Thesis grants will be released at 80% in the beginning and remaining 20% after the final report is made available.

The Terms of Reference for the National Research Cell:

- Propose revisions national normative guidance for improving research for TB control
- Revise and regularly update the operational and clinical research agenda
- Coordinate ethical approval for clinical and multi-site research conducted under RNTCP by any party.
- Commission research from the RNTCP priority operational and clinical research agenda; this includes issuing calls for proposals, reviewing and proposing selection of proposal(s), funding projects, and manage and monitor progress of research to ensuring the timely production of quality research deliverables.
- Maintain an active Panel of Experts for reviewing proposals.
- Maintain databases for commissioned research, as a national resource.
- Directly fund researchers both centrally-commissioned research and research approved by Zonal and State OR committees, including Postgraduate thesis; ensure smooth and timely flow of funds to researchers, and provide financial oversight for project implementation.
- Communicate priorities to potential research funders such as ICMR, DBT, and Welcome Trust etc.
- Promote research capacity development through organization of an annual TB research capacity development project, with approximately 10-15 mentored operational research studies produced and disseminated annually.
- Organize research dissemination through conference symposium and other dissemination activities as required.
- Commission evidence synthesis through systematic reviews to inform the consideration of priority areas for RNTCP where regular review of policies are required
- Monitor the progress in initiation and completion of research under the RNTCP priority operational and clinical research agenda.
- Publish an annual Research in TB report summary and translational recommendations.

Annex 5
Anti TB Drugs in NSP-RNTCP

List of 1st Line Anti TB Drugs

Sl. No.	Product Code Number	Product Description	Strength		Unit
1	Product Code-1 Treatment box for Cat-I patient	Treatment box for Cat.I patient. Each treatment box containing 24 combi-packs of Schedule-I in one pouch and 18 multi-blister calendar combi-pack of Schedule-2 in another pouch	Each combi-pack of Schedule-I containing 1 R Cap.of 450mg 2 H Tabs. of 300mg each 2 E Tabs of 600mg each 2 Z Tabs. of 750mg each	Each multi-blister calendar combi-pack of Schedule-2 containing 3 R Caps.of 450 mg each 6 H Tabs. of 300mg each 4 Pyridoxine Tabs of 5mg each	Treatment boxes
2	Product Code-2 Treatment box for Cat-II patient	Treatment box for Cat.II patient. Each treatment box containing 36 combi-packs of Schedule-I in one pouch and 22 multi-blister calendar combi-pack of Schedule-3 in another pouch	Each combi-pack of Schedule-I containing 1 R Cap.of 450mg 2 H Tabs. of 300mg each 2 E Tabs of 600mg each 2 Z Tabs. of 750mg each	Each multi-blister calendar combi-pack of Schedule-3 containing 3 R Caps.of 450 mg each 6 H Tabs. of 300mg each 6 E Tabs of 600mg each 4 Pyridoxine Tabs of 5mg each	Treatment boxes
3	Product Code-3 Treatment box for Cat-III patient	Treatment box for Cat.III patient. Each treatment box containing 24 combi-packs of Schedule-4 in one pouch and 18 multi-blister calendar combi-pack of Schedule-2 in another pouch	Each combi-pack of Schedule-4 containing 1 R Cap.of 450mg 2 H Tabs. of 300mg each 2 Z Tabs. of 750mg each	Each multi-blister calendar combi-pack of Schedule-2 containing 3 R Caps.of 450 mg each 6 H Tabs. of 300mg each 4 Pyridoxine Tabs of 5mg each	Treatment boxes

Sl. No.	Product Code Number	Product Description	Strength	Unit
4	Product Code-4 Treatment box for prolongation of Intensive Phase of Cat-I &Cat. II	Treatment box for Prolongation of Intensive Phase of Cat.I & Cat.II patient. Each box containing 5 pouches and each pouch containing 12 blister combi-pack of Schedule-1	Each combi-pack of Schedule-I containing 1 R Cap.of 450mg 2 H Tabs. of 300mg each 2 E Tabs of 600mg each 2 Z Tabs. of 750mg each	Treatment boxes
5	Product Code-5	Loose Packs of Streptomycin Vials	Each vial of 750mg	Vials
6	Product Code-6	Blister strips pack containing	Rifampicin Capsule of 150mg each	Strips of 10 caps.
7	Product Code-7	Blister strips pack containing	INH Tablet of 100mg each	Strips of 10 Tabs
8	Product Code-8	Blister strips pack containing	Pyrazinamide Tablets of 500 mg each	Strips of 10 Tabs
9	Product Code-10	Blister strips pack or Foil Packs containing	Ethambutol Tabs of 800mg each	Strips of 10 Tabs
10	Product Code-11	Blister strips pack containing	INH Tabs of 300mg each	Strips of 10 Tabs
11	Product Code-12	Blister strips pack containing	Rifampicin Capsule of 450 mg each	Strips of 10 Caps
12	Product Code 13	Treatment box for paediatric category (6-10 Kg).Each treatment box containing 24 combi-packs of Schedule-5 in one pouch and 18 multi-blister calendar combi-pack of Schedule-6 in another pouch	Each combi-pack of Schedule-5 containing 1 R Tab. of 75mg 1 H Tab. of 75mg 1 E Tab of 200mg 1 Z Tab. of 250mg Each multi-blister calendar combi-pack of Schedule-6 containing 3 R Tabs.of 75 mg each 3 H Tabs. of 75mg each 4 Pyridoxine Tabs of 5mg each	Treatment boxes

Sl. No.	Product Code Number	Product Description	Strength		Unit
13	Product Code-14	Treatment box for paediatric category (11-17 Kg).Each treatment box containing 24 combi-packs of Schedule-7 in one pouch and 18 multi-blister calendar combi-pack of Schedule-8 in another pouch	Each combi-pack of Schedule-7 containing 1 R Tab. of 150mg 1 H Tab. of 150mg 1 E Tab of 400mg 1 Z Tab. of 500mg	Each multi-blister calendar combi-pack of Schedule-8 containing 3 R Tabs.of 150 mg each 3 H Tabs. of 150mg each 4 Pyridoxine Tabs of 5mg each	Treatment boxes
14	Product Code-15 Treatment box for prolongation of intensive phase of paediatric cases (6-10Kg & 18-25 kg)	Treatment box for prolongation of intensive phase of paediatric cases (6-10Kg & 18-25 kg). Each box containing 5 pouches and each pouch containing 12 blister combipack of Schedule-5	Each combi-pack of Schedule-5 containing 1 R Tab. of 75mg 1 H Tab. of 75mg 1 E Tab of 200mg 1 Z Tab. of 250mg		Treatment boxes
15	Product Code-16 Treatment box for prolongation of intensive phase of paediatric cases (11-17Kg, 18-25 kg and 26-30kg)	Treatment box for prolongation of intensive phase of paediatric cases (11-17Kg, 18-25 kg and 26-30 kg). Each box containing 5 pouches and each pouch containing 12 blister combipack of Schedule-7	Each combi-pack of Schedule-7 containing 1 R Tab. of 150mg 1 H Tab. of 150mg 1 E Tab of 400mg 1 Z Tab. of 500mg		Treatment boxes
16	Product Code - 23	Blister strips pack containing	Pyrazinamide Tablets of 750mg each		Strips of 10 Tabs

R= Rifampicin; H= Isoniazid; E= Ethambutol; Z= Pyrazinamide; S.M= Inj. Streptomycin; X= Pyridoxine.

List of 2nd Line Anti TB Drugs in RNTCP

Sl. No	Product Code Number	Product Description	Strength	Unit
1	Product Code-8	Blister strips or foil pack containing	Pyrazinamide Tablets -500mg	Strip of 10 Tablets
2	Product Code-17	Loose Packs of Kanamycin Acid Sulphate Vials	Each vial - 500 mg	Vials
3	Product Code-18	Blister strips pack containing	Ofloxacin Tablets -200 mg	Strip of 10 Tablets
4	Product Code-19	Blister strips pack containing	Ofloxacin Tablets - 400 mg	Strip of 10 Tablets
5	Product Code-20	Blister strips pack containing	Ethionamide Tablets - 250 mg	Strip of 10 Tablets
6	Product Code-21	Blister strips pack containing	Ethambutol Hydrochloride Tablets - 200 mg	Strip of 10 Tablets
7	Product Code-23	Blister strips pack containing	Pyrazinamide Tablets - 750 mg	Strip of 10 Tablets
8	Product Code-24	Blister strips pack containing	Cycloserine Capsules - 250 mg	Strip of 10 Caps.
10	Product Code-25	Loose Packs of Sodium PAS Granules	Sodium PAS Granules - 100 gm container	Plastic Containers (100 gm.)
11	Product Code-26	Blister strips pack containing	Pyridoxine Hydrochloride Tablets - 100 mg	Strip of 10 Tablets

Annex 6

Key findings of research published in 2006-2011 and implications for TB control in India

Research Study	Main Findings	Implications
Improving case detection		
Smear-positive TB case detection among TB suspects with cough for 2 or 3 weeks or more among outpatients attending governmental health facilities *IJT 2008; 55:77-83*	More positive cases among chest symptomatics with cough of ≥2 weeks	By changing the definition of TB suspects to persons with cough of ≥2 weeks case detection rate is likely to increase
Public-Private-Partnership Rural Model in Tiruvallur *IJTLD, 2006; 10(12):1380-1385*	Feasible to create a link between private-public systems within RNTCP 10% Increase in case detection of New s+ cases due to involvement of PPs	Public Private Partnership has been beneficial to RNTCP
Modifications in sputum smear microscopy *IJMR, 2006; 124: 439-442*	The sensitivity of ZN method for sputum transported in CPC	The sensitivity of ZN method is low for sputum transported in CPC
Initial default among diagnosed sputum smear-positive pulmonaryTB patients in Andhra Pradesh, India. *International Journal of Tuberculosis and Lung Disease (2008) 12: 1055-1058.*	Reported initial default rates are very high and actual rates are nearly half the reported, owing to problems of recording and reporting patient treatment initiation status.	The study also revealed that pre-diagnostic counselling of patients and better address recording in laboratory registers of DMCs may help in patient tracing.
Measures to reduce workload		
Contribution from 4th month sputum smear examination in declaring Rx outcome *IJT, 2006*	Sputum examination at 2 months into continuation is required only for patients remaining smear positive at the end of IP (7.6% in CAT-I & 8.8% in CAT-II)	Routine sputum examination at 2M into CP may be deferred.
Care seeking pattern of TB suspects		
Care seeking behaviour of TB suspects and patients *IJTLD 2007; 11(2):161-167*	>80% chest symptomatics seek care on their own One third of patients attend health facilities >3 times before diagnosis	Passive case finding in RNCTP is justifiable 'Think TB' A*ctive case detection* needed

	93% sought care within one month. Half of them contacted Private practitioners (PPs) first	at health facilities PPs should be roped into the programme
Why do TB suspects bypass local services to attend TB sanatorium? *Lung India 2010; 27 (3): 111-114*	Multiple reasons foe attending TB sanatorium were popularity of the centre (82%), perceived availability of good treatment (52%), referral by earlier treated patients (36%), expectation of specialized care (22%), referred by treating physicians (13%) and for inpatient care (11%).	There is a need to improve community awareness of the availability of free diagnostic and treatment facilities locally under RNTCP
Risk factors for poor treatment outcome		
Risk factors for failures & deaths for TB patients in DOTS Programme *IJT 2008; 55:64-69*	MDR TB pts more often failed with treatment (33% vs 3%) Higher mortality in pts. <35 kg body wt. & previous ATT	Strict adherence to DOTS will prevent emergence of MDR Nutritional supplements may be essential for patients with low body weight
Do tuberculosis patients weighing less than 35kg need more attention? *J Empirical Res Soc Sci 2009; 4:33-39*	Mortality among males in the ≤35kg group was 2.5 times more as compared to females. The treatment success rate increased as the body weight increased and the increase in trend was statistically significant	There is a need to pay more attention to this group of patients who are underweight at the time of enrollment.
To study the contribution of migration to treatment default among tuberculosis patients treated under RNTCP. *IJT 2006; 53:33-36*	Of the 531 patients registered under TB programme in 3rd and 4th quarters of 2001, 104 (20%) had defaulted for treatment. Among defaulters, 24% had migrated. The reasons for migration were: occupational (48%), returning to the native place (28%), domestic problems (12%) and other illnesses (12%).	Availability of treatment under the DOTS strategy should be popularized among patients, providers and community.
To elicit reasons for treatment default from a cohort of TB patients under RNTCP and their DOT providers. *IJT 2007; 54:130-135* *IJT 2007; 54:66-70*	Main reasons given by the 141 patients and their DOT providers were: drug related problems (42%, 34%), migration (29%, 31%), relief from symptoms (20%, 16%), work related (15%, 10%), alcohol consumption (15%, 21%), treatment from other centers (13%, 4%), respectively.	Intensifying motivation and counselling are likely to improve patient compliance and reduce default.
Risk factors for treatment default among re-treatment TB patients in India, 2006. *10.1371/journal.pone.0008873 [doi].*	Amongst a large number of re-treatment patients in India, default occurs early and often.	Improved pre-treatment counselling and community-based treatment provision may reduce default rates. Efforts to retrieve treatment interrupters prior to default require strengthening.
Characteristics and programme-	RNTCP strategy of treating children using paediatric PWB is	

defined treatment outcomes among childhood TB patients under the National TB Programme in Delhi. *PLoS One (2010) 5: e13338 10.1371/journal.pone.0013338 [doi].*	effective in achieving programme defined treatment success rate.	
Source of previous treatment for re-treatment TB cases registered under the National TB Control Programme, India, 2010. *PLoS One (2011) 6: e22061. 10.1371/journal.pone.0022061 [doi];PONE-D-11-07281 [pii].*	Nearly half of the re-treatment cases registered with the national programme were most recently treated outside the programme setting.	Enhanced efforts towards extending treatment support and supervision to patients treated by private sector treatment providers are needed to improve the quality of treatment and reduce the number of patients with recurrent disease. In addition, the study recommended that the reasons for the large number of recurrent TB cases from those already treated by the national programme require urgent detailed investigation.
Drug susceptibility pattern		
Susceptibility profile of New cases *IJTLD, 2006; 10(1): 52*	Sensitive to HR 85% MDR TB 1.7%	Majority of new patients are sensitive to ATT drugs Treatment with CAT-I is justifiable
Drug Susceptibility profile among previously treated patients *IJTLD, 2006*	Sensitive to HR 59% MDR TB 12%	Majority of previously treated patients are likely to respond to CAT-II regimen
Susceptibility profile at the time of CAT-II failure *IJT, 2006; 53:141-148*	Sensitive to HR 29% MDR TB 32% Culture neg. 13% H Resistance 26%	One third of CAT-II failures likely to be sensitive to ATT One third were likely to be MDR TB
What is the magnitude of MDR TB in community? Is MDR TB increasing ? *IJTLD, 2006*	CAT 1 patients • 85% had sensitive bacilli • MDR - 1.4% Irrespective of prior Rx • MDR - 3.4%. • No increase in MDR TB over the 5-year period	Current RNTCP regimens adequate Strict adherence to DOTS to prevent MDR
Surveillance of drug-resistant TB in	Prevalence of MDR-TB among new cases is 2.4% (95%CI 1.6-	MDR-TB prevalence remains low among

the state of Gujarat, India. *International Journal of Tubercculosis Lung Diseases. 2009 Sep;13(9):1154-60.*	3.1) and among re-treatment cases it is 17.4% (95%CI 15.0-19.7%). XDR-TB levels about 3-4% of MDR-TB. Very high (25%) Ofloxacin resistance.	new TB patients in Gujarat, but is common amongst previously treated patients. The alarmingly high prevalence of OFX resistance among MDR- TB patients may threaten the success of the expanding efforts to treat and control MDR-TB.
The feasibility of managing MDR TB patients under field conditions where DOTS programme has been implemented *IJT 2007: 54: 117-124*	Of 66 MDR TB patients started on treatment, 20 (30%) were resistant to one or more second line drugs (Eto, Ofx, Km) including a case of "XDR TB". Less than half the patients stayed in the hospital for more than 10 days. Providing injection was identified to be a major problem. Successful treatment outcome was observed only in 37% of cases with a high default of 24%. Adverse reactions necessitating modification of treatment was required only for three patients	The challenge to reduce default can be addressed by identifying a provider closer to the patient who can also give injection, have social skills and manage minor adverse drug reactions.
To analyse the outcomes of MDR-TB patients treated at the Tuberculosis Research Centre, Chennai, with the RNTCP recommended 24 months standard treatment regimen (STR), under programmatic conditions. *IJMR 2011; 133: 529-534*	Of the 38 patients, Culture conversion rates at 3 and 6 months were 84% and 87% respectively. At the end of treatment, 25 (66%) were cured, 5 defaulted, 3 died and 5 failed. At 24 months, 30 (79%) patients, including 5 defaulters, remained culture negative for more than 18 months. Adverse drug reactions (ADR) were reported by 22 (58%) patients. No patient had XDR-TB initially, but 2 failure cases emerged as XDR-TB during treatment	Outcomes of this small group of MDR-TB patients treated with the RNTCP's STR is encouraging in this setting. Close attention needs to be paid to ensure adherence, and to the timely recognition and treatment of ADR**s**
Extensively drug-resistant tuberculosis: experience at the Tuberculosis Research Centre, *IJTLD 2011; 15(10):1323–1325*	Among the 10 XDR-TB patients, treatment could not be initiated in three, as one died due to massive haemoptysis and two defaulted. The remaining seven patients were treated with individually tailored regimens based on DST. During treatment, one patient defaulted and two died due to respiratory failure. The remaining three patients are still bacteriologically positive and continue on treatment. All patients experienced mild to moderate adverse drug reactions.	There is a need to develop rapid methods for culture and DST against SLDs, to ensure the availability of quality-assured drugs and to devise appropriate guidelines for the management of XDR-TB.
Economic impact of TB		
Prevalence of TB in different economic strata (Standard of Living Index) *IJTLD 2007; 11(9):1042–1045*	Prevalence of TB / 100,000 Low SLI 343 Medium SLI 169 High SLI 92	Bacillary TB is more among low SLI & TB impoverishes poor further

DOTS Reaches Socially Marginalized Population in the Community *J Commun Dis 40 (3) 2008 : 199-204*	The prevalence was nearly two times higher in colony compared to village 268 vs 140 (1.9:1). The notification in the colony and village was estimated to be 206 and 120 respectively; the ratio being 1.7:1 (data not tabulated) similar to the prevalence ratio (1.9:1). The successful treatment outcome was also similar in these two groups 75% and 78%.	People living in colony have equal access to DOTS as those in the village
Economic burden on health system *IJT, 2006;53:7-11.*	Unit cost: smear microscopy Rs 10/- radiography Rs 25/- drugs: CAT-I Rs 392/- CAT-II Rs 729/- CAT-III Rs 277/-. Overall unit provider cost to treat a TB patient Rs 1587/- to Rs 1924/-	Information is vital for budget allocation It is cost effective (Rs 1350 for diagnosis alone in Pre DOTS era)
Performance of a DOTS programme: administrative & technical challenges *IJT, 2006; 53:123-134*	Non-availability of staff, inadequate supervisory visits & review meetings is associated with poor treatment outcomes	Ensure availability of key staff, regular supervisory visits and review meetings
Improving Monitoring		
Estimating the risk of TB infection among children after implementing DOTS *IJTLD, 2006*	The ARTI estimates in three tuberculin surveys: 1.6%, 1.4% & 1.2% The annual decline from the first to the third survey 6%	Significant decline in the trend of TB infection after DOTS implementation
Monitoring drug susceptibility profile *IJTLD, 2006*	Levels of MDR TB are contained at 1.7% for newly diagnosed patients & 11.7% for previously treated patients, over a 5-year period of DOTS implementation	Good indicator of programme performance. Currently used RNTCP drugs are effective
Treatment outcome		
Efficacy of an intermittent 6-month SCC, CAT-I regimen in the treatment of new pulmonary tuberculosis (PT) patients with type 2 diabetes mellitus (DMTB) *IJT 2007; 54:168-176*	DMTB patients (100) similar clinical presentation as PTB, but atypical radiological presentation, higher bacillary load at the time of diagnosis (higher culture grading), a lower prevalence of anti-tuberculous drug resistance & excellent outcome to CAT I regimen (94% of 93 became culture negative at the end of treatment & 1% relapsed in 2 year follow-up) despite poor diabetic control.	CAT I regimen is effective in the treatment of new smear positive pulmonary tuberculosis patients with type 2 diabetes mellitus despite poor diabetic control. This finding supports the policy of RNTCP
Contacts of TB patients		

To assess the implementation of child contact screening and isoniazid preventive therapy (IPT) administration under the RNTCP. *IJTLD 2009; 13(12):1507–1512*	Among the 84 household children aged <6 years of 253 sputum positive pulmonary TB patients, only 16 (19%) had been initiated on IPT. The treatment cards of source cases lacked documentation of contact details. Focus group discussions revealed lack of detailed knowledge about procedures	Provision for documentation using a separate IPT card and focused training may help improve the implementation of contact screening and IPT.
Additional risk of developing TB for household members with a TB case at home at intake *IJTLD 2007;11(3):282–288*	The adjusted hazard rate was 3.4 for contacts of smear-positive patients and 1.7 for contacts of smear-negative patients as compared to non-contacts. Of 3942 incident cases, 337 (8.5%) came from households with a TB case.	Contacts need to be screened for TB
biological and behavioural risk factors associated with PTB *IJTLD 2007; 11(9):999–1003*	A total of 429 bacteriologically positive cases were detected during the survey. The adjusted prevalence ORs for age, sex, smoking and alcoholism were 3.3 (2.7–4.1), 2.5 (1.9–3.3), 2.1 (1.7–2.7) and 1.5 (1.2–2.0), respectively.	
Association of sputum conversion and cure with initial smear grading in PTB patients treated with Category-I regimen *IJMR 2006; 123:807-814*	The cure and sputum conversion rate decreased with increasing in smear grading. cure rate of 77% in 1+ and 72% in 3+; conversion rate 86% in 1+ and 73% in 3+ smear grade	More attention to be paid for patients with higher smear grading
Status of reregister cases under RNTCP *IJT 2007; 54:12-16*	Among the patients re-registered 38% had treatment success, 45% defaulted, 7% died and 10% failed.	Emphasizes need for continuing motivation and prompt default retrieval action
To assess the clinical, bacteriological, radiological status and health related quality of life (HRQoL) of PTB patients 14 -18 years after successful treatment with SCC at the Tuberculosis Research centre. *IJT 2009; 56:132-140*	The mean period after treatment completion for the 363 eligible participants was 16.5yrs; 25 (7 %) had been re-treated and 52 (14%) died. Among the investigated, 58 (29%) had persistent respiratory symptoms; 170(86%) had radiological sequelae but none had active disease. Abnormal PFT was observed in 96 (65%) with predominantly restrictive type of disease in 66(45%). The St Georges respiratory questionnaire (SGRQ) scores for activity and impact were high implying impairment in HRQoL.	Assessment of long term status of cured PTB patients showed an impairment of lung functions and HRQoL highlighting the need to address these issues in the management of TB that may provide added value to patient care.
Evaluation of post-treatment health-related quality of life of TB patients *IJTLD 2007; 11(8):887–892*	The mean scores for social, physical, mental and economic well-being were respectively 84, 74, 68 and 62 on a scale of 100. The well-being scores were significantly related to age, sex, education, employment and persistent symptoms. There was a significant association between economic and social well-being.	A year after successful treatment of TB patients, quality of life as measured by physical, mental and social well-being scores was comparable to that of the general population.

Status of TB patients 2-3 years after initiation of treatment under DOTS *IJT 2007; 54:199-203*	Mortality rate was 15% and among the remaining 18.6% had active disease.	
To identify the effect of weight gain among TB patients at the end of treatment *IJT 2009; 56:5-9*	The average change in weight was 3.22kg ranging from a loss of 4kg to a gain of 20kg. Gain in weight is associated with cure rate	
To identify the channels of communication available in rural areas *IJT 2006; 53:206-211*	The main source of communication as per interview was television (100%), wall posters (55%); publicity through panchayat office meetings (53%) and dandora (43%).	Should tap all these resources to educate the community, especially the rural community
HIV /TB		
To study rifampicin-NNRTI pharmacokinetic drug interactions *J Acquir Immun Defic Syndr 2006; 4: 36-41* *Antimicrob Agents Chemother 2009; 53: 863-8*	(i) It was possible to overcome decreased bioavailability of nevirapine by increasing its dose (ii) The dose of efavirenz may not be increased during rifampicin co-administration	These studies were done for the first time in Indian patients, and provided useful information to the National AIDS Control Programme.
HIV sero-prevalence among TB patients in India, 2006-2007. *PLoSOne. 2008 Aug 20; 3(8):e2970.*	HIV among TB patients varies widely in India and ranges from 1% to 13%.	Programme efforts to implement comprehensive TB-HIV services should be targeted to areas with the highest HIV burden.
Linking HIV-infected TB patients to Cotrimoxazole prophylaxis and anti-retroviral treatment in India. *PLoS One. 2009 Jun 22; 4(6): e5999*	among HIV-infected TB patients in India death was common despite the availability of free Cotrimoxazole locally as well as presence of ART via referral centres.	To minimize death rates, programmes should promote high levels of ART uptake and closely monitor progress in implementation.
Socio behavioural studies		
Willingness to participate (WTP) in future preventive HIVVTs among high risk populations & to explore their knowledge and attitude toward preventive HIV	82% of 501 were willing & the desire to be protected from HIV was the main reason. Main concern -unknown efficacy of the vaccine (50%) & the effects of an HIV vaccine on participants' lives (51%)	High-risk volunteers will be willing to enroll in HIVVTs. Health education will ensure participants' understanding of key concepts of HIVVTs.

vaccines. *AIDS Research and Human Retroviruses 2009; 25(2):*		
Percentages, Process, and Patterns of HIV Disclosure Among the Spouses of HIV-Infected Men. *J Int Ass of Phys in AIDS Care 2007; 10(1) 26-29*	69% 0f 201 women were sero +ve. 49% did not know the reason for their husbands HIV infection. HIV diagnosis was disclosed directly by the health providers for 50%(117) respondents only	More awareness about pretest counseling, informed consent, posttest counseling, and the importance of privacy and confidentiality should be created in the health facilities. Community-based programs to reduce stigma
To estimate prevalence of alcohol use and AUDs among TB patients in Chennai corporation health centres. *PLoS ONE, 2011; 6 (5) e19485*	Out of 490 TB pts, 29% (141) were found to consume alcohol. Among 141 current drinkers 52% (73) had an AUDIT score of 8. Alcohol related problems are more prevalent among Category II. Default rate was 44% in low risk group whereas it was 56% among TB patients with AUD	Alcohol use disorder needs to be addressed in the TB control programme. A larger study is being conducted to develop a model alcohol intervention program.
To evaluate the feasibility and effectiveness of PITC in detecting HIV-infection in TB patients and to assess the efficiency of linkage to HIV care and treatment for HIV infected TB patients. *Plos One December 2009; 4(12) e8389*	With implementation of PITC in India, HIV status was successfully ascertained for 70% of TB patients. Previously undiagnosed HIV-infection was detected in 6.4% of those TB patients newly tested, enabling referral for lifesaving anti-retroviral treatment. HIV infection among the 5299 registered TB patients was 468 (8.8%)- 268 (5.1%) known HIV-positive prior to TB diagnosis, & an additional 200 (3.8%) detected after TB diagnosis.	PITC for TB patients has been incorporated into policy and practice in higher HIV burden settings in India
To assess the feasibility of screening all TB patients for HIV through referral to a voluntary counselling *IJTLD 2007; 11(12):1296–1301*	Of 4802 patients invited, 69% were willing to participate in the test More women reported lack of awareness (48.2%) than men (32%)	Health providers need to be sensitised to the need to scale up HIV and TB collaborative efforts, keeping the interest of the patients in mind
To gain insight into the current Care Seeking Behavior of Chest Symptomatics after RNTCP implementation. *PLoS One. 2010; 5(9): e12379*	Six hundred and forty chest symptomatics were identified (R 314; U 326). The government facility was the first or initial point of contact for 38% of chest symptomatics in the pre RNTCP. This has significantly increased to 50% in post RNTCP. There is a significant increase in the shift from private to government	The relatively high levels of subsequent shifting to private health facilities calls for urgent action to make government facilities more patients friendly with quality care facilities in the delivery of RNTCP services.
To assess the effectiveness of the system of referral of TB suspects	Of 18 329 clients counselled, 1065 (6%) were identified as TB suspects and referred to DMCs. Of these, 888 (83%) attended	The ICTC-to-DMC referral system makes a significant contribution to the detection

from the integrated HIV counseling and testing centres (ICTCs) to the designated microscopy centres (DMCs) *IJTLD 2009; 13(2):221–225*	and 177 (17%) dropped out; 81% of the drop-outs were interviewed. Reasons for dropping out were multiple: 51% were due to the health system, 62% due to the disease and 62% due to personal reasons. Twelve per cent of DMC attendees were smear-positive.	of TB cases.
HIV serostatus of clients attending integrated counseling and testing centres (ICTCs) in Tamilnadu. *AIDS Research and Treatment 2011, Article ID 650321: 1-7*	Of 18329 clients counseled, 17958 (98%) were tested for HIV and 732 (4.1%; range 2.6 to 6.2%) were tested positive for HIV. HIV sero positivity was associated with HIV in the family (adjusted odds ratio 11.6), history of having sex with sex workers (AOR 2.9), age ≥31 years (AOR 2.8); being married (AOR 2.5), previously tested for HIV (AOR 1.9), illiteracy (AOR 1.7), unemployment (AOR 1.5), and alcoholism (AOR 1.5).	This group should be included in routine programme monitoring of sero-positivity and risk factors for better understanding of the impact of the National AIDS Control Programme. This would help in evolving appropriate policies and strategies to reduce the spread of HIV infection
Cross-referral between HIV counselling and testing centres and smear microscopy centres in Tamil Nadu *IJTLD 2009; 13(2):221–225*	Of 18,329 clients counselled, 1065 (6%) were identified as TB suspects and referred to DMCs. Of these, 888 (83%) attended and 177 (17%) dropped out; 81% of the drop-outs were interviewed. Reasons for dropping out were multiple: 51% were due to the health system, 62% due to the disease and 62% due to personal reasons. Twelve per cent of DMC attendees were smear-positive.	The ICTC-to-DMC referral system makes a significant contribution to the detection of TB cases. Reasons for dropping out were multiple, but are correctable. This study also probes into current policies on programme coordination and recommends strategies for strengthening the collaboration between the TB and HIV programmes.
Will adoption of the 2010 WHO ART guidelines for HIV infected TB patients increase the demand for ART services in India? *PLoS ONE (2011) 6(9): e24297. doi:10.1371/journal.pone.0024297*	In Karnataka, India, about nine out of ten HIV-infected TB patients were eligible for ART according to 2006 WHO ART guidelines. The efficiency of HIV case finding, ART evaluation, and ART initiation was relatively high with 78% of eligible HIV-infected patients actually initiated on ART, and 80% within 8 weeks of diagnosis.	This study recommended that ART could be extended to all HIV infected TB patients irrespective of CD4 count with relatively less burden on the national ART programme.

Annexure 7

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Annexure 8

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Annexure 9

List of States Large, Medium and Small as per population of NSP

Large State(> 30 Mn Population)		medium States10- 30 Mn Population)		Small States (<10 Mn Population)	
1	Assam	1	Delhi	1	A & N Islands
2	Gujarat	2	Punjab	2	Arunachal Pradesh
3	Karnataka	3	Chhattisgarh	3	Chandigarh
4	Kerala	4	Haryana	4	D & N Haveli
5	Madhya Pradesh	5	Jammu & Kashmir	5	Daman & Diu
6	Maharashtra			6	Goa
7	Rajasthan			7	Himachal Pradesh
8	Tamil Nadu			8	Lakshadweep
9	Uttar Pradesh			9	Manipur
10	West Bengal			10	Meghalaya
11	Andhra Pradesh			11	Mizoram
12	Bihar			12	Nagaland
13	Jharkhand			13	Pondicherry
14	Orissa			14	Sikkim
				15	Tripura
				16	Uttaranchal

Annexure 10

DETAILED BUDGET 2012-17							
Categories	**2012-13**	**2013-14**	**2014-15**	**2015-16**	**2016-17**	**Total**	**Percentage of total**
	Budget (Rs Lakh)	**Budget (Rs Lakh)**	**Budget (Rs Lakh)**	**Budget (Rs Lakh)**	**Budget (Rs Lakh)**	**Budget (Rs Lakh)**	
Investment Costs							
Civil Works	655	746	2,426	1,271	1,238	6,336	1.41%
Lab Equipment	590	1,042	1,651	1,937	2,289	7,509	1.67%
Office Equipment	149	239	401	247	303	1,339	0.30%
Vehicles	226	328	1,369	234	328	2,484	0.55%
Ist Line Drugs	9,115	10,256	12,566	13,784	14,135	59,857	13.30%
2nd Line Drugs	7,425	17,258	20,832	12,380	13,415	71,310	15.85%
Training	1,245	1,725	2,182	1,712	1,848	8,712	1.94%
Medical Colleges	1,315	1,791	1,995	2,393	2,570	10,064	2.24%
Advocacy, Communication and Social Mobilisation	1,495	1,627	2,434	2,985	3,175	11,715	2.60%
Contractual Services	15,981	22,104	28,173	28,447	28,508	1,23,214	27.38%
Consultancy Services and Research Studies	59	955	2,263	1,659	1,766	6,704	1.49%
NGO & PP Support	986	2,049	9,139	9,893	11,187	33,254	7.39%
Lab Materials (Round9-GFATM)		879	2,368	2,789	2,917	8,954	1.99%
Expand TB Project		978	-	-	0	978	0.22%

Sub Total	**39,242**	**61,977**	**87,799**	**79,733**	**83,680**	**3,52,430**	**78.32%**
Recurrent costs							
Printing	561	623	1,312	1,681	1,912	6,088	1.35%
Lab materials	1,474	2,547	5,783	8,973	11,125	29,903	6.64%
Counseling Charges	1,055	1,241	4,345	5,209	5,593	17,443	3.88%
Patient support & transportation charges	(0)	320	2,614	3,135	3,166	9,234	2.05%
Vehicle Operation	892	1,000	2,166	2,427	2,444	8,928	1.98%
Vehicle hiring	575	789	2,062	2,299	2,305	8,030	1.78%
Office operations	777	780	781	875	880	4,093	0.91%
Supervision & Monitoring	1,815	1,067	1,996	2,100	2,189	9,167	2.04%
Equipment Maintenance	11	54	301	366	405	1,137	0.25%
WHO Technical Assistance	300	603	843	886	930	3,562	0.79%
Sub Total	**7,458**	**9,024**	**22,205**	**27,949**	**30,950**	**97,585**	**21.68%**
Contingency @ 0%	**-**	**-**	**-**	**-**	**-**	**-**	**0%**
Total	**46,700**	**71,000**	**1,10,004**	**1,07,682**	**1,14,629**	**4,50,015**	**100%**

Annexure 11

RNTCP - National Strategic Plan 2012-17 - Component wise Budget 2012-13 to 2016-17 (5 years) All States							
	Projections						
Categories	2012-13	2013-14	2014-15	2015-16	2016-17	Total	Percentage of total
	Budget (Rs Lakh)	Budget (Rs Lakh)	Budget (Rs Lakh)	Budget (Rs Lakh)	Budget (Rs Lakh)	Budget (Rs Lakh)	
Institutional Strenghtening							
Infrastructure							
Civil Works	655	746	2,426	1,271	1,238	6,336	1%
Vehicles	226	328	1,369	234	328	2,484	1%
Office Equipment	149	239	401	247	303	1,339	0%
Vehicle Operation	892	1,000	2,166	2,427	2,444	8,928	2%
Vehicle hiring	575	789	2,062	2,299	2,305	8,030	2%
Equipment Maintenance	11	54	301	366	405	1,137	0%
Sub Total	2,506	3,156	8,726	6,844	7,022	28,255	6%
Human Resources							
HRD/Training	1,245	1,725	2,182	1,712	1,848	8,712	2%
Contractual Services	15,981	22,104	28,173	28,447	28,508	1,23,214	27%
Sub Total	17,227	23,829	30,354	30,159	30,357	1,31,926	29%
Outreach							
NGO & Private Sector	986	2,049	9,139	9,893	11,187	33,254	7%
Counseling Charges	1,055	1,241	4,345	5,209	5,593	17,443	4%
Patient support & Transportation	(0)	320	2,614	3,135	3,166	9,234	2%
Medical Colleges	1,315	1,791	1,995	2,393	2,570	10,064	2%

ACSM	1,495	1,627	2,434	2,985	3,175	11,715	3%
Sub Total	4,850	7,027	20,527	23,614	25,691	81,710	18%
Laboratory Services							
Lab Equipment	590	1,042	1,651	1,937	2,289	7,509	2%
Lab materials	1,474	2,547	5,783	8,973	11,125	29,903	7%
Global Fund Round 9 project		879	2,368	2,789	2,917	8,954	2%
Expand TB Project	-	978	-	-	0	978	0%
Sub Total	2064	5446	9802	13700	16331	47343	11%
Treatment Services							
Ist Line Drugs	9,115	10,256	12,566	13,784	14,135	59,857	13%
2nd Line Drugs	7,425	17,258	20,832	12,380	13,415	71,310	16%
Sub Total-Drugs	16,540	27,514	33,398	26,164	27,550	1,31,167	29%
Planning and Administration							
Printing	561	623	1,312	1,681	1,912	6,088	1%
Office operations	777	780	781	875	880	4,093	1%
Supervision and Monitoring	1,815	1,067	1,996	2,100	2,189	9,167	2%
Consultancy Services and Research	59	955	2,263	1,659	1,766	6,704	1%
Sub Total	3,212	3,425	6,353	6,315	6,748	26,052	6%
WHO Technical Assistance							
WHO Technical Assistance	300	603	843	886	930	3,562	1%
Sub Total	300	603	843	886	930	3,562	1%
Physical Contingency @ 2 %	-	-	-	-	-	-	0%
Total	46,700	71,000	1,10,004	1,07,682	1,14,629	4,50,015	100%

Annexure 12

Table 1 - Funding requirements of the National Strategic plan 2012-14 (Donors wise Budget)							
		INR in lakh					
Sl No	Budget Head	2012-13	2013-14	2014-15	2015-16	2016-17	Total
1	Key assumptions						
1.1	Number of TB patients put on treatment	16,55,390	16,83,576	17,08,681	18,62,213	18,89,177	87,99,037
1.2	Number of MDR-TB patients put on treatment	15,100	25,800	30,500	32,000	38,000	1,41,400
2	Budget Heads (All figures in Million INR)						
2.1	Civil Works, Office equipment	814	1039	3129	1884	1946	8812
2.2	Supervision and Monitoring	3507	3184	7594	7060	7266	28610
2.3	Human Resource	15981	22104	28173	28447	28508	123214
2.4	Training	1245	1725	2182	1712	1848	8712
2.5	Laboratory Services	2064	5446	9802	13700	16331	47343
2.6	Drugs (First Line)	9115	10256	12566	13784	14135	59857
2.7	Drugs (Second Line)	7425	17258	20832	12380	13415	71310
2.8	Printing	561	623	1312	1681	1912	6088
2.9	Outreach(PPM/ACSM)	4850	7027	20527	23614	25691	81710
2.1	Office operations	777	780	781	875	880	4093
2.11	Consultancy and Research	59	955	2263	1659	1766	6704
2.12	Technical Assistance	300	603	843	886	930	3562
	Total (2.1 to 2.12)	46700	71000	110004	107682	114629	450015
3	Confirmed sources of funding (Million USD@46)						
3.1	Global Fund Rolling Continuation Channel (RCC)* REVISED SSF (Changed for Year1	30142	66158	36,943	2,775		1,36,018
3.2	Global Fund Round 9**		0	0	0	0	0
3.3	UNITAID †	3657	2640				6,297
	Total Committed funding (3.1+3.2+3.3)	33799	68798	36943	2775	0	142315
4	Estimated Funding Gap (Total 2 - Total 3)	12901	2203	15,104	17,306	32,410	49,716
5	Funding Source to fill the funding gap						

5.1	Proposed World Bank Support for RNTCP-II extension	0	0	0	0	0	0
5.2	Contribution of Government of India	12901	2203	15104	17306	32410	49716
	Total (5.1+5.2)	12901	2203	15104	17306	32410	49716