SEA-TB-321
Distribution : Limited

Joint Monitoring Mission

Revised National Tuberculosis Control Progamme (RNTCP), India

15-28 April 2009

DFID Department for International Development
Investing in our future
The Global Fund
To Fight AIDS, Tuberculosis and Malaria
USAID
The World Bank
World Health Organization

SEA-TB-321
Distribution : Limited

Joint Monitoring Mission

Revised National Tuberculosis Control Programme (RNTCP), India

15–28 April 2009

World Health Organization
New Delhi

Writing group (in alphabetical order):

Karin Bergstrom, YoungAe Chu, Puneet Dewan, Victoria Francis, Haileyesus Getahun, Mark Goodchild, Malgorzata Grzemska, Kitty Lambregts, Pablo Panadero, Ranjani Ramachandran, Suvanand Sahu, Soren Thybo, Mukund Uplekar, Fraser Wares, Diana Weil

Contents

Abbreviations and acronyms

ACSM	advocacy, communication and social mobilization
AFB	acid-fast bacilli
AIDS	acquired immunodeficiency syndrome
AIIMS	All India Institute of Medical Sciences (New Delhi)
AMC	annual maintenance contract
ANC	antenatal clinic
ANM	auxiliary nurse midwife
API	Association of Physicians of India
ART	antiretroviral therapy
ARTI	annual risk of tuberculosis infection
ASHA	accredited social and health activist
AYUSH	Ayurveda, Unani, Siddha and Homoeopathy (a department of Ministry of Health and Family Welfare, Government of India)
BCC	behavioural change communication
BCG	bacille Calmette-Guérin (vaccine)
BHO	block health officer
BMO	block medical officer
BPHC	block primary health centre
C&DST	culture and drug sensitivity test
C&T	counselling and testing
C+	culture-positive
CCM	country coordination mechanism
CDC	Centers for Disease Control and Prevention (USA)
CDHO	chief district health officer
CDR	case-detection rate
CHC	community health centre
CMO	chief medical officer
CPT	co-trimoxazole preventive therapy
CRIS	communication resource information system
CTBC	community-based TB care
CTD	Central Tuberculosis Division (Ministry of Health and Family Welfare, Government of India)
DFID	Department for International Development (UK)
DHS	director of health services
DMC	designated microscopy centre
DNO	district nodal officer

DOT	directly observed treatment
DOTS	the internationally recommended strategy for TB control
DR	drug resistance
DRS	drug-resistance surveillance or survey
DST	drug susceptibility testing
DTCS	District TB Control Society
DTO	district tuberculosis officer
EQA	external quality assessment
ESI	Employees' State Insurance (India)
FDC	fixed-dose combination (or FDC anti-TB drug)
FEFO	first expiry, first out
FIND	Foundation for Innovative Diagnostics
GDF	Global TB Drug Facility
GDP	gross domestic product
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
Global Plan	The Global Plan to Stop TB, 2005-2006
GMP	good manufacturing practice
GMSD	Government Medical Stores Depot
GNP	gross national product
GoI	Government of India
GP	general practitioner
HIV	human immunodeficiency virus
HQ	headquarters
HRD	human resource development
IAP	Indian Academy of Paediatrics
IAPSO	Inter-Agency Procurement Services Office
ICMR	Indian Council of Medical Research (New Delhi)
ICS	Indian Chest Society
ICTC	integrated counselling and testing centre
IEC	information, education, communication
IMA	Indian Medical Association
INH	isonicotinic acid hydrazide
IPC	interpersonal communication
IQC	internal quality control
IRL	intermediate reference laboratory
ISTC	international standards for tuberculosis care
IUATLD	The Union
JALMA	National Institute of Leprosy and other Mycobaterial Diseases (Agra, India)

JMM	Joint Monitoring Mission (RNTCP, India)
KAP	knowledge, attitudes and practice
KNCV	Royal Netherlands Tuberculosis Association/KNCV Tuberculosis Foundation
LHV	lady health visitor
LT	laboratory technician
M&E	monitoring and evaluation
MDG	Millennium Development Goal
MDP	model DOTS project
MDR-TB	multidrug-resistant tuberculosis
MIFA	management of information for action
MO	medical officer
MO-DTC	medical officer, district tuberculosis centre
MOH&FW	Ministry of Health and Family Welfare (Government of India)
MO-PHI	medical officer, peripheral health institution
MoS	minister of state
MO-STC	medical officer, state tuberculosis centre
MO-TC	medical officer, tuberculosis control
MoU	memorandum of understanding
MPVHA	Madhya Pradesh Voluntary Health Association
MPW	multipurpose worker
NACO	National AIDS Control Organisation (India)
NACP	National AIDS Control Programme (India)
NCCP	National College of Chest Physicians (India)
NGO	nongovernmental organization
NICC	National Interagency Coordination Committee (India)
NIHFW	National Institute of Health and Family Welfare (India)
NRHM	National Rural Health Mission (India)
NRL	national reference laboratory
NSN	new smear-negative
NSP	new smear-positive
NTI	National Tuberculosis Institute (Bengaluru, India)
OI	opportunistic infection
OPD	outpatient department
OR	operational research
OSE	on-site evaluation
PHC	primary health centre
PHI	peripheral health institution

PIP	project implementation plan
PLHA	people living with HIV/AIDS
PMDT	Programmatic Management of Drug-Resistant TB
PMR	programme management report
PP	private practitioner
PPD	purified protein derivative
PPM	public-private mix
PWB	patient-wise boxes
QA	quality assurance
RBC	random blinded checking
RBRC	random blinded re-checking
RCH	reproductive and child health
RH	rural hospital
RNTCP	Revised National Tuberculosis Control Programme (India)
S+	smear-positive
SDH	subdivisional hospital
SDS	state drug store
SEAR	(WHO) South-East Asia Region
SLD	second-line drug
SOP	standard operating procedures
STB	Stop TB Department
STC	state tuberculosis cell
STCS	State TB Control Society
STDC	State Tuberculosis Training and Demonstration Centre
STLS	senior tuberculosis laboratory supervisor
STO	state tuberculosis officer
STS	senior treatment supervisor
TA	technical assistance
TAI	Tuberculosis Association of India
TAD	treatment after default
TB	tuberculosis
TB–HIV	tuberculosis-human immunodeficiency virus
TBHV	TB health visitor
TRC	Tuberculosis Research Centre (Chennai, India)
TU	tuberculosis unit
UNDP	United Nations Development Programme
UNITAID	international facility for the purchase of drugs to treat HIV/AIDS, malaria and TB
USAID	United States Agency for International Development
UT	Union Territory
VCTC	voluntary counselling and testing centre for HIV infection
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

Executive summary
(including main recommendations)

1. Revised National Tuberculosis Control Programme, India

The Revised National Tuberculosis Control Programme (RNTCP), India, is the largest national TB control programme in the world. It aims to serve, through linked public and private efforts, a full 20% of the global TB case burden. India was among the first countries to fully adopt and begin implementation of the WHO-recommended Stop TB Strategy in 2006. From 2006 to 2008, RNTCP screened 19.5 million TB suspects and notified 4.4 million TB cases. Of the notified TB cases, 1.8 million were new smear-positive cases, 1.2 million new smear-negative cases, 0.6 million extrapulmonary cases and 0.8 million re-treatment cases. The smear-positive case-detection rate increased from 66% in 2006 to 72% in 2008, and treatment success in new smear-positive TB consistently exceeded 85% (Figure 1). The default rates that had shown an increasing trend prior to 2006 are now showing a declining trend in both new and re-treatment cases (Figure 2). However, the default rate in the re-treatment cases remains high at 15% (2007 patient cohort). In addition, there is a great variation in performance between different states and districts in the country. Since the last Joint Monitoring Mission (JMM) in 2006, the multidrug-resistant tuberculosis (MDR-TB) management scale up has begun its first phase and collaborative TB/HIV intervention coverage has expanded dramatically.

Fig. 1. New smear-positive (NSP) case detection and treatment success rate in areas covered under RNTCP

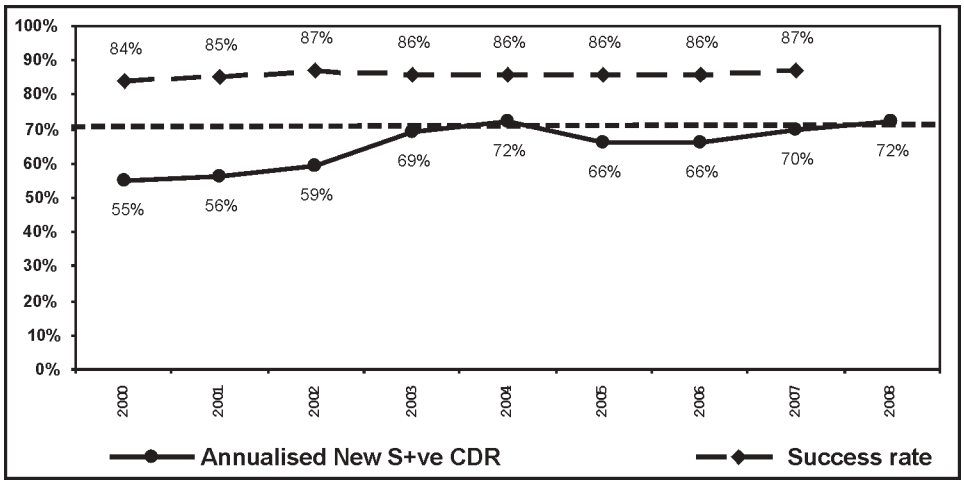
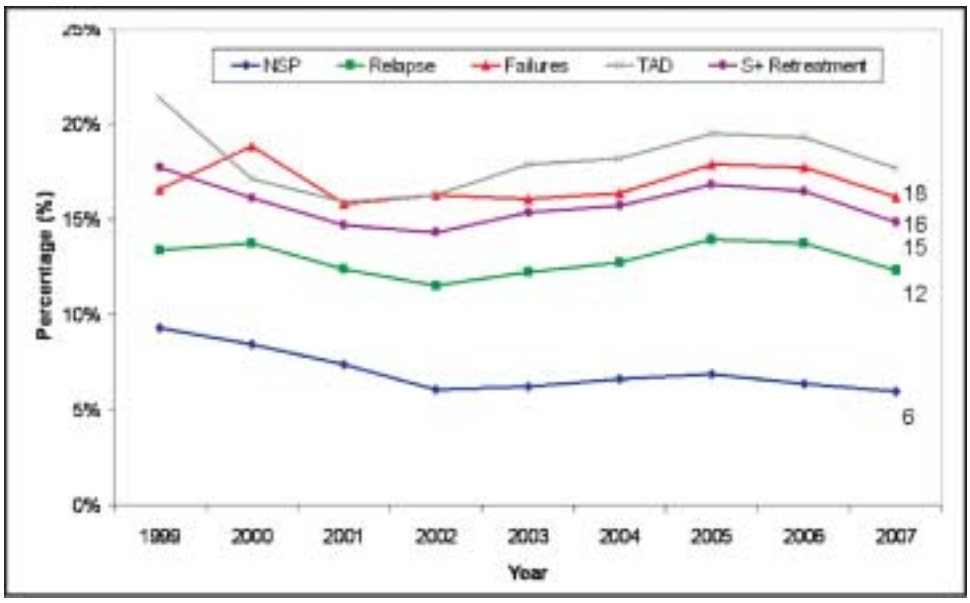


Fig. 2. Trends in default rates of different types of sputum smear-positive pulmonary TB cases



In 2006, India began the financing and implementation of its National Rural Health Mission (NRHM) which aims to significantly improve public health institutions, interventions and outcomes in rural areas, especially among the most vulnerable populations. These include improvement in reproductive and child health services, reduction in communicable diseases burden and expanded intersectoral action for health. It also includes pursuit of eight Indian Public Health Standards (IPHS), innovative local use of flexible financing to stimulate effective preventive and curative services, and greater accountability of the health system.

The RNTCP is fundamental to NRHM's aims. A complementary National Urban Health Mission may also be initiated soon, and a new prepayment scheme for inpatient services that targets persons living below the poverty line is being rapidly scaled up. A majority of the population, however, look to the private sector for their first point of care, so the public-private mix (PPM) approach is critical. All these efforts are likely to help advance TB care and control.

2. Joint Monitoring Mission

The current mission is the fourth in a series of JMMs organized at the request of the Government of India (GoI) to review progress in the implementation of RNTCP. The earlier missions took place in 2000, 2003 and 2006. The aim of

the JMM was to offer guidance on the design, implementation and sustainability of the programme and its place within the government's overall health plans.

The mission comprised of members drawn from technical and financing agencies, civil society, corporate sector, and professional and academic associations. As the timing of the mission coincided with the holding of the general elections in the country, the states and districts to be visited were chosen in such a way that these visits did not hinder the conduct of the electoral process in any way. Accordingly, the following five states were selected: Gujarat, Himachal Pradesh, Rajasthan, Tamil Nadu (and the adjoining Union Territory of Puducherry) and Uttarakhand.

3. Achievements of RNTCP

The RNTCP is a leader in terms of its organization, adoption and adaptation of policy, periodic revision of strategy, scale up of capacity and effective monitoring and evaluation of systems. It is committed to increase the epidemiological and social impact of its actions within a broader health and development agenda.

After achieving national coverage in 2006, the programme has worked to consolidate its efforts to improve the quality of its services. The number of reported TB suspects examined, case detection and treatment success rates continue to increase and have surpassed the global 2005 targets. These achievements were in evidence during the field visits of the mission. In addition, some of the more recent achievements that were noticed were:

- the first phase of MDR-TB implementation has begun with commitment from all levels;
- collaborative TB/HIV interventions have greatly accelerated with the implementation of an intensified package of services;
- implementation of the new policy for earlier identification and detection of smear-positive TB has been started;
- there has been increasing engagement of the new cadre of community-based accredited social and health activists (ASHAs);
- a secure supply system of drugs to patients has been established;
- revised schemes for engaging more providers have been developed and launched;
- some exemplary awareness-raising efforts have been initiated.

4. Challenges

The most important challenges and constraints identified by JMM include: ensure sustainable financing; inadequacies in staffing at all levels; lack of human resource development; over-reliance on TB-dedicated staff; weaknesses in supervision capacity and quality as well as in planning, monitoring and evaluation; sustaining a functional laboratory network; and limited engagement of non-programme providers and community. It was noted that these issues overlap closely with those raised by the 2006 JMM.

Inadequate enforcement of regulations for prescribing and sale of anti-TB drugs is also an urgent concern, particularly in the light of high levels of fluoroquinolone resistance reported from the initial cohorts of MDR-TB patients enrolled at the first RNTCP site.

All these concerns are inhibiting more rapid progress and, if not addressed, will jeopardize the success of the major planned efforts of RNTCP, including MDR-TB management scale up.

5. Recommendations

The Joint Monitoring Mission proposes that the Government of India consider the following main recommendations for taking forward the next phase of RNTCP. The donor agencies of the programme would like to refer to these recommendations, as well as the full report which suggests some benchmarks for further progress, in their respective review missions in the future.

5.1 Political commitment, management and health system strengthening

5.1.1 In line with the Stop TB Strategy, GoI and RNTCP to aim to achieve universal access for all forms of TB, going well beyond the 2005 targets of at least 70% case detection and 85% treatment success. To mobilize greater resources (both financial and human) and, in underperforming states and districts, to enhance political and administrative commitment and improve supervision and monitoring.

5.1.2 Review the financial requirements and commitments for the period 2010 to 2015, including those of GoI and external sources, to ensure that sufficient resources are available for the expected dramatic increase in costs for the planned MDR-TB management scale up and for meeting the 2015 TB-related targets. To leverage the increasing GoI commitment to health financing to meet the increasing financial needs of the TB programme.

5.1.3 The RNTCP should utilize the financing and service delivery mechanisms such as NRHM flexible pool funds, social welfare schemes, Indian

Public Health Standards, health insurance initiatives and other financing innovations at all levels. In particular, maintaining priority for TB within NRHM can help address the staffing, innovations, equipment and infrastructure needs.

5.1.4 Support need-based TB control planning and budgeting at state and district levels, and strengthen monitoring of flow of funds and expenditures against state and district action plans and performances.

5.1.5 Develop and implement a medium-term strategic plan, and subsequent annual operational plans, for human resource development (HRD), including the quality and quantity of staffing and training needed for all RNTCP components. Ensure coordination and integration of HRD activities with overall health workforce development and other initiatives. To ensure inclusion of financing for additional government-contracted staff at the Central and state levels.

5.1.6 As a complement to the HRD plan, develop a transitional plan for technical assistance which: (a) shifts the focus of the WHO-coordinated RNTCP consultants to technical advisory functions, especially to support the more challenging elements of the RNTCP strategic plan; and (b) comprehensively maps all technical assistance requirements, resources and gaps.

5.2 Case detection and treatment

5.2.1 In order to increase early and full case detection:

a. develop and implement systems for active identification and fast-tracking of TB suspects in outpatient departments with the involvement of paramedical workers;

b. systematically implement and monitor contact investigation for smear-positive patients;

c. regularly analyse local trends of suspects examined and initial default, and implement actions to improve case detection.

5.2.2 Further decentralize DOT to community level by exploring and addressing barriers at state level, improving training of DOT providers, enhancing their honorarium and making timely payments. Increase the availability of and convenience for injections for Category II and IV patients, and review and strengthen the supervision systems for DOT providers in view of the decentralization of the DOT network.

5.2.3 Focus default reduction efforts on smear-positive re-treatment cases and on districts and specific treatment units with high default rates in other patient groups.

5.3 Drug regulation, procurement and supply

5.3.1 Urgently work with all relevant national and state authorities to strengthen, expand and enforce regulations related to the sale of first- and second-line anti-TB drugs without prescription (OTC - over the counter) and other potential forms of misuse of drugs in order to improve treatment outcomes and prevent further emergence of drug resistance. This includes better implementation of the provisions under Schedule H of the Indian drug regulations through the State Drug Controllers and consider use of the provisions under clause 26B of the Drugs and Cosmetics Act. In addition, to promote self-regulation by individuals and commercial outlets to stop misuse of anti-TB drugs.

5.3.2 Continue preparing for increased GoI financing of first-line drugs in view of the expected reduction in external financing; continue reinforcement of purchase processes so that timely procurement of high-quality drugs is assured, and continue ongoing discussions regarding possible external support for a limited buffer fund.

5.3.3 Continue to work with concerned donors and technical partners towards harmonization on stringent quality standards for the first- and second-line anti-TB drugs as well as for prequalification of suppliers and products.

5.3.4 GoI to financially support RNTCP drug logistics management at the Central level to ensure sustainability, and address the shortage of safe and adequate storage space for anti-TB drugs at the six Government Medical Stores Depots and drug stores at state and district levels. Also, to coordinate with other drug management authorities at the Central and state levels.

5.4 Paediatric TB

The RNTCP to re-establish its earlier close collaboration with the Indian Academy of Paediatrics to update the RNTCP guidelines and arrange training for health workers to ensure quality of diagnosis and treatment of children with TB.

5.5 Engaging all providers

5.5.1 Organize a series of strategic reviews and consultations to guide innovations for strategic scaling up of public-private mix (PPM) experiences, and consider establishing an advisory group that includes

major current PPM task force partners (i.e. Indian Medical Association [IMA], NGOs and medical colleges) as well as others not previously engaged, such as the pharmaceutical sector, non-allopathic doctors, management and marketing experts, HIV-focused NGOs, independent medical stores/chemist shops, affected patients and community representatives.

5.5.2 Empower intermediary organizations such as NGOs and IMA to scale up PPM activities while strengthening programme capacity at the Central state levels to undertake a stewardship role for PPM development.

5.5.3 Consider phased scale up using a comprehensive intensified strategy with substantively new and comprehensive approaches, beginning with a few willing states with strong RNTCP performance, a good foundation of initial PPM efforts in TB control, and possibly other GoI initiatives on partnering with the private sector. This could also include a state-level advisory group.

5.5.4 Work further with associations of health professionals to ensure that they actively support implementation of the endorsed International Standards of TB Care (ISTC) in partnership with RNTCP, including its recommendation on notification of TB cases by all care providers.

5.5.5 Assess steps required to move towards developing a system for the mandatory notification of all TB cases in the country.

5.6 Laboratory strengthening

5.6.1 As part of HRD plan, address staffing and capacity constraints in order to implement all components of the RNTCP Quality Assurance protocol for sputum microscopy in all states and districts.

5.6.2 Design a comprehensive laboratory network for drug-resistant TB (DR-TB) diagnosis and management that clearly outlines the roles and responsibilities (criteria for infrastructure and staffing, technologies, supervisory tasks, proficiency testing and training tasks) at all levels of the network that is guided by: (i) the programmatic experiences within the DOTS-Plus pilot projects; (ii) the results of demonstration projects involving new technologies; and (iii) the overall scale-up plan for the management of DR-TB in India.

5.6.3 Build capacity of an in-country national team exclusively to implement and support the laboratory scale-up plan, including specialists on laboratory procedures, biosafety, laboratory design/ventilation/equipment engineering

and infection control, through facilitation by a core international laboratory team and under the overall guidance of the national laboratory committee.

5.6.4 Procure equipment from a list of internationally-reputed vendors for standard laboratory equipment, with a comprehensive contract for installation, certification and extended warranty and maintenance, in order to ensure good-quality equipment, faster procurement and functional efficiency conforming to international biosafety standards.

5.7 MDR-TB management

5.7.1 Review bottlenecks experienced during the initial phase of MDR-TB management scale up, including human resource development, laboratories, clinical management, logistics and drug supply and management, and address them carefully while planning further expansion, including development of an appraisal mechanism and criteria for expansion to new sites.

5.7.2 Urgently address the emergence and potential spread of resistance to second-line drugs (SLDs) by strengthening regulations concerning use of TB-specific SLDs and quinolones (see also Recommendation 5.3).

5.7.3 Review and analyse all existing data from Category IV treatment sites and institutions pursuing SLD resistance research in order to be able to revisit the current MDR-TB treatment regimen.

5.7.4 Strengthen SLD drug-resistance surveillance and build capacity to test for second-line drug resistance at state level.

5.8 Collaborative TB/HIV interventions

5.8.1 The Central TB Division (CTD) and the National AIDS Control Organisation (NACO) to carefully plan and closely monitor the implementation of the nationwide expansion of the intensified TB/HIV package by 2012.

5.8.2 All state health authorities to strengthen coordination mechanisms by ensuring regular TB/HIV Coordination Committee/Technical Working Group meetings and for SACSs and State TB Cells to include TB/HIV as a regular agenda item at NRHM and State Health Society meetings.

5.8.3 CTD and NACO to improve the linkage of intensified TB case-findings at the integrated counselling and testing (ICT) and antiretroviral treatment (ART) centres, especially in low-prevalence states, and facilitate the decentralization of ART services in order to ensure ART access for HIV-infected TB patients.

5.9 Infection control

Finalize national guidelines on airborne infection control, pilot test and prioritize their introduction in the following settings: HIV testing, treatment and care settings, MDR-TB care facilities, TB laboratories and heavily-utilized clinical care units.

5.10 Recording, reporting, monitoring and supervision

5.10.1 Further invest in building the capacity of district and state managers to interpret basic epidemiological and operational data and perform evidence-based problem-solving. This may be achieved by scaling up the use of the participatory training module *Management of Information for Action*.

5.10.2 Transition from target-focused monitoring of performance to analysis of trends in key process and outcome indicators at district and state levels to improve performance.

5.10.3 For every state, RNTCP should periodically convene an external consultation (with participants from outside of the state) to objectively and transparently assess the validity and accuracy of data collection and reporting at every level of the state's performance. Findings should be shared widely and used to improve performance.

5.11 Equity, gender and social issues

5.11.1 Review the implementation of the established strategies on migrants, the Tribal Action Plan and the urban poor and consider approaches to effectively reach other most vulnerable populations, including use of better-targeted communication strategies.

5.11.2 New schemes for sputum collection and transportation need to be fully implemented, especially to serve communities living in remote areas.

5.11.3 Develop a guidance note and strategies to build greater social support systems and linkages with other social welfare schemes, health initiatives and community-based organizations such as *mahila mandals* (women's groups), village health committees, self-help groups, *panchayats* (village council), etc.

5.11.4 Develop model questions for future household-based studies (district-level household surveys – DLHS) for more disaggregated data on social groups and pursue the already defined research priorities.

5.12 Advocacy, communication and social mobilization

5.12.1 Engage professionals and/or partners to strengthen and lead the advocacy, communication and social mobilization (ACSM) strategic planning at national level, provide support across the RNTCP network and work closely with NRHM communication stakeholders. Modify the ACSM part of the planning format to focus on priorities and use output/outcome monitoring indicators.

5.12.2 Concentrate on achieving universal awareness of the right to and availability of free TB treatment and care. Learn from the best practices and emerging initiatives such as the newly-formed partnership on TB care and control.

5.12.3 Initiate social mobilization through existing community self-help groups and *panchayati raj* institutions. Prioritize interpersonal communication (IPC) approaches at district level and below. Enhance provider communication targeted at different categories of patients so that the right person discusses the right message at the right time.

5.13 Operational research

5.13.1 Strengthen operational research capacity at the Central and state levels and at coordination and activity levels through engagement of a resident expert adviser.

5.13.2 Proactively promote the recruitment of a wider network of researchers to conduct operational research through sharing of guidelines, protocols and follow-up, establish a fast-track mechanism for proposal review/support, and disseminate information on all operational research using the website.

5.13.3 In collaboration with other programmes/initiatives, conduct research to understand and address the role of social and clinical risk factors for TB, including malnutrition, smoking, diabetes, alcohol abuse, indoor air pollution, etc.

Introduction

India is the second-most populous country in the world and has more new TB cases occurring annually than in any other country. In 2007, out of the estimated global annual incidence of 9.27 million TB cases, 1.96 million (21%) were estimated to have occurred in India, of whom 0.87 million were infectious cases.[1] The disease is responsible for over 330,000 deaths in India annually. The TB problem is further compounded by the existence of drug-resistant TB, HIV-associated TB, and several socioeconomic and health factors that promote continued transmission of the disease. TB control efforts are faced with a number of challenges such as the magnitude of the problem, the diversities within the country, the large number of non-State health care providers and the free availability of anti-TB drugs in the market with a potential for misuse.

In order to control TB, the Government of India (GoI) is implementing the Revised National TB Control Programme (RNTCP). The RNTCP started in 1997 and went through a phase of expansion of DOTS-based TB services, achieving countrywide geographical coverage by March 2006. Thereafter, the focus of the programme shifted to maintaining good-quality DOTS services while scaling up the other components of the WHO Stop TB Strategy. The RNTCP monitoring strategy includes a 3-yearly Joint Monitoring Mission (JMM), coordinated by WHO with the participation of all partners of the programme. Three JMMs have been conducted so far - in 2000, 2003 and 2006. Based on a request from the Government of India, the fourth JMM was organized from 15 to 28 April 2009. This mission coincided with the mid-term review of the World Bank RNTCP Phase II project.

The objectives of the RNTCP JMM 2009 were to:

1. Provide assessment information to the national programme as planned by the Ministry of Health and Family Welfare (MoH& FW);
2. Assess the progress towards the TB-related Millennium Development Goals (MDG) targets;
3. Assess the status of implementation of the Stop TB Strategy;
4. Review TB prevention and control plans up to 2015;
5. Create enhanced advocacy for increased commitment for TB control at all levels.

Participants in the JMM included representatives from all major national and international partners of RNTCP. The list of participants is given at Annex 1.

[1] (2009) Global Tuberculosis Control: Epidemiology, Strategy, Financing. Geneva, Switzerland: World Health Organization. WHO/HTM/TB/2009.411 WHO/HTM/TB/2009.411.

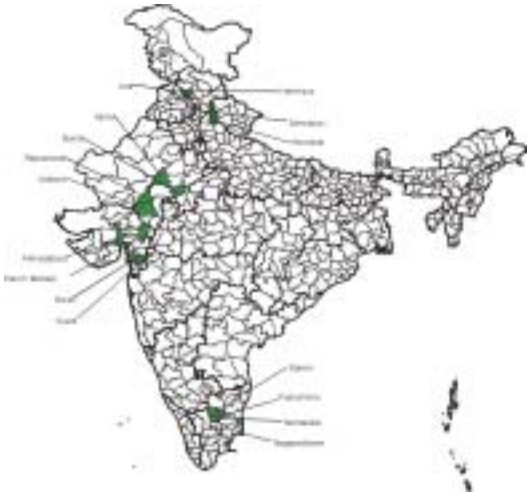
The JMM began its work on 15 April 2009 in New Delhi with a detailed briefing by the officials of the Government of India covering all aspects of the programme. This was followed by field visits to five states and one Union Territory (UT), where the teams visited a total of 17 districts - five in Gujarat, four in Rajasthan, three in Tamil Nadu, two each in Himachal Pradesh and Uttarakhand and one in Puducherry.

States/UT and districts visited by Joint Monitoring Mission 2009

State / UT	Districts visited
Gujarat	Ahmedabad, Panchmahal, Surat, Surat Municipal Corporation, Vyara
Himachal Pradesh	Hamirpur, Una
Rajasthan	Ajmer, Bundi, Rajsamund, Udaipur
Tamil Nadu	Nagapattinam, Namakkal, Salem
Uttarakhand	Dehradun, Haridwar
Puducherry (UT)	Puducherry

The states were selected randomly after taking into consideration the fact that the Mission teams' visits to the field should not clash with the dates when voting for the ongoing general elections was to take place in the respective areas. Within each state, some districts were selected randomly and the others were selected purposively, in order to include districts that were adjacent to the randomly-selected districts (to facilitate travel) and where additional programme activities could be seen by the teams.

Map showing the states and districts visited by JMM 2009



Within the states the teams assessed state-level institutions and facilities and visited selected districts. State-level institutions included reference laboratories, drug stores and other partners. Briefing and debriefing meetings were held with state administrative and health authorities. During visits to districts, the teams met with district authorities and local partners, visited health facilities, interviewed staff and patients, and reviewed records and reports.

Following the field visits, the JMM members had consultations and meetings in New Delhi to review the thematic areas under the programme. Plenary sessions were held on the scaling up of MDR-TB services, including laboratory facilities, public-private collaboration, case detection and treatment. Group work focused on topics such as epidemiology, health system strengthening, laboratory, programme surveillance, TB/HIV, drug-resistant TB, infection control, advocacy, communication and social mobilization (ACSM), financing, procurement, human resource development (HRD), equity issues, other determinants of TB, operational research and paediatric TB. The summary findings and recommendations were developed subsequently and presented to the Government of India on 28 April 2009.

This report contains the detailed findings and recommendations of the Joint Monitoring Mission 2009.

1. TB epidemiology in India

Observations and findings

The RTNCP publishes cross-sectional notification, treatment outcome and other programme data in the quarterly and annual reports but does not routinely conduct a detailed trend analysis of programme data. For the JMM, however, CTD presented the mission with a comprehensive trend analysis of programme surveillance data. The essential findings are summarized below.

Progress towards the Millennium Development Goals

Relative to the WHO 1990 estimates for TB mortality and prevalence, by 2007 India had reduced mortality by 33% and TB prevalence by 52% (Fig. 3a, 3b). These reductions represent a remarkable achievement. However, the current assumptions feeding into the WHO prevalence estimates need to be reviewed, and it may be advantageous for the programme to reset the national prevalence target for 2015.

Observations from the Tuberculosis Research Centre's model DOTS Plus project area in Thiruvallur district of Tamil Nadu support these estimates of declining disease prevalence. In this project area, the disease prevalence has been observed to be falling at the rate of approximately 12% per annum.

The mission noted that the mortality estimate after a steady decline has remained static over the period 2006-2007.

Fig. 3a: Progress towards the 2015 MDG targets for TB mortality

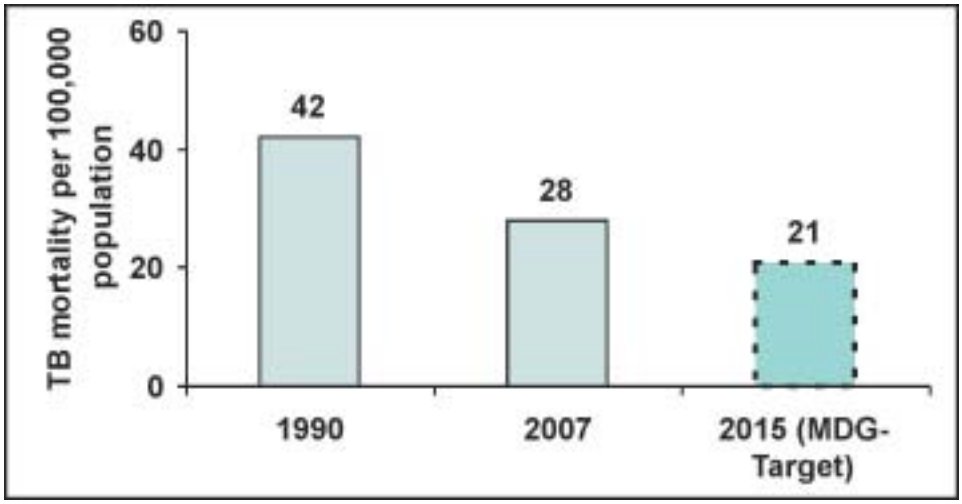
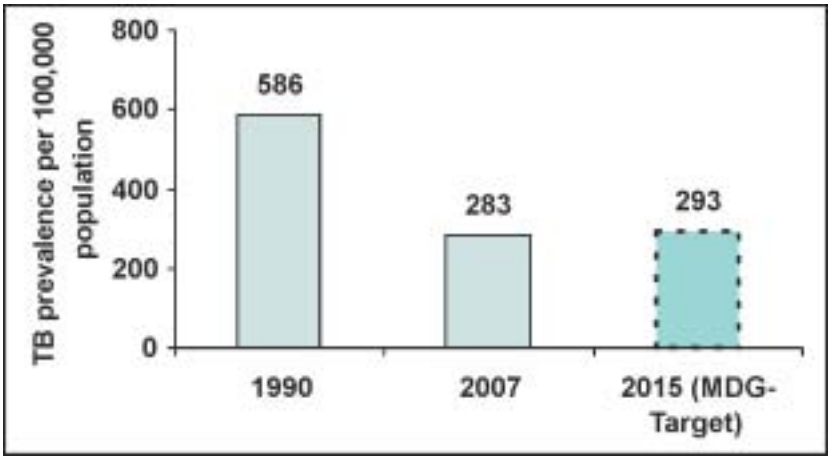


Fig. 3b: Progress towards the 2015 MDG targets for TB prevalence



Case notifications

New smear-positive case notification has continued to rise over the past three years, albeit with a slower rate of increase than previously observed (Fig. 4a). With the current assumption of flat TB incidence, the estimated number of new smear-positive cases has continued to rise with increase in the country's population (Fig. 4b). Relative to these estimates, the proportion of detected cases has continued to climb and has recently crossed the global case-detection target of 70%.

Fig. 4a: New smear-positive case notification, 1999-2008

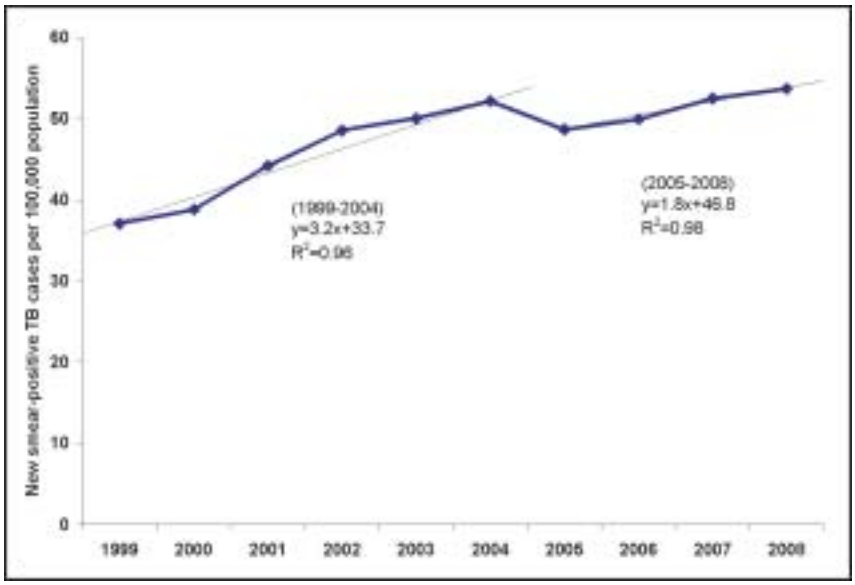
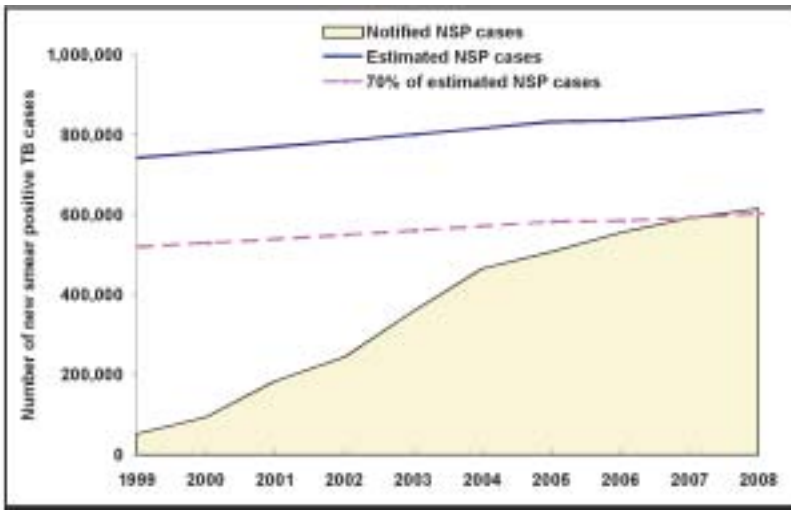
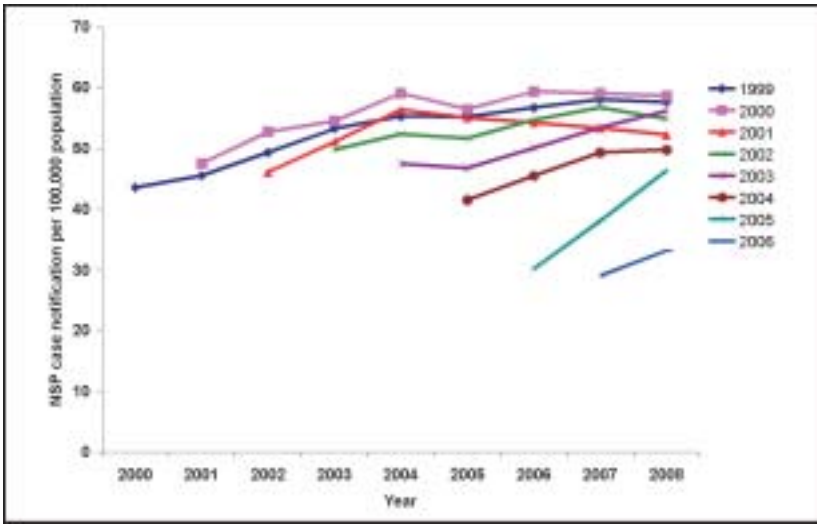


Fig. 4b: New smear-positive TB cases, 1999-2008



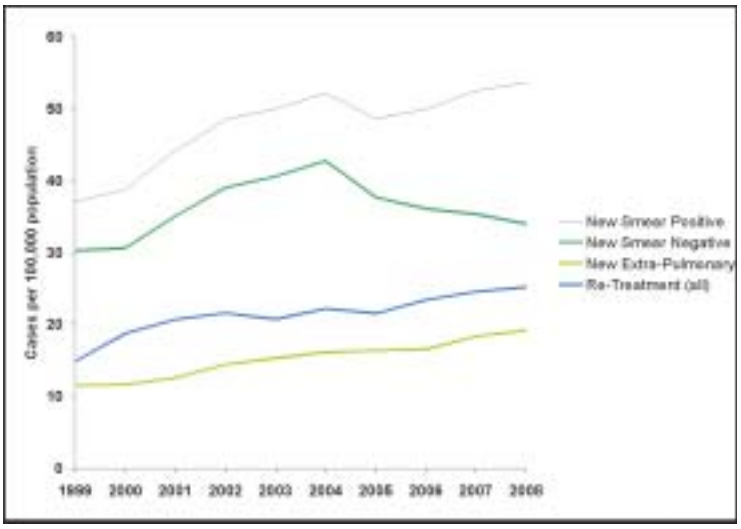
A more detailed analysis provided by CTD suggested that much of the gains in NSP notification over the past few years have been achieved in poorly-performing states that had only recently implemented RNTCP. By comparison, those regions of the country that have been implementing RNTCP for a longer time showed relatively static NSP case notification (Fig. 5).

Fig. 5: New smear-positive TB case notification rate, by implementation cohort, 1999-2008. Each separate line represents data from those districts that began implementing RNTCP during that calendar year

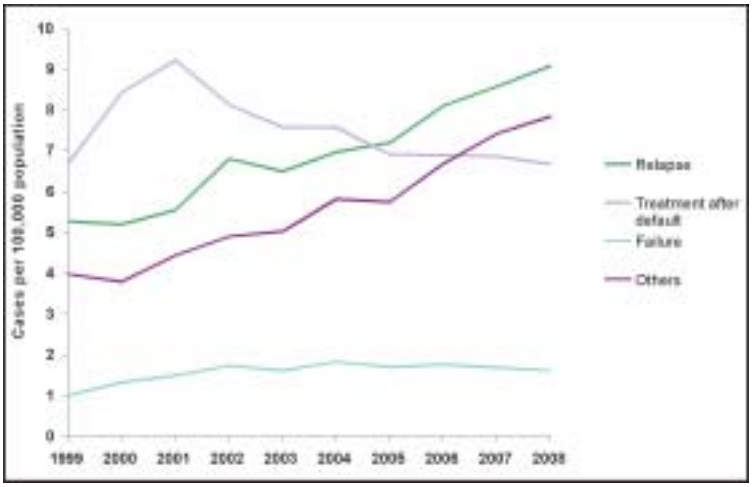


Among case notifications, three remarkable trends were discernable. First, total and NSP case notification rates have continued to climb. Second, increases in NSP case notification have been matched by similar decreases in new smear-negative (NSN) case notification (Fig. 6). Third, the rise in the re-treatment notification rate has proportionately outpaced the rise in total notification, particularly in the 'relapse' and 'other' registration types. The mission speculated that the rise in relapse notification rates may be associated with (a) the overall increase in the pool of previously treated patients in India (both under RNTCP and by the private sector); (b) the 2005 change in the programme definition of relapse (from previously successfully treated under RNTCP to previously treated by a physician); or (c) worse-than-expected long-term treatment outcomes – by RNTCP, the private sector, or both.

Fig. 6: RNTCP case notification rates, by registration type, 1999–2008. Major registration categories (below), and re-treatment notification sub-types (far below) (Note that y-axis scale differs by tenfold.)

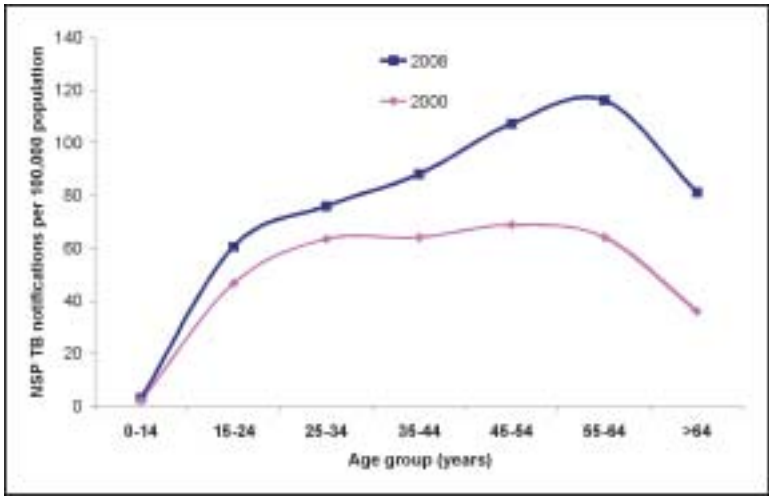


Changes in the age structure of RNTCP NSP notification rates were observed in the data presented by CTD (Fig. 7). Any interpretation of the age-group notification rates should be made with caution, as data on the age-group denominators are made from projections from the 2001 census. These projections assume equal growth in each age group, which would be contrary to historical experience in rapidly-industrializing nations. Hence, some revision of the age-group denominators would be expected after the results of the 2011 census are available. Furthermore, RNTCP usually expanded



from urban areas outwards, so the population covered in 2000 may have over-represented these areas, where TB epidemiology and age structure of population may differ from rural areas. With these caveats, NSP case notification rates increased in all age groups, but particularly in the older 45–64 years age groups. Interestingly, the drop off of case notification rates in the >65 years age group is contrary to TB epidemiology, suggesting some under-reporting of TB cases among the very elderly. This finding has been observed at the local level (sub-district level in Tamil Nadu) by the Tuberculosis Research Centre, Chennai.

Fig. 7: New smear-positve age group-specific case notification rates, 2000 and 2008



Plans for impact assessment

To assess trends in *incidence*, the CTD has a second national annual risk of tuberculosis infection (ARTI) survey (2007-2010) under way which would provide a 5-year interval from the first survey and allow for an assessment of the trends in the prevalence of infection among children. ARTI estimates will be used to model disease incidence and then, by extension, disease prevalence and mortality.

To assess absolute *disease prevalence*, the incidence estimates derived from the ARTI survey would be modelled into prevalence estimates as done with the data from the first ARTI survey. The mission members noted with concern that there remain some unresolved methodological questions surrounding this modelling exercise. For *adjunctive information on trends in disease prevalence*, a series of sentinel sites have been selected for serial community-based prevalence surveys. The mission noted with concern that there were no planned areas of overlap between the ARTI national survey and the prevalence sentinel surveys, with the exception of the model DOTS Plus project area in Thiruvallur (i.e. the Chengalpet BCG vaccine trial area where detailed epidemiological surveys of TB have been conducted serially for more than 40 years).

To assess *mortality*, the incidence estimates derived from the ARTI survey would be modelled into mortality. A large prospective community-based mortality survey is under-way across the country (the "one-million deaths study"), which will also provide information about TB-specific mortality. While community-based mortality surveys for all-cause mortality may be conducted by the Registrar General of India, there appears to have been little progress or communication between CTD and the Registrar General's office to ensure that the TB-related estimates are calculated appropriately. TB-specific mortality surveys, using verbal autopsy methodology, were conducted by RNTCP in the states of Andhra Pradesh and Orissa in 2006-2007. However, these studies were reportedly plagued by methodology concerns, and no report has been published.

Assumptions used by WHO for estimating incidence, prevalence and mortality are summarized below (Table 1). Several assumptions were highlighted as requiring re-consideration in a more detailed consultation.

Table 1: Assumptions used for the modelling of incidence, prevalence and mortality, WHO 2009

Category	Value	Comments
Annual risk of tuberculosis infection (ARTI)	1.5%	For comparison to the 2009-10 ARTI, re-calculation of the incidence using the regional and urban/rural stratifications should be considered, given the urban population growth in the country.
Styblo ratio ARTI:incident pulmonary TB cases	50	Validated from MDP area, but should be revised based on additional information if more prevalence survey sites conduct ARTI surveys.
ARTI-disease prevalence ratio	Not currently used in the WHO estimates	From MDP project area. Not currently used, but could be an adjunct to prevalence estimation if more prevalence survey sites conduct ARTI surveys.
Disease incidence trend	Flat	Should be re-visited after ARTI survey results. Direction of trend would be likely informed by direction in ARTI.
HIV prevalence in TB patients	5%	National estimate 4.8%, but may be revised next year with data from routine reporting of HIV status among TB patients. (Note: As yet data only from those states implementing the intensified TB/HIV package).
Disease duration (HIV-) (in yrs) DOTS Non-DOTS Untreated	S+ ,S- 0.8, 1.8 2.7 3.8, 2.0 2.0	Disease duration in patients treated by Non-DOTS should be re-visited, as this may not be applicable in an era with improved health infrastructure

Category	Value	Comments
		and wide availability and market dominance of relatively inexpensive FDCs. Disease duration in untreated not compatible with low case-fatality rate in S- TB.
Proportion of cases treated DOTS Non-DOTS Untreated	S+ ,S- 68%, 65% 12% 15% 20%, 20%	Should be re-visited; proportion of patients untreated may be lower in an era with improved health infrastructure and wide availability of medical services, especially in non-public sector. Proportion of patients in Non-DOTS likely correspondingly higher than assumed previously.
HIV+ case-fatality rates DOTS Non-DOTS Untreated	S+ S-, 10%, 10% 38% 50%, 83% 74%	Should be re-visited; available cohort data suggests HIV+ case-fatality rate may be higher than 10% in DOTS areas. Case-fatality rate in untreated HIV+ patients would be expected to approach 100%.
HIV- case-fatality rate DOTS Non DOTS Untreated	S+ S-, 10% 5% 30%, 15%, 70% 20%	Should be re-visited; S+ and S- case-fatality rate is observed as lower than modelled in DOTS patients. Case-fatality rate in patients treated by Non-DOTS may not be applicable in an era with improved health infrastructure and wide availability and market dominance of relatively inexpensive FDCs. Case-fatality rate in smear-negative patients compared to smear-positive patients needs reassessment, as smear-negative patients would likely *become* smear-positive before death.

Recommendations

1. Include the detailed multi-year trend analysis of suspect examination, case notification, treatment outcomes and other key descriptive information on TB epidemiology and programme performance in the RNTCP annual report. The Epidemiology Briefing submitted to the JMM members would be a useful model for the expanded analysis of programme surveillance information that could be included.

2. Prior to the availability of results from the 2nd ARTI survey, hold a national consultation to re-evaluate the assumptions used to transform ARTI results into incidence, prevalence and mortality.

3. At the earliest priority, to inform revisions of the assumptions used in impact assessment modelling and expand the number of specific areas that conduct both ARTI and prevalence surveys. Prevalence survey sites in Jabalpur (RMRCT) and Wardha (MGIMS) were identified as good options to add an ARTI survey. Special attention should be given to procurement of adequate tuberculin of identical specifications to that used in the nationwide ARTI survey to facilitate comparability of results.

4. Expand and support research to measure the impact of smoking, malnutrition, diabetes, HIV prevalence coupled with increasing ART uptake, and other risk factors of TB that may influence trends in TB incidence in the future.

5. Conduct a detailed assessment across multiple sites of the accuracy of the RNTCP TB surveillance data by comparing local notification data with local prevalence survey results and local prevalence of TB infection estimates. Such an assessment could indicate the extent to which notification data could be used as a proxy for incidence estimation in the future. The successful implementation of recommendation 3 (above) would be crucial to enable this assessment.

6. The current assumptions feeding into the WHO prevalence estimates need to be reviewed, and it may be advantageous for the programme to reset the national prevalence target for 2015.

7. In order to continue to further reduce the mortality, RNTCP needs to expand case detection and strengthen other life-saving interventions, such as ART to HIV-positive TB patients, second-line anti-TB drugs to drug-resistant TB cases, etc.

2. Health systems strengthening

In pursuing the Stop TB Strategy, RNTCP aims, among others, to contribute to national and local health systems strengthening ranging from financing and human resources to delivery systems. Since the last Joint Monitoring Mission in 2006, there have been significant developments in health systems strengthening initiated by the Government of India (GoI) with potentially important implications for TB care and control. These efforts are aimed at providing equitable access to quality health services by all people as well as health promotion in the community. Innovations have included partnerships with the private sector, nongovernmental organizations and civil society as well as multisectoral support for social development efforts. The government has also increased its average investments in health, and placed special emphasis on meeting the needs of the poor and vulnerable populations.

Among the top developments has been the launch of the National Rural Health Mission (NRHM) by the GoI in 2005. The NRHM has addressed many challenges that overlap with the top concerns of RNTCP. These include increasing early demand for and access to TB diagnosis, reducing financial burden throughout the course of treatment, addressing the needs of hard-to-reach communities and tribal populations, improving retention of health staff and their capacity as well as infrastructure quality, and offering incentives to involve private providers in view of their dominant role in health care in India.

The Government of India has also increased investments in health in general, and as a share of its budget is helping RNTCP and other sponsored public health programmes through NRHM.

The plan for a National Urban Health Mission (NUHM) is at an advanced stage of preparation. It is expected to be among the priorities for implementation by the new government at the Centre. It is expected to introduce significant reforms, particularly to reach high TB-risk populations concentrated in urban areas by strengthening service provision in municipal corporations and by supporting unorganized network of providers.

Some states in India have more funds than others to make investments in health services provision and in other areas of development. Similarly, some of the major cities visited by the JMM teams seemed to have more investment capacity. But economic and social development in the country is uneven and all states and districts cannot afford to spend as much on health.

Findings

The JMM team's meetings with stakeholders at national, state, district and service levels suggest that NRHM is providing important support for TB care and control

through funds, human resources and delivery mechanisms. The level of opportunities varies, given the focus of NRHM on poor and rural districts. The utilization of these opportunities also varies. It was difficult for JMM to investigate sufficiently the opportunities availed and those missed, in view of the wide range and depth of ongoing efforts of the GoI and partners in health care. However, the trajectory of collaboration between RNTCP and NRHM and related initiatives seems to be positive and should be further supported.

The NRHM is principally focused on advancing reproductive and child health interventions. But it also collaborates with 13 national health programmes of the GoI. Furthermore, flexible resources available at state, district and sub-centre levels offer tangible support by providing supplies and helping in infrastructural development which benefit TB control efforts.

The JMM specifically noted the following points with regard to RNTCP-NRHM linkage:

a. The Central TB Unit of RNTCP has staff that are actively engaged in the planning and coordination meetings of NRHM, including discussions related to budget and financing. It has worked to get TB indicators included in the monitoring and evaluation of NRHM.

b. There is still room for expanded RNTCP engagement in Central and state initiatives for health systems financing and improvements in infrastructure, service and community-based primary health care (PHC). The reproductive child health (RCH) programme elements may be easier to engage as many of the initiatives, including the overarching NRHM, were especially designed to address the needs of mothers and children. Still, the JMM teams found that some states were benefiting substantially more (e.g. for lab and communications equipment) from the flexible financing stream offered by NRHM, while some state TB officers or TB cells were not seeking or negotiating financial support from NRHM.

c. The eight public health standards promoted formally by NRHM are seen by stakeholders to provide a critical tool for promoting further support for RNTCP efforts and its improved performance. All public health institutions (PHIs) must aim to achieve these standards so that RNTCP can further promote the one-by-one linkage of these standards to TB programme performance.

d. In many cases, district TB officers are already devoting some of their time to support district-wide health priorities and management, given the formation of District Health Societies under which the pre-existing District TB Control Societies have been subsumed. Some district tuberculosis officers (DTOs) have struggled to balance their TB jobs and other functions while others were well aware of other public health programmes and were ready to make their contribution, particularly in relation to medical colleges.

e. The proposed National Urban Health Mission is expected to be a significant asset in the future for TB care and control, especially given the challenges RNTCP faces currently working with diversely structured municipal corporations and their severely strained cadres of health workers as well as the complexity of players in private health care provision in urban areas. As noted in the section on public-private mix, there appears to be not sufficient scrutiny about which of the private sector collaboration efforts will yield the maximum gain for providing effective and safe TB care. Working with NUHM may yield some advantage to leverage large-scale impact for the TB programme.

f. It is not immediately evident that intensified efforts to scale up laboratory capacity for TB diagnosis are integrated in or aligned with overall MoH&FW's priorities and initiatives for laboratory resources. Collaboration may exist but it was not clearly spelled out during the JMM. TB microscopy is often performed in general primary health care or hospital laboratories and collaboration between RNTCP and the National AIDS Control Organisation (NACO) is taking place to enhance TB/HIV-related screening and diagnosis. Therefore, there is integration but little information is forthcoming on any bold steps being taken to improve government laboratory capacity. There are explicit efforts under way to expand the engagement of private laboratories to meet the daunting scale-up time line to enable drug-susceptibility testing and MDR management, or further advance early detection of those with smear-negative disease.*

g. Some states have teams that are rolling out a new initiative; for example, the Rashtriya Swasthya Bima Yojna (RSBY) which offers a government-financed pre-payment scheme for hospital care for below-the-poverty-line individuals using SMART cards and pre-accreditation of providers. Other states have myriad pilot approaches for reducing/removing financial barriers to health care or specific RCH interventions such as addressing transport constraints that limit institutional birth. Some of the innovations beyond TB include use of novel software and technology; other innovations concern new ways of contracting and motivating partners (public or private). The Department for International Development (UK) (DFID) has supported the preparation of a compendium of RCH-related innovations catalogued by state and/or type of intervention. This might be a useful stimulus for RNTCP network discussion of models that the TB programme could learn from or collaborate in.

---

* The Ministry of Health and Family Welfare held emergency internal meetings to prepare the government's response to the challenge. The national response to the flu pandemic raises several issues that relate directly to those addressed by RNTCP and JMM, including the need for urgent strengthening of laboratory capacity, infection control in health care settings and the need for improvement in the timeliness of local purchase of medicines and their safe storage. The standardized systems developed for RNTCP and for other major public health programmes, including the RCH and polio programmes, may be major mode ls and/or building blocks for the response to the influenza pandemic should it emerge seriously in India.

Recommendations

1. As RNTCP moves to expand coverage beyond the estimated 70% case detection to universal access for patients with all forms of TB, increasing formal linkages with major health systems strengthening initiatives will be critical. The RNTCP can foster more proactive engagement by state and district TB officers and their teams in local initiatives. The RNTCP should continue its active role in NRHM coordination and do even more to use the NRHM platform to promote the next phase of its efforts to ensure universal access for all forms of TB and by all populations and communities.

2. The NRHM leadership has suggested that RNTCP has the strongest structures, management support and information systems among public health programmes and lessons learnt from RNTCP should be further shared. In a complementary fashion, RNTCP can draw much more on the NRHM-instituted eight public health standards to be applied in support of public health institutions that had documented the linkage to specific TB control elements and outcomes.

3. More strategic discussions are needed to be held with NRHM leadership on how they can help overcome the critical shortage of key cadres of core health service staff, including frequent transfer of medical officers and absence of laboratory technicians and pharmacists, which is having serious repercussions on the performance of RNTCP. Some kind of human resources training and retention efforts of NRHM may provide new solutions.

4. The CTD should document how different states have become involved in NRHM activities and benefited from its flexible financing, and what impact this may be having on programme performance. With this, CTD and state TB officers can do more to build capacity of district TB staff to engage with NRHM-financed initiatives.

5. District TB officers are, in many cases, devoting some of their time to support district-wide general health activities well beyond TB, which is a positive development, aided by the creation of State and District Health Societies. The RNTCP can help document where DTOs may be struggling to maintain their balance of efforts on improving TB performance and on other integrated duties, and where, in contrast, DTOs have enhanced RNTCP performance through leveraging other PHC and public health programme activities. This analysis could help guide support to improve performance across the board. More effort may be needed to ensure that TB is regularly on the agenda of District Health Societies.

6. The DFID and others are supporting more strategic reviews and analytical work to support NRHM and the proposed NUHM. Under these contracts with

institutions such as National Health System Resource Centre (NHSRC) and the Public Health Foundation of India (PHFI), CTD/RNTCP could find opportunities to examine some of the outstanding bottlenecks in order to improve RNTCP performance, drawing on the well-developed information system of RNTCP which would also help NRHM measure its performance. For example, what are NRHM surveys revealing about TB control performance.

7. The substantial roles in some states and districts now played by the new ASHA cadres should be well-documented and the impact on case detection and patient support assessed. If well supervised by female health supervisors and medical officers as well as senior treatment supervisors (STSs), ASHAs could represent a critical new resource for achieving RNTCP aims.

8. The RNTCP to further explore how to engage with a wider range of partners among NGOs and civil society. It is evident that NRHM and related initiatives are creating more avenues for client responsiveness and client engagement in planning RCH efforts.

9. Similarly, NRHM is supporting a wide range of ACSM-related initiatives in RCH and RNTCP could take advantage of these by learning from the most successful programmes and discussing ways to collaborate in joint efforts as a complement to TB-specific ACSM programmes.

10. The RNTCP should try to be engaged in the NUHM planning process so that new cadres available to support the complex task of outreach in urban communities can be exploited for the TB programmes; the well-established and functioning RNTCP programme structure should also be seen as an asset for use in NUHM initiatives.

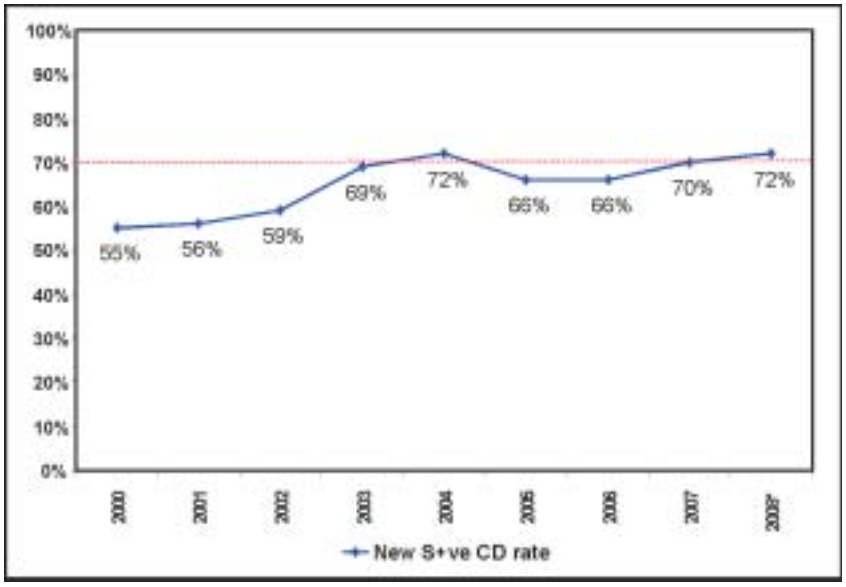
11. Given the critical importance of expanding the spread and capacity of laboratories performing TB diagnosis and drug susceptibility test (DST) function, further RNTCP efforts should be documented on how it is best leveraging other public health laboratory strengthening work today, and how it is interacting with institutions most influential in the field other than medical colleges.

12. The RNTCP needs to pursue a thorough canvassing of its major new initiatives such as RSBY and other schemes which aid poor populations through financing and delivery innovations as well as those that are in the process of nation-wide expansion. The RNTCP can gain more by adopting or adapting innovations that are driving expanded coverage in other fields as well as by spreading more awareness of its own innovations.

3. TB case detection

After reporting a slight decline in TB case detection between the end of 2004 and the beginning of 2006 (noted during the 2006 JMM), RNTCP enhanced efforts to identify smear-positive cases. It has now not only reached its target but has also exceeded the global target. 72% case-detection rate of new sputum smear-positive cases was reported in 2008 (Fig.8).

Fig. 8: Trends in new smear-positive case detection under RNTCP



This is a commendable achievement, bearing in mind the multiple range of providers (public and private hospitals, medical colleges, individual private providers, NGOs and community workers), who have been referring suspects and reporting cases to RNTCP throughout the period of programme implementation.

During the JMM's visit to the states[2], the review teams noted with concern some degree of complacency in the efforts to expand case-finding to reach undetected cases. A decreasing trend was noted in the number of suspects referred for sputum smear microscopy in many districts. However, a striking difference was observed in Rajasthan, where the state government is pursuing the target of detecting 90% of existing smear-positive cases and successfully treating 90% of them ('90/90 target').

[2] Three out of five states visited reported over 70% case-detection rate in 2008, the exception being Tamil Nadu and Uttarakhand.

The very recently-introduced '2/2 policy' recommends that a referral for sputum examination should happen after two weeks of productive cough (earlier three weeks) and that two sputum samples (one of which should be an early morning sample) should be submitted to the designated microscopy centre (DMC). That policy has begun to be known and implemented, but mainly through RNTCP staff, while other general health workers, including medical officers based at government hospitals, are not fully aware of the change. This new policy is attempting to reach more respiratory symptomatics and, at the same time by decreasing the number of specimens, to limit the number of patient visits to laboratories and decreasing the laboratories' workload. However, in some DMCs visited by the JMM, only one sample was collected and tested.

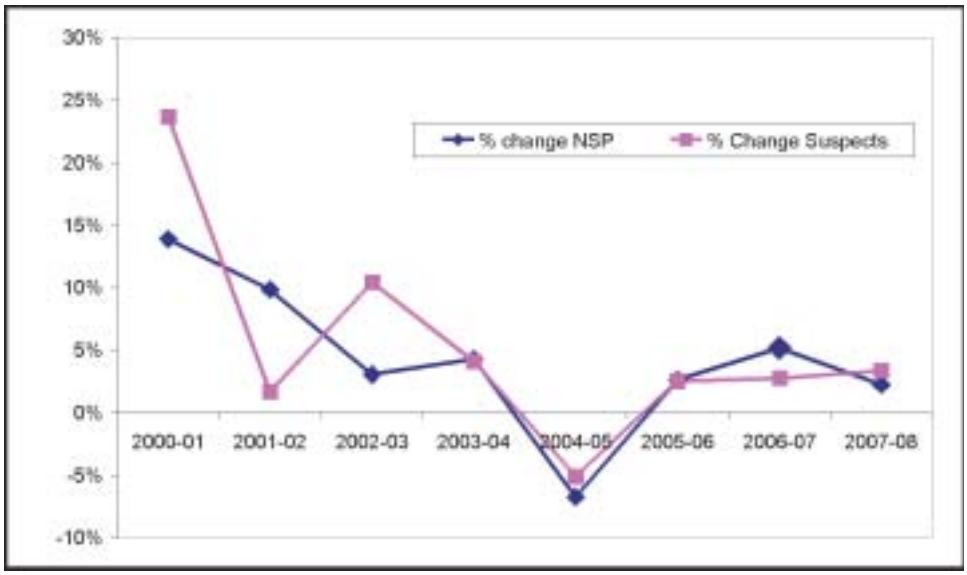
These problems are solvable. For example, Rajasthan has implemented a so-called '1-Day Diagnosis' initiative where respiratory symptomatics identified by an ASHA are immediately given a sputum container and instructed on how to collect an early-morning sputum specimen. On the following day, the patient travels to the nearest DMC with the early-morning sample and submits a second specimen on the spot in the DMC.

Observations in the districts visited indicate that the referral of TB suspects among outpatient attendants is suboptimal. Patients with respiratory symptoms, meeting the definition of a 'TB suspect', are examined by medical officers but are not referred for sputum microscopy. Many of them are referred for chest X-ray (or other tests) and receive prescription for anti-TB treatment outside of RNTCP. Use of fluoroquinolones for patients with respiratory symptoms was commonly observed. Screening for cough is not conducted at the registration desk or at the patient waiting area, where there are opportunities for identifying TB suspects and fast-tracking sputum examination as well as limiting the possibility of a nosocomial transmission to other OPD attendants and health facility staff. There is no system in place to record the chest symptomatics in the available OPD registers. It is, therefore, unclear how the chest symptomatics are identified and what proportion of them is referred to sputum microscopy. Self-referral of patients with respiratory symptoms is very low, as the awareness of TB and availability of free diagnosis and treatment is uncommon. In addition, some DMCs require medical officer's (MO) signature on the referral for sputum examination, which limits the access as well as increases the cost to the patient. Similarly, patients referred by private providers are often asked to go to a public health facility for a referral form which may result is further diagnostic delays and loss of patients referred.

At the same time, the RNTCP data presented to the team clearly shows that the TB suspects examination is very closely associated with smear-positive case notification (Fig. 9). Therefore, efforts to increase TB suspects examination by DMCs may lead to an increase in case notification. Thus, the number of TB suspects examined can

be a good monitoring indicator for case-detection activities at DMC, subdistrict and district levels since district and subdistrict case-detection rates are unreliable targets.

Fig. 9: Annual national change in suspects explains change in S+ve cases



Contact investigation among the diagnosed smear-positive cases is not systematically implemented or monitored, and offers a major opportunity for improving case detection. This can be done by asking about respiratory symptomatics among adult family members of the diagnosed smear-positive cases; should they have such symptoms, they should be referred for smear microscopy and TB diagnostic evaluation. These questions could be asked by directly observed treatment (DOT) provider several times during the course of treatment (as family members might come down with TB at any point of time): first before the treatment is initiated (month 0), second when the intensive phase is completed, and lastly, at the end of the treatment.

A number of "initial defaulters", i.e. sputum smear-positive patients (new and re-treatment) detected by DMCs who do not report for treatment, were noted. The average proportion of such cases annually constitutes about 10% (this varied between 7% and 18% in the states visited). Although reported to CTD, these cases are not included in the case-notification record (and subsequently not reflected in the case-detection rate).

Delay of diagnosis was noted among many current patients who, before reaching the DMC, first presented to a private practitioner or a hospital and were required to bear the cost of many tests and prescribed medicines (sometimes including anti-TB drugs, both first- and second-line). This delay of diagnosis, from the programme perspective,

may have resulted in a high proportion of sputum smear-positive patients, many of them with heavy bacillary load on sputum examination, among all notified patients; in some districts, more than 70% of smear-positive TB patients were 2+ or greater. In addition, patients may be detected in a more advanced stage and, if treated earlier with some anti-TB drugs, the risk for a drug-resistant disease is increased.

New smear-negative patients constitute a small proportion among all detected cases. It appears that the RNTCP-recommended algorithm for smear-negative diagnosis is not strictly observed in many places. Lack of access to X-ray facilities in some remote areas may contribute to this situation. It is also possible that some patients may be lost during the path of that algorithm. Some will improve on the broad-spectrum antibiotic treatment and will not return for further sputum test. However, some patients may refer to the private sector and never get proper diagnosis and treatment. It was noted with concern that the ratio of new smear-negative to new smear-positive patients has fallen dramatically in some states and districts.

The proportion of extrapulmonary patients depends on the availability of and access to tertiary-care facilities and specialists, and ranges from 9% in Bihar to 42% in Delhi.

The proportion of smear-positive re-treatment cases among all smear-positive cases varied greatly between states and between districts, but it is, on average, high and was reported to be 24% on the national scale in 2008. In four states out of the five visited, smear-positive re-treatment cases constituted 30% and above among all smear-positive cases reported. This phenomenon is frequently attributed to prior treatment in the private sector as well as improving ascertainment of prior TB history and categorization. But the JMM teams also noted that a considerable proportion of those patients classified as relapses had a history of previous treatment in RNTCP. In some districts, it was observed in addition that the number of re-treatment cases diagnosed without bacteriological confirmation, i.e. smear-negative PTB cases, was high.

Recommendations

1. The CTD should promote the concept of universal access in programme policy and monitoring to ensure that the problem of undetected patients is addressed.

2. Systematically implement and monitor contact investigation for smear- positive patients. This can be done through asking about respiratory symptomatics among adult family members of the diagnosed smear-positive cases and encouraging them to refer for smear microscopy examination.

3. Develop and implement systems for active identification and fast-tracking of TB suspects in outpatient departments with the involvement of paramedical workers at the registration counter, which is the first point of contact.

4. In the light of the close association between the TB suspects examined and the case notification of smear-positive TB cases, make systematic efforts to increase TB suspects examined per unit population. Explore the feasibility and value of maintaining a register on 'chest symptomatics' at health-facility level.

5. Monitor at district level the trend of TB suspect examination and the proportion of initial defaulters on a quarterly basis in order to promptly identify and pursue opportunities for improving case-finding.

6. Explore options for inclusion of initial defaulters in case notification and cohort analysis after considering and addressing challenges regarding recording and reporting for this group of patients.

7. Increase access through implementation of innovative approaches, such as the "1-day diagnosis" approach observed in Rajasthan by:

   - Promoting early identification of respiratory symptomatics by field staff, including ASHAs, NGOs, community DOT providers and other community-level health workers;
   - Providing sputum containers to respiratory symptomatics through field staff network;
   - Ensuring referral to DMC for submission of an early-morning sample, and collection of a spot specimen;
   - Considering a scheme of incentives for suspect identification.

8. Provide refresher training to all providers to inform of "2 weeks/2 sputum" guidelines and other new policies of RNTCP.

9. Enhance engagement of the Indian Medical Association (IMA) in promoting International Standards for Tuberculosis Care (ISTC) and referral of suspects by:

   - sensitization of MOs and training of those who show interest and initiatives;
   - encouraging IMA members to serve as DMC and DOT providers.

10. Develop and regularly update mapping or line-listing of all providers and referral facilities.

11. DMCs should accept direct referrals from private practitioners and provide feedback to referring doctors.

12. Operational research to identify reasons for the high proportion of re-treatment cases should be carried out, preferably in areas where RNTCP was implemented before 2000.

4. Laboratory services

Laboratory network for smear microscopy, culture and drug susceptibility testing and quality assurance system

A comprehensive and well-functioning laboratory network has been established in the country to carry out sputum smear microscopy, culture and drug susceptibility testing (DST). The network assures quality of services through an external quality assurance (EQA) programme for smear microscopy, culture and DST laboratories.

The National Laboratory Committee, consisting of the national TB programme manager, directors and senior microbiologists of the national reference laboratories, designated members of the Central TB Division (CTD), WHO India staff and other laboratory partners, works as the national task force to guide laboratory-related activities of RNTCP.

The network consists of the national-level reference laboratories (NRLs), state-level intermediate reference laboratories (IRLs) and peripheral-level designated microscopy centres (DMCs).

The four designated NRLs are: Tuberculosis Research Centre (TRC), Chennai; National Tuberculosis Institute (NTI), Bengaluru; Lala Ram Sarup Institute of Tuberculosis and Allied Sciences (LRS), New Delhi; and National Institute of Leprosy and other Mycobacterial Diseases (JALMA), Agra. In addition, TRC also functions as one of the WHO-designated supranational reference laboratory (SNRL) for the WHO South-East Asia Region.

EQA for smear microscopy is conducted by NRLs as annual on-site evaluations (OSE) to IRLs as per RNTCP EQA protocol. State IRLs are equally distributed among the NRLs. OSE and panel testing of supervisory staff at IRLs is conducted along with review of random blinded rechecking (RBRC) data of routine DMC smears. In addition, NRLs conduct regular training in EQA for IRL personnel. Issues concerning quality of smear microscopy identified during OSE visits form the background reference and training material for orientation training to state-level programme managers on quality improvement.

There are 27 IRLs at state level, with at least one IRL in every major state. At the peripheral level, district TB centres (DTCs) at all district headquarters, subdistrict TB units (TUs) and 12 705 RNTCP-designated microscopy centres (DMCs) provide TB diagnostic services.

The IRLs are located in the state tuberculosis training and demonstration centre (STDC) campuses or an identified location in one of the major state government hospitals. The IRL conducts on-site evaluation visits to districts for sputum microscopy at least once a year. The IRL undertakes panel testing of senior tuberculosis laboratory supervisors (STLS) at each district tuberculosis centre (DTC). The IRL ensures the proficiency of staff performing RNTCP smear microscopy activities by providing training to laboratory technicians and STLSs. The IRLs are state-level culture and DST facilities for addressing the multidrug-resistant TB (MDR-TB) in the respective states. Twenty-seven microbiologists are hired on contract by the programme and are placed with IRLs for this purpose. The CTD also provides all basic laboratory equipments for carrying out TB bacteriological investigations. The district TB centre (DTC) is the nodal point for all TB control activities in a district. The DTO is responsible for coordinating all TB diagnostic and treatment activities in the area. The maintenance of regular supply of good-quality laboratory consumables and reagents to all DMCs and organizing EQA activities through random blinded rechecking (RBRC) are the other additional mandatory responsibilities of DTO.

The programme has hired senior tuberculosis laboratory supervisors on a contractual basis, one each at the TU (at subdistrict level), for carrying out EQA through on-site evaluation visits to DMCs and RBRC of routine DMC slides. STLSs prepare the staining solution for smear microscopy, check the quality through internal quality control slides, and ensure adequate supplies to DMCs.

The most peripheral laboratory under the RNTCP network is called the designated microscopy centre (DMC), which serves a population of around 100 000 (50 000 in tribal and hilly areas). The RNTCP has provided finance to upgrade existing health facilities, supplied a binocular microscope for each DMC, and ensured adequate supply of staining reagents and consumables at the DMCs. An additional microscope at each district is provided for the purpose of RBRC. The DMCs are manned by a trained laboratory technician of the state public health system. In 20% of the DMCs, RNTCP has provided laboratory technicians on contractual basis.

A number of DMCs have been designated in sectors like NGOs, public health facilities other than the health system, and private and corporate sector facilities as part of laboratory network. In addition, the new NGO/public-private (PP) schemes encourage active participation of other partners in the programme. Sputum collection and transportation schemes have been developed through NGO/PPs' involvement to augment case-finding.

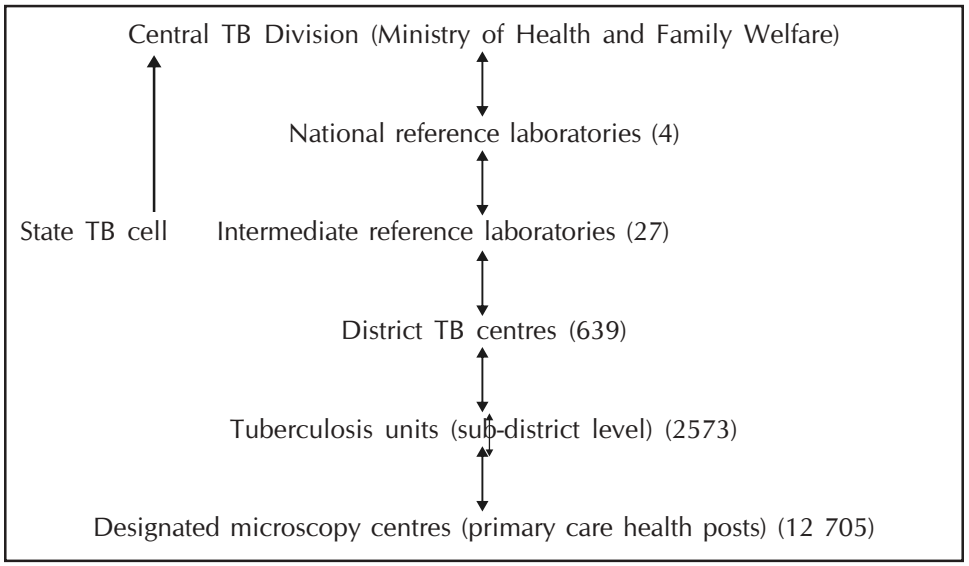
Although good-quality binocular microscopes are made available at all DMCs, the maintenance of microscopes pose many challenges. The annual maintenance contracts or service and repair provisions need to be made more effective in certain states.

Infection control measures require special emphasis, including enforcing the biomedical waste management guidelines of RNTCP at the peripheral level.

IRLs face special challenges with regard to manpower and their mobility in the field for performing EQA and culture and DST functions.

Overall, a well-established network of microscopy centres and a good logistics system are in place in the country to ensure quality of smear microscopy.

Fig. 10: RNTCP laboratory network



Laboratory network of culture and DST laboratories (including IRLs and other culture and DST laboratories)

The existing 27 IRLs are proposed to be used for culture and DST to meet the diagnostic and follow-up requirements of Category IV services in the country. The CTD has provided thirteen of these laboratories with culture and DST equipment. Nine culture and DST laboratories including seven IRLs (Gujarat, Maharashtra, Andhra Pradesh, Delhi, Kerala, Tamil Nadu and Rajasthan) and two private sector laboratories (Blue Peter Research Centre (BPRC), Hyderabad, Andhra Pradesh, and Christian Medical College (CMC), Vellore, Tamil Nadu), have been accredited by NRLs. Another six IRLs (Haryana, Chhattisgarh, Jharkhand, Orissa, Uttarakhand and West Bengal) and five medical college laboratories (All India Institute of Medical Sciences (AIIMS), New Delhi, King George's Medical University (KGMU), Lucknow, Uttar Pradesh, BJ Medical College, Pune, Maharashtra, Postgraduate Institute of Medical Education and Research (PGI), Chandigarh, and Armed Forces Medical College

(AFMC), Pune, Maharashtra), are presently in the process of accreditation and are expected to be accredited by end 2009. The remaining IRLs will be accredited by 2010.

The accredited culture and DST laboratories are the diagnostic units for the Category IV services in their respective states for MDR-TB diagnosis and management. Accordingly, the diagnosis and treatment services facilities for MDR-TB are now available in eight states, namely, Andhra Pradesh, Delhi, Gujarat, Haryana, Kerala, Maharashtra, Tamil Nadu and West Bengal. The programme has enrolled around 400 patients on Category IV for MDR-TB treatment.

Quality assurance for culture and drug susceptibility testing

MDR-TB is at present diagnosed through culture on solid medium (Lowenstein-Jensen), identification of mycobacterial species by biochemical tests (niacin, nitrate reduction/catalase at 68 °C and sensitivity to 500 μg para-nitrobenezoic acid) and anti-TB drug susceptibility testing for four of the first-line anti-TB drugs (streptomycin, isoniazid, rifampicin, ethambutol) in DOTS regimen by the economic variant of the 1% proportion susceptibility testing. Although the present laboratory capacity is limited, it is envisaged that MDR-TB is diagnosed by providing culture and DST services to all patients who are declared as failures on Categories I, II and III. Culture and DST services will be expanded in a phased manner to cover the entire country by 2012 and are expected to be available to all smear-positive patients initiated on re-treatment by 2015.

For ensuring the quality of culture and DST at IRLs, NRLs oversee the process of accreditation for IRLs and other diagnostic culture and DST laboratories and ensure continuous quality assurance by the process of annual proficiency testing. Briefly, the process of accreditation consists of confirmation of the presence of minimum requirements of infrastructure, staffing and technical proficiency for culture and DST by the established process of retesting and panel testing as per the RNTCP guidelines (ref: RNTCP accreditation document).

The programme has been engaged proactively in the inclusion of private laboratory facilities through a process of RNTCP accreditation for culture and DST, promotion of public-private partnerships and utilization of TB culture and DST services for the programme through purchase of their laboratory services by making use of NGO-PP schemes. Two such laboratories have been accredited in Andhra Pradesh and Tamil Nadu and they will be shortly assisting the programme to scale up MDR treatment services in these states. The process of inclusion of medical colleges for culture and DST services and DOTS Plus treatment is also ongoing and five medical colleges are in line for accreditation by RNTCP.

The accreditation is initially granted for a period of two years and is then subjected to on-site evaluation within one year, and a re-assessment before the end of two years. Thereafter, re-assessment is carried out every two years. Accredited labs carry out testing activities within the scope of accreditation to meet the needs of RNTCP. The accredited laboratories are expected to regularly and satisfactorily participate in the proficiency testing programmes/rounds conducted by NRLs.

Newer tools for rapid diagnosis (viz. line-probe assay-LPA) of MDR-TB have recently been introduced by the programme with assistance from Foundation for Innovative and New Diagnostics (FIND), Geneva, as validation and demonstration projects in two IRLs (viz. Hyderabad and Ahmedabad) and SMS Medical College, Jaipur. The EQAP for this project is being done by JALMA, Agra. The national scale-up plan for laboratory expansion and MDR-TB treatment services is based on the use of rapid methods like LPA and liquid culture systems (MGIT-960) along with solid culture back-up in a majority of IRLs.

Even with all these initiatives the laboratory capacity available for culture and DST is still very limited. Most IRLs are busy with basic reference laboratory functions (EQA, training, supervision, drug-resistance surveillance). The current diagnostic capacity of IRLs and collaborating labs (medical colleges, private labs) is too limited to substantially contribute to programme targets.

In order to be able to comply with the scale-up plans the following laboratory plan is proposed:

Table 2: Additional laboratory services to be established during 2009-2012

	2009-10	2010-11	2011-12	Total
Enhanced solid/sputum processing & human resources	12	13	18	43
Molecular (3 sites existing from Foundation for Innovative and New Diagnostics (FIND) demo study)	12	13	18	43
Subset to establish liquid capacity (1 site existing from FIND demo study)	13	9	11	33
Total sites strengthened (including 3 sites from FIND demo study)	12	13	18	43
Expected annual DST capacity	8000	35 000	120 000	

The JMM wishes to re-emphasize that these laboratories need to be established in the context of a comprehensive laboratory network design that allows for flexibility (to absorb new technologies) and includes accredited laboratory capacity in the private sector and in medical schools, especially those medical schools that will also accept to become a designated PMDT training site.

Challenges and constraints

Although significant differences were observed among the sites visited, with some laboratories accredited and functioning well, but most laboratories share the same challenges and constraints, which are summarized below:

1. The design of a comprehensive TB laboratory network that determines the roles and responsibilities at all levels has not yet been finalized.

2. There are insufficient human resources, both in quantity and quality.

3. There is insufficient national reference laboratory (NRL) capacity to: i) offer pre-accreditation technical assistance; ii) accredit new IRLs; iii) supervise and guide newly-accredited laboratories; and iv) ensure periodic proficiency testing and on-the-spot corrective training post accreditation.

4. There is a large turnover of key staff, especially microbiologists, due to unattractive employment conditions. Predominantly, contractual staff is in place with an annual tenure and low, non-competitive salaries. It is impossible to establish a quality-assured laboratory network for culture and DST without this issue being addressed urgently and solved. This situation also applies to at least three of the four NRLs.

5. There are barriers to the procurement of equipment that meets international standards and specifications. Some equipment cannot be procured within India. The same applies to some key consumables, such as drug powder for DST. Regulations concerning international procurement on a named-source basis hamper the upgrading of laboratories.

6. Installation and maintenance of equipment (such as biosafety cabinets) is problematic throughout India.

7. Infection control measures are lacking in the majority of laboratories. In Gujarat, laboratory technicians at district level are exposed to large numbers of smear-positive MDR-TB suspects and patients without any personal protection under risky environmental conditions (airflow direction is from the patients to the laboratory technician).

8. Lack of coordination of national and international technical assistance and information-sharing.

9. Lack of an electronic information system that links the laboratory, PMDT site and district units.

Recommendations

1. The JMM commends RNTCP for having developed an ambitious laboratory scale-up plan for the management of drug-resistant TB. However, having noted the challenges faced by RNTCP in establishing the first few quality-assured culture and DST laboratories, it is recommended that careful planning be undertaken to ensure both quality and speed in developing laboratory infrastructures, equipment procurement, laboratory staffing, training and proficiency testing.

2. The JMM recommends that RNTCP design a comprehensive laboratory network for drug-resistant TB diagnosis and management that clearly outlines the roles and responsibilities (e.g. criteria for infrastructure and staffing, technologies, supervisory tasks, proficiency testing and training tasks) at all levels of the network which is informed by: i) the programmatic experiences within the DOTS-Plus pilot projects; ii) the results of demonstration projects involving new technologies; and iii) the overall RNTCP scale-up plan for the management of DR-TB in India.

3. Give the highest priority to the strengthening of the existing NRLs and selected IRLs that will be involved in technical assistance, supportive supervision and proficiency testing within the rapidly expanding lab network.

4. Strengthen IRLs' staffing positions on a priority basis by recruiting at least two microbiologists, one to look after EQA of smear microscopy and another for culture and DST. Also, each IRL should have at least four laboratory technicians (LTs) for culture and DST and one for EQA on-site evaluation (OSE) visits. Ensure legal commitment (by an MoU) to appoint dedicated key contractual staff, e.g. microbiologists and senior laboratory technicians, for a minimum of 2-3 years and offer them competitive salaries and benefits, thus ensuring continuity and sustainability of services for MDR-TB diagnosis and treatment monitoring.

5. Assign: i) a mentoring and supervisory role for the leading state IRL within the (expanding) state laboratory network; and ii) establish zonal IRLs to meet future supervisory and proficiency testing demands.

6. The introduction of newer diagnostics to scale up laboratory services will require additional infrastructural facilities, human resource development and technical assistance.

7. Build country-level capacity through a dedicated national TB laboratory expert team (laboratory task force) to implement and support the laboratory scale-up

plan as envisaged. This team should include specialists on laboratory procedures, biosafety, laboratory design/ventilation/equipment, engineering and infection control, who would be trained and mentored by a core international laboratory team representing various lead technical agencies involved in TB control activities. The entire exercise may be executed with assistance from WHO and other partners in coordination with the Central TB Division and the National Laboratory Committee.

8. Ensure that technical assistance for laboratory strengthening is well-coordinated, with adequate information-sharing and joint problem-solving discussions, especially when international partners and new technologies are involved.

9. Procure equipment from internationally-reputed vendors, with a comprehensive contract for installation, certification and extended warranty and maintenance, to ensure good quality, faster procurement and functional equipment conforming to international biosafety standards. Consider import/purchase from single source only for quality proprietary items such as inspissator, McCartney bottles, etc.

10. Revise recruitment qualifications for microbiologists and senior laboratory technicians. Wherever a medical microbiologist is not available, a Master's degree holder in microbiology, with adequate experience in good laboratory practice, may be considered for the post of TB microbiologist. A senior laboratory technician may be a person with a graduate degree in biosciences with a minimum of two years' experience in clinical microbiology. Additional staff to be planned at the IRL level to implement newer technologies as and when these are introduced.

11. Develop and implement an effective annual maintenance contract for binocular microscopes using agencies with known, documented track record for maintenance of microscopes and make available spare microscopes (2-5 nos) at the district level to serve as immediate replacement for the defective ones within the district, until the defective microscope(s) can be repaired, to avoid disruption of services at DMC.

12. Practise appropriate solid waste management as per the RNTCP Phase II biowaste management guidelines at all DMCs.

13. Conduct training and retraining of STOs, STDC directors, DTOs and MOs-TC to address EQA in sputum smear microscopy and other laboratory activities. This would ensure timely corrective measures, including the accountability of LTs and STLSs, and train all microbiologists of IRLs on workshop mode in laboratory management and effective networking as a quality improvement exercise.

14. Strengthen the laboratory network and ensure the quality of culture and DST services, by implementing national standard operating procedures (SOPs) and assess periodically the performance indicators.

15. Plan, design and establish a laboratory information and management system for timely reporting and data analysis for quality assurance of TB diagnosis under the programme.

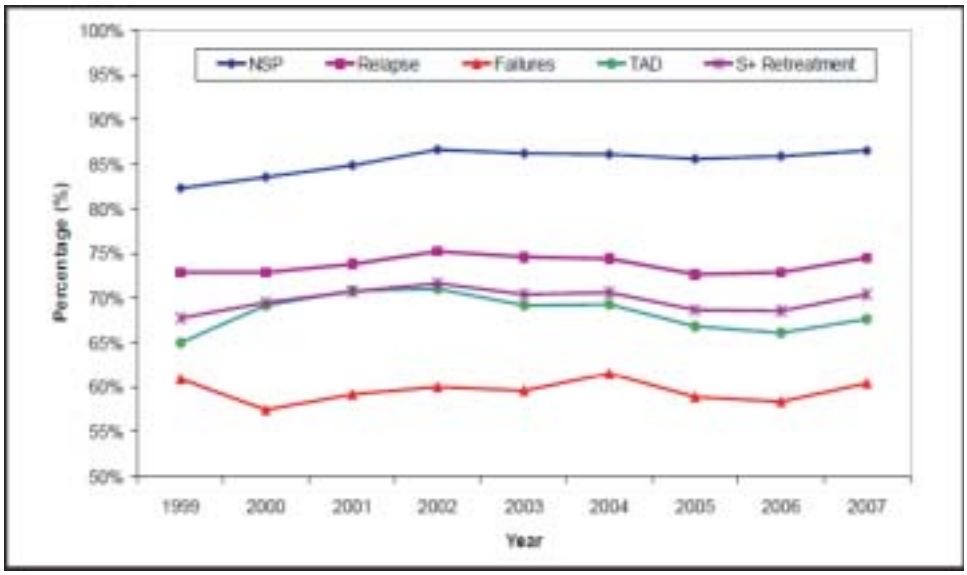
16. Ensure that all laboratories responsible for culture and DST for PMDT comply with infection control guidelines, with focus on laboratories handling MDR-TB suspects and specimens. Often simple administrative, environmental and respiratory protection are sufficient to minimize the risk of transmission.

17. Plan, design and establish a laboratory information and management system for timely reporting and data analysis for quality assurance of TB diagnosis under the programme, which is part of an overarching comprehensive and integrated electronic information system for MDR-TB services which links the C&DST laboratories, the PMDT sites and the respective districts.

5. TB treatment

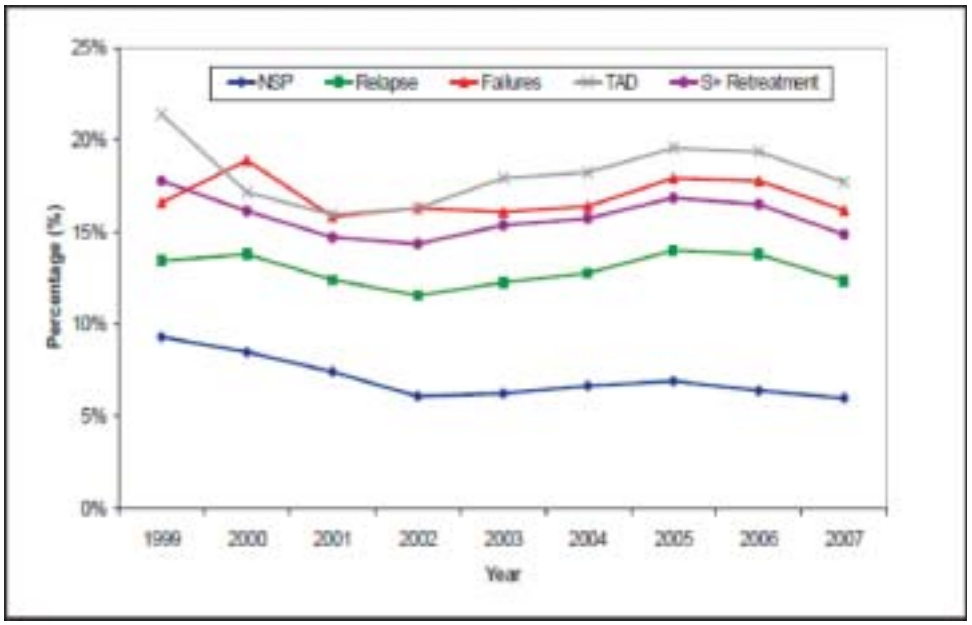
At the time of the last JMM in 2006, RNTCP had just expanded to achieve national coverage. Since then, as illustrated by the graph below, RNTCP has succeeded in maintaining a treatment success rate of new smear-positive pulmonary TB cases (NSP) which has been very satisfactory and above the target of 85%, with the most recent annual cohorts of 2006 and 2007 reporting treatment success rates of 85.9% and 86.6% respectively. Thus, it appears that the programme has managed to consolidate its key function of removing infectious TB patients from the pool of prevalent TB cases transmitting tuberculosis.

Fig. 11: Reported treatment success among smear-positive pulmonary TB cases, new and re-treatment, 1999–2007



The achievement of rendering infectious cases as non-infectious has been considerably less in sputum smear-positive PTB re-treatment cases, especially among the treatment-after-failure cases. This represents a major challenge for RNTCP, particularly given the very large burden of notified smear-positive re-treatment cases. Treatment outcomes among relapse cases have also been unsatisfactory, with a success rate considerably lower than what would normally be expected. Inadequate case-holding of re-treatment cases is reflected by the overall 14.9% default rate among smear-positive re-treatment PTB cases registered in 2007.

Fig. 12: Default rates among different types of smear-positive TB cases



The RNTCP has supplied regularly drugs of high quality to all districts without any stockouts and has continued to make the treatment available to the patients in the form of patient-wise boxes that ensures uninterrupted drug supply for all individual patients treated under RNTCP. TB drugs for the national programme are being procured through the Global Drug Facility (GDF) with a grant from the Department for International Development (DFID) through the World Bank credit, and with grants from the Global Fund for AIDS, Tuberculosis and Malaria (GFATM), through mechanisms that ensure quality control at all stages of procurement and distribution.

However, in spite of the performance of RNTCP with respect to treatment of TB cases, this cannot be seen in isolation from the overall Indian setting. The Global TB Drug Alliance in 2006 estimated that the annual total market value of TB drugs in India was US $94 million, of which 74% was represented by the private market share outside the RNTCP drug procurement mechanisms. Furthermore, the study found that first-line drugs made up over 90% of the total Indian TB drug market, and three fourths of the TB drugs sold in the private market were in the form of fixed-dose combinations (FDC). Whatever the consumption of drugs, prescribed either by private practitioners or sold without any restriction over the counter, these do not guarantee similar bio-availability or quality as the drugs used by RNTCP, nor is there any guarantee that these private-market TB drugs are used rationally. The likely consequence of the use of substandard drugs and substandard treatment regimens is the widespread development of drug resistance.

Second-line anti-TB drugs are also freely and widely available in private pharmacies, with or without a prescription. Although the private market share of these second-line anti-TB drugs is estimated to be smaller than for first-line drugs, the widespread use of fluoroquinolones especially may have a considerable negative impact on the prospects for curing MDR-TB cases. A very high proportion (>50%) of ofloxacin resistance has been observed among those patients who failed a re-treatment regimen and were recruited into the first cohort of MDR-TB patients in Gujarat in 2007.

With the maintenance of high treatment success rates among new TB cases, it is surprising that a high proportion of sputum-positive PTB patients are re-treatment cases. The national average proportion of re-treatment smear-positive patients is high by any standards (24%), but in some large states like Gujarat and Rajasthan, the percentage is over 30% and in some districts it is around 40%. Very little data is available to indicate the source of prior treatment, but small studies have suggested that most re-treatment patients were exposed to anti-TB drugs from the private sector. This situation may be due to poor case-holding in the private sector, and acquired drug resistance may be playing an important role in this. Operational research is needed to quickly assess the source of prior treatment. Regardless of this, a multicentric prospective cohort study under programmatic conditions is urgently required to assess the rates of recurrent TB and provide evidence about the long-term effectiveness of treatment under RNTCP.

A patient-centred adherence strategy, including supervised treatment agreeable to the patient, and proper treatment regimens using quality drugs, are the best guarantee for successful and durable treatment and for limiting the development of drug resistance. In the districts visited during the JMM, the number and range of DOT providers has been expanded since the last mission in 2006. A lot of this expansion has been achieved by involving more health care staff as DOT providers (e.g. TB health visitors in urban areas). In addition, a new and very promising community health person, the accredited social and health activist (ASHA) worker, who is available for a rural population of approximately 1000, has been involved by RNTCP as DOT providers. The ASHA initiative is part of NRHM and has potential to be of great benefit for high-quality and accessible DOT provision in rural areas. However, ASHAs are not available in all states and do not cover urban areas, and not all of them have been trained in DOT provision. Where AHSAs have been nominated and trained by RNTCP, many more patients can receive supervised treatment at a convenient place near their homes. Consideration, however, must be given to the fact that the increased number of DOT providers will require extra efforts in terms of training and supervision, especially by the contractual staff (senior TB treatment supervisor). More agreeable terms of contract and salary levels are essential to retain and motivate these contractual staff.

Category II and IV patients require injections during the intensive phase of their treatment. Innovative mechanisms of addressing the issue of how best to guarantee convenient DOT while ensuring that the injections are administered by trained persons (e.g. general practitioners for a fee-for-service payment, multipurpose health workers, etc.) need to be considered by RNTCP.

Medical colleges have been increasingly involved in RNTCP activities, and DOT centres have been established in these institutions which diagnose and refer to RNTCP approximately 15% of all new smear-positive TB patients for treatment. A system of transfer for continuation of RNTCP treatment is in place for those patients who are diagnosed with TB in a medical college and are initially registered in the tuberculosis unit (TU) in which the medical college is situated. In addition, a mechanism exists for patients diagnosed at medical colleges which allows them to be referred for registration and treatment at the TU and DOTS site nearest to their home. During the field visits, the JMM teams found that these mechanisms have been put in place by RNTCP, although 'in-house' referrals of TB patients by departments other than the Chest and TB departments in medical colleges seem to vary in quantity and quality.

It was noted that treatment outcomes of patients treated by private providers in collaboration with RNTCP are no different from patients treated under the public sector system. As mentioned earlier, it was observed that the contribution of private practitioners and NGOs under the various PPM schemes to DOT provision is limited. The availability of 'DOT directories' listing all DOT providers in a district is a step in the right direction. The RNTCP-IMA collaboration, discussed later, has been recently attempting to improve the participation of private providers in treatment activities.

The proportion of smear-positive patients put on non-DOTS regimen is around 1%. The large majority (87%) of NSP patients were put on DOTS treatment within a week of diagnosis. However, as reported in the RNTCP annual report (2009), among the NSP patients interviewed, 27% did not receive fully supervised treatment as per guidelines.

The RNTCP wishes to simplify the drug regimens that it offers, and is considering to treat new smear-negative pulmonary TB and extrapulmonary cases (i.e. Category III patients) with the same 4-drug regimen as it uses for the new smear-positive cases. This is in line with the established practice in many other countries and with WHO guidelines.

Achievements

1. Consolidation of the core case-holding functions of the programme after achieving national coverage in 2006.

2. Highly satisfactory national treatment success rates among new smear- positive pulmonary tuberculosis (PTB) patients since the 2006 JMM; during the last two years these rates have been above 86%.

3. The referral and reporting systems are in place and allow patients to be referred for registration and treatment at the TU and DOTS sites nearest to their homes.

4. Inclusion for DOTS of TB patients diagnosed while being inpatients at medical college hospitals.

5. Some expansion in the number of health care providers as DOT providers, both from the public health care system as well as the private and NGO sectors.

Constraints

1. Completely uncontrolled and unregulated market of widely accessible first- and second-line anti-TB drugs, the volume of which is by far much larger than the volume of TB drugs procured and used by RNTCP.

2. An unknown, but considerable, proportion of TB patients are treated outside of RNTCP, either by private practitioners or by public health staff prescribing drugs of unknown quality, for use in non-standardized regimens, and with no mechanisms for adequate supervision and follow-up in place.

3. The proportion of smear-positive PTB re-treatment cases among all smear-positive PTB cases is very substantial.

4. The outcome of smear-positive PTB re-treatment cases is unsatisfactory, with a very high default rate.

5. The feedback mechanism regarding initiation of treatment for referred cases needs strengthening.

6. Ineffective retrieval of patients interrupting their treatment, both among new cases and especially among previously treated cases.

7. A considerable proportion of new smear-positive TB cases had unsupervised treatment, partly because DOT services were provided by an insufficient number of DOT providers. In some settings, patients had to travel long distances to receive treatment.

8. The proportion of NSP cases completing treatment, i.e. without a final sputum examination, is reported as zero from many districts. The implausibility of this finding raises doubts on the validity of that aspect of reporting.

9. Inadequate number of community-based non-health DOT providers. Yet a large number of them are identified (e.g. ASHAs and others), but are underutilized.

10. Inconvenient timings at peripheral health institutions for working people.

11. Limited counselling and interpersonal communication skills among health staff.

12. Lack of motivation among staff (both regular and contractual).

13. Low salary levels with no benefit package for contractual staff.

14. Honorarium for community DOT providers frequently paid late or not at all.

15. High turnover of medical officers who may often not be sufficiently trained in or be conversant with RNTCP guidelines.

Recommendations

1. **National initiatives to be taken to enforce and implement existing government regulations:**

   1.1 That anti-TB medicines can only be dispensed against a prescription from a registered medical doctor – i.e. no sale "over the counter";

   1.2 Notification of TB by all doctors, especially by those working in the private sector.

2. **New regulations**

   2.1 In line with the recent directives about standards and regimens for HIV treatment, advocate for similar directives for TB treatment and diagnostic procedures.

   2.2 Oblige doctors to use only supervised TB treatment regimen according to RNTCP guidelines. (Improper prescriptions by registered medical doctors amount to OTC sale, hence there should be a regulation for prescribing anti-TB drugs).

   2.3 Work with medical associations to ensure that they support the implementation of the International Standards for TB Care (ISTC) in partnership with RNTCP.

3. **To inform decision-making on the future evolution of anti-TB treatment regimens in India, and in addition to current plans for additional surveys on first-line anti-TB drug resistance, research is urgently required to elucidate:**

   3.1 The source of and reasons for re-treatment with respect to previous treatment history and other important determinants.

   3.2 Rates of recurrent TB, discerning reinfection from relapse, for NSP cases.

   3.3 Rates of acquisition of new drug resistance in patients who fail treatment or have recurrent TB.

3.4 Prevalence of fluoroquinolone resistance among NSP and re-treatment cases

4. **In tuberculosis units with a high default rate, special attention should be given to:**

4.1 Treatment-after-default patients, as these patients have a high risk of interrupting their treatment again.

4.2 Retrieval of patients who interrupt their treatment, both among new and re-treatment cases, must be made a priority.

5. **In those TUs and districts where the cure rate is virtually the same as treatment success, the validity of outcome classification and adherence to follow-up sputum examination needs to be monitored carefully by intensive supervision.**

6. **DOT provision should be:**

6.1 Decentralized for the convenience of TB patients to the level that is feasible for monitoring and supervision.

6.2 Improved for Category II and IV patients who must have injections during the intensive phase, through the use of private providers and registered medical providers during intensive phase, and by linking patients to community DOT providers during continuation phase.

7. **DOTS providers, both health or non-health persons, should be:**

7.1 Trained to acquire good counselling and interpersonal communication skills.

7.2 Properly supervised.

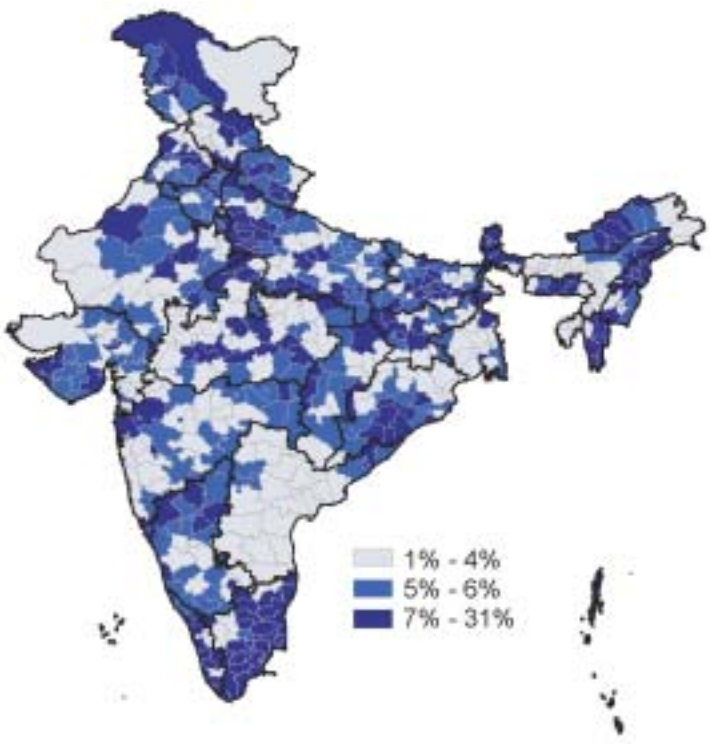
8. **The CTD should proceed with the plan of making a single regimen for all new patients; the programme should consider whether maintaining registration of the currently existing treatment categories (I and III) have value in terms of patient management or for monitoring and evaluation purposes.**

6. Paediatric TB

Children can present with TB at any age, but the most common age is between 1 and 4 years when there is an increased risk of progression from infection to disease. Case notification of childhood TB depends on the intensity of the epidemic in the area, the age structure of the population, the available diagnostic tools, and the extent of routine contact investigation.

Although the extent of childhood TB in India is unknown, it is estimated to be 10.2% of the total adult incidence (1). From the annual RNTCP data, it appears that the case notification of paediatric TB cases is low and, in 2008, it was 6% of all notified cases at the national scale (range at state level 3% to 14%) (2). In addition, the WHO recommendation to notify children in two age ranges 0-4 years and 5-14 years is not implemented. It is not known whether this low proportion of the notified paediatric cases results from true under-diagnosis or whether children with TB are diagnosed outside of, and hence not reported to, RNTCP.

Fig. 13: Percentage of paediatric cases out of all new cases in India by district, 2008



The field visits by the mission teams revealed contrasting findings. In DOTS centres at the district level, there was very little evidence of childhood TB being diagnosed and treated within RNTCP, except for a few cases. RNTCP staff stated that children diagnosed with TB were usually managed by paediatricians (public and private sector). Many interviewed health staff (including medical officers) were not fully aware of the RNTCP's diagnostic algorithm for children in whom TB disease is suspected. Paediatricians interviewed at the district level mentioned difficulties with diagnosis and treatment due, respectively, to the lack of tuberculin and child-friendly drug formulations (such as dispersible tablets or syrups) under the programme. Routine and systematic contact investigation or use of isoniazid preventive therapy (IPT) as per RNTCP guidelines was not observed in most places. The situation was somewhat different in the DOTS centre based at a medical college visited* where there were five children with TB (out of eleven cases currently on treatment) being managed.

Lack of a simple, definitive diagnostic test to diagnose TB in children and difficult access to X-ray facilities, tuberculosis sensitivity test (TST) and bacteriological culture, and lack of coordination between the paediatric fraternity (both public and private) and the programme are the underlying reasons leading to this situation. The RNTCP data clearly shows that the paediatric case notification differs widely between states and is the highest in Delhi (where access to tertiary and specialist care is readily available).

Overall, there is a strong commitment by CTD to improve the management of children with TB. The paediatric patient-wise boxes (PWBs) in four different weight bands (6-10 kg; 11-17 kg; 18-25 kg; 26-30 kg) were distributed to all DOTS centres and were available at the time of the JMM, although not fully utilized in many of the districts visited.

In a recently published paper in *Indian Paediatrics*, a concern was expressed that there is a risk of under-dosing of individual drugs for many of the RNTCP's weight categories for children with TB (3). In addition, there is no provision for increasing the dosages if the child gains weight during the 6-9 months of treatment.

Recommendations

1. The RNTCP to re-establish its earlier close collaboration with the Indian Academy of Paediatrics to update the RNTCP guidelines and arrange training for health workers to ensure quality of diagnosis and treatment of children with TB.

2. Dosing of drugs in the paediatric PWBs to be reviewed and increased accordingly in line with the revised WHO recommendations. As much as operationally possible, child-friendly formulations (such as dispersible tablets) should be

* The medical college at Tanda in Kangra district, Himachal Pradesh, was visited.

used. If during treatment a child gains weight, the dosage of the drugs should be adjusted accordingly.

3. Appropriate referral system, linkages and feedback to be strengthened between DOTS centres and paediatricians practising in the public health system.

4. Recording and reporting to be updated to account for the two WHO-recommended age ranges: 0-4 years and 5-14 years.

5. Contact investigation among contacts of all adult smear-positive pulmonary tuberculosis (PTB) cases should be reinforced, routinely implemented and closely monitored.

6. Children below six years of age that are identified in the household of an adult smear-positive PTB case to be evaluated for active TB disease; isoniazid preventive therapy to be routinely provided to all children below six years of age when active disease is excluded by a paediatrician (or a medical officer if a paediatrician is not available), and recorded and monitored.

7. The RNTCP to evaluate the quality and strength of tuberculin available in the country in order to provide access to a standardized tuberculosis sensitivity test.

References

1. Nelson LJ, Wells CD. Global epidemiology of childhood tuberculosis. *Int J Tuberc Lung Dis* 2004; 8: 636-47.

2. TB India 2009. RNTCP Status Report. Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, March 2009.

3. Lodha R, Menon PR, Kabra SK. Concerns on the Dosing of Antituberculosis Drugs for Children in RNTCP. *Indian Paediatrics* 2008; 45: 852-54.

7. Engagement of all care providers

Public-private mix for TB care and control

India has the highest burden of tuberculosis. It also has the largest private sector—voluntary, commercial, corporate—that caters to a large proportion of TB symptomatics and cases across all urban and rural areas of the country. Only a tiny proportion of RNTCP-notified TB cases are managed outside the state sector, even though those providers account for an estimated 80% of all outpatient care in the country. Several public sector entities that do not work directly under RNTCP also provide TB care; these include medical colleges, state insurance schemes, Indian Railways (the single largest employer in the world), ports, mines, oil refineries, etc. Systematic and sustained engagement of diverse—both organized and unorganized, formal and informal—TB care providers is essential for a variety of reasons: to improve access to TB care; to reduce patient costs and inconvenience; to achieve early case detection; to promote rational use of anti-TB drugs; to prevent M/XDR-TB; and to move beyond 70% case detection for universal access to quality-assured TB care. Uncommitted efforts and insignificant engagement of care providers outside RNTCP could potentially undo the consistent efforts and commendable achievements of the national TB programme.

For over a decade since its launch, RNTCP has gathered a wealth of experience related to implementing public-private mix (PPM) in diverse settings. There have been over a dozen well-documented examples which have demonstrated the feasibility, effectiveness and cost-effectiveness of PPM for TB care and control in India. Based on the findings of these projects, RNTCP scaled up PPM in 14 cities by providing additional dedicated human and financial resources. This limited scale up has also been demonstrated to have worked in diverse urban settings, with increases in case detection and success rates. Major contribution seems to have come from medical colleges as a result of well-organized efforts of the national- and state-level task forces set up for the purpose. Both the participation and contribution of individual private providers, who are often the first point of contact for TB symptomatics, have been very limited. The cost-effectiveness of PPM scale up has been documented as well[3]. The involvement of medical colleges specially has shown that the returns from investments in non-programme providers are proportionate to time, efforts and human and financial resources expended. These initiatives require specific structures at sub-national and local levels to support all interventions.

[3] A. Pantoja, K. Lönnroth, S. S. Lal, L. S. Chauhan, M. Uplekar, M. R. Padma, K. P. Unnikrishnan, J. Rajesh, P. Kumar, S. Sahu, F. Wares, K. Floyd. Economic evaluation of public-private mix for TB, India. Part II. Cost and cost-effectiveness of intensified efforts. Int J Tuberc Lung Dis 2009; 13: 706-712.

The RNTCP has been collaborating with the Indian Medical Association (IMA) since October 2007 as part of a Global Fund-supported project. Thousands of private practitioners have been sensitized and trained across six states, who are expected to contribute to TB care and control. In order to promote the use of the International Standards for TB Care, a coalition of associations of medical professionals of different disciplines—Indian Medical Professional Associations Coalition against TB (IMPACT)—has been formed. The outcomes of the project in terms of the contribution made to case detection and treatment supervision are yet to be determined.

Taking into consideration the experience of the NGO and PP schemes in use, RNTCP has revised the existing schemes through a consensus and new schemes have been introduced since October 2008. Collaboration with the large network of facilities of a faith-based organization, namely, Catholic Bishops' Conference of India (CBCI), partnerships with NGO groups such as National Tuberculosis Consortium (NTC) and Indian Coalition Against TB (ICAT), and the support provided to the setting up of a national partnership to stop TB have been other important milestones in PPM and partnership development in the country. Interventions to prevent the unregulated supply and irrational use of anti-TB drugs are yet to be attempted.

The observations of the mission teams visiting different states were strikingly similar. While there are success stories, efforts made to engage NGOs and PPs appear to be patchy. If investments and activities on the ground are any indication, engagement of private care providers—NGOs or PPs—does not seem to be a high priority for RNTCP. There are no focal persons assigned for PPM at any level, and the available staff at all levels have little capacity to undertake PPM-related activities seriously. The revised schemes are yet to be disseminated in some sites. While there is a module to train PPs, a training module to first prepare RNTCP staff to implement PPM is yet to be developed. Given the scope, scale and sophistication of data management within RNTCP, the absence of meaningful data measuring the active engagement of private providers suggests a lack of priority for this issue. This low priority is also reflected in the expenditure figures: during 2008, the total budget expended under the NGO/PP schemes amounted to Rs 28 239 385 (or US$ 588 000) representing just 1.5% of the total state-level TB expenditure (Table 3).

As a result, with rare exceptions, the lack of trust and enthusiasm to engage with each other for a common purpose continues. The name of the referring non-programme provider is rarely recorded and no feedback is sent. The mission observed cases of delays as well as non-payment of reimbursements for the implementation of schemes, prompting other NGOs and private practitioners to stay away from signing any new schemes. The mission felt that the current approach of offering the schemes with limited sensitization and training were incapable of going to scale and producing results in terms of contribution to early case detection and high treatment success rates for patients not managed within RNTCP.

Table 3: Expenditure on NGO/PP schemes, January - December 2008

Name of the state / Union Territory	Total expenditure (in Rs)	Expenditure* on NGO/PP schemes (in Rs)	% expenditure on NGO / PP schemes
Andaman & Nicobar	1 068 581	0	0.00
Andhra Pradesh	138 818 108	2 210 166	1.59
Arunachal Pradesh	17 734 149	0	0.00
Assam	51 566 932	81 500	0.16
Bihar	81 305 669	407 500	0.50
Chandigarh	5 703 341	99 500	1.74
Chhattisgarh	35 972 810	25 000	0.07
Dadra & Nagar Haveli	2 832 143	0	0.00
Daman & Diu	1 159 534	0	0.00
Delhi	65 567 064	2 270 047	3.46
Goa	4 543 082	0	0.00
Gujarat	113 233 289	1 387 068	1.22
Haryana	36 267 801	17 315	0.05
Himachal Pradesh	23 340 796	26 000	0.11
Jammu & Kashmir	25 153 356	25 000	0.10
Jharkhand	38 324 172	315 500	0.82
Karnataka	87330 791	1242089	1.42
Kerala	52 763569	97 945	0.19
Lakshadweep	768 179	0	0.00
Madhya Pradesh	75 501 573	426 350	0.56
Maharashtra	183 186 317	3 432 448	1.87
Manipur	21 060 480	530 500	2.52
Meghalaya	13 307 857	89 500	0.67
Mizoram	12 776 255	137 500	1.08
Nagaland	18 679 424	0	0.00
Orissa	71 154 250	742 434	1.04
Puducherry	1 842 655	0	0.00
Punjab	40 882 897	37 500	0.09
Rajasthan	82 908 540	152 000	0.18
Sikkim	6 754 849	20 000	0.30
Tamil Nadu	94 795 920	2 672 201	2.82
Tripura	6 468 506	0	0.00
Uttar Pradesh	310 822 075	6 143 532	1.98
Uttarakhand	19 222 381	27 000	0.14
West Bengal	132 877 558	5 623 790	4.23
Grand Total	**1 875 694 903**	**28 239 385**	**1.51**
US$ equivalent	**39 076 977**	**588 321**	

**NGOs/PPs also collaborate outside the formal RNTCP schemes*

The mission observed that anti-TB drugs were widely available in private pharmacies without a prescription. At one site, the mission team came across seemingly popular, though irrational, formulations of three and four drugs fixed- dose anti-TB combinations in a dispersible powder form packed in sachets (SCC-4, SCC-3 and SCC-LW, the LW standing for "light weight"). Given the widespread availability of anti-TB drugs, it is not surprising that the proportion of re-treatment cases tends to be relatively high in many sites.

The mission teams highlighted both the absence of and a need for the alignment of the advocacy, communication and social mobilization (ACSM) and PPM approaches that could benefit both. These may be wide-ranging initiatives targeted at public and private care providers as well as TB patients and communities. For example, creating mechanisms for communication among care providers offering clear information to patients and communities about quality TB care and where and how to get it, and creating a demand for convenient access, not only through strengthened TB care at public sector clinics but also at non-programme NGO and private clinics.

In summary, while the mission acknowledges CTD's increased attention and efforts to scale up PPM, its conclusions may not be very different from those of the 2003 and 2006 missions which stated: "There is a large untapped potential for further action to involve providers not yet linked to the TB programme. In many districts, PPM activities receive insufficient attention and the staff responsible for implementing RNTCP is often not sufficiently equipped to efficiently scale up PPM."

Recommendations

1. Organize a series of strategic reviews and consultations to guide innovations for strategic scaling up of PPM experiences and consider establishing an advisory group that includes current PPM task force leads (Indian Medical Association [IMA] partnership, NGO partnership and Medical Colleges Task Force) as well as others not previously engaged, such as the pharmaceutical sector, non-allopathic doctors, management/marketing experts, HIV-focused NGOs, independent medical stores/chemist shops and affected patients and community representatives.

2. Empower intermediary organizations such as NGOs and IMA to scale up PPM, while strengthening programme capacity at the Central and state levels to undertake a stewardship role for PPM development.

3. Consider phased scale up using a comprehensive intensified strategy with substantively new and comprehensive approaches, beginning with a few willing states with strong RNTCP performance, a good foundation of initial PPM efforts in TB control and possibly other GoI initiatives related to partnering with the private sector. This could also include a state-level advisory group.

4. Work further with associations of health professionals to ensure that they actively support the implementation of the endorsed International Standards of TB Care (ISTC) in partnership with RNTCP, including its recommendation on the notification of TB cases by all care providers.

5. Assess steps required to move towards developing a system for the notification of all TB cases in the country.

6. Drawing lessons from medical colleges' involvement and intensified PPM in 14 cities and allocate greater financial and human resources to scale up PPM.

7. Align ACSM and PPM approaches to facilitate inter-provider and patient-provider communications as well as community involvement to create a demand for access to quality TB care from both public and private care providers.

8. Develop a PPM module for the training of RNTCP staff that incorporates guiding steps to implement revised schemes.

9. Increase field-level interaction of RNTCP staff with collaborating NGOs, IMA and PPs.

10. Increase public recognition of collaborating NGOs, PPs and other providers by high-level political leaders and programme staff.

11. Incorporate into the existing supervision and monitoring system indicators to measure both the inputs given by RNTCP staff to PPM implementation and contribution of non-programme providers other than medical colleges to TB control.

12. Access market research data on the levels and trends of the sales of anti-TB drugs in the private sector and incorporate it into routine programme reviews.

13. Through a comprehensive approach, in consultation with the drug industry, IMA, other health professionals' associations, health activists, pharmacies and community representatives, engage regulatory and political authorities to enact/ enforce laws in order to restrict OTC sales of anti-TB drugs and irrational drug formulations and ensure TB case notification by all care providers.

14. Seek collaboration with other health programmes and partners to set up initiatives to try out innovative approaches to help scale up PPM, such as the use of mobile phones, provision of incentives and enablers, certification and accreditation systems and insurance schemes.

8. TB/HIV

India developed a National Framework for Joint TB/HIV Collaborative Activities in February 2008 that defined the package of services for the high and low HIV-prevalence settings. The framework has leveraged remarkable nationwide implementation of joint TB/HIV collaborative activities. Nine high HIV-prevalence states implement the Intensified TB/HIV Package of services that includes routine offer of referral to all TB patients for HIV counselling and testing of TB patients, provision of co-trimoxazole preventive therapy (CPT) and antiretroviral therapy (ART), intensified TB case-finding at HIV services centres (integrated counselling and testing centre - ICTC, ART and Care and Support centres), training of programme officials and field staff, and expanded recording and reporting. Two more states have recently initiated implementation of the Intensified TB/HIV Package. The nationwide coverage of the package is planned for 2012. Between 2006 and 2008, the number of TB patients tested for HIV doubled, while the number of people living with HIV (PLHIV) referred for TB diagnosis tripled. Six ART centres are planned for the pilot testing of the implementation of isoniazid preventive therapy (IPT). Priority operational research areas to further improve the implementation of joint TB/HIV activities have been identified in the national TB/HIV framework and there has been some progress in that direction.

Key findings and observations

Mechanisms of coordination

A national TB/HIV technical working group has been established and has started to meet every second month to plan and review nationwide implementation of TB/HIV. TB/HIV has been identified as one of the priority areas for the National AIDS Control Organisation (NACO). The CTD and NACO plan to conduct joint monitoring training. National performance indicators and targets for TB/HIV collaborative activities have been developed. Coordination committees have been established in most states according to national guideline and in some instances include NGOs or community members. Such committees have also been established in some districts.

Full-time TB/HIV focal points are not in place in the State AIDS Control Society (SACS) and the State TB Cell of most states. TB/HIV is not discussed regularly at state level in the monthly or quarterly meetings of NRHM and State Health Societies as, organizationally, the State AIDS Control Societies are separate entities and do not routinely attend these meetings.

District TB/HIV coordination committees have been established but are not functional in many districts. District AIDS prevention and control units are planned to be established in all category A and B districts (total 195).

Monitoring and evaluation of the implementation of joint TB/HIV collaborative activities are in place, and revised registers with space for recording of HIV status and treatment information are used in most states. NACO and State AIDS Control Societies of all states have websites with enriched HIV/AIDS information and enhanced utility by programme staff at all levels.

Partnerships and community involvement in TB/HIV activities were noted. PLHIV networks have been engaged for RNTCP activities such as DOT providers and field staff was observed in some of the high HIV-prevalence districts (e.g. Namakkal district in Tamil Nadu). Limited evidence of involving 'Targeted Intervention' NGOs for HIV prevention for TB awareness creation and referral was available. Similarly, little engagement and linkage of RNTCP activities with community care centres was observed

Reducing the burden of TB in PLHA

In most ICTCs and health facilities visited, IEC materials on TB and HIV were available. In some of the antiretroviral therapy (ART) centres, materials describing both TB drugs and ARTs were seen. In Tamil Nadu, HIV-infected patients were generally being initiated on TB treatment promptly by ART medical officers at the ART centres visited.

Intensified case-finding at ICTCs was observed and was remarkably well-established; however, reporting on intensified TB case-finding activities from ICTCs was subject to misunderstanding and misclassification of TB by the ICTC counsellors. Intensified TB case-finding activities were observed at the ART centres but these activities were driven by the local ART medical officers and were not systematically implemented throughout the nationwide network of ART centres. Furthermore, no system for reporting from ART centres on intensified TB case-finding activities is available.

While good practices of TB infection control measures were observed in some ART centres—Salem and Nammakal (Tamil Nadu) in particular, which had open and well-ventilated environment and a system of triage of TB suspects for prompt diagnosis—some other sites were lacking in such infection control practices and facilities.

Reducing the burden of HIV in TB patients

Very high level of acceptance of HIV testing was observed among those TB patients who reached ICTCs. For example, in the facilities visited in Tamil Nadu, HIV test acceptance among new TB patients ranged from 80% -100% during the first quarter of 2009.

Suboptimal ICTC services, including lack of confidentiality during counselling (e.g. sharing the same room between two counsellors), the use of non-standardized registers and poor referrals, were observed in some districts. There is poor linkage with

treatment services once TB patients are tested HIV-positive, particularly in low HIV-prevalence districts.

Although provision of monthly supply of co-trimoxazole for prophylaxis is included in the intensified TB/HIV package and was available at ART centres, it was not available at the general health facilities in many states as specified in the national guidelines. Very poor documentation of CPT and ART on TB records was observed and no clear standard system for transfer of HIV treatment information between ART and RNTCP was found to be implemented.

Recommendations

1. CTD and NACO to carefully plan and closely monitor the implementation of the nationwide expansion of the intensified TB/HIV package by 2012.

2. CTD and NACO to conduct joint field supervision visits more regularly, as suggested in the national guidelines.

3. CTD and NACO to ensure higher visibility for TB/HIV in their respective websites and the websites of SACSs, with dedicated web page and visibility for TB/HIV.

4. CTD and NACO to enhance and strengthen the involvement of PLHIV networks in RNTCP activities, including as DOT providers and for IEC and social mobilization.

5. CTD and NACO to improve linkage of intensified TB case-finding and ICTC and ART centres, especially in low-prevalence states, and facilitate the decentralization of ART services in order to ensure ART access for HIV-infected TB patients.

6. CTD and NACO to further improve the provision of HIV testing to TB patients by improving the referral mechanisms between ICTC and RNTCP.

7. CTD and NACO to accelerate the implementation of the priority operational research areas identified in the national TB/HIV framework by commissioning studies.

8. CTD and NACO to expedite the planned piloting of isoniazid preventive therapy (IPT) implementation in the six ART centres and rapidly draw lessons for the scaling up of interventions.

9. CTD and NACO to ensure the placement of RNTCP education materials in ICTCs and HIV education materials in designated microscopy centres (DMCs).

10. NACO and SACS should ensure that ICTC staff receive updated training for correctly classifying and reporting smear-positive, smear-negative, extrapulmonary and non-TB cases in their monthly report on intensified TB case-finding activities.

11. NACO and SACSs should try to enhance the quality of HIV counselling and testing services through refresher training that lays due emphasis on TB/HIV and implementation of the standardized registers according to the national guidelines.

12. NACO and state health authorities to facilitate timely establishment of district AIDS prevention and control unit in all districts, which has to be established within the district health office, to facilitate coordination with RNTCP.

13. NACO to consider incorporation of TB training, awareness, screening and linkage to RNTCP for TB diagnosis and treatment into the routine activities of 'Targeted Intervention' NGOs in order to improve TB services for high HIV-prevalence risk groups.

14. State health authorities to ensure placement of full-time TB/HIV focal points as per the national guidelines.

15. State health authorities to ensure inclusion of SACSs in the monthly or quarterly meetings of NRHM and State Health Society.

16. State health authorities to ensure establishment and functionality of district TB/HIV coordination committees according to the national guidelines.

17. State health authorities should encourage close participation of SACSs in the State Health Society meetings and ensure that TB/HIV is discussed regularly.

18. Health authorities at all levels to improve airborne infection control, particularly in ICTC and ART centres, according to the national guidelines.

9. Drug-resistant TB

Background

India is a high-burden multidrug-resistant tuberculosis (MDR-TB) country where 131 000 cases, of which 86 000 are smear-positive, are emerging annually (2007 WHO estimates). As per drug-resistance (DR) surveys conducted in the states of Gujarat and Maharashtra (2005-06), the prevalence of MDR is <3% in new TB cases and 14%-17% in previously treated cases. Based on these surveys, there are about 50 000 detectable (smear-positive) MDR-TB cases under RNTCP.

The second-line drug sensitivity test (DST) of MDR-TB isolates detected in the Gujarat DR survey shows 4% extensively drug-resistant tuberculosis (XDR-TB) among the MDR-TB detected in the smear-positive re-treatment cases. This translates into at least 120 XDR-TB cases in Gujarat state on an annual basis (estimate based on the 2008 notification data). The rates turned out to be even higher (10%) in MDR-TB patients at diagnosis stage and after six months of treatment in the initial DOTS-Plus site in the state: six XDR-TB cases among 60 MDR-TB patients (three cases at the start of Category IV treatment and three cases who amplified their resistance patterns to XDR-TB after six months of treatment [2007 patient cohort data]).

As worrisome is the extremely high rate (>50%) of pre-treatment resistance to quinolones seen among the first annual cohort of 60 MDR-TB cases diagnosed in the initial RNTCP DOTS-Plus site in Gujarat (33/60). However, these rates are higher than those reported from other sites, indicating that second-line drug resistance (SL-DR) may vary within India. Obviously, these high rates of resistance to key second-line drugs may seriously affect the outcome of MDR-TB treatment, as is clearly shown in Gujarat (see the portion on Gujarat below).

Since the introduction of the Global Stop TB Strategy, the programmatic management of drug-resistant TB is included within national TB programmes. For that reason the term "DOTS Plus" has been abandoned and replaced by Programmatic Management of Drug-Resistant TB (PMDT). As India incorporates MDR-TB management within the context of RNTCP, it is proposed that RNTCP shifts the terminology and uses PMDT from now on to be in conformity with the international terminology.

Scale-up plan for the Programmatic Management of MDR-TB

Over the last few years, RNTCP has been preparing for the integration and scale up of the programmatic management of drug-resistant TB within the context of the regular DOTS programme. The achievements include:

- A national-level DOTS-Plus committee established in 2005 and meeting regularly;

- RNTCP DOTS-Plus guidelines developed and available from 2006;
- First MDR-TB patients initiated on RNTCP Category IV treatment in August 2007 (Gujarat) and September 2007 (Maharashtra);
- To date, RNTCP has 10 (eight government and two private) laboratories accredited for Lowenstein–Jensen media culture and DST;
- MDR-TB treatment ongoing in eight states with >400 patients on RNTCP Category IV treatment;
- Ongoing research into newer, more rapid diagnostic tests (with FIND and WHO).

The RNTCP has recognized: i) the threat to public health of an increasing 'silent' M/XDR epidemic; ii) the amplification of drug resistance from MDR-TB to XDR-TB due to ineffective treatment outside subsidized programme settings; and iii) the demand for MDR-TB services by state governments, medical associations and civil society and therefore the need to accelerate the scale up of RNTCP's PMDT services in India. The cost of the revised plan is high but the cost of inaction will be much higher. After all, as long as RNTCP does not offer free access to diagnosis and treatment of MDR-TB, patients will seek inappropriate and unaffordable care outside of the programme, both in the public and private sectors, which will result in the emergence and spread of highly-resistant M/XDR-TB strains.

The key components of the revised framework plan proposed by RNTCP are:

- RNTCP Category IV services introduced in all states in 2010;
- By 2012, access under RNTCP to laboratory-based quality-assured MDR-TB diagnosis and treatment for all smear-positive re-treatment cases and failures of Category I or III treatment cases;
- By 2015, universal access to MDR-TB diagnosis and treatment for all smear-positive TB cases (new and re-treatment) registered under RNTCP.

The RNTCP plans to initiate at least 30 000 MDR-TB cases on treatment annually by 2012-13.

However, there is a major gap between the current status of PMDT activities and the ambitious plans of RNTCP and the related milestones in 2010, 2012 and 2015.

Although JMM applauds and fully supports the RNTCP's plan and framework for the expansion of PMDT activities, it wants to stress that the DOTS-Plus expansion can only be achieved if all PMDT framework components are implemented simultaneously. The programmatic management of drug-resistant tuberculosis is a complex intervention

that requires smooth communication, collaboration and cross-referral between designated laboratories, referral hospitals and all levels of RNTCP, down to the lowest levels (including the community-based link workers and ASHAs). As experiences worldwide show, sufficient numbers of motivated and qualified human resources are required in the PMDT machinery. While international donors may provide drugs, equipment and technical assistance, relevant authorities need to take their responsibilities seriously to ensure appropriate staffing (microbiologists, pharmacists, RNTCP key staff) to use those facilities. This requires major political and administrative commitment at all levels – Central, state and district.

The findings of JMM illustrate that several issues related to staffing are undermining the performance of RNTCP in general and that of PMDT activities in particular. Clearly, the scale-up plan can only succeed if these staffing issues are addressed.

Recommendations

1. For GoI to urgently address the emergence and spread of resistance to second-line drugs (SLDs) by:

    1.1 Enforcing current regulations and exploring innovative measures to limit the irrational use of second-line drugs in order to prevent an uncontrollable M/XDR-TB epidemic;

    1.2 Reviewing and analysing the second-line drug-resistance data available from the initial PMDT treatment sites and other sources in order to revisit the current RNTCP Category IV MDR-TB treatment regimen;

    1.3 Strengthening and expanding SL-DR surveillance (for at least quinolones and kanamycin);

    1.4 Building quality-assured second-line DST capacity (for at least quinolones and kanamycin) at state level;

    1.5 Procuring SLDs under RNTCP that meet international quality standards.

2. For GoI and states to recognize and address the key constraint to the scale up of PMDT services, i.e. the lack of qualified human resources, especially microbiologists, pharmacists and key RNTCP staff.

    2.1 Develop a comprehensive HRD plan that is guided by and takes advantage of the experiences of the initial RNTCP PMDT sites, and is based on the standard job descriptions and related operating procedures;

    2.2 Add human resource development (HRD) staff at CTD level;

    2.3 Regular staff (e.g. MO) should remain in post for at least three years;

2.4 Enhance salary scales of contractual staff and consider issuance of longer contracts to key contractual staff such as microbiologists;

2.5 Regularize well-performing contractual staff in a phased manner to ensure medium- to long-term sustainability of the programme;

2.6 Increase staffing at state level for supervisory activities and avoid dependence on nongovernmental staff (regular or contractual);

2.7 Fill vacancies, especially of pharmacists, as early as possible.

3. To design and establish a comprehensive laboratory network that clearly outlines the roles and responsibilities (criteria for infrastructure and staffing, technologies, supervisory tasks, proficiency testing and training tasks) at all levels of the network that is based on: i) the programmatic experiences within the initial RNTCP PMDT sites; ii) the results of demonstration projects involving new technologies; and iii) the overall RNTCP scale-up plan for the management of DR-TB in India.

4. For CTD to:

4.1 Develop appraisal criteria and systems for inclusion of new PMDT sites as an in-built safety mechanism during scale up;

4.2 Along with the RNTCP National PMDT Committee, to guide, monitor and regulate the scale up of Category IV services and implement the appraisal criteria;

4.3 Finalize, disseminate and pilot airborne infection control guidelines (minimal package to be implemented in laboratories and health facilities serving MDR-TB suspects and patients);

4.4 Develop guidelines for the storage of second-line drugs (see report on Gujarat below);

4.5 Develop and implement a comprehensive and integrated electronic information system for the MDR-TB services to link the culture and drug susceptibility test laboratories, PMDT sites and respective districts.

5. To apply to Global Fund Round 9, ensuring that all relevant budget lines are represented, and that the Global Fund proposal is guided by the experiences of the initial PMDT sites.

6. To maintain and further strengthen the regular DOTS programme, also looking into:

6.1 The high proportion of re-treatment cases;

6.2 The unusually low MDR-TB prevalence among failures of Category I treatment. [4,5]

7. To benefit from the experiences gained in the upscaling of MDR-TB services worldwide by the involvement of the Green Light Committee (GLC) and Global Drug Facility (GDF) in technical assistance and programme monitoring.

Laboratory services for the diagnosis and follow-up of DR-TB cases (Refer also to Chapter 4. Laboratory services)

MDR-TB management in initial PMDT site (Gujarat)

The RNTCP's MDR-TB-related activities in Gujarat were initiated in 2007 and are characterized by a strong political and administrative commitment at the state level and motivated staff. All staff involved in the programme have been trained and key staff serve as trainers for other states. Overall, the MDR-TB activities are doing very well and are in compliance with the national guidelines. As in every new activity there is room for improvement. (For more details, see report by the Green Light Committee.) The intermediate reference laboratory (IRL) has been upgraded and accredited and is undergoing a third reconstruction in the light of the introduction of line probe assay (LPA) (with assistance from FIND).

Since 2007, all patients failing Category II treatment have been identified as MDR-TB suspects and are referred for culture and DST. In October 2008, the suspect criteria were enlarged and now also include patients failing RNTCP Category I or III treatment. All suspects and confirmed cases are counselled by lay DOT providers, peripheral health care workers, DTO and MDR-TB expert at the PMDT site. However, counselling methods and messages are not standardized.

Treatment is coordinated and monitored by the MDR-TB expert committee at the PMDT site (termed the "PMDT site committee"), and after an initial short period of hospitalization, delivered at the most decentralized level involving urban link workers and DOT centres near the patient's house. A review of the treatment results of the 2007 patient cohort showed that patients were either doing well right from the beginning or remained positive, with deaths frequently occurring between months 9 and 12. The first 12-month interim report for the initial 60 patients shows a 60% smear conversion, 52% culture conversion, 26% culture positivity, 10% death and 12% default. A more detailed analysis indicated that patients with initial resistance to ofloxacin appeared to do worse, whereas patients with susceptibility to this drug in general appeared to respond well.

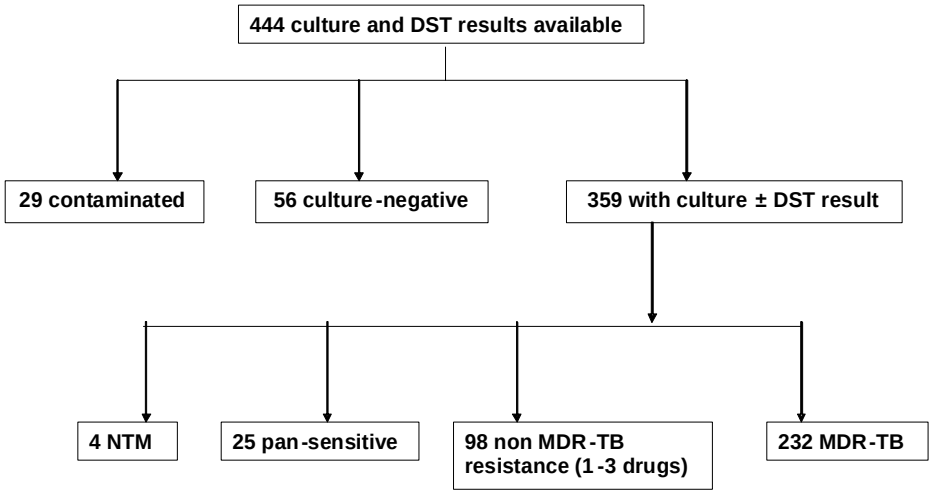
[4] T.Santha, PG Gopi, Rajeswari Ramachandran et al. Is it worth treating Category I failure patients with Category II regimen? Indian J Tuberc 2005; 52: 203-206.

[5] R.Singla, D Srinath, S Gupta et al

Main challenges include the following:

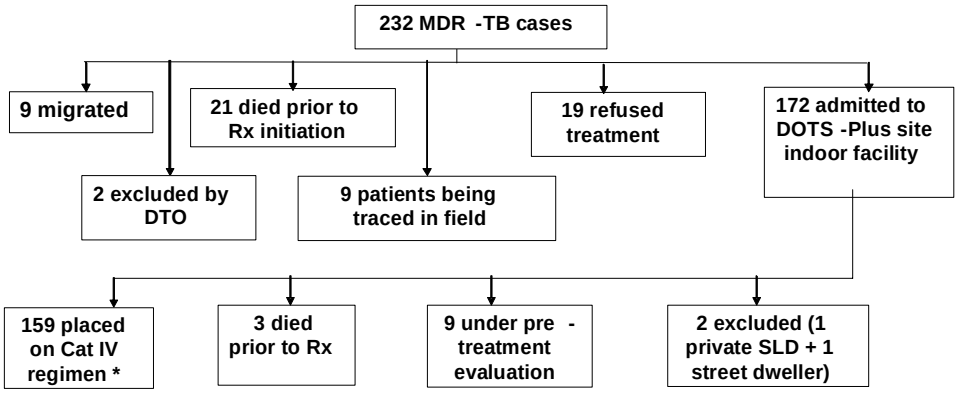
- Delays between the identification of suspects and the initiation of Category IV treatment are still too long (6-7 months) even after accreditation of the IRL. This has probably contributed to the death of some patients in the interim.
- Insufficient staffing at the IRL in the wake of introduction of new technologies, increasing workload and future supervisory functions related to the scale up of the laboratory network in Gujarat.
    - The only key microbiologist is a contractual staff with serious uncertainty for continuity.
    - Introduction of line probe assay (LPA) has interfered with conventional culture activities resulting in 100% culture contamination for a six-week period reflecting insufficient technical assistance.
    - The coordination and information-sharing between international and national partners is suboptimal. This is an important issue in view of laboratory network being planned at the national level.
- Initial default (N = 63 in 2007) is a reality as a result of death (23), refusal (31) and migration (9).
- There are high levels of resistance to ofloxacin (> 50%;33/60) and XDR-TB (6/60 including amplification).
- There is a lack of adequate infection control at high-risk sites (DMCs, MDR-TB ward, district TB centre).
- No culture/DST results are available at the initiation of treatment.
- MDR suspects reporting more than one-month treatment with SLDs are excluded from Category IV treatment.
- Unacceptable storage conditions for SLDs (at 44 degrees Celsius).

Fig. 14: Diagnosis of MDR-TB cases in Gujarat



Status as on 31 March 2009

Fig. 15: Treatment initiation for MDR-TB as per RNTCP Category IV regimen



* 1 patient re -registered after default / 3 patients HIV -infected of 116 tested

Status as on 31 March 2009

Recommendations

1. Develop a comprehensive expansion plan that links three key components: i) the design and establishment of a state-level laboratory network; ii) treatment services; and iii) a related HRD plan (covering all staff involved).

2. Develop and implement an appraisal system for expansion to new PMDT sites with well-defined benchmarks (combined activity of staff at initial sites and national team).

3. Ensure all identified MDR-TB cases have second-line DST performed.

4. Develop second-line DST capacity for quinolones and kanamycin at IRLs (state level).

5. Strengthen the information system to:

   a. reduce current diagnostic delays;

   b. introduce performance indicators on different types of delays;

   c. evaluate programme performance to aid further policy development.

6. Develop a standardized counselling approach for different stages of MDR-TB suspect and patient management to improve uptake and acceptance of Category IV services.

7. Limit the counselling of identified MDR-TB patients to medical staff (instead of involving DOT providers as the first one to convey the diagnosis), who have been trained using appropriate methodologies such as role play.

8. Facilitate the cumbersome process of obtaining approval for operational research (OR) and initiate essential OR as early as possible (e.g. on proportion of re-treatment cases, reasons for default from Category II, etc.).

MDR-TB management in other states visited

The teams reported preparations for PMDT and lab-capacity building in all sites visited. In the meantime, confirmed and non-confirmed MDR-TB cases are being treated both by public and private providers. Generally, providers do not adhere to national guidelines for the diagnosis and treatment of MDR-TB and even if they do, patients are often not able to comply with treatment because of financial constraints (cost of drugs) and lack of monitoring and social support. Several states report treatment of MDR-TB without laboratory confirmation of drug resistance.

The mission teams confirmed that second-line drugs are available without prescription, including expensive drugs that are exclusively used for M/XDR-TB such as cycloserine (Cs) and PAS. As there is no reliable method to test for resistance to these drugs, the level of Cs and PAS resistance remains unclear. However, the high levels of ofloxacin resistance and the existence of XDR-TB in Gujarat indicate that over-the-counter sales of SLDs is a reality that has the potential to undermine current and future attempts to manage and control MDR-TB in India. Further development and spread of resistance

to first- and second-line drugs will result in an unmanageable M/XDR-TB epidemic from the cost, management and societal perspectives.

However, as mentioned above, RNTCP is preparing an ambitious plan for the scale up of programmatic MDR-TB management in India.

In Himachal Pradesh, there is no accredited laboratory that can perform quality-assured culture and drug susceptibility testing. But there are concrete plans to establish an IRL (space identified; equipment to be provided by CTD; training in JALMA, Agra). In addition, the medical college at Tanda in Kangra district has shown interest and has the potential for establishing an IRL and managing MDR-TB patients.

In Rajasthan, the laboratory capacity for culture and DST has been established: the IRL at Ajmer has been accredited and the laboratory at Jaipur is ready for accreditation. The upgrade of the medical college lab in Udaipur is being considered. A PMDT site for MDR-TB management and referral has been identified and a STS and a STLS have been trained. However, the mission team reported that refresher training was necessary and that the MDR-TB module used, lacked an ACSM component.

In Uttarakhand, PMDT has not yet been established and the IRL needs to be upgraded. There is potential to involve the Himalaya Institute for Medical Sciences, a private medical college in the state.

In Puducherry, the IRL has the culture and DST capacity but it still needs to be accredited. The laboratory staff requires retraining. Adequate human resources and funding are available.

In Tamil Nadu, the laboratory has already been accredited and culture and DST is being offered to MDR-TB suspects. However, most of the lab equipment supplied by the government is not functional. An additional microbiologist needs to be appointed.

Recommendations

To expedite the development of strong RNTCP PMDT services in Himachal Pradesh, Rajasthan and Uttarakhand through:

1.1 Establishment of IRLs in the context of the national laboratory network planning, with adequate human resources, proficiency testing and supportive supervision;

1.2 Involvement of medical school laboratories in the culture and DST laboratory network;

1.3 Establishment of PMDT referral and treatment sites, involving capacity at medical schools, with clear assignment of roles and responsibilities to RNTCP and medical school staff within the context of a comprehensive human resource development plan;

1.4 Benefiting from these linkages between RNTCP and medical schools, to profile RNTCP and to develop strong PPM models;

1.5 Strengthening of case-holding, making optimal use of all Employees State Insurance (ESI) institutions and ACSM initiatives (patient-centred community DOT by ASHA and LINK workers, Anganwadi workers, etc.);

1.6 Establishment at all relevant levels of appropriate storage facilities for second-line drugs (temperature below 25 degrees Celsius) with adequate inventory management;

1.7 Application of at least a basic package of infection control interventions in high-risk settings (laboratory, MDR-TB ward, counselling site, etc.);

1.8 Technical assistance from first PMDT sites, thus benefiting from lessons learnt.

10. MIS/Programme surveillance

Recording, reporting, monitoring and supervision

A core function of RNTCP is to collect accurate and timely information about tuberculosis patients under the management of the programme. Data generated by the reporting system is essential for evidence-based policy decisions and is the vehicle for programme evaluation and performance monitoring. This necessitates systematic collection, recording, reporting and monitoring of key variables at district and state levels, with subsequent submission and analysis at the national level.

It was observed during this review, from a process perspective, that the reporting system remains functional and strong. RTNCP case-finding and treatment outcome records and reports were revised in 2007, and to a large extent, harmonized with WHO recommendations – including HIV diagnosis and treatment information for TB patients – and the new system has been implemented nationwide. Data collection and maintenance of TB registers at district and state levels appear to be complete and reflect the reality, with a few exceptions. Tuberculosis unit and district- and state-level Epi-Centre-based quarterly reports are timely and comprehensive. Electronic transfer of data and email-based feedback is utilized to enhance communication. Internal systems for monitoring and supervision were in place in all districts reviewed; however, the commitment to and quality of this monitoring was weak. Feedback and supervisory meeting discussions often do not contain relevant or instructive information to enhance performance, nor was there a mechanism for documenting corrective actions to ensure accountability. The subdistrict-level supervisors (e.g. STS and STLS) continue to serve the fundamental supervisory role for RNTCP and there is considerable variability in the capacity and effectiveness of these key positions. The availability and implementation of treatment cards are in place in most areas. However, monitoring of DOT providers continues to pose a challenge to the programme. Field supervisory visits from CTD are taking place; however, the frequency and intensity of supervision at state and district levels vary greatly. In general, the RNTCP supervisory registers are not in use. ICTC TB/HIV reports were noted to be prone to systematic error of misreporting as smear-negative TB cases those TB suspects who were smear-negative on initial smear microscopy.

Despite noteworthy performance in generating and disseminating a large volume of programme data, from an operational perspective, the RNTCP reporting system is not utilized for relevant programme action and planning. Key supervisory positions (e.g. STO, DTO, MO) demonstrate limited insight and capacity to conduct evidence-based problem-solving at district and state levels. Performance indicators are target-orientated and primarily focus on detection and treatment outcome of RNTCP NSP cases,

without due attention to programme management, case-finding processes and case-holding processes. Upon achieving national targets, district and state programmes appear complacent and are not challenged to set more appropriate goals based on local trends in performance. While the verticality of the information system has yielded some advantages for RNTCP, there is very limited engagement with the larger health system, including the private sector, for the collection of relevant performance indicators. This is a limitation of RNTCP data, and programme indicator-based analyses should be interpreted with caution when applied for the purpose of epidemiological interpretations.

Recommendations

1. Invest further in building the capacity of district and state managers to:

   a) perform evidence-based problem-solving;

   b) translate data into effective programme action.

   This will require education and training on how to conduct and interpret basic epidemiological analyses with special emphasis on how to translate findings into public health practice. This may be best achieved by scaling up the use of the Managing Information for Action (MIFA) participatory training model, which includes a causal model that employs participant-derived hypotheses from analysis of programme data and its use for developing evidence-based action plans to improve programme performance.

2. Make transition from target-focused monitoring of performance to analysis of trends in key process and outcome indicators at district and state levels in order to improve performance. Establish state-level committees to develop appropriate process indicators for local planning and monitoring to augment national targets.

3. For every state, RTNCP should periodically convene an external consultation (with participants from outside of the state) to objectively and transparently assess the validity and accuracy of data collection and reporting at every level of the state's performance. Findings should be shared widely with all health, administrative and political leaders of the district and state government and relevant national authorities and used to improve performance.

4. Communicate to senior-level state and district authorities the message to lay strong emphasis on accuracy and validity over achieving performance targets. To reinforce this message, consider publishing RTNCP internal evaluation programme statistics (i.e. accuracy and validity ratings) in addition to programme targets.

5. Develop and distribute a standardized supervisory site-visit report that includes both qualitative and quantitative variables and ample space for comment, in order to document corrective actions as well as successful completion.

6. To improve local action at district- and sub-district levels, vertical transmission of surveillance data from districts upwards should be augmented by local distribution of such data as well as RTNCP data.

7. Consider the use of external data to augment programme data collection (e.g. dummy patient surveys, local pharmaceutical sales and population-level KAP surveys).

8. The revised RTNCP Programme Management Report format should be finalized, distributed and field-implemented.

9. Revise the programme indicators in the *Strategy document for the supervision and monitoring of the RNTCP* to include the new components of the programme, including TB/HIV and MDR-TB.

10. Continue funding support to maintain the network of full-time RNTCP senior treatment supervisors and senior tuberculosis laboratory supervisors.

11. The internal evaluation format is exhaustive and needs re-tooling to be more priority focused, with an emphasis on translating these data into action. The format also needs to be updated to include new management information system (MIS) indicators for the newer components of the programme (e.g. DOTS Plus, MDR-TB variables).

12. Explore potential collaboration with the Field Epidemiology Training Programme (FETP) to enhance operational research capacity and to empower local officers with epidemiological mentorship afforded by FETP. The emerging public health challenge of MDR-TB and its management strategy is in line with the FETP mission and may be considered mutually beneficial.

13. Build RNTCP capacity to support the implementation and maintenance of EpiCentre software by identifying state-level support for training / help desk service through one-to-one engagement at district level.

14. At the national level, the mechanism for data reporting and monitoring is strong; however, the follow-up for corrective action is weak. It is, therefore, recommended that the MIS unit at CTD be strengthened to follow up on corrective actions.

15. District tuberculosis officers (DTOs) rely heavily on data entry operators for even the basic features of EpiCentre; therefore, consider a refresher course on the basic introduction and orientation for all STOs and DTOs. This may be best addressed through the MIFA training (see Recommendation 1).

16. Ensure the distribution and utilization of all registers in their latest version at all points of data collection and entry (e.g. DOT providers, DMCs, ICTCs).

11. Infection control

Achievements

The RNTCP has begun to pay attention to the issue of airborne infection control. The JMM noted that, in 2008, sensitization sessions on airborne infection control were organized as part of the national programme review and four Zonal Task Force meetings, which involved state TB programme officers, field consultants and medical college partners. In July 2008, CTD conducted a week-long initial infection control assessment in Delhi, Hyderabad and Kolkata in several clinical settings, including DOTS-Plus wards, medical colleges, chest clinics, primary health centres and laboratories. A national committee on airborne infection control has been constituted with diverse membership that includes specialists in TB, MDR-TB, medical architecture and HIV. One meeting of the group was held in September 2008.

Constraints

Despite the achievements, the actual progress has been slow. The efforts made to reduce the risk of TB transmission in health facilities have been organized sporadically and these have lacked standardization. The JMM noted that states, districts and health institutions await national guidelines to operationalize infection control. Improvements in health infrastructure were appreciated, with facilities being renovated by using NRHM and state funds to conform with the provisions in the Indian Public Health Standards. However, in the new and renovated buildings, little evidence was available of attention being given to ventilation and airborne infection control, suggesting limited awareness about the problem. The Indian Public Health Standards do not as yet incorporate consideration of the prevention of airborne disease transmission. The National Committee has not had a second meeting in the six months since their initial meeting in September, suggesting a lack of priority given to the issue.

Opportunities

The generally successful adoption of universal precautions and biomedical waste management across the health system throughout the country gives the hope that airborne infection control is also possible. Interventions recommended by the JMM to improve case detection may, if effectively implemented, also reduce the risk of TB transmission in health-care settings. In particular, active identification of TB suspects in outpatient departments and their fast-tracking for evaluation can reduce the time, and hence, respiratory aerosols that infectious TB patients can generate. Local patient benefit funds under NRHM can be tapped to improve the safety of health care facilities.

The recent epidemic of influenza A (H1N1) has created awareness about the importance of infection control in health care facilities, which can be leveraged for improved commitment from national, state and district health authorities.

Recommendations

1. Finalize national operational guidelines on airborne infection control as a high-priority programme activity, pilot test their effectiveness, revise them on the basis of lessons learned, and disseminate them systematically throughout the health system.

2. Prioritize the implementation of airborne infection control measures in the following settings: HIV treatment and care settings; MDR-TB care facilities; heavily-utilized clinical care units like medical colleges; and TB laboratories.

3. Build a cadre of national consultants on airborne infection control capable of evaluating and making basic recommendations to health care facilities. This cadre should be multidisciplinary that should include doctors, engineers/architects, and public health consultants.

4. Seek incorporation of design interventions to reduce airborne infection transmission into the Indian Public Health Standards. Engage with and sensitize public works departments, medical architects and engineers on the need to incorporate the consideration of airborne transmission risk into health facility design, construction and renovation.

5. Engage with NRHM for the support of airborne infection control activities as a patient-safety intervention and to incorporate a mandate for NRHM-sponsored patient benefit societies to fund modification of health facilities for improved ventilation in high-risk areas.

12. Advocacy, communication and social mobilization

The well-honed technical and logistic components of this the largest TB control programme in the world can be likened to a train ready to serve a huge and diverse population. The team reviewing the RNTCP's advocacy, communication and social mobilization (ACSM) component sought to understand what the programme is doing to engage political leaders, the community and non-programme providers to come on board. This includes advocacy to those in position of influence, communication with people so that they know, trust and are ready to avail free TB diagnosis and care, and communication with patients during diagnosis and lengthy treatment (around 42 contacts during the course of first-line treatment expanding to some 700 over the two years of MDR-TB management), and mobilization of communities to demand, use and lend support to RNTCP services so that TB control becomes a people's movement.

Achievements

The mission teams noted some positive achievements in the field. As noted in the 2006 JMM report, there is a stated strategy. Tools for targeting ACSM include results from a nationwide knowledge, attitude and practice (KAP) survey and the Tribal Action Plan for targeting neglected and hard-to-reach populations. The national ACSM advisory committee contributes to training and guidance on media activities and services, functioning more through the inputs of individual members than as a 'think tank'. Tools for implementing decentralized ACSM include a comprehensive analysis of state-level ACSM capacity to identify training needs and modalities; for example, the recent ACSM training aimed to involve STOs, information, education and communication (IEC) officers and communication facilitators jointly for needs-based planning, although the buy-in by STOs was not uniform. There is a national framework for TB/HIV collaborative activities that includes a specific component for ACSM. Twenty-eight states have IEC officers and 45-50 communication facilitators are working in around 11 states, although, as noted hereafter, this initiative requires a critical review.

The mission teams were impressed by the potential of interpersonal communication (IPC) to impact case-finding and reduce default rates, and saw dedicated STSs and DOT providers communicating persuasively with the patients. The potential of cured patients is recognized and used by some proactive district-level staff but is yet to be promoted as a key IPC intervention. In all the states visited, the teams noticed that the main (and, in some cases, the only) thrust for ACSM activities is around World TB Day, which, if followed through, could provide an impetus for sustained efforts throughout the year. Three recently-aired TV spots portray the popular film actor,

Vivek Oberoi, as a postman and DOT provider raising awareness about TB symptoms and RNTCP services. Formal evaluation data of these spots was not available during the time of the JMM, but, anecdotally, people seemed aware of the spots, programme staff appreciated their high quality, and TV was mentioned as the main source of information about TB in the urban settings visited by the teams.

The JMM teams found some examples of localized approaches and innovations that take into account India's diversity. For example, Rajasthan provided a mine of ideas that included a game about TB health-seeking for schoolchildren being developed by the IEC officer, visual materials to support engagement with *bhopas* (faith healers) developed by the communication facilitator with DTO input in Udaipur, and a 400-km Scout Guides rally across four districts in the Bharatpur zone, organized by the communication facilitator in collaboration with RNTCP staff. Good partnership examples with government agencies include working with the Integrated Child Development Scheme (ICDS) to sensitize ASHA *Sahyoginis* and with the National Service Scheme (NSS). Partnerships with NGOs include the Impact Project in Ajmer, which demonstrates effective engagement with schools and provides models for interpersonal patient-provider communication.

Constraints and gaps

While the JMM teams found examples of enthusiasm and creativity, these were limited to a few motivated STOs, IEC officers and their partners. There was limited evidence of well-planned, synchronized and strategic ACSM. Some teams did not find any activities on the ground.

There was a notable disconnect between interventions envisaged at the national level and what was happening in the field. The objectives and components laid out in the National Health Communication Strategy are not being reflected at state and district levels. Officers are either not aware of the national strategy or do not know how to translate it into their IEC plans of action. State and district IEC action plans are not based on an analysis of needs, programme data or existing KAP survey data. The promise that IEC should be process- rather than product-oriented, is not delivered in the field. There is an over-production of the same type of IEC material (such as pamphlets, posters and hoardings), which does not target specific audiences with specific messaging and are not field-tested prior to mass production. For example, text-heavy materials are displayed in areas of high illiteracy, and some visual materials portraying predominantly adult male patients are used in areas where the key challenge is young women facing stigma. Under RNTCP, exemplary tools and materials have been produced and could be used as illustrative examples on needs-based planning and audience engagement, but they are not utilized for maximum benefit (e.g. PPM kit, documentation on ACSM processes from the DANIDA TB programme and materials on the electronic IEC resource centre).

The IEC terminology has been partially replaced with ACSM as recommended by the previous JMM. However, advocacy, communication and social mobilization seems to be understood differently by RNTCP officers at all levels. Currently, the predominant focus is on communication as one-way information dissemination. The advocacy and social mobilization components have received little attention.

Engagement of civil society is generally low due to mutual mistrust. The JMM teams observed that the concept of empowering patients and communities to play a role in TB control needs urgent consideration and special efforts are needed to promote RNTCP as a people's movement encouraging convergent action on awareness creation, case detection and treatment by formal and informal groups at village, block, *taluka* (subdistrict), district, state and national levels. Ideas on how to achieve this are described under Recommendations.

There is a significant lack of ACSM capacity at the national, state and district levels. At district level, DTOs are assigned responsibility for planning and implementing ACSM but they, along with other clinical staff, have neither the skills and the time nor the resources to plan and implement ACSM on top of their core duties. In addition, this component still suffers from poor perception, poor consideration and inadequate recognition for ACSM staff. This is resulting in low motivation and lack of innovation, although there are notable exceptions.

The monitoring and evaluation of ACSM activities remains a key challenge. The monitoring and evaluation framework recommended by the 2006 JMM was not implemented. The focus at all levels remains on outputs (e.g. number of community meetings held) rather than outcomes (e.g. communities committed to supporting patients). This has resulted in lack of evidence to demonstrate that ACSM activities can have an impact on key indicators (e.g. level of stigma, TB knowledge, case detection and treatment adherence).

The communication facilitator initiative offers huge potential to provide networking with those who understand communication at district level, but the team found that the initiative had been hastily implemented without adequate piloting and documentation of lessons learnt. While the experience with some communication facilitators provides optimism, other teams encountered frustration and confusion with regard to the role of communication facilitators. The geographical spread of 4-5 districts is over-ambitious, and the allocation of Rs 20,000 per district per year is clearly inadequate for the scope of work as currently described. In some extreme cases, states have decided to discontinue the initiative altogether, and some others never adopted the innovation in the first place.

While some aspects of TB detection and treatment are frequently covered in ACSM, the teams noted areas that until now have received less attention. There is a scarcity

of messages on prevention such as cough hygiene among TB patients, suspects and the general population. Little consideration is given to the known risk factor of smoking (the prevalence of tuberculosis is three times more among smokers).

Stigma and discrimination still remain one of the greatest barriers to case detection and treatment adherence. The teams found limited community-level interventions addressing misconceptions about the disease, its transmission and its treatment. Similarly, the teams found no examples of ACSM to address the endemic issue of 'shopping around for TB care' in the private sector for symptomatic relief.

There is a paucity of material for patient education, nuanced for different categories of treatment. Some patients interviewed by the JMM teams had little awareness of their disease or treatment duration. The requirements for enhanced counselling for DOTS and management of MDR-TB have not been defined in terms of information, styles and frequency for different categories of patients (new smear-positive, new smear-negative, re-treatment cases). There is very limited material addressing drug resistance. The challenge of co-messaging of TB and HIV requires careful oversight to minimize confusion and avoid reinforcing stigma.

Reviewing materials through a gender lens is not at present habitual. The JMM teams noted instances where men are more visibly portrayed; for example, the new patient booklet depicts double the number of males than females. IEC funding (and some schemes) based on population coverage creates disincentives to work in remote, sparsely populated areas, resulting in inequity in services and information.

Recommendations

1. *Engage professionals and/or partners to strengthen and lead ACSM strategic planning at the national level, support across the RNTCP network, and work closely with NRHM communication stakeholders*

    1.1 Modify the ACSM part of the planning format to focus on priorities; use output/outcome monitoring indicators. The state IEC officer and STO should appraise district ACSM action plans and CTD should appraise the ACSM action plan of the state programme implementation plans submitted annually, along with corresponding budget heads, to ensure it reflects state priorities.

    1.2 Consider alternatives to undertake district-level ACSM planning, implementation and monitoring (e.g. the new NGO scheme). DTOs and STSs are too overstretched to undertake this role.

2. *Concentrate on achieving universal awareness of the right to, and availability of, free TB treatment and care*

2.1 Strengthen efforts to raise the profile of RNTCP and work with partners to consistently communicate a limited number of core messages to target audiences, and to achieve universal awareness of the right to, and availability of, free TB treatment and care. Demonstrate the added value of ACSM by documenting achievements in TB control in India and communicate within the programme and outside for advocacy.

2.2 Take stock of, and utilize, good practice interventions, materials and emerging initiatives such as the new "National Partnership for TB Care and Control". The CTD should document ACSM best practices within the country. These should be evidence-based, e.g. provide concrete pre- and post-intervention data, and should be assessed from a scaleability perspective. Such evidence does not need to come from nationwide studies but from small-scale examination of how targeted interventions are changing awareness and behaviour. Disseminate these practices widely and present them at high-level meetings to promote cross-learning and replicability according to local needs.

2.3 Revive the National ACSM Advisory Committee and maximize its inputs by holding quarterly meetings and ensure attendance by at least one STO and DTO at these meetings. All key RNTCP staff at the national level, including the official in charge of IEC in NRHM (to ensure convergence with other health programmes), should be invited to the meeting and the minutes circulated to all relevant RNTCP officers. The composition of the advisory group to include representatives of patients, civil society and the private sector.

2.4 The communication facilitator initiative has potential. Assess current status and revise/clarify accordingly. Consider reducing the geographical area of work for communication facilitators from the current five or six districts to one district, while increasing the remuneration to a sum that will be attractive for a competent individual/organization to work with RNTCP. The communication facilitators' work should be focused on poor-performing districts and their role should be limited to the following specific tasks: (i) advise district RNTCP team on strategic ACSM action planning based on priority challenges; (ii) identify and liaise with key partners in the district who can support ACSM implementation; and (iii) monitor ad hoc activities (such as community meetings and patient-provider meetings) and provide feedback.

3) Enhance social mobilization and interpersonal communication

3.1 Actively promote RNTCP as a people's movement through social mobilization activities that aim to create demand, based on the

understanding of people's rights and entitlements. A model patients' charter should be developed as to the entitlements of the TB patients, which should be endorsed by the health system in each state.

3.2 Formal and informal groups should be involved at the village, block, *taluka*, district, state and national levels. These groups could be self-help groups, cured patients' groups and *panchayat* (village council) -level organizations. Political parties should be encouraged to endorse the control of TB in their agendas.

3.3 Proactively encourage NGOs with track record in community mobilization to apply for existing NGO schemes. Ensure that there is a mechanism to get feedback on how the new NGO scheme is working; this should include information on the knowledge of NGO about the scheme, user friendliness of the application forms, time required in processing applications and fund flow. The budget availability and schemes should be transparent and made available to all patient groups and PPM partners. Key NGOs could also be designated as community watchdogs to oversee budget development and spending of finances allocated for TB programme.

3.4 Prioritize interpersonal communication approaches at district level and below. Maximize the potential of cured patients as communicators.

3.5 Enhance provider communication targeted at different categories of patients so that the right person discusses the right message at the right time. All training of providers should include targeted, skills-based IPC/counselling. Guidance should be provided as to what type of messaging is needed for different categories of patients (new smear-positive, new smear-negative, re-treatment cases, MDR-TB).

3.6 Incorporate community-based patient monitoring of the quality of care in diagnosis and treatment (patient satisfaction surveys).

13. Human resource development

As was noted by the 2006 JMM, with the completion of the 100% population coverage and its expansion to implement all aspects of the Stop TB Strategy, RNTCP enters a new, more complex phase with regard to human resource development (HRD). The complexity relates to i) the need to maintain and further develop staff competencies and motivation to improve performance of existing staff, and ii) increasing the number of staff.

The RNTCP structure for capacity building for DOTS implementation has allowed the programme to expand to full coverage and to further improve 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".

HRD for DOTS implementation is well-reflected in the RNTCP guidelines. There is a separate HRD unit at the CTD; functions of the State TB cell, State TB Demonstration Centre, 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 IEC officer and accountant, district-level staff and PHI staff are clearly defined. Standardized material and schedules for initial training in DOTS in RNTCP, EQA TB/HIV and initial training for medical college staff, as well as schedules for retraining, have been developed. Work is ongoing to develop training materials for new initiatives, e.g. MDR-TB management, and a national consultant for HRD has just been recruited.

However, as with the performance of other components of the strategy, the performance in the implementation of HRD activities varies greatly among different states and districts. Most of the things observed during this JMM were also noticed during the 2006 JMM. The persisting weaknesses in the long-term management of HRD activities have not been addressed in a comprehensive way; these are now seriously threatening the gains made so far and are proving to be serious bottlenecks in expanding the management of MDR-TB.

Many of the weaknesses of the system with regard to competence of staff and staffing issues were observed during the previous three monitoring missions in 2000, 2003 and 2006, and pertinent recommendations were made to address these weaknesses. The implementation of those recommendations has, however, been slow, as has been pointed out earlier as well.

It needs to be recognized that many of the recommended improvements in the area of HRD are long-term activities. However, it has now become urgent that the overall staffing issues related to recruitment, performance, retention, reducing vacancies and rotation, as well as capacity building, are addressed in a considerably more strategic and comprehensive way by RNTCP as well as by departments and organizations responsible for overall workforce development. It is also essential that issues related to staffing and training are recognized as crucial by state- and district-level staff. This is, unfortunately, not the case in most places where HRD is seen merely as training, and training management most often in practice means organizing a few training courses. The RNTCP is not likely to progress further towards universal access well beyond the targets of 70% case detection and 85% treatment success unless the HRD-related issues are addressed in a major way. There seems to be a tendency of 'over-reliance' on the premise that the structure for capacity building exists, and thus insufficient attention is paid to the need to constantly monitor and improve the functioning of the structure/system.

Implementation of all components of the Stop TB Strategy poses major challenges to all aspects of HRD. This is particularly the case for management of MDR-TB. The same rigorous framework as 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, etc.) does not seem to have been followed in the preparation for the scale up of the management of MDR-TB.

Key overall challenges

- Programme expansion has outpaced Central- and state-level capacity to ensure quality of services.
- Staff shortages at Central and state level remain a major concern, which, with the scaling up of the management of MDR TB, will only get accentuated.
- There is no medium-long-term comprehensive strategic plan for all aspects of HRD for the implementation of all aspects of the Stop TB Strategy (Central and state). Current district- and state-level plans include training activities as per standard format. However, there is no evidence that these are prepared based on an analysis of data in the quarterly reports or other needs assessment.
- Compared with what was said by the 2006 JMM, more concerns have been raised this time about the low/poor performance of the contractual staff.

Challenges related to staffing

- There are vacancies, shortages of staff, high turnover and problems related to staff retention at all levels, in both RNTCP contractual staff positions and the general health system.

- Staff motivation is variable, and health system deficiencies are affecting motivation.
- Many staff at state- and district-levels have to perform multiple functions which add to staff being overburdened. There is no 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 increased following the recommendations of the 6th Pay Commission.
- Allowances for training differ between programmes (HIV/AIDS in particular).
- The incentive packages for staff working in tribal areas (recruitment and retention) are not sufficient.

Challenges related to training

- The managerial capacity at district and state levels (including for 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. Training activities are included in district and state plans; however, these are, in most cases, not linked to the needs based on the reporting system or following supervisory visits.
- The quality of training is suboptimal and is not routinely assessed, with poor adherence to recommended methodologies, schedules, batch size, ratio of facilitators to trainees, and limited evaluation.
- Supervision is not linked to follow-up training, or is not used for identification of retraining needs.
- Training for new initiatives such as MDR-TB (including availability of demonstration sites) is insufficient.

Recommendations

Many of the recommendations made by the 2006 JMM were aimed at improving the quality of HRD activities. These recommendations still remain valid. Those

recommendations are not being repeated in this chapter; however, they should be reviewed and taken into account together with what is being recommended here.

It is now even more urgent to give all aspects of HRD a higher priority within RNTCP and to implement the recommendations in a comprehensive way, particularly in the light of the planned scale up of the management of MDR-TB.

1. Strengthen management of HRD within RNTCP at Central level

1.1 Develop a medium-term strategic plan for all aspects of HRD (staffing and training for all components; quality and quantity) for the implementation of the Stop TB Strategy with subsequent annual implementation plans (all aspects listed below should be addressed by the plan).

1.2 Ensure coordination and integration of HRD activities for the implementation of all aspects of the Stop TB Strategy, with overall health workforce development and other initiatives such as the Public Health Foundation of India and the National Health Systems Resource Centre.

1.3 Establish 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. If this is not possible within a relatively short time frame, efforts to be made to contract staff as a short-term solution.

1.4 Ensure that the salaries of contractual staff are on par with the increases made in the 6th Pay Commission for other staff.

1.5 Develop a performance-based reward system for contractual staff.

1.6 Coordinate with NRHM for training, motivation and retention of ASHAs and auxiliary nurse midwives.

1.7 Ensure strengthening of the syllabi of the basic training institutions for the staff involved in the implementation of the Stop TB Strategy.

1.8 Strengthen human resources under the regular budget in CTD and at state level.

1.9 Strengthen the development of comprehensive packages for staff retention and motivation in remote and rural areas.

1.10 Strengthen competence development activities by:

- Improving the quality of training (adherence to recommended schedules, material methodologies, batch sizes, evaluations);

- Improving the management of training: timeliness of training of new staff, TB/HIV, retraining based on needs assessment, refresher training, use of supervisory visits and meetings for on-the-job training;
- Following up on the recommendations from the HRD workshop in Chennai in February 2008.

2. Strengthen capacity at state and district levels

2.1 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.

2.2 Increase regular staffing of the state TB cells and STDCs. As this may take time, the respective state governments may consider the contracting of staff as a short-term solution.

2.3 Strengthen all training activities (quality and quantity) at state and district levels.

2.4 Continue developing the management skills of state and district staff, particularly the capacity of supervisors to use programme data for action. This includes management training beyond the current standard TB training courses.

2.5 Consider refresher training of key staff at STDCs.

2.6 Reduce the often multiple assignments of DTOs and STOs.

3. Strengthen HRD for MDR-TB management

3.1 Determine (on review) the roles and functions of all staff categories for MDR-TB management at all levels.

3.2 Review and assess, in detail, the staffing needs of all categories based on their respective roles and functions and workload for the planned scale up of MDR-TB management at all levels.

3.3 Develop competency-based training materials for all staff categories.

3.4 Expand the structure for training, including the identification and training of master trainers beyond the traditional training-of-trainers methods, skills-based evaluation and follow-up.

3.5 Ensure availability of additional staff as a prerequisite for scaling up of MDR-TB at state level.

14. Financing

Financing tuberculosis control in India

The challenges of health financing in India are well-known. They stem from a long history of under-investment in the public health sector. In 2006, India spent just 1.0% of its total GDP on public health compared to an average of 2.0% for other lower-middle income countries in the world.[6] In terms of budget allocation, India allocated just 3.4% of the total government expenditure to health compared to an average of 8.3% in other lower-middle income countries. This issue has been recognized by successive governments as well as by a range of advisory bodies including the National Commission on Macroeconomics and Health (NCMH), which recommended that the country should increase its public expenditure on health to 3.0% of its GDP.[7] Accordingly, the government (2004-2009) pledged in its Common Minimum Programme (CMP) with its coalition partners to increase the spending on public health to at least 2-3% of GDP, which was to be achieved through increased spending in primary health and communicable disease control programmes.[8]

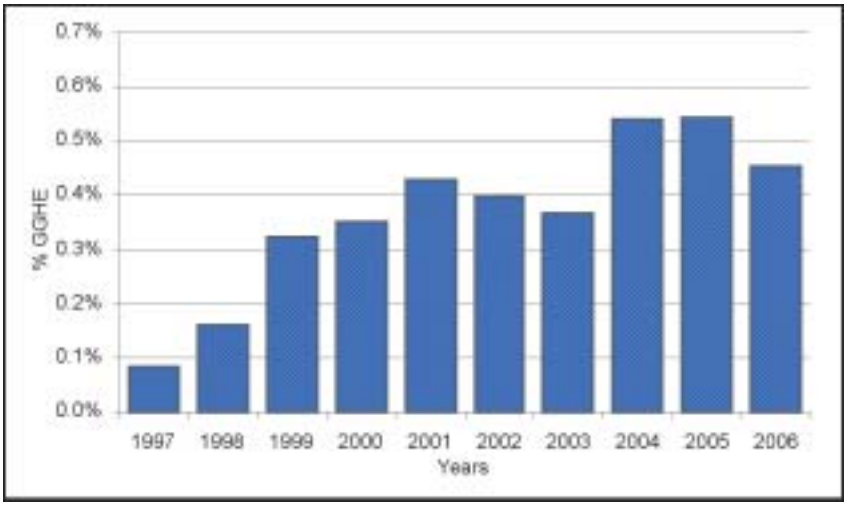
Recent Central budgets confirm a substantial increase in funding allocated for the public health sector, with a growth of 20% per annum over the five years from 2003/04 to 2008/09[9]. In addition, the National Rural Health Mission (NRHM) was launched in 2005 with the aim of carrying out the necessary architectural correction in the basic health care delivery system to enable it to manage more effectively the increased allocations promised under the CMP. The NRHM's plan includes increasing expenditure on health, reducing regional imbalances in the primary health centre infrastructure, pooling resources, integration of organizational structures, optimization of manpower, decentralization and district management of health programmes. Generally speaking, the strong increase in health funding being channelled through NRHM represents an opportunity to source domestic funds for the growing financial needs of the TB control programme.

The RNTCP was launched as a Centrally-sponsored scheme in 1997 and national coverage was achieved in 2006. Much of the scale up of the TB control programme was, therefore, implemented prior to the CMP or to NRHM. Fig. 16 shows the history of RNTCP expenditure as a proportion of total general government health expenditure. This period covers the scale up phase, and so, the RNTCP budget was

[6] http://www.who.int/nha/country/en/index.html
[7] http://mohfw.nic.in/reports/reports/Report_on_NCMH/ReportoftheNationalCommission.pdf
[8] http://pmindia.nic.in/cmp.pdf
[9] Union budget revenue and capital expenditures allocated to Health & Family Welfare, AYUSH and Health Research.

generally increasing as a proportion of the total public health spending due to the strong growth in the number of patients. Recent years have seen this proportion fall slightly despite the continued growth in the RNTCP expenditure. This is because there has been a stronger spending growth in the public health services outside of RNTCP, reflecting in part the government's commitment to increase spending on primary health infrastructure and services.

Fig. 16: RNTCP expenditure as a proportion of general government expenditure on health[10]



Funding for the scale up of RNTCP was planned under the wider umbrella of the government's 10th Five Year Plan from 2001/02-2005/06 and was delivered through a system of specially-created state and district TB control 'societies'. As part of the implementation of NRHM, the 'societies' created for most of the Centrally-sponsored schemes, including RNTCP, have been merged into the integrated NRHM 'health societies' although funds for TB control are maintained in a separate account. The annual funding cycle for RNTCP is now coordinated centrally between CTD and NRHM under the wider umbrella of the 11th Five Year Plan (2006/07-2010/11) as shown in the table below. This Plan covers Phase II of RNTCP, which has been approved by the Cabinet Committee on Economic Affairs, and involves a total outlay of Rs 1447 crore (approximately US$ 333 million).[11] The year-wise allocations proposed by the Indian Planning Commission increase by 58% in nominal (non-inflation-adjusted) terms from Rs 202.2 crore in 2006/07 to Rs 320 crore in 2011/12[12].

[10] Goodchild M, Sahu S, Wares F, Dewan P, Floyd K & Chauhan LS. *The economic impact of scaling up tuberculosis control in India*. Draft working paper. New Delhi. WHO, 2009.
[11] Conversion based on an average exchange rate of 43.39 INR/USD http://www.federalreserve.gov/releases/g5a/current/
[12] Ministry of Health & Family Welfare (2009). *RNTCP status report 2009*, Government of India, New Delhi.

Table 4: Allocation by Planning Commission and actual expenditures by RNTCP

Financial year	Actual Allocation (Rs Crore)	RNTCP Expenditure (Rs Crore)	Budget Utilization % Allocation
2006-07	202.2	221.0	109%
2007-08	267.0	262.1	98%
2008-09	275.0	279.9	102%
2009-10	285.0	n/a	n/a
2010-11	300.0	n/a	n/a
2011-12	320.0	n/a	n/a

In terms of funding sources, Phase II involves a total outlay of US$ 256.9 million which includes the World Bank credit of US$ 170 million and commodity assistance of anti-TB drugs from the Department for International Development (DFID) through WHO for US$ 62.5 million and the balance by the Government of India. Additionally, the Global Fund Rounds 1, 2, 4 and 6 support RNTCP in seven states, while the Rolling Continuation Channel (RCC) project proposal, which seeks to extend the Global Fund support until 2014/15, has recently been approved. Phase II includes a planned reduction in some external financing sources, and so it is important to continue preparing for increased GoI financing of first-line drugs to maintain programme continuity. Similarly, current commitments do not yet encompass the financial resources required to meet the planned scale up of MDR-TB services. Therefore, it is important to continue to review 2010-2015 financial requirements and commitments, including both of GoI and external sources, to ensure that sufficient resources are available for the expected dramatic increase in costs for the planned MDR-TB management scale up and for meeting the 2015 TB-related targets.

The financial planning and reporting framework of RNTCP is often regarded as a 'leader' in India's public health sector and there is good coordination between CTD and NRHM during the annual planning cycle. However, the state and district programmes need to engage themselves more with their local NRHM counterparts to maintain TB as a priority. The planning cycle begins with the development of district annual action plans based on a set of national norms (unit costs of RNTCP activities) meant to act as guidelines for local needs-based planning. These district annual action plans are consolidated into state annual action plans, which are then submitted to CTD for inclusion in the state NRHM project implementation plan. Within this process, it has been noted that some states and districts have less local planning capacity than others as reflected in the budget approval rates and expenditure realizations. The CTD should, therefore, provide further technical support to low-

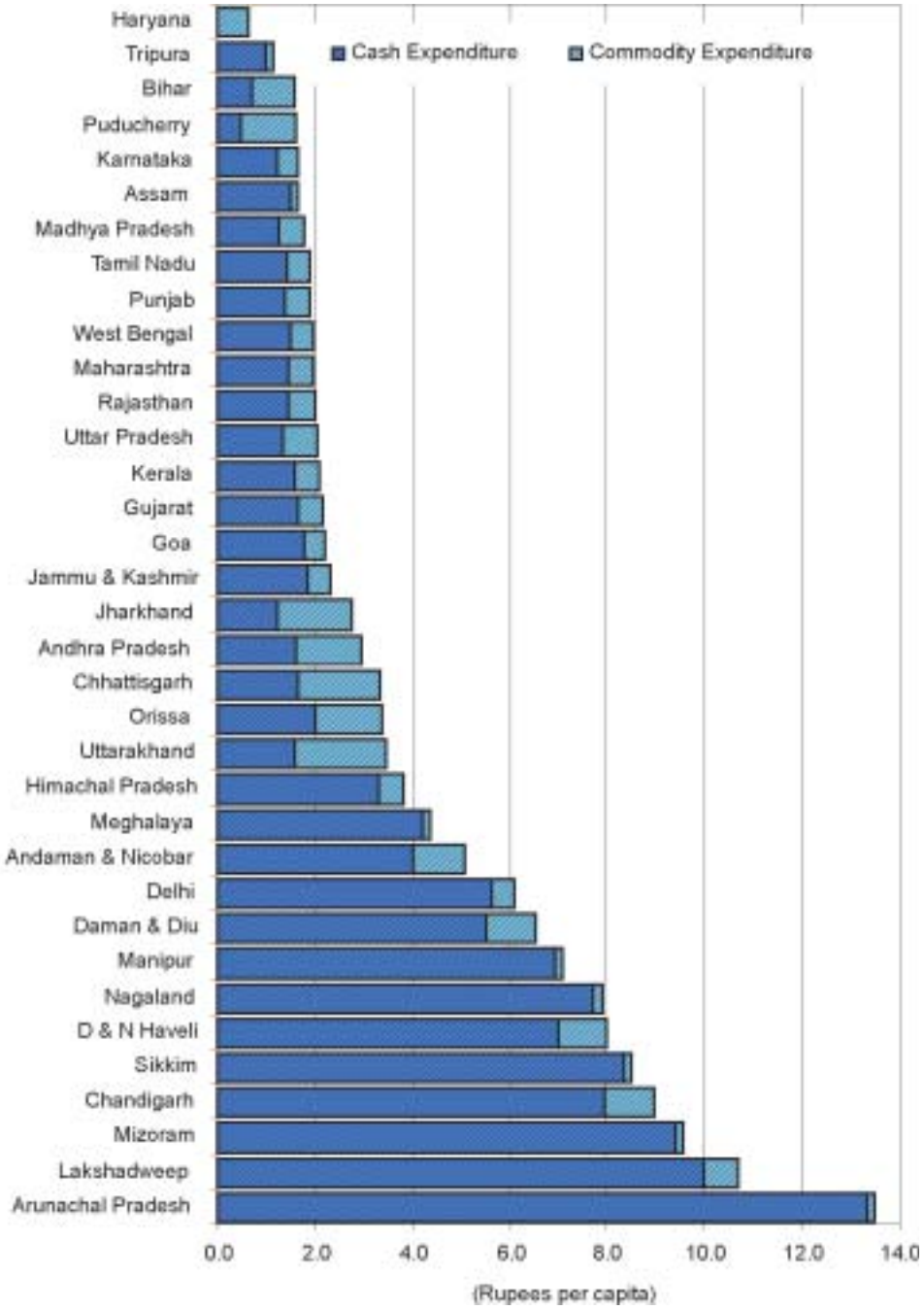
spending state programmes. It was also noted that some of the entitlements of the staff (e.g. honorariums, lodging rates, travel allowances) required periodic review to maintain parity with those allowed to staff in other public programmes.

The approved allocation for each state TB programme is determined by CTD and NHRM on the basis of each state's annual action plan, past expenditure, and in accordance with the annual allocation for RNTCP. The Finance Division of MoH&FW disburses each state's allocation bi-annually in April-May and October-November. During the 2006 JMM, it was noted that state disbursements tend to be linked more to past expenditures than to state annual action plans, which raised the potential to place weaker states in a vicious cycle of under-disbursement due to past under-spending. While the fund flow appears to have improved since 2005, this concern was nonetheless echoed by participants of the 2009 JMM. In addition, it was felt that the programme could explore the possibility of further decentralization in some areas.

The RNTCP expenditure for 2008/09 is reported to be Rs 279.9 crore compared to the Planning Commission's approved allocation of Rs 275 crore. The data for 2006/07-2008/09 indicates that the budget utilization by RNTCP as a whole has typically been high. However, there is a high degree of variation in budget utilization across states and districts, reflecting different levels of local programme capacity in planning, budgeting and expenditure realization. This is illustrated in Fig. 17 which shows the RNTCP expenditure on a per capita basis by each state in 2007/08. The 10 highest-spending state TB programmes spent an average of Rs 8.7 per capita compared to an average of Rs 1.6 per capita in the 10 lowest-spending state TB programmes (i.e. the best-performing states were able to spend roughly five times more on a per capita basis). Although some of this variation may also reflect economies of scale in states with larger populations, the findings nonetheless reinforce the need to further support budgeting and expenditure practices in low-performing states.

Beyond RNTCP there has been strong growth in the range of financing mechanisms potentially available to support state- and district-level programme activites - as well as their patients. This includes the NRHM flexible pool funds, social welfare schemes, Indian Public Health Standards, public and private health insurance and other locally-piloted financing innovations. In particular, the NRHM flexible pool funds can help address funding gaps in local programme priority investments and non-recurrent expenditures. The RNTCP, at all levels, should seek to utilize new financing mechanisms to increase investment and expenditure on TB control.

Fig. 17: RNTCP expenditure per capita by state and Union Territory, 2007-2008



Recommendations

1. Leverage the growing GoI commitment to health financing to meet the increasing financial needs of the TB programme.

2. Review the financial requirements and commitments for 2010-2015, including those of GoI and external sources, to ensure that sufficient funds are available for the expected substantial increase in costs for the planned MDR-TB management scale up and for meeting the 2015 TB-related MDG targets.

3. The RNTCP, at all levels, should utilize financing and service delivery mechanisms such as the NRHM flexible pool funds, social welfare schemes, Indian Public Health Standards, health insurance mechanisms and other financing innovations. In particular, maintaining priority for TB within NRHM would help address staffing, innovation, equipment and infrastructure needs.

4. Support needs-based planning and budgeting of TB control activities, including through the routine monitoring of low-performing states and districts. Strengthen monitoring of the fund flow and expenditures against state and district action plans and performances.

5. Continue to review budget norms, particularly those relating to staff and human resource needs, to maintain a level of parity with wider public health sector developments.

15. Drug regulation, procurement and supply

The drug management system under RNTCP is functioning well. The main inventory management guidelines and principles, including the first-expiry-first-out (FEFO) policy, are generally followed by pharmacists and staff in the states visited, with documentation normally kept in good order and matching the existing supplies in stock. This explains that no major stock-outs were noticed and an adequate supply of patient-wise boxes (PWBs) with sufficient shelf-life found in the locations visited. However, in the case of loose drugs such as streptomycin 750 mg, expired stocks were found in some states while for rifampicin 150 mg, shortages and minor stock-outs were noticed at some of the sites. This will require strengthening of inventory management at various levels and reducing the procurement lead times.

The accumulation of stocks of loose drugs, including streptomycin, and the expiry of some of the drugs mentioned above in various storage sites, are partly due to the success of the RNTCP DOTS strategy. Despite the efforts of RNTCP to ensure utilization of these loose drugs by reconstituting them into PWBs and prolongation pouches as recommended by JMM 2006, some expiring stocks will be written off as per existing procedures.

The Drug and Logistics Cell at CTD has been supported, through technical assistance from WHO, by a private agency responsible for drug inventory management and drug distribution under RNTCP. The sustainability of this function is a key element for the optimal functioning of the drug management system, especially in view of the new challenges related to drug management and logistics of second-line drugs, and should, therefore, be guaranteed through either continued technical assistance or increased support from GoI funds.

The drug storage conditions vary widely from location to location in terms of space, facilities and equipment available, although space constraints and lack of adequate temperature control were almost universally observed. Both first- and second-line drugs were found at temperatures above 40 degrees Celsius. Temperature control measures such as false ceilings and fans are available only at some locations. The storage requirements for second-line drugs demand that these are kept below 25 degrees Celsius, which would require air-conditioning in most of the settings in India. Similarly, the introduction of Category IV services for MDR-TB have not been comprehensively planned for at state, district and TU levels, i.e. neither sufficient space nor human resources have been made available for dealing with the increased workload resulting from managing storage, packaging and distribution of second-line drugs. In addition, the space constraints identified during the last JMM for government

medical stores depots (GMSDs) still remain, despite the infrastructural improvement undertaken, a hindrance to the smooth functioning of the anti-TB drug supply chain.

Lack of adequate training of concerned staff was identified by some JMM teams as one of the causes of the logistics shortcomings in the programme. The importance of CTD continuously training state and district staff to enable them to conduct further training on drug management issues for subdistrict staff was, therefore, highlighted. The specific aspects related to drug management of second-line drugs, i.e. detailed guidelines on logistics management, constitution of PWBs for intensive and continuation phases, stock reporting forms, etc., should be incorporated into the RNTCP state and district drug store training modules.

The widespread availability of both first- and second-line anti-TB drugs over the counter at most pharmacies and drugs stores was highlighted by all teams as a matter of critical concern for likely repercussions in further aggravating the emergence of drug resistance in India. A sub-team of the JMM met with the Drug Controller General of India (DCGI) in New Delhi to discuss ways to address the issue of restricting the widespread availability of anti-TB drugs over the counter. The DCGI reiterated his commitment to the action points agreed during a recent meeting with RNTCP, which include convening a meeting with the Drug Controllers of the states to increase awareness of the crucial importance of better enforcement of the Schedule H regulations of the government for anti-TB drugs in order to improve treatment outcomes and prevent further development of M/XDR-TB in the country. In addition, DCGI informed that an amendment to the Drugs & Cosmetics Act (Amendment 26 B) had recently been passed by Parliament, which enables the DCGI to 'regulate or restrict the manufacture, sale or distribution' of a drug in the event 'of an emergency arising due to an epidemic or natural calamity'. The enforcement of this amendment would further enhance the capacity of DCGI to restrict the availability of anti-TB drugs over the counter. In addition, self-regulation and market-based approaches will also be considered. The DCGI also suggested that WHO may organize a meeting of both first- and second-line anti-TB drug manufacturers to increase awareness about the WHO prequalification process in order to enable more companies to apply for empanelment, thereby increasing the base of WHO prequalified suppliers.

The procurement methods and the quality assurance standards utilized for the procurement of anti-TB drugs were discussed during the JMM consultations held in New Delhi. While the commitment given by GoI in 2009 to procure first-line anti-TB drugs only from manufacturers whose sites had been prequalified by WHO was appreciated as a positive step towards wider availability of the highest quality anti-TB drugs, further work was required with concerned donors and technical partners for harmonization on stringent quality assurance standards for both first- and second-line anti-TB drugs as well as prequalification by WHO of suppliers and products.

The sub-team of the JMM was informed of the concern of the programme for sustainability beyond 2010 of the procurement of first-line anti-TB drugs for 500 million people, which is currently being done with financial support from DFID, and this mechanism provides an alternative supply chain for anti-TB drugs. Until the government's Empowered Procurement Wing (EPW) takes over the procurement of health supplies for MoH&FW, dependency on a single procurement mechanism for the supply of anti-TB drugs should be avoided and, if possible, the current dual supply structure should be maintained in order to reduce the risk of disruption of supplies.

The EPW of MoH&FW has developed a web-based Procurement Management Information System (PROMIS) to streamline the procurement and inventory management systems. The software addresses through its various modules (Forecasting, Planning, Bid Processing, Bid Evaluation, Supply Orders, Quality Assurance, Stocks, Inter-warehouse Transfers, Bills & Invoices, etc.) the main components of the internationally-recommended best practices in procurement and logistics. The RNTCP has been selected for the pilot testing of the software and the commencement of live data entry has started from April 2009.

Recommendations

1. GoI and partners to urgently work, with all relevant national and state authorities, to strengthen, expand and enforce regulations related to the sale of first- and second-line anti-TB drugs without prescription (over the counter) and other potential forms of misuse of drugs to improve treatment outcomes and prevent further emergence of drug resistance. This includes better implementation of the provisions under "Schedule-H" of the Indian drug regulations via the state-level drug controllers, and consideration of the use of the provisions under Clause 26B of the Drugs & Cosmetics Act. In addition, consider promotion of self-regulation, focused IEC campaigns to educate patients as well as drug retailers and other market-based approaches.

2. GoI to ensure harmonization of stringent quality assurance standards for procurement (including WHO prequalification) for both first- and second-line anti-TB drugs.

3. RNTCP to continue preparations for increased financing of first-line anti-TB drugs by GoI, given the planned reduction in external financing, continue reinforcement of the procurement processes so that timely procurement of high-quality drugs is assured, and continue ongoing discussions regarding maintenance of a dual supply structure.

4. The Central TB Division to revise RNTCP state and district drug store SOP manual to incorporate the requirement for air-conditioning, storage space and drug logistics guidelines for second-line drugs.

5. Provision of necessary funds for addressing the required improvements (air-conditioning and infrastructure improvement) should be coordinated with other drug management authorities at Central and state levels, including accessing funding available under NRHM.

6. Development by RNTCP of a scorecard for various aspects of programme implementation, including inventory management at state and district levels, for continuous monitoring of logistics functions. The scorecard should contain information about stock position, expiry, storage conditions, transport arrangements, etc.

7. CTD to continue quarterly analysis of drug stock levels in collaboration with stake holders, and include in it the second line anti-TB drugs, whose stocks need to be closely monitored due to shorter shelf life and existing uncertainties in the rate of increase of notification of MDR-TB patients.

8. GoI to consider additional funding for increasing the available space at the various GMSDs in coordination with CTD.

9. GoI to financially support RNTCP drug logistics management at Central level to ensure sustainability and reduce dependence on external funding.

10. CTD to strengthen the current implementation of drugs logistics training by developing and implementing a training plan which includes capacity building by CTD of states to undertake training (both initial and retraining/update training) for all concerned staff at district and subdistrict levels.

16. Equity issues, poverty and other determinants of TB

Poverty, equity, gender and social issues

Tuberculosis is a disease of poverty. In a country such as India, with marked social and economic disparities, poor and deprived populations are not only disproportionately affected by disease and death but also have to face greater barriers to access health care services. A comparison of basic health indicators such as infant and child mortality rates according to social class and geography clearly show that the health indicators of the general population are better than of those belonging to Scheduled Castes and Scheduled Tribes, while urban populations in general have better health indicators than those of rural populations. A further disaggregation, however, shows that health indicators among the urban slum populations are worse than those of people living in rural areas.

These disparities seem uneven among TB patients as well. A comparison of key TB programme indicators among people living in 80 tribal districts and 140 districts identified by India's Planning Commission as having mostly poor and disadvantaged populations, shows that, while case detection among tribal populations is higher than that among general populations (82% versus 72%), it is lower (66%) in districts categorized as poor and disadvantaged.

The RNTCP has been making efforts to improve access to TB care for the disadvantaged groups through decentralized and patient-friendly DOTS services. The programme has developed specific strategies and provides increased resources for the disadvantaged groups such as tribal and remote rural populations, the urban poor, migrants and prison inmates. Some states like Gujarat, Puducherry and Tamil Nadu have developed linkages with social welfare schemes and support systems under which patients belonging to Scheduled Castes and Scheduled Tribes and other disadvantaged categories are provided financial and material support.

The mission observed that the Tribal Action Plan was not implemented in some states and was partially implemented in others. Many senior RNTCP staff were not aware of the social welfare schemes from which TB patients could benefit. Marginalized groups had problems accessing quality TB care, beginning with sputum collection. Suspected TB patients from remote rural areas, backward districts and hamlets on the outskirts of villages often encountered delays in diagnosis. Awareness about TB symptoms and free TB care at government facilities was particularly low among poorer patients. Low awareness and high levels of social stigma and high out-of-pocket expenditure at the private sector health facilities often led to delayed

presentations. Despite a decade of DOTS implementation and efforts to spread awareness about TB around it, social stigma towards the disease is still widespread and the worst affected are younger women. Instances of the very poor and the destitute getting uneven care at the hands of health care providers were noticed. Problems of continuity of TB care for migrant populations were observed in almost all settings.

Recommendations

1. Assign focal persons at the Central and state levels to support and monitor equity and social issues and review the effectiveness of existing strategies for TB care and control among urban slums, migrants and tribal and other disadvantaged groups.

2. Ensure dissemination and use of relevant revised schemes such as systems for collection and transport of sputum samples from remote, isolated and scattered settings.

3. Develop, disseminate and help implement a guidance note elaborating steps to establish linkages with existing social welfare schemes in order to enhance social support to TB patients among disadvantaged groups. This should also include sensitization of care providers on issues related to equity, gender, social stigma and special needs of the very poor and the destitute.

4. Assist in building greater community ownership by linkages with community-based organizations such as women's groups, village health committees, *panchayats* (village councils), *etc.*

5. Identify and engage civil society groups to improve programme performance and facilitate linkages with social welfare schemes and other health programmes to help address social determinants of health.

6. Address the problems faced in providing TB care to migrant workers considering:

    6.1 alternative approaches such as home-based care with a family DOT provider or self-administered non-rifampicin-containing treatment regimens for patients who cannot access DOT centres;

    6.2 engagement of employers of contract workers to ensure support to migratory workers on TB treatment;

    6.3 strengthening of the referral and feedback systems across districts and states on the lines used for managing patients presenting to medical colleges.

7. In order to identify and implement innovative solutions to effectively reach vulnerable populations, especially migrants, daily wage workers and women:

   7.1 develop communication strategies to address vulnerable groups, empower them with information and influence their health-seeking behaviour;

   7.2 try out innovative solutions to reduce default, especially among migrants from non-bordering states;

   7.3 commission social research on patients' health care-seeking behaviour and barriers to access health services and TB care;

   7.4 develop model questions for future household-based studies in India for more disaggregated data on social groups.

17. Operational research

The RNTCP set for itself a target to detect 70% of all infectious cases of tuberculosis and to cure at least 85% of them. In order to achieve this target, RNTCP adopted many of the global scientific and operational guidelines.

Most of the states in India have achieved this target and attempts are being to made to improve the performance in other states. The RNTCP has emphasized that the programme should not limit itself to 70% case detection but should aim higher to detect and cure all TB cases in the country.

During the implementation of the programme and during the internal and external evaluations, many constraints and challenges to sustain the progress were identified. In order to find solutions, RNTCP encouraged operational research (OR) within the programme to generate more information and evidence to effect necessary changes in its policies and management practices to make TB control more effective and sustainable.

In 2005, RNTCP identified the priority areas for operational research to be undertaken at various levels to achieve the wider objectives of improving DOT services to make them more patient-friendly, ensuring that treatment is directly observed, and increasing case detection of smear-positive cases. In 2006, the JMM reviewed the progress of the programme and pointed out that though there was an increased awareness and preparedness at the Central level for OR, the capacities of the states were inadequate to carry out this activity. The JMM observed that there were not many examples to suggest that the states were using OR to evaluate solutions to local programme challenges. The capacity to carry out OR was limited to a few national institutes and medical colleges. Practically no OR was being carried out at state level where funds remained underutilized.

During the current review, it was noted that much progress had been made since the last review. This included the completion of a number of OR activities on initial default (Andhra Pradesh State TB Cell), risk factors for default among re-treatment cases and TB-HIV activities (CTD). More than eight proposals funded under RNTCP were in progress. In collaboration with FIND and WHO, RNTCP is evaluating newer diagnostics in four sites. The CTD has recently issued national guidelines for operational research which were developed in 2008 and reviewed by an external consultant. In these guidelines, a clear-cut process for review and funding has been established for proposals to be submitted by individuals and institutions. The research agenda has listed the priority areas of OR such as: interventions to improve case detection and diagnosis; improve microscopy; treatment outcomes; TB/HIV; drug-resistant TB;

engagement of all health care providers; and community access to TB services. As suggested by the 2006 JMM, concept notes on some of the RNTCP priority OR topics have been prepared to guide the development of high-quality proposals that effectively address the problems in the programme.

However, many of the weaknesses observed by the JMM 2006 still remain unresolved. There are long delays in the review, revision, re-submission and approval of proposals that have already been submitted. Since 2006, committees at the national, zonal and state levels were formed to assist in the planning, approval and monitoring of OR activities. These tiered OR committees, however, have not been successful in their assigned tasks. OR funds remain under-utilized, only a few OR proposals have been submitted, and only a small number of the reviewed proposals was judged to be of adequate quality and priority to warrant funding support. The national-level OR committee has not met regularly and has not engaged itself with the issue of OR capacity building. Many of the recommendations of the previous JMM such as building OR capacity, expanding the use of CTD-commissioned OR for priority topics and making states responsible for the annual generation of at least one OR activity, have not been implemented.

Recommendations

While at the national level there is substantial commitment to OR and a strong tradition of translating research findings into improved policies and procedures, establishment of a dedicated team to coordinate and build capacity for OR is much needed. The latest OR guidelines offer excellent policy solutions that may address issues to some extent, but their implementation will require greater human resources than have currently been committed. In order to further improve OR, the JMM recommends the following:

1. *Strengthen capacity for operational research at national and state levels*

   1.1 RNTCP should engage a full-time expert for OR capacity building and coordination of critical centrally-commissioned research activities.

   1.2 Consider transfer of functions of the CTD Research Cell other than planning, supervision and approvals, to a suitable research institute.

   1.3 The RNTCP consultants' capacity should be enhanced so as to enable them to assist states to undertake at least one significant OR activity annually under the leadership of STO/DTO and STDC.

   1.4 Develop regular OR capacity-building workshops for programme managers and other institutional partners which may be undertaken in collaboration with research institutes and technical agencies.

2. *Promote and recruit a wider group of researchers to conduct TB OR*

2.1 As envisaged in the 2009 OR guidelines, regularly disseminate nationwide the OR research agenda and guidelines to all medical college departments dealing with microbiology, public health, community medicine, chest, medicine and paediatrics, and to the newly-formed public health institutions.

2.2 Establish a fast-track mechanism at the Central level in order to initiate high priority proposals without delay.

3. *Increase publicly-disseminated knowledge of OR activities*

3.1 Post and update on the RNTCP website a list of the approved proposals, the sites at which they are being carried out, and the summary outcomes of completed studies so that OR activities can be disseminated irrespective of the success or failure of the researcher in getting the research published in a peer-reviewed journal. The study protocol itself can be placed on the web so that other sites using the same protocol can carry out similar studies if necessary. This will encourage more sites to get involved in OR.

4. *Prioritized the following research activities as critical for the TB programme to be completed within the next two years*

4.1 Although the research agenda has detailed more than 60 OR studies that are relevant for the programme, the mission likes to highlight the following priority studies to be commissioned by CTD and completed as soon as possible:

4.1.1 Health-seeking behaviour and reasons for TB diagnostic delay in vulnerable populations, including tribal communities and urban slum dwellers.

4.1.2 A prospective, community-based, long-term cohort study of patients registered and treated under RNTCP, evaluating multiple key treatment-related questions that have been raised by the programme.

4.1.3 Source and treatment history of re-treatment patients, including those registered as smear-negative 'Others'.

4.1.4 Risk factors for second-line anti-TB drugs resistance among patients with MDR-TB, and association with RNTCP Category IV treatment response.

Annexes

Annex 1 - List of participants

Joint Monitoring Mission, RNTCP
15-28 April 2009

Participant	Agency	Contact details
Catharina Lambregts van Weezenbeek	Green Light Committee	KNCV Tuberculosis Foundation P.O. Box 146, 2501 CC The Hague The Netherlands Email: lambregtsk@kncvtbc.nl
Emanuele Capobianco	World Bank	1818 H Street NW Washington DC Email: ecapobianco@worldbank.org
Soren Thybo	World Bank	1818 H Street NW Washington DC Email: sthybo@dadlnet.dk
Anne Bossuyt	World Bank	70, Lodi Road New Delhi 110 003 Email; abossuyt@worldbank.org
Victoria Francis	World Bank	Health Communication Specialist 1818 H Street NW Washington DC Email: victoria.francis@blueyonder.co.uk
Robin Mardeusz	USAID	Health Development Officer U. S. Embassy Chanakyapuri, New Delhi 110 021 Email: rmardeusz@usaid.gov
Sangeeta Kaul	USAID	U. S. Embassy Chanakyapuri, New Delhi 110 021 Email: skaul@usaid.gov
Susan Bacheller	USAID	U.S. Agency for International Development Ronald Reagan Building Washington, D.C. 20523-1000 Email: sbacheller4@usaid.gov
Gavin MacGregor Skinner	USAID	Senior Laboratory Advisor U.S. Agency for International Development Ronald Reagan Building Washington, D.C. 20523-1000 Email: gmacgregor-skinner@usaid.gov
Billy Stewart	Dept. for Int. Development (DFID)	Senior Health Adviser B-28, Tara Crescent Qutab Institutional Area New Delhi 110 016 Email:billy-stewart@dfid.gov.uk

Participant	Agency	Contact details
Arundhati Roy Choudhury	Dept. for Int. Development (DFID)	B-28, Tara Crescent Qutab Institutional Area New Delhi 110 016 Email: A-Choudhury@dfid.gov.uk
Sabina Bindra Barnes	Dept. for Int. Development (DFID)	Human Development Adviser B-28, Tara Crescent Qutab Institutional Area New Delhi 110 016 Email: s-barnes@dfid.gov.uk
Ellora Guhathakurta	Dept. for Int. Development (DFID)	Programme Officer B-28 Tara Crescent Qutab Institutional Area New Delhi 110 016 Email: guhathakurta@dfid.gov.uk
Annick Manuel	The Global Fund	Senior Technical Officer – Performance Evaluation South & West Asia Chemin de Blandonnet 81214 Vernier, Geneva Email: Annick.Manuel@TheGlobalFund.org
Jeffrey Scott Morey	The Global Fund	Fund Portfolio Manager South & West Asia Chemin de Blandonnet 81214 Vernier, Geneva Email: jeffrey.morey@theglobalfund.org
Guy Stallworthy	The Bill & Melinda Gates Foundation	Senior Programme Officer PO Box 23350 Seattle, WA 98102 Email: guy.stallworthy@gatesfoundation.org
Patrick Moonan	Centers for Disease Control (CDC)	Senior Epidemiologist U.S. Centers for Disease ControlAtlanta, GA, USA Email: pmoonan@cdc.gov
Nigorsilton Mouzafarova	Global TB Drug Facility	Technical Officer (GDF) WHO Regional Office for South-East Asia, World Health House, I P Estate, Mahatma Gandhi Marg New Delhi 110 002
Young-Ae Chu	Stop TB Partnership	20 Avenue Appia1211 Geneva 27 Switzerland Email: chuy@who.int

Participant	Agency	Contact details
Guy-Patrick Massoloka	Stop TB Partnership	20 Avenue Appia1211 Geneva 27 Switzerland Email: guypatrickm@yahoo.com
C N Paramasivan	Foundation for Innovative New Diagnostics (FIND)	Head of TB Laboratory Support, 71 Avenue Louis-Casaï P.O. Box 93, 1216 Cointrin - Geneva Switzerland E-mail: cn.paramasivan@finddiagnostics.org
Chen-Yuan Chiang	The Union	International Union Against Tuberculosis and Lung Disease 68, Boulevard Saint-Michel, 75006 Paris, France Email; cychiang@theunion.org
Rohit Sarin	DOTS-Plus Committee	AMS & HoD, TB Control, LRS Institute of TB & Respiratory Diseases, New Delhi 110 030 Email: drsarin@yahoo.com
Selvakumar N	National Lab Committee	Tuberculosis Research Centre Indian Council of Medical Research Mayor V R Ramanathan Road Chetput, Chennai 600 031 Email: selvakumarn@trcchennai.in
K. K. Banik	Indian Medical Association	NWG Member IMA-GFATM RNTCP Project 7A, Kalimohan Banerjee Lane Kolkata 700 025 Email: Banik_kajal@yahoo.co.in
Thomas Abraham	National Tuberculosis Consortium	Technical Advisor, GLRA-India 4 Gajapati Street, Shenoy Nagar, Chennai 600 030 Email: thambu49@gmail.com
N. Somshekar	National Tuberculosis Institute	TB Specialist, No. 8, Avalon, Bellary Road, Bangalore 560 003 Email: somu_dr@rediffmail.com
N. K. Sethi	Planning Commission	Senior Adviser (Health) Parliament Street, New Delhi 110 001 Email: nk.seth@nic.in
Nalini Krishnan	Indian Coalition Against TB	Director, Projects REACH No.9/5, State Bank Street, II Floor, Mount Road Chennai - 600 002 Email: nalinikrishnan@gmail.com

Participant	Agency	Contact details
Rupak Singla	LRS Institute of Tuberculosis and Respiratory Diseases	Head, Deptt. of TB & Respiratory Diseases, LRS Institute of TB & Respiratory Diseases, New Delhi 110 030 Email: drrupaksingla@yahoo.com
Aleyamma Thomas	Tuberculosis Research Centre	Dy. Director (Sr Gr) Indian Council of Medical Research Mayor V R Ramanathan Road Chetput, Chennai 600 031 Email: aleyammat@trcchennai.in
P. R. Narayanan	REACH	Former Director, Tuberculosis Research Centre, Old 2, New 7, Deivasigamani Road, Royepettah, Chennai 600 014 Email: prnarayanan@gmail.com
L. P. Singh	Country Coordinating Mechanism (CCM)	Professor, IIHMR, 1, Prabhu Dayal Marg, Sanganer Airport, Jaipur - 302011. Email: lps@iihmr.org
Bhavana Mukhopadhyay	National ACSM Advisory Group	Voluntary Health Association of India (VHAI), B-40, Qutab Institutional Area, New Delhi 110 016 Email: hpdcu@yahoo.co.in
K. R. John	Zonal Task Force	Professor, Deptt of DOTS & Community Health, CMC Hospital, Vellore 632 002 Email: mony@cmcvellore.ac.in
Rahul Thakur	National AIDS Control Organisation (NACO)	Chandralok Building, 36 Janpath, New Delhi 110 001 Email: drrahulthakur@gmail.com
Vinay Gulati	National Task Force	Asstt Professor, Medicine All India Institute of Medical Sciences Ansari Nagar New Delhi 110 016 Email: drvinaygulati@gmail.com
Satish Kaipilyawar	PATH	Project Director, India Country Project, PATH, 2nd Floor, State Immunization Complex, Directorate of Health, Sultan Bazar, Hyderabad Email: SKaipilyawar@path.org
Sai Babu	RNTCP	State TB Officer, Andhra Pradesh, O/o. Directorate of Health, Sultan Bazar, Koti, Hyderabad Email: stoap@rntcp.org

Participant	Agency	Contact details
P Saxena	RNTCP	Chief Medical Officer (TB), Central TB Division, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi 110 011 Email: saxenap@rntcp.org
Devesh Gupta	RNTCP	Chief Medical Officer (NFSG), Central TB Division, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi 110 011 Email: guptadev@rntcp.org
Diana Weil	Stop TB Department	WHO-HQ 20 Avenue Appia 1211 Geneva 27 Switzerland Email: weild@who.int
Malgosia Grzemska	Stop TB Department	WHO-HQ 20 Avenue Appia 1211 Geneva 27 Switzerland Email: grzemskam@who.int
Mukund Uplekar	Stop TB Department	WHO-HQ 20 Avenue Appia 1211 Geneva 27 Switzerland Email: uplekarm@who.int
Haileyesus Getahun	Stop TB Department	WHO-HQ 20 Avenue Appia 1211 Geneva 27 Switzerland Email: getahunh@who.int
Karin Bergstrom	Stop TB Department	WHO-HQ 20 Avenue Appia 1211 Geneva 27 Switzerland Email: bergstromk@who.int
W Jakubowiak	Stop TB Department	WHO-HQ 20 Avenue Appia 1211 Geneva 27 Switzerland jakubowiakw@who.int
Jean de Gieu Iragena	Stop TB Department	WHO-HQ 20 Avenue Appia 1211 Geneva 27 Switzerland Email: iragenaj@who.int

Participant	Agency	Contact details
Ranjani Ramachandran	WHO-SEARO	Medical Officer -TB (Laboratories) Regional Office for South East Asial P Estate, Mahatma Gandhi Marg New Delhi 110 002 Email: ramachandranr@searo.who.int
Nani Nair	WHO-SEARO	Regional Adivser - TUB Regional Office for South-East Asial P Estate, Mahatma Gandhi Marg New Delhi 110 002 Email: nairn@searo.who.int
Puneet Dewan	WHO-SEARO	Medical Officer (TB)I P Estate, Mahatma Gandhi Marg New Delhi 110 002 Emal: dewanp@searo.who.int
Fraser Wares	WHO-India	Medical Officer (TB) Shriram Bharatiya Kala Kendra Bldg. 1 Copernicus Marg New Delhi 110 001 Email: waresf@whoindia.org
Suvanand Sahu	WHO-India	NPO-TB Shriram Bharatiya Kala Kendra Bldg. 1 Copernicus Marg New Delhi 110 001 Email: sahus@searo.who.int
Ritu Chauhan	WHO-India	NPO-Microbiology WHO Country Office for India 537, A Wing, Nirman Bhavan, New Delhi-110011 Email: chauhanr@searo.who.int

Annex 2 - List of team members for field visits

Joint Monitoring Mission, RNTCP
15-28 April 2009

Participants	Agency	Field visit	
		State	District(s)
Rohit Sarin	DOTS-Plus Committee	Gujarat	Panchmahal, Ahmedabad, Vyara, Surat, Surat Municipal Corporation
Nigorsilton Mouzafarova	GDF		
Catharina Lambregts van Weezenbeek (Kiity Lambregts)	GLC		
Selvakumar N	National Lab Committee		
Fraser Wares	WHO-India		
Soren Thybo	World Bank		
Guy Stallworthy	BMGF		
K K Banik	IMA		
Thomas Abraham	NTC		
Somshekar N	NTI		
Diana Weil	WHO-HQ		
N K Sethi	Planning Commission		
Anne Bossuyt	World Bank		
Arundhati Roy Choudhury	DFID	Himachal Pradesh	Hamirpur, Una
Sabina Barnes	DFID		
Nalini Krishnan	ICAT		
P R Narayanan	REACH		

Participants	Agency	Field visit	
		State	District(s)
Devesh Gupta	RNTCP		
Malgosia Grzemska	WHO-HQ		
Emanuele Capobianco	World Bank		
Rupak Singla	LRS	Rajasthan	Ajmer, Bundi, Udaipur, Rajsamund
Gavin MacGregor Skinner	USAID		
Susan Bacheller	USAID		
Ranjani Ramachandran	WHO-SEARO		
Victoria Francis	World Bank		
Ritu Chauhan	WHO-India		
L P Singh	CCM		
Patrick Moonan	CDC		
Bhavana Mukhopadhyay	National IEC Advisory Committee		
Mukund Uplekar	WHO-HQ		
Suvanand Sahu	WHO-India		
Ellora Guhathakurta	DFID	Tamil Nadu/ Puducherry	Puducherry, Nagapattinam, Salem, Namakkal
C N Paramasivan	FIND		
P Saxena	RNTCP		
Young-Ae Chu	Stop TB Partnership		
Guy-Patrick Massaloka	Stop TB Partnership		
Nani Nair	WHO-SEARO		
K R John	ZTF		
Billy Stewart	DFID		

Participants	Agency	Field visit	
		State	District(s)
Rahul Thakur	NACO		
Chen-Yuan Chiang	The Union		
Sangeeta Kaul	USAID		
Haileyesus Getahun	WHO-HQ		
Puneet Dewan	WHO-SEARO		
Annick Manuel	Global Fund	Uttarakhand	Dehradun, Haridwar
Vinay Gulati	NTF		
Satish Kaipilyawar	PATH		
Sai Babu	RNTCP		
Aleyamma Thomas	TRC		
Robin Mardeusz	USAID		
Karin Bergstrom	WHO-HQ		

Annex 3 - Summaries of state reports:

Key findings and recommendations

Gujarat

State profile

Population:	57 184 000 (2009)
Administrative set-up:	30 districts, 134 TUs, 713 DMCs, 1 058 PHIs Other than DMCs, 15 358 DOT centres
Districts visited:	Ahmedabad, Panchmahal, Surat, Surat Municipal Corporation, Vyara
RNTCP:	DOTS strategy implemented since 1999; full geographical coverage achieved in 2004
Trends in key programme indicators:	70% CDR / 85% success achieved for last three years

Key findings

1. Strong commitment by district- and state-level authorities, reflected in proactive planning for RNTCP activities, with no financial constraints or issues raised.
2. RNTCP integrated in the general health system, except in urban settings, and perceived as a strong public health programme to be supported under NRHM activities/funding; integration into NRHM appears effective, which has enhanced RNTCP activities (e.g. use of NRHM funds to upgrade IRL, etc.).
3. Potential opportunity for including RNTCP care into health-care package under the new health insurance scheme initiative.
4. Essential staff in place and a proactive stance in relation to staffing issues, e.g. swift filling of vacant MO posts, etc.
5. Closed User Group telecommunication system by the state has improved communication between staff.
6. State government welfare scheme covering TB patients in place.
7. New smear-positive case-detection target consistently achieved, and new diagnostic algorithm and case definition implemented from 1 April 2009.
8. Overall quality of smear microscopy laboratory services good, with internal quality control (IQC) and external quality assessment (EQA) in place and biomedical waste management practices implemented.

9. Proactive response to poor EQA results in 2008.

10. DOT services effectively decentralized, especially with the use of link and ASHA workers.

11. High cure rate across the state, including tribal areas, with all the patients interviewed expressing satisfaction overall with their management and treatment.

12. Records well maintained and reports validated at all levels in districts.

13. On-line test for block health officers and MOs conducted, with subsequent refresher training organized for those identified as having areas of weakness.

14. The staff and community-based workers interviewed appeared well trained and knowledgeable about programme and their respective tasks in it.

15. Patient-wise boxes (adult and paediatric) available at all levels, and good drug management with flexibility/adaptability shown when stocks go low.

16. Good initiation of activities for the engagement of all providers; sensitization of private providers, using professional associations; partners have signed up for schemes, with approximately 15% of notified cases contributed by private practitioners (PPs).

17. Medical colleges first/early source of care for many low-income patients, especially for diagnosis and ICTC link; assignment of full-time TB staff completed.

18. NACO-funded NGOs reach important urban risk populations for TB as well as HIV and success in referring for ICTC.

19. Posters on TB diagnosis (incorporating new diagnostic algorithm) and treatment widely displayed in health facilities.

20. Programme staff discuss TB at *panchayat* (village council) meetings; direct dialogue with ASHA workers from the state level via SATCOM.

21. Strong TB/HIV programme collaboration, with important expansion of ICTC network and ART access having taken place; TB/HIV interventions implemented according to the National AIDS Control Programme's (NACP) district categorization; revised treatment cards and TB registers in place in advance market commitment (AMC); CPT available and now in use for HIV-positive TB patients; and a plan to implement intensified case-finding package across all districts this year.

22. RNTCP Tribal Action Plan well implemented in Panchmahal, but more work needed in Vyara.

23. Gujarat playing a leadership role in the country in relation to implementation of Category IV services for MDR-TB cases; basic processes and systems in place with 159 MDR-TB patients having been placed on RNTCP Category IV treatment to date.

24. Implementation of Category IV services have led to the strengthening of overall RNTCP case-holding services and outcomes.

25. Recognition of infection control an issue; it needs further attention and strengthening.

Challenges and constraints

1. Transfers of regular staff frequent; high turnover of contractual staff; high percentage of vacancies among pharmacists (Panchmahal, Vyara) and lab technicians (LTs) (Surat); key programme officers holding multiple functions.

2. Process of payment of Social Welfare Scheme benefit long, and payment often released only after completion of treatment.

3. Insufficient human resource capacity at the state and some district levels to perform required supervision. Supervisory registers from 2007 to early 2008 not available (Panchmahal), and infrequent supervision from the state to district level.

4. High smear positivity among suspects and high percentage of 2+/3+, suggesting late presentation or pre-screening by X-ray; high percentage of TB suspects said to present to private sector first, but low contribution of private sector to referred and diagnosed cases.

5. Very low percentage of new smear-negative cases among new pulmonary tuberculosis cases, high percentage of smear-positive pulmonary tuberculosis re-treatment cases of all smear-positive pulmonary tuberculosis cases, and low percentage of paediatric TB cases out of the total registered.

6. Capacity of IRL insufficient in relation to MDR-TB expansion plan and introduction of new technologies, and insufficient NRL capacity to establish/ accredit new culture and drug sensitivity testing (C&DST) labs.

7. Insufficient coordination and sharing of information between partners assisting in RNTCP laboratory strengthening and introduction of new technologies.

8. Poor infection control measures at the designated microscopy centre (DMC) level, especially in view of implementation of services for DR-TB suspects and patients.

9. High percentage of DMCs with high fault errors in 2008; maintenance of stock inventory poor in some DMCs.

10. Treatment outcomes variable across districts and TUs, with consistent poor outcomes in smear-positive re-treatment cases, and unusually low percentage of treatment completion and transfer-outs.

11. Suboptimal use of available data for programme performance monitoring at the peripheral level for analysis and action.

12. Outdated methodology for training, high percentage of staff trained some years ago, and underutilized joint training opportunities with other programmes.

13. Issues related to retention of staff; HRD plans do not take into consideration implications of new initiatives, e.g. MDR-TB expansion; some staffing issues outstanding in some tribal areas.

14. No buffer stock of streptomycin available at the state, district or TU levels, with some stocks available at PHI level; no rifampicin 150 mg available at any level. Expired ethambutol at state drug stores; drug inventory management weak in some sites, especially where a pharmacist not in position; drug stores are often of poor structure, too small and without temperature control.

15. No record documenting isoniazid preventive therapy (IPT) in children available.

16. First- and second-line anti-TB drugs widely available over the counter from private pharmacies.

17. Establishing real partnership with other providers takes time, commitment, effort, trust; incomplete utilization of all potential health facilities in urban settings; integration of other health providers (e.g. Employees State Insurance - ESI) into RNTCP remains limited; no dedicated staff for PPM activities; low yield of diagnosed cases per site (except medical colleges); current involvement of private practitioners in health limited; gap between nominal involvement and real activity; no engagement of medical stores (despite common availability and sale of TB drugs in urban areas) and unqualified private providers; limited engagement of full range of key departments in medical colleges beyond laboratory and Chest & TB departments; majority of cases diagnosed at medical colleges, including inpatients, are referred without registration; missed opportunities in medical colleges for diagnosis of smear-negative pulmonary tuberculosis.

18. Weak NGO sector, particularly in the area of community mobilization; low yield in suspect referral and DOT.

19. TV slots remembered only by a small proportion of people met in urban areas. RNTCP logo recognized; however, the fact that treatment is free was not remembered.

20. Lack of clear focus/strategy on ACSM and underutilization of collaborators; no known active community demand and engagement (beyond ASHA and other community-based workers).

21. Acceptance and uptake of testing uncertain among TB patients referred for ICTC.

22. Approval mechanism for operational research proposals cumbersome.

23. Expansion of Category IV services across the entire state will be a major challenge.

24. Diagnostic delays remain very long (6-7 months); refusal of a percentage of detected MDR-TB patients to accept RNTCP Category IV treatment; counselling of MDR-TB patients by multiple staff and non-health care workers with unstandardized messages; very high levels of initial ofloxacin resistance impacting on treatment outcomes; lack of required capacity in the country to undertake the second-line DST; lack of an electronic information system linking diagnostic, treatment and management units; and challenges posed by the introduction of new technologies and their consequences for diagnostic and treatment practices.

Recommendations

1. Regular staff should remain in position for at least three years; salary scales for contractual staff should be enhanced and longer contracts given to key catgories of staff, e.g. microbiologists. Consider the regularizing of well-performing contractual staff in a phased manner (e.g. 15% per annum) to ensure sustainability of programme; fill vacancies in a timely manner and consider temporary contracting for pharmacists; strengthen capacity at the state level for supervisory activities.

2. Continue to strengthen joint planning opportunities and analysing/addressing cross-cutting human resources issues (numbers and quality); explore opportunities offered under new health insurance scheme; work with DTOs to understand and engage in health initiatives.

3. Streamline procedures for approval and timely release of payments to TB patients under the state government social welfare scheme.

4. Continue to improve case detection well beyond the 70% target; ACSM activities need to be strengthened in order to increase demand for the public TB services; widen contact-tracing activities to children over six years of age who are contacts

of smear-positive pulmonary tuberculosis cases; strengthen capacity of MOs in relation to diagnosis and management of paediatric TB by specific refresher training; and explore reasons for initial default in order to reduce it to the minimum.

5. Operational research to be conducted to investigate the low percentage of new smear-negative cases and high percentage of smear-positive pulmonary tuberculosis re-treatment cases; also to find out reasons for patients defaulting from Category II treatment.

6. Strengthen staff capacity of IRL to ensure sustainable services to meet the needs of MDR-TB expansion and introduction of new tools; and consider future use of IRL as mentor to other C&DST laboratories in the state.

7. Review existing infection control measures and revise institutional infection control plans accordingly, especially in the light of MDR-TB service implementation.

8. Monitor impact of retraining of laboratory technicians (LTs) on random blinded rechecking (RBRC) results; and strengthen inventory management in DMCs.

9. A comprehensive HRD plan needs to be developed based on standard operating procedures (SOP) and new interventions; start capacity building of programme managers in the use of data.

10. Improve conditions of drug stores; strengthen drug inventory management and training methods; ensure focused attention on drug management during supervisory visits with CTD; shortages of streptomycin and rifampicin 150 mg need to be urgently addressed; and enforce the regulation that anti-TB drugs are to be sold on prescription only.

11. With CTD, consider new strategy to intensify efforts; consider partner entities and state leaders that could help stimulate all provider engagement and assist in coordination, and follow up with providers (allopathic, non-allopathic, selected NGOs, pharmacies); consider appointment of a coordinator for strengthening PPM or partnering; given the concentrated volume of patients at medical colleges and their teaching and research role, medical colleges should continue to be first priority for engagement by RNTCP; tailor engagement to a limited number of NGOs with the potential to contribute to RNTCP activities; strengthen integration with other health providers (public, e.g. ESI, and private), especially in urban settings; and address DOT decentralization issues, particularly in urban areas.

12. Link with professional counterparts to help develop ACSM approaches; utilize the potential offered by ASHA workers to the maximum; and evaluate the impact of ACSM activities and review/revise plans accordingly.

13. In the light of the planned expansion of the intensified TB/HIV case-finding package across all districts of the state, monitor the yield and impact of TB/HIV collaborative activities in specific target areas, especially in the Category C and D districts.

14. With CTD, review and streamline existing operational research procedures and, if required, revise them to facilitate timely approval and initiation of research proposals.

15. Develop a comprehensive MDR-TB Category IV service expansion plan for the state, linked to the establishment of the C&DST laboratory network and HRD plan; with CTD, develop and establish an electronic information system linking the laboratory, DOTS-Plus site and districts to streamline transmission of information, and specifically to decrease diagnostic delays; assist CTD in the development and implementation of a standardized counselling approach for different stages of patient management to improve the uptake of RNTCP Category IV services; ensure that all identified MDR-TB cases have a sample sent to the relevant NRL for having a second-line DST performed; and, with the respective NRL, consider developing second-line DST capacity at IRL.

Himachal Pradesh

State profile

Population:	6 610 000 (2009)
Administrative set-up:	12 districts, 41 tuberculosis units (TUs), 168 DMCs (of which four run by NGOs), 410 PHIs other than DMCs, 3 274 DOT centres
RNTCP:	DOTS strategy implemented since 1995 (in Hamirpur district) Full state coverage reached in 2002
Trends in key programme indicators:	Case-detection rate - 82% (2008) Treatment success rate - 89% (cohort 2007)
Districts visited by JMM:	Hamirpur, Una

Key findings

The RNTCP was first implemented in Hamirpur in 1995 and was expanded to achieve state-wide coverage by 2002. Overall, the state achieved 82% case-detection rate (CDR) and 89% treatment success rate in 2008, but the performance varies in different districts.

The basic components that are necessary for TB control are in place. These are:

- Network of general health facilities and RNTCP;
- Trained staff (general health and contractual);
- Uninterrupted drug supply; patient-wise boxes, both for adult and paediatric cases, being available in DOTS centres;
- Network of DOT providers in some districts reaching out at community level;
- Successful involvement of medical colleges;
- Recording and reporting system in place;

  Sensitization of key administrative staff.

Constraints

1. Varying degrees of commitment was noticed at the top administrative level of the state. The Health Secretary was aware of RNTCP and was planning to involve the general health staff to sustain the programme, but there was, surprisingly, limited involvement of the State Tuberculosis Officer (STO) who was about to retire in two months, and no replacement had been identified. The absence of a functional State Tuberculosis Training and Demonstration Centre (STDC) affects an assessment of the human resources needs and the quantity and quality of training. The consultant working under the WHO-RNTCP technical assistant project (former DTO of a district) is heavily involved in programme implementation.

2. At the district level, posts of DTO have been filled, but there is a striking difference in their commitment to and engagement in programme management and supervision in the two districts visited.

3. While the senior staff at Una showed competence and full involvement in the programme, the same level of commitment was missing in Hamirpur.

4. The vacancies of general health staff and their functions are assigned by STSs and STLSs, thus overburdening them further. The consultants working under the WHO-RNTCP technical assistant project are burdened with programme implementation. There is over-reliance on contractual staff, and frequent transfers of staff affect continuity and quality.

5. There is little involvement in RNTCP of general health staff, public hospitals and clinics as well as private practitioners in RNTCP, which results in low referral of suspects. Hence, a decreasing trend in case suspect examination and detection was observed.

6. There is under-notification of children with TB: in 2008, paediatric TB cases constituted only 4% of the total TB patient load.

7. Medical officers in government hospitals do not routinely refer suspects and diagnosed patients to RNTCP and prescriptions to purchase anti-TB drugs in the market are given to the patients[13].

8. The proportion of re-treatment cases is high (25%-30%). In Hamirpur, a majority of the patients were previously treated in RNTCP. That may raise questions about the quality of DOT.

[13] Information obtained through interviews with patients.

9. EQA is not routinely implemented and striking differences were noted between the two districts.

10. The IRL is not functional. The space for the lab has been refurbished and awaits equipment from the Central TB Division (CTD) (after the personnel are appointed and trained).

11. The TB/HIV coordinator is not in place, but some referral between the two programmes has been initiated.

12. Though the TB treatment success rate is high and has been sustained over the years of programme expansion, the high default rate has been attributed to migratory populations.

13. Anti-TB drugs (first- and second-line) are available over the counter in local pharmacies (against the existing regulation for sale on prescription).

14. ACSM plans are not available. There is little awareness of TB by patients, and the social stigma exists, especially among young women.

15. Supervision by DTO and the Chief Medical Officer (CMO) was suboptimal in Harmirpur.

16. There is a lack of clarity on the design and role of NRHM, and plans at the state level are not well understood in districts where NRHM is perceived mostly as a funding mechanism.

Recommendations

1. Programme management and commitment

    1.1 Engage general health staff (MOs, lab technicians and paramedical staff) in suspect identification and referral, case detection, diagnosis and treatment.

    1.2 Staff vacancies need to be filled at the earliest.

    1.3 Identify replacement for STO.

2. Human resource development

    2.1 Develop detailed HRD plans as early as possible.

    2.2 Evaluate the quality of training to ensure up-to-date knowledge and skills.

    2.3 Limit frequent rotation of staff who have been trained and involved in RNTCP activities.

2.4 Revise the salary scales for STSs and STLSs and increase their emoluments to retain them in the system.

3. Case detection

3.1 Update refresher training of health workers (especially MOs at outpatient departments), community DOT providers and STSs to ensure early referral of adult and paediatric TB suspects.

3.2 State authorities to monitor and analyse trends in suspect examination to identify low-referral MOs based in government hospitals.

3.3 Ensure training of MOs on updated diagnostic algorithm of paediatric cases.

3.4 Engage other providers (including community-based DOT providers) in identifying respiratory suspects and referring them for smear microscopy; laboratories should accept sputum specimens without the need for the referring MO's signature.

3.5 Analyse the reasons for the high proportion of re-treatment cases, their source and the time of previous treatment.

4. Laboratory

4.1 Engage all regular LTs in the routine smear microscopy work.

4.2 STLSs should focus on EQA.

4.3 Establish sputum collection and transportation mechanism in tribal and scattered populations to ensure access to TB diagnosis.

5. Treatment and treatment support

5.1 DOT should be decentralized to reach out at the community level in order to ensure completion of treatment.

5.2 Consider alternative DOT approaches (e.g. home-based) for patients who cannot access DOT centre or DOT provider.

5.3 Coordinate with labour contractors / employers in the state to ensure treatment support is provided to migratory workers.

5.4 Propose innovative solutions to decrease default among migrants such as:

a. issue of referral cards to other districts and states;

b. supply of drugs for the remainder of treatment (with self-administration of family DOT provider).

6. Recording, reporting, monitoring and supervision

6.1 Supervision should be strengthened at all levels beyond the network of STSs and STLSs and CMOs should be involved on a daily basis.

6.2 Monthly meetings should discuss RNTCP performance, and where problems are identified, these should be analysed and solutions found.

6.3 Each supervisory visit report – with detailed comments - should be recorded in supervisory registers to help in follow-up and improvement of performance during subsequent visits.

7. Drugs and supplies

7.1 An appropriate location for the state-level drug store should be identified and the store established, which could also stock other essential drugs.

7.2 A trained pharmacist should be recruited to ensure proper store maintenance and distribution to districts and DOT centres.

7.3 Enforce the existing regulation of banning the over-the-counter (OTC) sale of anti-TB drugs as well as other antibiotics.

8. Engage all providers (PPM)

8.1 Further efforts should be made to actively involve other non-RNTCP providers with the use of revised schemes.

8.2 Further involve IMA and trained medical college faculty in RNTCP advocacy and sensitization of private practitioners.

8.3 Through operational research, analyse private sector contribution (PPs, medical colleges, general hospitals) and provide feedback to referring providers.

9. Advocacy, communication and social mobilization

9.1 An ACSM plan should be developed with technical assistance from communication experts (communication facilitators), laying emphasis on community awareness and social mobilization activities.

9.2 Communication strategies should be developed to address issues of particular concern to vulnerable groups (migrants, poor people, women, etc.).

9.3 Community groups and leaders to be trained and engaged in suspect identification and DOT.

9.4 DOT providers should be trained in proper counselling of patients who start treatment.

9.5 Visual, non-written material and existing RNTCP inter-personal communication material should be used during staff training and community meetings.

10. Health systems and National Rural Health Mission

10.1 TB control (suspect identification, diagnosis, treatment and monitoring and evaluation) be routinely implemented by all government health providers as per RNTCP guidelines.

10.2 The RNTCP, at both the state and district levels, should further utilize financing and service delivery mechanisms such as NRHM flexible pool funds, social welfare schemes, Indian Public Health Standards, health insurance initiatives and other financing innovations. In particular, maintaining priority for TB within NRHM can help address staffing, innovations, equipment and infrastructure needs.

11. TB/HIV collaborative activities

11.1 State and district TB/HIV coordinators need to be appointed.

11.2 All HIV-infected persons in whom TB diagnosis is established should be placed on DOTS.

11.3 All HIV-infected TB patients should be offered referral to the ART centre and should receive CPT.

11.4 RNTCP education material should be made available in ICTC, and HIV education material placed in DOTS centres.

12. Management of MDR-TB

12.1 MDR prevention should become a priority through decentralization of DOT and more engagement of other sectors.

12.2 The current plan for the establishment of IRL and implementation of MDR-TB diagnosis and treatment within RNTCP at the state level needs to be pursued without delay.

12.3 Links between medical colleges and the public health system should be strengthened with clear assignment of roles – especially for follow-up of patients on MDR-TB treatment.

12.4 Medical colleges should be involved in a clinical role (diagnosis and treatment), while RNTCP staff should undertake management and monitoring and evaluation responsibilities.

Puducherry

State profile

Population:	1 092 000 (2009)
Administrative set-up:	1 district, 4 TUs, 20 DMCs, 37 PHIs other than DMCs, 45 DOT centres
RNTCP:	DOTS strategy implemented since 2004
District visited by JMM:	Puducherry

Key findings

1. The Union Territory (UT) of Puducherry has three outlying TB Units which are geographically separated from each other (they are nearly 900 kms apart), have three different languages, and are surrounded by three different states. This poses a challenge in the monitoring and supervision of RNTCP activities. In addition, the STO and the DTO posts are held by a single person, which makes supervision of the TUs almost impossible.

2. The new smear-positive (NSP) case detection for 2008 was 79%, with medical colleges contributing to a substantial proportion of patients for case detection. After the implementation of RNTCP, the cure rate of NSP cases has improved steadily from 69% in 2004 to 84% in 2008. Likewise, the default rate of NSP has declined from 18% in 2004 to 4% in 2007. This remarkable fall in default rates is attributed to improved staff motivation and additional contractual staff in place.

3. There is a well-functioning state-level laboratory that is performing routine culture and drug susceptibility testing (DST) with accreditation ongoing and support provided as per RNTCP.

4. There is exceptionally good collaboration between RNTCP and the medical colleges in the territory, which involves posting of doctors and nurses from the medical colleges to the DMCs so that services can be offered over an extended period of time.

5. There are adequate stocks of drugs, with the drugs being stored as per RNTCP guidelines. In addition, stock registers and monitoring by pharmacists are being adequately carried out. First expiry, first out (FEFO) being followed seriously and records being maintained properly.

6. There is a follow-up of transfer-out patients to the adjoining Tamil Nadu state through monthly meetings with the DTOs in bordering districts. However, information and follow-up of patients discharged from the medical colleges is lacking.

7. Supportive political and administrative commitment was observed. More than 9% of the Union Territory budget was allocated for health. However, Puducherry is not among the top priority states for NRHM and hence funding levels are lower than other states. The per capita out-of-pocket expenditure remains high at Rs 1200 – Rs 1800/year.

8. Nonetheless, NRHM has provided opportunities for contracting additional staff and flexible mission pool funds have been utilized to procure additional equipment and supplies for the laboratory.

9. HIV case detection among TB patient has been optimized and a state-level coordination committee has been set up. However, issues relating to cross-referral and follow up of patients between the services at the operational level are not addressed adequately.

10. There is limited involvement of the private sector as well as NGOs and private practitioners in RNTCP despite the fact that there are 150 active NGOs in the Union Territory. There is also limited involvement of community DOT providers in the programme.

11. Limitations were observed in the culture and DST services provided. For example, DST was being carried out with drugs obtained from non-standard sources. Accreditation process was still pending and improvements are needed to be made in good laboratory practices (GLP).

12. There is top-down approach and no engagement of patients, communities and other stakeholders in planning or implementing activities.

13. The post of IEC Officer was vacant and IEC activities implementation currently being carried out by the already over-burdened STS.

14. Posts of four medical officers and four TB health visitors (TBHVs) were vacant at the four medical college DMCs involved in RNTCP. In addition, no faculty from medical colleges has been trained at the national level as master trainers. Medical colleges are not following modular training but only continued medical education (CME).

15. Surplus stocks of ethambutol (800 mg) and isonicotinic acid hydrazide (INH) (300 mg) were available in the district drug store.

16. There was underutilization of funds: for example, it was noted that around Rs 18.5 lakhs were carried forward from the financial year 2006-07. Fund utilization for 2007-08 was around 67%.

17. Incentives were not paid to the extent envisaged. In this context, it is felt that incentives as per RNTCP norms for volunteers for DOTS should be paid also to the government staff to keep them motivated.

Recommendations

1. The Union Territory (UT) health department to consider appointment of an additional person at the level of district TB officer (DTO) for overall programme management of the three outlying TUs (Karaikal, Mahe and Yanum) since the STO cannot fulfil this responsibility as per RNTCP norms.

2. DTO to ensure that patients from adjoining states need to be linked with their respective PHCs by organizing periodic cross-border meetings between STOs/DTOs.

3. DTO to ensure stigma and prejudice about TB disease and treatment is addressed suitably.

4. DTO to ensure current that IEC plans are based on need and evidence and have a specific objective or a target population.

5. The UT health department to improve the performance of the intermediate reference laboratory (IRL) by providing training at the NRL to the microbiologist in charge and other lab staff in culture and DST activities and by facilitating the accreditation process.

6. The UT health authorities at all levels to ensure more involvement of community DOT providers and to train all DOTS providers to improve treatment adherence and success.

7. The UT health department to ensure that all vacant posts, e.g. IEC officer at State TB Cell and long-term post at Mannadipet DMC, are filled urgently.

8. DTO to ensure that the surplus stocks of ethambutol (800 mg) and INH (300 mg) are transferred to State Drugs Store, Chennai, for immediate conversion to Category II patient-wise boxes (PWBs).

9. The UT health authorities at all levels to strengthen efforts to ensure that the remaining four medical colleges and NGOs are engaged in RNTCP activities, including IEC and community mobilization.

10. The UT health authorities at all levels to ensure that the IEC plans include specific objectives and monitoring indicators are based on evidence and data and are

specifically targeted (e.g. TB, TB/HIV, drug resistance) and involve collaboration with NGOs.

11. The UT health authorities to ensure the engagement of existing HIV peer educators as DOT providers through training in RNTCP activities.

12. The UT health authorities to ensure allocation of special budget for the involvement of NGOs and private sector,with active community participation.

13. The UT health authorities to conduct regular meetings between the staff of HIV and TB programme to discuss and strengthen referral and follow-up of patients.

Rajasthan

State profile

Population:	65 710 000 (2009)
Administrative set-up:	32 districts,150 TUs, 814 DMCs, 1343 PHIs other than DMCs, 13 967 DOT centres
RNTCP:	DOTS strategy implemented since 1999; full geographical coverage achieved in 2001
Trends in key programme indicators:	- Consistently well-performing state - TB control targets exceeded for many years - Current case-detection rate 81%; cure rate 88%.
Districts visited by JMM:	Ajmer, Bundi, Rajsamund, Udaipur

Key findings

Rajasthan has been achieving the RNTCP objectives of case detection and treatment success for a number of years. In 2008, 370 000 suspects were examined for TB and a total of 112 192 TB patients (all forms) were registered for treatment. Out of all smear-positive cases, 33% were re-treatment cases, which is high when compared to the national average of 24%. Case notification per 100 000 population varied across districts from 44 to 111. Districts with lower case detection are clustered in the western part of the state and in a belt extending across the middle of the state from west to east. In general, RNTCP has performed consistently well in the state.

The following observations are made:

1. TB is accorded a high priority in the Health Society meetings at the state and district levels. It was included in the new Chief Minister's first 100-days programme. The state has set itself a higher benchmark of 90% case detection and 90% cure rate (90/90), which is a good goal.

2. The state has a system of regular quarterly review meetings of RNTCP which are chaired by the Principal Secretary of Health. In addition, there is a monthly review of the programme by the Executive Committee of NRHM. Budget

deficiency has been managed by temporary loans from NRHM. However, coordination with other health programmes was found to be suboptimal.

3. Human resources in general appeared to be adequate. Induction training has been conducted for all staff, but there is a need for refresher training and retraining. Allowances, including travel allowance, are lower for RNTCP staff than for other health programme personnel.

4. Budget deficiencies in the past have been addressed by temporary loans from NRHM. However, in future, the state may no longer be allowed to take loans from NRHM, which may affect the TB programme.

5. The smear microscopy network appears to be adequate and all components of external quality assessment (EQA) for smear microscopy have been implemented. The IRL at Ajmer has been recently accredited for culture and DST.

6. Interviews with patients and providers suggested delays in diagnosis. The notification of smear-negative pulmonary TB is less than expected in many districts. Contact screening for adults in the household is not systematically implemented. Category II treatment has been centralized at health facilities and subcentres which, in some instances, is inconvenient for patients.

7. The intent of interpersonal communication slip on patient-wise boxes is good, but there is no mechanism for monitoring the implementation of this innovation.

8. Clinical issues included non-adherence to dosage recommendations of streptomycin (for age and low weight), difficulties in excluding TB prior to start of INH prophylaxis and dosing of INH for prophylaxis.

9. Overall, DOT is good but is often centralized, leading to inconvenience to patients. The full potential of ASHA workers (accredited social and health activists) and other community volunteers in DOT has not been tapped.

10. Detection and management of childhood TB is very weak.

11. In the TB/HIV register the TB suspects that are initially smear-negative are all recorded and reported as smear-negative TB (including those who do not have TB).

12. In the TB and Chest departments of the Jaipur and Udaipur medical colleges, the team found several patients on MDR-TB treatment outside of RNTCP. Treatment was un-observed in both places.

13. Commitment for public-private collaboration is very weak at both the state and district levels. Mainly non-allopathic practitioners have been involved. The Indian Medical Association (IMA) is yet to be involved in TB control. TB

patients managed by public-sector doctors in their private practice are often not notified under RNTCP. The new RNTCP guidelines for the involvement of NGOs and private practitioners have not been disseminated despite being in operation since October 2008.

14. The medical college 'referral-for-treatment' system implemented in Udaipur Medical College is excellent with more than 80% feedback received. This example needs to be documented and replicated by all large hospitals in the state.

15. Innovatory approaches to ACSTM at the State level are impressive and good cooperation is established between STO, IEC officer, communication facilitators and partners. But ACSM throughout the districts is still managed on an ad hoc basis with insufficient provision for supervision. Community participation and social mobilization activities were patchy. Social stigma towards TB remains an issue.

16. Rifampicin 150 mg had been out of stock in the state drug store since August 2008 while ethambutol was found in excess and was nearing expiry date (June 2009). The state has a contract with a transport agency to transport drugs to districts, which seems to be functioning well.

17. In general, the programme mainly rests on its own and contractual staff. Commitment of the general health services staff is uneven, reflected by the poor involvement of Medical Officer-Tuberculosis Control (MO-TC) in many areas.

Recommendations

1. The State TB Officer (STO) and DTOs should take advantage of the priority accorded to TB under the new Chief Minister's "100-days programme" and prepare and implement action plans by seeking support for financial and human resources required for the programme.

2. Focus on improving the planning and refresher training for the programme and health system staff.

3. Consider provision of enablers to make the medical officer, TB Control, commit time for TB programme activities. The chief medical and health officers (CMHOs) should review their MO-TC's performance in monthly review meetings at district level.

4. At busy DMCs where more than one laboratory technicians are available, the provision of more than one microscope should be considered.

5. Promote early case detection by actively seeking and involving popular first points of contact for chest symptomatics - private traditional practitioners, faith healers, pharmacies, etc.

6. Undertake systematic screening of both child and adult contacts and strengthen detection and management of childhood TB, addressing current inappropriate practices.

7. Consider decentralizing Category II treatment by identification and use of community-based practitioners who are authorized to give injections.

8. CTD is recommended to expedite procurement of rifampicin 150 mg and prevent future stockouts of drugs.

9. Expedite payment to community DOT providers / ASHA workers by considering on-the-spot payments as is done in the Janani Swasthya Yojana, a government programme for delivering mothers, or enforcing a deadline for payment (e.g. one week following completion of treatment).

10. Train voluntary counselling and testing (VCT) counsellors on the recording and reporting of TB/HIV and make the printed TB/HIV register available. Use TB intensified case-finding (ICF) tool for antiretroviral treatment (ART) centre and fast-track TB suspects' diagnosis and treatment.

11. Maximize cross-ventilation in VCT and ART centres by keeping the windows open and replacing glass with wired mesh.

12. Expedite the start of DOTS-Plus under RNTCP in Udaipur. RNTCP needs to support the medical colleges for the establishment of drug susceptibility testing (DST) laboratories.

13. The state and district health authorities to refrain from procuring second-line drugs locally using public funds.

14. Disseminate the new RNTCP public-private mix (PPM) guidelines by conducting workshops at the state and district levels. Engage IMA in PPM activities.

15. Document the Udaipur Medical College referral for treatment success and disseminate it via RNTCP annual reports/peer-reviewed journals.

16. Sensitize public-sector providers and build their capacity for public-private collaboration. Identify ways to record and report TB cases managed by public-sector doctors in their private practice.

17. The districts need to prepare a strategic plan for ACSM based on needs assessment, prioritizing activities required to address local programme gaps.

18. Make funds available in the IEC head as per RNTCP norms and monitor the utilization of funds by districts.

19. Develop more communication materials targeting patients, including messages on collection of sputum and adherence to treatment.

20. Undertake operational research to identify and address constraints to routine programme implementation and design innovative solutions to persisting problems.

Tamil Nadu

State profile:

Population:	66 937 000 (2009)
Administrative set-up:	30 districts, 142 TUs, 782 DMCs, 1198 PHIs other than DMCs, 11001 DOT centres
RNTCP:	DOTS strategy implemented since 1999; full geographical coverage achieved in 2002
Districts visited:	Nagapattinam, Salem, Namakkal

Findings and observations

1. In general, there is a functioning and enabling health system with adequate financial resources at health facilities in the fight against tuberculosis.

2. There is supportive environment of NRHM for RNTCP at all levels, including the state Health Secretary and NRHM Director who were aware of the critical problems of RNTCP.

3. There is a 100% recruitment of medical officers in most of the primary health care facilities in the state. Many PHCs have more than one medical officer.

4. The financial flow through NRHM is smooth for the implementation of RNTCP. There were no delays reported regarding needs to get agreement from the Deputy Director-General, Public Health (DDPH), or District Collector for approved RNTCP activities in most districts. Financial and procurement guidelines are followed by RNTCP at state and district levels.

5. RNTCP has been supported by district authorities in most districts, including District Collectors, who chair the regular meetings of district health societies and NRHM.

6. Laboratory and treatment registers are well kept in the majority of Tuberculosis Units (TUs), and revised recording formats are being utilized; external quality assessment (EQA) was in place and laboratory supplies were adequate.

7. The majority of TB suspects identified had their sputum examined according to the national guidelines.

8. Patients, including people living with HIV (PLHIV), were generally being initiated on treatment promptly.

9. There was adequate stock of drugs available and no short expiry drugs were observed; and the first-expiry-first-out principle was being followed.

10. There is engagement of celebrities (movie stars and the World Chess Champion) in promoting TB awareness. Knowledge of TB symptoms is being promoted through IEC materials and community meetings.

11. TB screening among PLHIV in the ART centres and ICTCs is in place according to the national guidelines. Triage of patients with cough for prompt TB investigation was in place in some ART centres.

12. A very high-level acceptance of HIV testing among TB patients was observed.

13. Staffing for RNTCP at state level was severely inadequate as three senior state-level TB positions (STO, Director STDC, and Deputy STO) were being managed by a single person.

14. There is a Directorate of Public Health and a Directorate of Medical Services in Tamil Nadu, with PHCs reporting to the former and DTOs to the latter. This creates challenges in supervision and monitoring, as collaboration between the two directorates was considered to be insufficient.

15. In general, the quality of the programme has been declining in the state, partly because support, supervision and monitoring from the state level to the district level seemed insufficient and because the budget for programme implementation was in place but was underutilized.

16. Most DTOs have multiple functions and have limited time to run the programme, to regularly hold district review meetings and to supervise and monitor primary health centres (PHCs) for programme implementation.

17. The Senior Tuberculosis Supervisor (STS) and the Senior Tuberculosis Laboratory Supervisor (STLS) have only one vehicle for monitoring. As a result, both are usually travelling together which reduces the efficiency of field visits.

18. The quality of smear was unsatisfactory in some designated microscopy centres (DMCs) visited. The quality of EQA is questionable in TUs reporting no errors, including quantification error.

19. The state-level freezing of recruitment by District Health Societies has affected RNTCP performance in most districts, and there were vacancies of laboratory technicians in most settings.

20. The number of suspects examined has been declining and health workers at PHCs were ineffective in identifying proper TB suspects. The proportion of positives among suspects examined was relatively high in some DMCs (low number of suspects examined) and very low in others (inadequate number of suspects examined). As a result, more than half of the districts have a low case-detection rate.

21. "2 smears/2 weeks" policy not yet implemented in the majority of DMCs.

22. The quality of DOT was unsatisfactory and there was limited involvement of field staff in DOT.

23. The default rate has been increasing, especially among re-treatment cases.

24. IEC efforts and expenditure skewed towards the last quarter of the year (Q4) and World TB Day celebrations.

25. The state and district IEC action plans are not based on needs or evidence and the technical capacity of IEC officers was limited in some districts.

26. The state- and district-level IEC plans are not compatible with the national health communication strategy and are not based on the knowledge, attitude and practices (KAP) surveys conducted in the past.

27. The engagement of private medical practitioners and involvement of the Indian Medical Association was limited. This was exceptionally absent in Nagapattinam district. Minimum budget planned and nearly no funds utilized.

28. In one instance, an untrained STLS was monitoring lab activities; training and knowledge among MOs of some districts were insufficient.

29. The quality of ICTCs in many districts is sub-optimal, and CPT pouches were not available in the state.

30. Shortage of rifampicin-150 mg was observed in Salem and Namakkal districts. The State Medical Supplies Corporation does not support RNTCP.

Recommendations

1. The state health authorities to immediately fill the three vacant senior RNTCP posts in the State TB Cell by appointing separate persons as STO, Deputy STO and Director, STDC.

2. Deputy Director, TB, and Deputy Director, Health Services, should collaborate closely and work together to enhance the engagement of PHC health workers for RNTCP activities.

3. The state health authorities need to closely monitor and supervise the implementation of RNTCP through regular review meetings and supervisory visits to districts.

4. The state and district health authorities at all levels to improve the utilization of funds through regular monitoring of the execution of plans and identifying barriers to fund utilization.

5. The state health authorities to closely monitor progress at district level as against the action plan as well as head-wise expenditures, and ensure that no delays occur in financial reporting that could jeopardize timely disbursement of funds from the Central level.

6. The state and district health authorities need to ensure effective integration of NRHM and RNTCP activities at district level, particularly at PHCs.

7. The state and district health authorities to review and intensify efforts to increase suspect identification by all health cadres in all facilities.

8. The state health authorities to fill all current vacancies, particularly the posts of laboratory technicians.

9. The state health authorities to ensure training of clinical and laboratory staff on case-finding, including orientation about the recent change of case-detection policy

10. The state and district health authorities to improve the quality of sputum microscopy, including evaluation of the quality of EQA performance.

11. The state and district health authorities to enhance training and supervision of DOT providers, including interpersonal communication, and ensure quality DOT provision for patients in all districts.

12. The state health authorities to expand community DOT providers in all districts and enhance the engagement of field staff, particularly health inspectors and village health nurses for the supervision of DOT providers.

13. The state and district health authorities to promote the re-designation of interested medical officers as medical officer, tuberculosis control (MOTC) to improve TU-level supervision rather than automatically assigning the block MO-PHC to MO-TC.

14. The state health authorities to ensure the provision of an additional vehicle for STSs and STLSs to improve monitoring and supervision activities.

15. Health authorities at all levels should seek to monitor the impact of trainings as part of routine programme management.

16. Health authorities at all levels to improve the engagement of NGOs and private practitioners for RNTCP activities.

17. State authorities to ensure the engagement of state IEC and publicity officers in the development of district action plans, and ensure the inclusion of clearly-defined IEC objectives and indicators in those plans.

18. Health authorities at all levels to ensure the implementation of IEC and community mobilization activities according to targeted and need-based plans, in coordination with other stakeholders in the health system including NGOs.

19. The state and district authorities to ensure that state and district IEC plans are in line with the National Health Communication Strategy.

20. Health authorities at all levels to improve the quality of ICTC through training and ensure the implementation of the standardized registers according to the national guidelines.

21. Health authorities at all levels to improve the referral mechanisms between ICTC and RNTCP for HIV testing among TB patients and TB screening among people living with HIV according to the national guidelines.

22. Health authorities at all levels to improve airborne infection control, particularly in ICTC and ART centres, according to the national guidelines.

Uttarakhand

State profile

Population:	9 636 000 (2009)
Administrative set-up:	13 districts, 30 TUs, 142 DMCs, 364 PHIs other than DMCs, 4000 DOT centres, around 10 000 trained ASHAs
RNTCP:	DOTS strategy implemented since 2002; RNTCP achieved full coverage in 2004
Trends in key programme indicators:	Case notification shows declining rate Cure rate of NSP and re-treatment cases declining Treatment success rate of NSP and re-reatment declining Default rates in NSP and re-treatment increasing Failure rates in NSP and re-treatment cases increasing.
Districts visited by JMM:	Dehradun, Haridwar

Key findings

1. Some talented, motivated and dedicated staff doing very good work despite difficult conditions.
2. RNTCP has achieved full coverage in the state since 2004. The programme has achieved a case-detection rate of 57% of NSP cases and a success rate of 86%.
3. The total strength of RNTCP contractual staff, with the exception of laboratory technicians, is satisfactory.
4. The community of DOT providers has been enlarged through ASHAs and other community-based individuals and networks.
5. Drug management is generally good.
6. The preparation of state quarterly reports and feedback to districts is timely.
7. Some innovative approaches and initiatives in IEC activities have been started which aim at raising the awareness of different groups of people.

8. TB/HIV collaborative activities have been started.

9. Civil works for the establishment of IRL and preparations for its accreditation are progressing well.

Constraints and concerns

1. Case detection is below target and has not improved in the past five years. Referral of chest symptomatics from PHIs is low as is referral from hospitals (big and small). Detection of new smear-negative (NSN) cases is low due to lack of proper X-ray facilities.

2. The treatment success rate for NSP in some districts is below target. The treatment success for re-treatment cases is also below target. Defaults, referral for treatment and transfer-outs are of concern.

3. Insufficient decentralization of DOT to the community.

4. Limited involvement of medical colleges, private practitioners and professional bodies.

5. TB/HIV collaboration is suboptimal; cross-referral is limited from both sides.

6. The quality of the laboratory system varies from district to district.

7. Low participation of civil society due to lack of trust between RNTCP and NGOs.

8. IEC activities suboptimal and IEC material, specifically for DOT providers, lacking.

9. Suboptimal use of supervision as a problem-solving and motivating tool, including use of quarterly/monthly/weekly meetings; checklists are not used everywhere.

10. Suboptimal planning and follow up on action plans by staff in supervisory positions.

11. Suboptimal HRD management; major challenges related to the health workforce: shortages of staff, particularly medical doctors and lab technicians; recruitment and retention of staff and their posting to remote areas; low motivation, knowledge and performance of existing staff (in particular STSs, STLSs, LTs); work overload of existing staff; unsatisfactory procedures for recruitment and performance appraisal of contractual staff; and insufficient training activities.

12. Preparation for MDR-TB management is insufficient in areas of drugs, treatment sites, staffing and training.

13. Infection control and waste management is a major problem (e.g. ventilation, disposal of sputum cups).

14. Payment of dearness allowance and payments to NGOs need improvement.

Recommendations

1. Case detection

1.1. Improve referral from hospitals and PHIs (including use of new guidelines).

1.2. Improve IEC for community awareness.

1.3. Strengthen PPM activities for better involvement of public and private sectors.

1.4. Improve laboratories.

1.5. Improve involvement of civil society (NGOs).

2. Treatment outcome

2.1. Ensure DOT, including community DOT (decentralization of treatment).

2.2. Improve defaulter and transfer tracing; also inter-district communication and meetings.

2.3. Improve patient information, especially to re-treatment cases (including development of flip charts and other tools to assist in information dissemination; improve specialist counselling).

2.4. Establish patient treatment support networks.

3. TB/HIV collaborative activities

3.1 Ensure functioning of the coordinating committees.

3.2 Regular review at district and state levels under the established mechanism of coordinating committees.

3.3 Strengthen ongoing supervision and monitoring of collaborative activities.

4. Human resource development

4.1 Improve staff management, e.g. workload, placement of staff, vacancies, motivation, performance management, adhering to RNTCP procedures for recruitment of contractual staff, use of incentives including insurance schemes, improvement of salary scales.

4.2 Organize urgently training of new staff and conduct training with revised modules; start retraining based on needs assessment, provide refresher training by use of supervisory visits and organize meetings for on-the-job training.

5. *Supervision at all levels*

5.1 Move from routine data collection to a proactive approach for achieving programme goals.

5.2 Improve planning of visits, including prioritization.

5.3 Ensure the use of supervisory checklists.

5.4 Improve analysis of data for problem-solving (especially related to low case detection and poor treatment outcomes).

5.5 Increase staff motivation.

5.6 Use supervisory visits for follow-up of trained staff, identification of retraining needs and on-the-job training.

6. *Management of MDR-TB cases*

6.1 Strengthen the implementation of IRL, including the IRL in the private medical college (Himalaya Institute of Medical Sciences).

6.2 Start planning for the management of second-line drugs (provision of cold storage facilities).

6.3 Accelerate planning for treatment sites, staffing and training.

7. *Infection control and waste management*

7.1 Improve triage and cross-ventilation in OPDs.

7.2 Improve management of infectious materials and wastes (use of sputum disposal pits).

8. In view of the overall performance of RNTCP in the state and the introduction of the management of MDR-TB cases, review the possibility of the state Principal Secretary for Health declaring RNTCP a priority programme to improve the focus and make hospitals responsible to implement TB control services.