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Abbreviations

ACSM	advocacy and social mobilization
AFB	acid-fast bacillus
AIDS	acquired immunodeficiency syndrome
AMC	annual maintenance contract
ANC	antenatal clinic
ANM	auxiliary nurse midwife
API	Association of Physicians of India
ART	antiretroviral treatment
ARTI	annual risk of tuberculosis infection
ASHA	accredited social and health activist
AYUSH	Ayurvedic, Unani, Sidha and Homeopathy
BCC	behaviour change communication
BCG	bacillus Calmette–Guerín
BHO	Block Health Officer
BM	binocular microscopes
BMO	Block Medial Officer
BPHC	Block Primary Health Centre
C&T	counselling and testing
C+	culture positive
CCM	country coordination mechanism
CD	compact disc
CDC	Centers for Disease Control and Prevention
CDHO	Chief District Health Officer
CDR	case detection rate
CHC	community health centre
CIDA	Canadian International Development Agency
CMO	Chief Medical Officer
CPT	co-trimoxizole preventative therapy

CRIS	communication resource information system
CTD	Central Tuberculosis Division
DANIDA	Danish International Development Assistance
DFID	Department for International Development
DHS	Director of Health Services
DM	District Magistrate
DMC	designated microscopy centres
DNO	District Nodal Officer
DOTS	Directly Observed Treatment, Short-course
DRS	drug resistance surveillance
DST	drug susceptibility testing
DTC	District Tuberculosis Centre
DTCS	District TB Control Society
DTO	District Tuberculosis Officer
ECL	Eastern Coalfield Limited
EQA	external quality assessment
ESI	Employees State Insurance
FCHM	Financial Commissioner of Health and Medical Education
FEFO	first expiry first out
GDF	Global Drug Facility
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GMP	Good Manufacturing Practices
GMSD	government medical drug stores
GOI	Government of India
GP	general practitioners
HFM	Health and Family Welfare Minister
HIV	human immunodeficiency virus
HQ	headquarter
HRD	human resource development
IAPSO	Inter-Agency Procurement Services Office
ICS	Indian Chest Society

ICTC	Integrated Counselling and Testing Centres
IEC	information, education and communication
IMA	Indian Medical Association
INH	isonicotinic acid hydrazide
IPC	interpersonal communication
IQC	internal quality control
IRL	intermediate reference laboratory
ISTC	international standards for TB care
IUATLD	International Union Against Tuberculosis and Lung Diseases
JMM	Joint Monitoring Mission
KAP	knowledge, attitude and practice
KNCV	Royal Netherlands Tuberculosis Association
LT	laboratory technician
M&E	monitoring and evaluation
MDG	Millennium Development Goal
MDP	model DOTS project
MDR-TB	multidrug-resistant tuberculosis
MHW	Ministry of Health and Welfare
MO	Medical Officer
MODTC	Medical Officer District Tuberculosis Centre
MOHFW	Ministry of Health and Family Welfare
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 Organization
NACP	National AIDS Control Programme
NCCP	National College of Chest Physicians

NGO	nongovernmental organization
NICC	National Interagency Coordination Committee
NIHFW	National Institute of Health and Family Welfare
NRHM	National Rural Health Mission
NRL	national reference laboratory
NSN	new smear-negative
NSP	new smear-positive
NTI	National Tuberculosis Institute
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
PMR	programme management report
PO	purchase order
PP	private practitioner
PPD	purified protein derivative
PPM	public–private mix
PWB	patient-wise boxes
QA	quality assurance
RBRC	random blinded rechecking
RCH	Reproductive and Child Health (Programme)
RH	rural hospital
RNTCP	Revised National Tuberculosis Control Programme
S+	smear positive
SDH	subdivision hospital
SDS	State Drug Store
SEAR	South-East Asia Region

SLD	second-line drug
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	travel allowance
TAD	treatment after default
TB	tuberculosis
TB–HIV	tuberculosis–human immunodeficiency virus
TBAI	Tuberculosis Association of India
TBHV	TB health visitor
TRC	Tuberculosis Research Centre
TU	tuberculosis unit
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
UT	union territory
VCTC	Voluntary Counselling and Testing Centre
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

1. Executive summary

Achievements

Under the technical leadership of the Central Tuberculosis Division (CTD), Ministry of Health and Family Welfare (MOHFW), the Revised National Tuberculosis Control Programme (RNTCP) has achieved coverage of all 632 districts in the world's largest and fastest expansion of population coverage for a tuberculosis programme implementing the DOTS strategy. Since the Programme began expansion in 1997, the RNTCP has trained more than half a million staff, evaluated more than 24 million people with suspected tuberculosis (TB), examined more than 100 million sputum slides, treated more than six million patients, and prevented more than a million TB deaths. The RNTCP has established an effective drug logistics management system; quality-assured drugs are available throughout the entire country free of charge for patients. A case detection rate (CDR) of 66% and a treatment success rate of 86% were reached in 2005. The CDR continues to be above the global average. In the second quarter of 2006, more than 1.5 million people with suspected TB were examined by sputum microscopy, and each month more than 100 000 patients are put on treatment.

Programme service delivery is well integrated into the health system; TB care is provided by the general health staff. Programme organization has been established at all levels. External quality assessment (EQA) has been implemented in the microscopy network. There is an excellent system of recording and reporting, with indicators for monitoring and evaluation (M&E). Medical colleges have been effectively involved and other partners are increasing their collaboration, including nongovernmental organizations (NGOs), private practitioners (PPs), and the Indian Medical Association (IMA). A consensus protocol for paediatric TB has been developed. Coordination between the RNTCP and National AIDS Control Programme (NACP) for the collaborative management of TB–HIV interaction is evidenced in a joint action plan, and implementation has begun. A plan to address multidrug-resistant TB (MDR-TB) has been prepared. Expansion of patient access to TB care through community volunteers and PPs has begun to grow.

Means to measure epidemiological impact, particularly the risk of infection and drug resistance, have been established and additional studies are planned. The RNTCP strategy applied in a study area has been proven to be successful in reducing TB prevalence and transmission, as measured by active community surveys.

Challenges

In order to preserve and strengthen these very substantial achievements, it is important to address warning signs of deterioration of the Programme. Many of these warning signs are known, but their correction is often outside of the authority of programme managers.

As stated in the Joint Review of 2003, the rapid expansion of the Programme has outpaced the capacity of Central and state levels to effectively supervise and ensure Programme quality. The rapid expansion has also revealed and been limited by the weaknesses of the general health system. Although some states are generally performing well, insufficient Central- and state-level capacity has led to an overall decline in case detection, a small but discernable decrease in cure rates, and increase in treatment default rates in some areas over the past two years. This could result in avoidable transmission of TB and deaths.

Staff shortages, frequent transfers and other weaknesses of the general health system present major challenges for the Programme, particularly in certain states. The framework of the National Rural Health Mission (NRHM) calls for convergence and integration, and this is a positive development for the RNTCP. The NRHM can improve equitable access and convenience of services. The review team was informed that NRHM policy-makers recognize the importance of protecting the core elements of TB control and other priority programmes to promote effective patient care.

Though the Government has made substantial financial commitments to sustaining the Programme, there remains heavy dependence on external technical assistance and emergency procurement, and continued reliance on donors for a proportion of Programme funding. Systems for efficient procurement, human resource development (HRD) and monitoring need further strengthening. Without ongoing financial and technical support, the existing systems at national and state levels may not be able to maintain and improve the Programme to achieve a long-term impact.

Capacity at state level to plan, supervise and monitor tuberculosis control needs more attention. There is very limited capacity at state and district levels for human resource, Programme and financial management. In certain states there is persistently poor Programme performance and, in several states, improvements in performance have been short-lived.

Although recording and reporting is a strong point of the Programme, the capacity to analyse, interpret and improve performance based on findings is limited. Information collected and reported is overly complex.

There is limited effectiveness of activities in the community to increase awareness of the location of services for the free diagnosis and treatment of TB.

Collaboration with the NACP has begun but needs expansion, particularly in areas with the highest numbers of HIV-infected people. The focus should be on implementing an action plan designed for the maximal benefit of patients (e.g. identification and management of TB in HIV-infected people and of HIV infection among TB patients, and the limitation of nosocomial transmission of TB among those infected with HIV). The current limited availability of decentralized HIV testing and treatment restricts progress. In many states, the District Tuberculosis Officer (DTO) has been given the additional responsibility of overseeing HIV activities in the district, thereby reducing supervisory capacity for the RNTCP.

Effective implementation of the RNTCP is the most effective means of preventing further development of MDR-TB. However, the programmatic structure for the diagnosis and management of MDR-TB has not yet been implemented. In particular, accredited laboratory services are not yet available for the diagnosis of MDR-TB. At the same time, costly second-line drugs (SLDs) are widely prescribed by the private sector, medical colleges and TB hospitals, risking the development of SLD resistance, extensively drug-resistant TB (XDR-TB) and incurable TB.

Although there has been progress in involving the large and growing private sector, this involvement is not yet sufficient to provide maximal benefit to patients. Similarly, although the involvement of various public sectors has improved, coordination is still limited.

Key recommendations

The RNTCP has achieved countrywide coverage and is entering a new phase. The following recommendations aim to guide national efforts to strengthen

core DOTS implementation, ensure quality, improve access to TB care, and achieve sustainable epidemiological impact in the next decade.

Address long-term financial and human resource sustainability of the Programme

- Ensure that sufficient financial resources for the Programme are included in the MOHFW budget lines and at both the Central and state levels to ensure sustainability independent of external funding.
- Strengthen the human resources of the CTD under the regular Ministry budget to reduce dependence on external support.
- Strengthen the capacity of the Ministry for efficient procurement of drugs and equipment of the highest quality and standards.
- Work with external technical and financial partners to ensure long-term sustainability of the Programme in order to reach the Millennium Development Goals (MDGs).

Maintain a high priority for TB control in the National Rural Health Mission

- Ensure that core full-time RNTCP staff, TB-specific reporting and financing, and central level anti-TB drug procurement are continued under the NRHM, and ensure maximum use of the new staff available.
- Proactively support the NRHM to identify and address weaknesses in the health system, including frequent transfers and widespread vacancies of key staff (notably laboratory technicians [LTs] and medical officers [MOs]).

With the expanding opportunities for the Programme under the NRHM, it is essential to increase capacity at Central and State levels

- To promote effective service delivery and integration, establish new regular posts of at least six dedicated zonal-specific MOs within the CTD to supervise and support state-level staff.

- Advocate with state authorities to fully support TB control as a critical health priority.
- Increase the number of regular staff in, and capacity of, state cells, particularly in all larger states, if necessary with Central resources.
- Increase the responsibility assigned to, and improve the capacity of, State TB Control cells and existing State Tuberculosis Demonstration and Training Centres (STDCs) to plan, analyse, interpret and use data for action; existing STDCs should report to and be part of the State TB Cell.
- Improve the capacity of supervisors at all levels to evaluate and use programme data for action to improve performance.
- Build the capacity of WHO national consultants, revise their terms of reference to ensure their technical role and maintain their objectivity in feedback, while limiting their involvement in data collection and administrative matters. To do this, it is necessary to establish an intermediate level for the supervision and support of WHO consultants.
- Ensure identification and vigorous follow up of districts where reports are not accurate and continue this follow up until inaccuracies are resolved, with the involvement of political and administrative leaders of districts and states.
- Institute a process to identify and reward consistently well-performing or rapidly improving districts.
- Continue to develop the skills and performance of state- and district-level staff. Improve regular and annual state and national meetings by having state and competitively selected District officers conduct presentations and peer evaluations, to promote corrective interventions based on in-depth analysis of their own data.

Improve programme effectiveness

- Increase case detection by improving training of general medical officers and paramedical staff, and implementing interventions such as systematic screening for cough by non-medical and paramedical staff, retrieving initial defaulters, using community workers to increase referrals and community awareness, and further increasing the

involvement of all health sectors including PPs, TB hospitals, NGOs and other providers.

- Improve patient management and treatment outcomes by further decentralizing DOT and making treatment observation more convenient for patients, particularly in slum and tribal areas. Increase the use of community volunteers, community health workers (including accredited social and health activists [ASHA] under the NRHM) and PPs as treatment providers.
- Simplify and reduce routinely collected information.
- Conduct induction training of new staff and update training of all levels of staff.
- Using effective strategies, improve effective communication in the community, in particular, to expand awareness of the location of free microscopy centres and free TB care.
- Review the EQA systems for microscopy, evaluate the usefulness of various methods and simplify procedures, data collection, analysis and interpretation.

Further develop and implement strategies for MDR-TB and TB-HIV

- Establish as a priority the planned accredited network of intermediate reference laboratories (IRLs) for quality-controlled culture and drug susceptibility testing (DST) to diagnose MDR-TB, at least among patients who fail Category II treatment. Until this network is in place, utilize existing resources including medical colleges, national institutes and other facilities as systems for culture and DST.
- Accelerate implementation of the national Programme plan to manage MDR-TB. Clinicians currently treating MDR-TB, particularly those in medical colleges and TB hospitals, should adhere to national policies based on international guidelines for diagnosis, treatment and management.
- For TB–HIV, establish a TB–HIV technical working group at the national level to ensure implementation and scaling up of collaborative activities outlined in the National Framework for Joint TB/HIV Collaborative Activities.

- Implement an action plan to integrate and improve management of TB–HIV patients, particularly in areas with large numbers of HIV-infected people. Improve and sustain coordination mechanisms to ensure an effective two-way referral system, and subsequent referral of TB–HIV patients for necessary HIV care and treatment.
- Implement simple administrative and environmental control measures to reduce nosocomial transmission of TB such as training of health-care workers, rapid assessment of cough/prompt diagnosis of TB, collection of sputum in an open environment, limitation of hospitalization for TB patients, improvement in ventilation of hospitals and use of hospital cleaning techniques that limit potential aerosolization of *M. tuberculosis*.

2. Introduction and terms of reference

Country profile

India is the second most densely populated country in the world with a projected population of 1114 million in 2006. With only 2.4% of the world's surface area, India supports about 16.87% of the world's population. The country is administratively divided into 35 states and union territories (UTs), which are subdivided into over 600 districts. There is a striking diversity between the states in size, terrain, culture, health status and socioeconomic development; for example, 25% of the country's population lives below the national poverty line and 35% below the international standard of less than US$ 1 per day (1). Despite increasing urbanization, 72% of the population lives in rural areas. During the decade 1991–2001, the growth rate of the rural population was 1.8% per annum, while that of the urban population was 3.1% per annum. One-fourth of the population lives in villages that have less than 1000 residents. As per the 2001 Census, 16% belongs to the scheduled castes and 8% to the scheduled tribes[1]. Over 42 million people live in urban slums, making up 15% of the total urban population in the country[2].

India has the highest burden of tuberculosis (TB) globally, accounting for one fifth of the global incidence and two thirds of the cases in South-East Asia. Nearly 40% of the Indian population is already infected with the TB bacillus. Each year, 1.8 million new cases of TB occur in the country, out of which about 0.8 million are highly infectious new smear-positive (NSP) pulmonary TB cases (2). The incidence of TB in India, based on findings of the nationwide annual risk of TB infection (ARTI) study

[1] Scheduled castes and scheduled tribes are castes and tribes that the Government of India officially recognizes as socially and economically "backward" and in need of special protection from injustice and exploitation.

[2] Slum: For the purpose of the Census of India, 2001, slum areas broadly consist of:

All specified areas in a town or city notified as "slum" by the state/local government; and

A compact area of at least 300 population or about 60–70 households of poorly built, congested tenements, in an unhygienic environment usually with inadequate infrastructure and lacking in proper sanitary and drinking water facilities.

conducted in 2000–03 was estimated at 1.5%, i.e. 75 NSP pulmonary TB cases are expected annually per 100 000 population. The prevalence of TB for the year 2000 was estimated at 3.8 million bacillary cases (3).

India is also one of the countries where the TB control programme has made rapid progress in recent years. The Revised National TB Control Programme (RNTCP) based on the WHO-recommended Directly Observed Treatment, Short-course (DOTS) strategy to control TB, was launched in 1997. By March 2006, India's RNTCP had expanded coverage of DOTS to the entire country and currently treats over 100 000 TB patients every month. Since the inception of the Programme, over 6.2 million patients have been placed on treatment. The Programme has consistently achieved the global targets of >85% treatment success rate and the NSP case detection rate was 66% in 2005, close to the 70% target. In 2005 alone, 1.3 million TB patients were treated through the RNTCP, saving an additional 200 000 plus lives. In addition to the basic DOTS strategy, the RNTCP implements public–private mix (PPM) services involving a wide range of service providers, TB/HIV collaborative activities and several initiatives aimed at mobilizing communities. The RNTCP also initiated activities to start treatment of multidrug-resistance (MDR) TB in early 2007.

While the progress on TB control in India has been remarkable in recent years, several challenges need to be addressed in order to reach the TB-related Millennium Development Goal (MDG) by 2015[3]. These challenges include sustaining and further improving the quality of DOTS implementation, and effectively addressing second-generation issues such as MDR-TB and TB/HIV.

The RNTCP has conducted joint programme reviews by national and international experts in 2000 and 2003. The last review was carried out in September 2003 by a team representing the World Health Organization (WHO), United States Agency for International Development (USAID), Danish International Development Assistance (DANIDA), Global Fund for AIDS, Tuberculosis, and Malaria (GFATM), Global Drug Facility (GDF), Canadian International Development Agency (CIDA), Centers for Disease Control and Prevention (CDC), International Union Against Tuberculosis and Lung Diseases (IUATLD), Royal Netherlands Tuberculosis Association (KNCV), representatives from the Planning Commission, National Institute

[3] Indicators listed under MDG 6, target 8, call for 50% reduction in the prevalence of TB and deaths due to TB by 2015 from the 1990 baseline levels.

of Health and Family Welfare (NIHFW), Indian Medical Association (IMA), leading medical colleges, National Tuberculosis Institute (NTI), Tuberculosis Research Centre (TRC), NGOs, and state- and district-level Programme staff. At the time of the 2003 review, a population of 740 million had access to DOTS and nearly 2.4 million patients had been placed on treatment with over 85% treatment success. The review appreciated the extraordinarily rapid expansion of the RNTCP while maintaining high levels of treatment success, and noted that it was highly economical. The review also pointed out several areas which required strengthening. The recommendations made were to increase managerial capacity and staffing at Central and state levels; increase coverage, case detection, and quality of diagnosis and treatment; ensure the quality and regular availability of drugs; ensure wider dissemination and support for the RNTCP at all levels; and promote long-term Programme sustainability. The Joint Monitoring Mission held in September 2003 provided valuable guidance for the RNTCP over the past three years.

Considering the progress India has made since the Programme review in 2003, it was considered timely that a joint monitoring mission be undertaken in 2006 to take stock of the situation and address the significant challenges that lie ahead.

The Joint Monitoring Mission (JMM) 2006 was jointly organized by the Government of India and WHO from 3 to 17 October 2006, and consisted of a team of 24 national experts (from the IMA, NIHFW, leading medical colleges, central TB institutes, NGOs, Programme staff at state and district levels) and 36 international TB experts (CDC, DFID, GDF, GFATM, IUATLD, KNCV, USAID and WHO). The objective of the 2006 JMM was to review the performance and plans of the RNTCP, and to recommend steps needed to sustain and further improve the Programme.

Terms of reference

- To review the performance of the revised TB control strategy in India (RNTCP) taking as a base the review carried out in 2003;
- To review technical policies, especially of the more recent or new activities to be implemented in the second phase of the RNTCP (EQA of sputum microscopy, prevalence surveys, drug-resistance surveillance, DOTS-Plus, etc.);

- To formulate recommendations on the above two objectives so as to move towards achieving the TB-related MDG by 2015 and eventually achieve TB control in India;
- To assess the sustainability of activities under the RNTCP to achieve the desired epidemiological impact for TB control.

Selection of sites

Of the 35 states and UTs, the smaller UTs and states (population <20 million) and states where field visits were not feasible for security or travel- and logistics-related reasons were excluded from the randomized selection process. For reviewing the preparatory activities for DOTS-Plus, the state of Gujarat was selected as it is expected to start DOTS-Plus activities by June 2007. Similarly, to observe TB/HIV activities and to visit the NTI for human resource development (HRD) issues, the state of Karnataka was selected. Three other states were randomly selected from the north and east of the country (since Gujarat and Karnataka are from the West and South). For this selection, the states were stratified as large states in the north with weaker health systems and a variety of challenges (Madhya Pradesh or Uttar Pradesh), states in the north with better health systems but other programmatic issues and challenges (Haryana and Punjab), and states in the east with a different set of issues (Orissa and West Bengal). Since Orissa and Uttar Pradesh were visited by the 2003 monitoring mission, the states selected for visits in these two strata included Madhya Pradesh and West Bengal. Punjab and Haryana, being smaller states, were combined as one unit for the review.

A total of six states and 20 districts were evaluated by the Mission members. Districts within the states were selected randomly. The states and districts selected are given below:

States	Districts
Madhya Pradesh	Damoh, Vidisha, Dewas and Indore
Gujarat	Ahmedabad, Sabarkantha, Mehsana and Anand
Karnataka	Bangalore City, Tumkur, Mysore and Chikmagalur
West Bengal	Nadia, Bardhman, Kolkata and North 24 Parganas
Punjab	Roopnagar and Patiala
Haryana	Karnal and Rewari

For each state, two teams were constituted. However, for Haryana and Punjab, only one team visited each state as these two states are smaller than the others. Each team was subdivided into subteams of four members, with each subteam visiting two districts. The district visits were made from 4 to 12 October 2006. These 20 selected districts covered a population of 60.3 million (5% of the total population). Two tuberculosis units (TUs) and four designated microscopy centres (DMCs) were randomly selected from each of the 20 districts. The teams visited more than 40 TUs, 80 DMCs and interviewed over 160 patients in the community. They also interviewed administrators, health staff and community members; reviewed records, collected and analysed information on organization of services, diagnosis and treatment; and reviewed Programme data.

At the start of the field visit, each state team briefed the state administration (Health Secretary and Director of Health Services [DHS] and other relevant staff). Before the district visit, each team briefed the District Magistrate (DM) and Chief Medical Officer (CMO), and also debriefed them before ending the district visit. At the end of the state visit, the state teams debriefed the state administration about the findings of their visits.

At the Central level smaller subgroups were formed, which, with Government of India officials from the Ministry of Health and Family Welfare (MOHFW), also discussed arrangements for the RNTCP under National Rural Health Mission (NRHM), TB/HIV coordination and HRD-related issues. At the end of the mission, the main findings and recommendations of the JMM were presented to Hon'ble Health and Family Welfare Minister (HFM), Minister of State (MOS) and concerned officials of the Ministry and funding partners.

This report summarizes the findings of the joint review and presents the main conclusions and recommendations. State-specific findings and recommendations are given in the Annexures.

3. Epidemiology of TB in India: a brief overview of prevalence, incidence and mortality

Incidence of TB disease

A nationwide standardized tuberculin survey on ARTI was carried out during the period 2000–2003 (4–9). For the purpose of the survey, the country was stratified into four zones (north, west, south and east). An identical methodology of sampling and tuberculin testing was used throughout the country. Table 1 details the major findings, based on the mirror-image technique, and shows interzonal as well as rural/urban differences in the rates of transmission of infection.

Table 1: *Results of the National ARTI survey, 2000–2003*

Zone	ARTI (95% CI)		
	Rural	**Urban**	**Total**
North (7)	1.6 (1.3–2.0)	2.6 (2.3–2.9)	1.9 (1.3–2.5)
East (5)	1.2 (1.0–1.5)	1.7 (1.1–2.3)	1.3 (1.0–1.6)
West (8)	1.5 (1.1–1.8)	2.4 (1.6–3.4)	1.6 (1.0–2.2)
South (9)	0.8 (0.4–1.2)	1.6 (0.9–2.2)	1.0 (0.7–1.4)
Total (6)	**1.3 (1.0–1.5)**	**2.2 (1.8–2.6)**	**1.5 (1.4–1.6)**
Orissa statewide survey (10)	1.6 (1.3–1.9)	2.5 (1.3–3.7)	1.7*

*ARTI for Orissa calculated using cut-off methods. Using the mirror-image method, the ARTI for Orissa was 1.8%.

A national ARTI of 1.5% has been derived from these zonal estimates (6). The operational advantages of using uniform zonal and national figures are evident. However, the heterogeneity in the ARTI figures could lead to underestimation of detection rates in the south and overestimation in urban areas.

Estimates for incident smear-positive TB have been made from ARTI data using the frequently applied "Styblo conversion" estimate of 50 incident cases of NSP pulmonary TB per 1% ARTI per 100 000 population (11).[4] This conversion has recently been validated in a community survey in south India (12).

A statewide survey was carried out in Orissa with DANIDA support in 2002–2003, with a similar testing methodology and estimation procedures as the nationwide survey (10) (Table 2). For Orissa, the ARTI survey estimate (1.7%) suggests an incidence of 85 per 100 000 persons, which is greater than that for the east zone. The Orissa statewide ARTI estimates overlapped with the confidence limits of the east zone part of the national survey, in which a site from Orissa was included. However, the Orissa statewide ARTI point estimate is closer to that of the north zone than to that of the east zone. This comparison highlights the challenges of precise estimation of ARTI in such a large, heterogeneous population such as that in India.

Table 2: *Estimated zonal annual risk of tuberculosis infection (ARTI) and incidence of new smear-positive tuberculosis, 2000–2003*

Zone	ARTI (95% CI)	Estimated incidence of new smear-positive TB per 100 000 (confidence interval)
North	1.9 (1.3–2.5)	95 (65–125)
East	1.3 (1.0–1.6)	65 (50–80)
West	1.6 (1.0–2.2)	80 (50–110)
South	1.0 (0.7–1.4)	50 (35–70)
Total	**1.5 (1.4–1.6)**	**75 (70–80)**

Prevalence of tuberculosis disease

Limited data exist to inform current prevalence estimates. Prevalence was likely falling prior to implementation of the RNTCP, but the current rate of

[4] For the south and east zones, the national ARTI of 1.5% is used to calculate the estimated incidence for purposes of case detection estimation.

change is unknown. One study carried out in the bacillus Calmette–Guerin (BCG) trial area in Tiruvallur district, Tamil Nadu, showed that before implementation of the RNTCP, the prevalence of culture-positive TB had declined by 1.8% per annum, and smear-positive TB had declined by 2.1% per annum (13). These data are described in more detail below.

The prevalence of TB in India has been estimated from available ARTI data using the observed relationship between ARTI and prevalence of bacillary TB from Tiruvallur district (3). Estimates for 2000 are shown in Table 3. It should be noted that this methodology differs from that used by WHO to calculate the 2004 prevalence estimate of 3.394 million persons for all forms of TB (14).

Table 3: *Estimated burden of tuberculosis in India*

	Number (millions) (95% CI)	**Rate per 100 000 persons (95% CI)**
Incidence (2004 estimate) (14)		
All cases	1.824	168
AFB smear-positive	0.815	75
Prevalence (2000 estimate) (3)		
All cases	8.5 (6.3–10.4)	826 (612–1011)†
AFB-positive	1.7 (1.3–2.1)	165 (126–204)†
Bacillary*	3.8 (2.8–4.7)	369 (272–457)†
Abacillary**	3.9 (2.9–4.8)	379 (281–466)†
Extrapulmonary	0.8 (0.6–0.9)	77 (58–87)†

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

** Defined as a person with sputum results that are smear and culture negative, but with a chest radiograph read as possible or probable TB, who was likely to break down with TB during the one-year period. For calculation purposes, it was assumed that 30% of persons in this category may develop TB in this time period. This represents period prevalence, rather than point prevalence as with the other estimates.

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

Evidence of impact of DOTS on TB prevalence and transmission from the MDP project area in Tiruvallur district, Tamil Nadu

The Model DOTS Project (MDP) area in Tiruvallur district, Tamil Nadu has provided evidence of the potential effectiveness of DOTS implementation under the RNTCP. The epidemiology of TB in Tiruvallur has been closely evaluated by epidemiologists from the Tuberculosis Research Centre (TRC), Chennai, for more than 30 years. The RNTCP was implemented in Tiruvallur district in 1999. Three sequential ARTI surveys have suggested that the incidence of TB in this area has significantly decreased (15) (Table 4). Incidence has again been estimated for consistency using the Styblo conversion, although local estimates from this area are available (11, 12). From the first to the third survey, the annual rate of decline in the prevalence of infection in children <10 years of age has been estimated at 5.8%. Consecutive ARTI surveys provided some evidence of the potential effectiveness of DOTS in reducing disease burden.

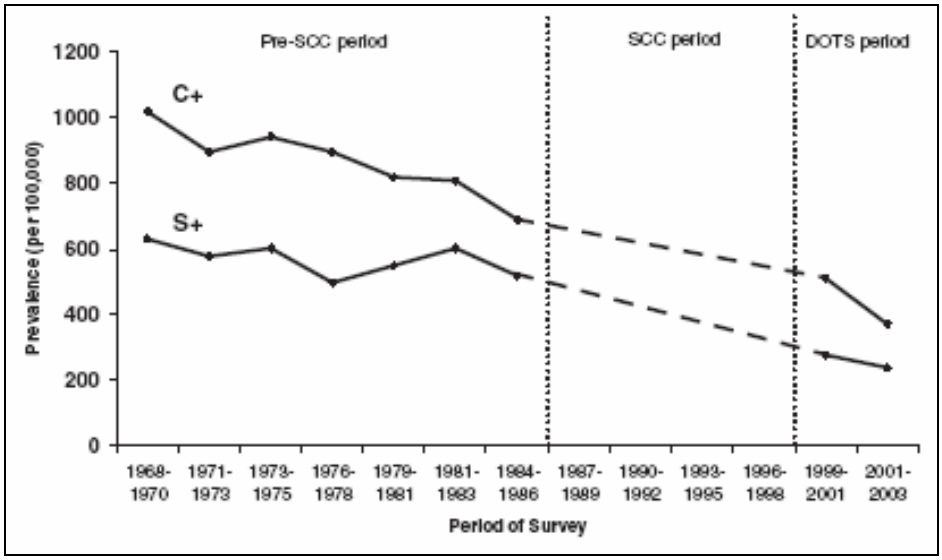
Table 4: *Results of consecutive ARTI surveys in the MDP project area, Tiruvallur district, following RNTCP implementation*

Year	Prevalence of infection (95% CI)	ARTI (95% CI)	Estimated incidence new smear-positive TB, per 100 000 (confidence interval)
1999–2001	7.8 (7.1–8.6)	1.6 (1.5–1.8)	80 (75–90)
2001–2003	6.9 (6.2–7.6)	1.4 (1.3–1.6)	70 (65–80)
2004–2005	6.0 (5.2–6.7)	1.2 (1.1–1.4)	60 (55–70)

Additional support for the findings of reduced disease burden is available from sequential disease prevalence surveys in the same area (1999–2001 and 2001–2003). These surveys have demonstrated a change in prevalence of smear-positive TB from 328 to 259 per 100 000 persons (16). This corresponds to an annual decline of 9.0%. The rate of decline in smear-positive TB observed in 2.5 years of RNTCP implementation is more than double the 4.3% rate of decline observed in the same area from 1984

to 1999. It remains to be determined if this decline is significantly lower than previously observed, and if the decline in TB prevalence in this area will continue to accelerate.

Figure 1: ***Trends in prevalence of culture-positive (C+) and smear-positive (S+) TB in South India, 1968–2001(16) (age–sex standardization with reference to the 1968–70 population survey)***



Mortality and premature death due to TB

Since the RNTCP era, case fatality has remained below 5% for new cases. The case fatality rate, however, has been noted to be higher in the few districts with high (>3%) HIV seroprevalence among antenatal clinic (ANC) attendees, suggesting a possible contribution of HIV to TB-related mortality.

Limited community-based data are currently available on TB mortality in India. WHO has estimated that in 2004, 329 000 persons in India died of TB (mortality rate 30 per 100 000 persons) (14). Data from a community-based verbal autopsy survey in 45 villages in two districts of Andhra Pradesh state suggested that TB accounted for one third of infectious disease-related

deaths, or about 4% of overall mortality and 11% of overall mortality among children aged 5–14 years (17).

A large, retrospective case–control study has demonstrated an association between tobacco use and TB mortality in India; this merits further exploration and consideration (18).

Anti-TB drug resistance in India

Though drug resistance against isoniazid and rifampicin (i.e. MDR-TB) has been frequently reported in India, the vast majority of the available information is hospital-based and anecdotal, and quality-controlled laboratories were not used for DST. Available data from the limited number of standardized and quality-controlled district-level drug resistance surveys show that the incidence of MDR-TB among new cases is 1–3% (19) (Table 5).

Table 5: *Prevalence of MDR-TB among new and previously treated patients*

Area surveyed	New cases		Previously treated	
	Number evaluated	MDR among new, (%, 95% CI)	Number evaluated	MDR among previously treated, (%, 95% CI)
1997 Tamil Nadu	384	13 (3.4%, 2.0–5.7%)	*	
1999 North Arcot	282	8 (2.8%, 1.4–5.5%)	*	
1999 Raichur	278	7 (2.5%, 1.2–5.1%)	*	
2000 Wardha	197	1 (0.5%, 0–2.8%)	*	
2002 Jabalpur	273	3 (1.1%, 0.4–3.2%)	*	
2005 Gujurat	1399	34 (2.4%, 1.7–3.4%)	929	148 (15.9%, 13.7–18.4%)

* Anecdotal data in very small numbers of patients; data not included here

No population-based data are available from India on resistance to second-line drugs (SLDs). However, with the widespread, indiscriminate and unsupervised use of SLDs in India, it is highly likely that SLD resistance and extensively drug-resistant TB (XDR-TB; isolates resistant at least to isoniazid and rifampicin, in addition to any fluoroquinolone, and to at least one of the three following injectable drugs: capreomycin, amikacin and kanamycin) exist in the country.

Plans for monitoring prevalence, incidence, mortality and drug resistance, and JMM Team recommendations

Three key activities are planned for monitoring prevalence and incidence under the RNTCP. These activities are:

- The Second National ARTI Survey, 2007–09: Using the same methodology as the 2000–03 ARTI survey, the change in ARTI after 4–8 years of RNTCP implementation will be evaluated.
  - Members of the JMM team reviewed the ARTI plan; the plan was appreciated as being well developed and the most representative method for monitoring disease impact.
  - Team members observed that India is one of the few countries in the world where ARTI surveys have proven useful, but cautioned that future surveys may be difficult to interpret as the prevalence of infection falls. This has been demonstrated previously in the south zone survey. Therefore, for future zonal ARTI surveys, the current methodology may have limited utility beyond the second round of surveys in 2007–09.
  - The importance of securing a stable supply of 1 TU of purified protein derivative (PPD) for future rounds of surveys was emphasized.
- Disease prevalence surveys, 2007–09: Using standardized methods, disease prevalence surveys will be undertaken in at least five districts from each of the four zones of the country. These data will form the baseline for future disease prevalence surveys in the same areas.
  - Members of the JMM team reviewed disease prevalence surveys, and appreciated the extent and intent of the plans, but raised concerns regarding the methodology.
  - In particular, the use of symptom screening prior to sputum microscopy was felt to add uncertainty to the prevalence estimates, as the sensitivity and reproducibility of symptom screening has been quite variable in other settings.
- Mortality surveys, 2005–08: Field surveys to estimate TB-specific mortality rates in the states of Andhra Pradesh, Orissa and

Uttaranchal are ongoing or near initiation, again forming the baseline for future TB mortality surveys.

  - Members of the JMM team appreciated the efforts of the Programme to complement existing epidemiological impact data with mortality surveys. In the absence of effective vital registration, these surveys are of key importance in measuring progress towards the MDGs.

- Drug resistance surveillance (DRS) 2005–08: Presently, a series of state-representative DRS studies are being conducted, or planned, in selected states (Andhra Pradesh, Gujarat, Maharashtra, Orissa and Uttar Pradesh) in accordance with the WHO/IUATLD global project on anti-TB drug resistance surveillance. It is hoped that data from these surveys will provide valid estimates of the prevalence of MDR-TB and allow for future monitoring of trends.
  - Plans for DRS were felt to be in accordance with international recommendations; no additional recommendations or comments were made.

4. Health systems strengthening

Health systems barriers for an integrated TB programme

The diagnosis and treatment of TB under the RNTCP is integrated into the general health-care system, and is largely carried out by multipurpose general health staff. The RNTCP contributes to the organization of services, provides technical and operational guidelines and training materials, ensures resources (mainly drugs) and quality control (mainly of drugs and microscopy services), and monitors operational results and epidemiological impact. Programme supervision is partly carried out by TB-specific contractual staff, but also relies on the supervision and governance functions of the general health system at the state, district and subdistrict levels.

Being an integrated programme, the RNTCP thus depends on a functioning health system with sufficient infrastructure, outreach and access, and adequate, well trained and motivated staff at all levels. It also depends on functioning referral, transfer and information-sharing mechanisms between various public and private health-care providers.

The RNTCP has achieved full geographical coverage and the priorities now are to sustain and improve its quality and access. Deficiencies in the general health-care system constitute the main barriers to further improvements in programme performance, especially in a number of large states with high TB burdens and weak health systems, such as Bihar, Madhya Pradesh and Uttar Pradesh.

Public health expenditure is very low in India, about US$ 8 per capita, which corresponds to 0.9% of the gross domestic product (GDP). Moreover, public expenditure is biased towards the hospital sector, especially in urban areas. In India 84% of health expenditure is private, and 70% is private out-of-pocket expenditure. Pooling of health financing through taxation is limited and health insurance coverage is very low and restricted to special insurance schemes for government employees and workers in large companies.

Limited public resources for health have contributed to a weak public health-care infrastructure. It has also translated into low salaries for health staff, with consequences for recruitment, staff turnover and staff morale. Many health positions in rural areas are vacant due to the poor working and living conditions for staff. Frequent transfer of staff at all levels increases training load and reduces quality. Staff absenteeism and practice in private clinics to augment income are other problems. Complex bureaucracies also contribute to low morale and inefficient management and supervision.

A recent analysis showed that TB case notification and rate of TB suspect investigation is associated with outpatient visits to general health facilities which, in turn, may be associated with the general state of the health system. The Mission teams made similar observations in the six states visited. Long delays between symptom onset and patients reaching RNTCP services in the general health system is a common phenomenon, suggesting that patients waste time and money shopping for care in a complex and poorly coordinated health system of private and public providers.

Opportunities and challenges in health sector development

The National Rural Health Mission

A reform aimed to address several of the above-mentioned deficiencies in the general health system is under way in India – the National Rural Health Mission (NRHM). The primary goal of the NRHM is to improve the availability of and access to quality health care by people, especially those residing in rural areas, the poor, women and children. The main components of the NRHM are:

- Increased funding for primary health care
- Improved infrastructure of primary health centres (PHCs)
- District-wise situational analysis and development of comprehensive district health plans, with special attention to preventive medicine and social development
- Additional staffing, including nurses and community outreach workers called accredited social and health activists (ASHA)
- Improved structures, in PHC facilities and through ASHA, for implementing different national health programmes, in particular Reproductive and Child Health (RCH)

- Involvement of other sectors, including private providers, NGOs, and Ayurvedic, Unani, Sidha and Homeopathic (AYUSH) systems of health
- Improved monitoring of the performance of PHCs and of national health programmes
- Stimulation for the development of local health insurance
- A key mechanism of the NRHM, intended to facilitate comprehensive health planning at the district level and improve coordination between the different national health programmes, is the merging of specific health programme societies into one common district health society.

In view of its importance to the future of TB control in India, the Mission paid special attention to the NRHM and the Mission teams' observations can be summarized as follows:

- The reform is ongoing and its final operational structure has not yet crystallized in any of the states visited. One of the states visited had not yet signed the MoU for implementing the NRHM (Haryana).
- Separate budget heads for TB in state and district health societies is current national policy; it appears that this has translated into separate budget heads for TB, at least in all the states visited in which the NRHM was under implementation.
- Organizational structures for the new health societies vary across and within states:
  - Some districts have a health society with all programmes fully merged into it; others have an umbrella health society with subcommittees for different programmes, which meet separately.
  - The District Collector is the chair in most districts, while the Panchayat President (democratically elected) is the chair in others. The latter is the case in all districts in Karnataka, as per the decision of the State Government.
  - Some districts have separated "health society" (including TB) from "medical society" (including HIV/AIDS) (Gujarat).

  - The DTO can use funds after approval of the district TB action plan in some districts, but not in others.

- In the current transition period, many states and districts have not established routines for regular meetings of the society. Where district TB societies have been fully merged into the health society, a gap has been created in Programme review and coordination.
- Recruitment and training of ASHA has taken place in many districts, though their role in TB control activities is not yet clear. Improvement of the general health infrastructure and staffing under the NRHM has not yet started on any significant scale.
- Involvement of the private sector, NGOs and AYUSH under the NRHM has not yet started.
- In one of the states visited (West Bengal), district TB societies had already been merged into umbrella health societies in 2002, and the change seems to not have affected TB control significantly.

The Mission thus found that the NRHM is at an early stage of implementation and the consequences for RNTCP implementation are therefore not fully assessable at this point in time. However, the main opportunities and challenges were identified as follows:

Opportunities

- Infrastructural improvements in PHCs and additional staff in public facilities could improve OPD attendance and thereby the number of TB suspects identified in public facilities.
- Involvement of the private sector, NGOs and indigenous systems of medicine, and creation of posts for ASHA could help expand the referral network for TB suspects and support for treatment.
- The stronger supervisory function of subdistrict/Block Medical Officers (BMOs) can be harnessed for improving RNTCP supervision.
- Devolution of power to District TB Officers (DTOs) to implement activities according to approved action plans and budgets may improve the efficiency of Programme implementation.

Challenges

- Merging of the District TB Control Society (DTCS) into a unified district health society can dilute the attention to TB control and divert resources. Though it has been clearly stated by the Centre that the budget for TB control should remain separate when TB societies are merged, and this is currently the situation in all states visited, the situation could change in the future.
- Depending on the nature of changes in the decision-making and programme execution structure, planning and budgeting for and implementing TB control activities may be weakened, e.g. if the executive role of the DTO is weakened or the district collector/magistrate is no longer the chair of the societies.

World Bank health sector development projects

The World Bank has been funding health sector development projects in several states. These are second-generation projects with a focus on development of primary health care, previous projects having supported infrastructure development for referral services. These states include Karnataka, Orissa, Rajasthan, Uttaranchal and Uttar Pradesh. It is important to ensure that the development of TB-related services remains an integral part of these projects. Different approaches to primary health care development are also being pursued in these projects. In Uttar Pradesh, for example, a major emphasis has been on contracting out PHC services to NGOs capable of providing them. In such instances, it would be crucial to include the DOTS package in relevant contracts and also ensure that NGO staff is trained adequately in the delivery of services under the RNTCP.

RNTCP experiences and innovations can help strengthen the health system

The RNTCP has greatly improved parts of the health system which are essential for performance of the TB programme, such as human resource (HR) management, laboratory infrastructure and quality, and the functions of recording, reporting, monitoring, supervision and evaluation. This has been done partly through contractual RNTCP staff, but has also involved general

staff at all levels. The capacity built in the field is benefiting the general health system, and can serve as a model for further strengthening public health functions under the NRHM. In particular, the strong emphasis on performance monitoring in the RNTCP sets an example for other public health programmes. Moreover, as discussed above, analysis of RNTCP performance at the district level can help identify deficiencies in the general system which can feed into situational analysis and development of district health plans.

The RNTCP has proactively involved a range of different health-care providers in programme delivery through several novel public–private mix (PPM) approaches. These providers can also play potentially important roles in other public health programmes, and the PPM experiences under the RNTCP can help shape strategies for wider public health-oriented PPM. This is of particular relevance under the NRHM with its special attention to involvement of private providers, NGOs and AYUSH. To date, however, PPM experiences of the RNTCP have been shared to a very limited extent with other national health programmes and the general health system.

Recommendations

(1) Actively participate in efforts to improve the health system

(a) The CTD should continue to take part in discussions on how to implement the NRHM, as well as in other national forums for discussions and planning on strengthening of general health systems.

(b) The CTD should actively promote participation by State Tuberculosis Officers (STOs) and DTOs in the state and district health societies, respectively, along with other TB control partners, in order to help identify and address constraints in the general health system which affect TB control activities.

(c) At the state level, promote the use of TB control management and performance indicators as indicators for the general system. In particular, case notification, sputum positivity, number of suspects examined, can indicate problems with access, staffing/attendance, and quality of work by medical officers (MOs), laboratory technicians (LTs) and other staff of the general health system.

(d) The RNTCP should work closely with the state governments implementing World Bank-funded health sector development projects, as well as the relevant officers of the World Bank. It may be useful to prepare a checklist jointly with World Bank officers and the respective states to ensure that the requirements for TB-related primary and referral services are properly taken care of as part of all health sector development.

(e) Share innovations and experiences from TB control that can benefit other national programmes and the general health system, particularly in the context of the NRHM.

(2) Protecting TB control during health sector reform

The CTD, STO and DTO should ensure that essential, "non-negotiable" functions are protected at the state and district levels during implementation of the NRHM and other health sector development initiatives by:

(a) Ensuring TB-specific action planning;

(b) Ensuring an uninterrupted supply of quality-assured drugs and maintaining procurement of anti-TB drugs as a function at the national level.

(c) Continuing the dedicated anti-TB drug supply line through the TB drug stores at state, district and subdistrict levels.

(d) Protecting the post of a dedicated, full-time State TB Officer (STO).

(e) Ensuring that the DTO works full time for TB only, unless the TB burden is low and/or the district is small; in any case, the programme officer appointed as DTO must prioritize TB first, and is not given responsibility for other larger programmes.

(f) Ensuring the capacity for dedicated TB supervision at district and TU level.

(g) Ensuring standard quarterly recording and separate TB reporting to the District Tuberculosis Centre (DTC), State Tuberculosis Centre (STC), CTD; the reporting frequency should not be changed to a monthly format, and reports to the NRHM should be generated from standard quarterly reports.

(h) Maintaining a separate budget head for TB in the district health plan as well as a separate bank account.

(i) Separating the TB subcommittee, or equivalent, under the district health society, or securing time for TB at all health society meetings.

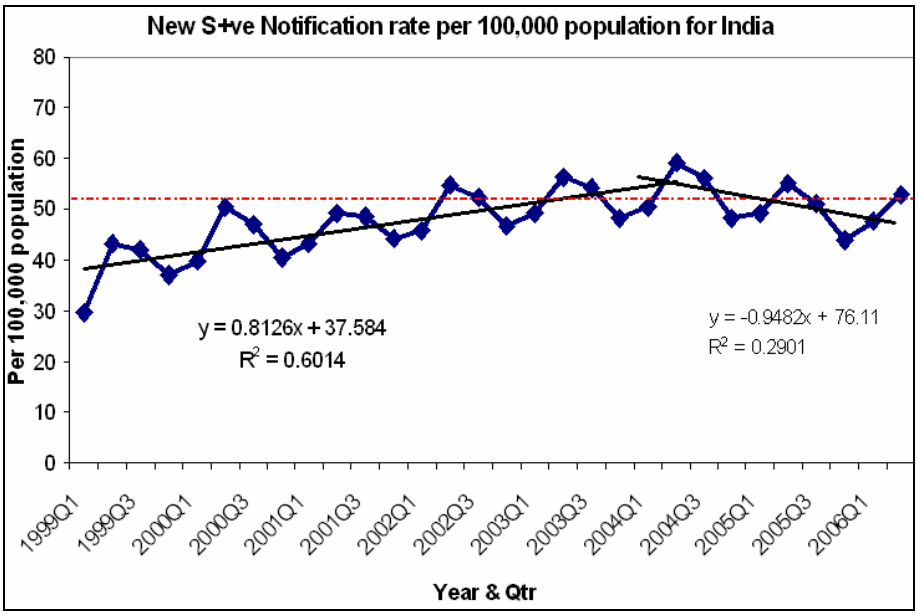
(j) Promoting maximum flexibility for the DTO to use the budget as per the action plan without the need for approval from the chair of the society.

5. Case detection and diagnosis

Detection of suspects

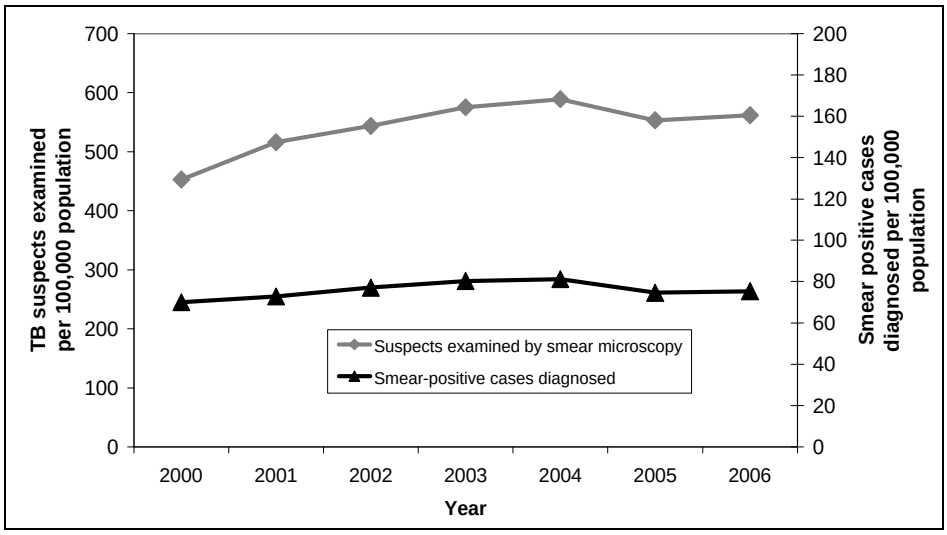
The RNTCP reported an increase in cases detected since its implementation in pilot areas and on expanding geographical coverage. However, in the past two years the case notification rate of NSP cases has declined (Figure 2).

Figure 2: ***New smear-positive case notification rate in India, 1999–2006, with trends before and since 2004***



Although this could be due to several reasons, including a reduction in incidence and prevalence, the most probable reason is the reduction in evaluation of TB suspects (Figure 3).

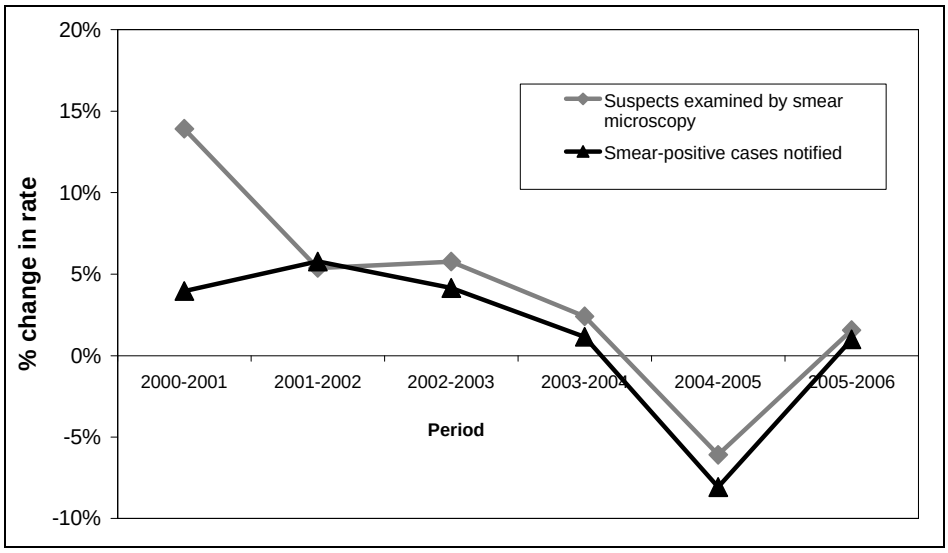
Figure 3: ***TB suspects examined by smear microscopy and smear-positive cases diagnosed, India, 2000-2006***



Changes in the rate of examination of TB suspects by smear microscopy have closely correlated with the diagnosis of smear-positive cases over the past 6 years (Figure 4). Interestingly, since 2004, the rate of examination of suspects was observed to have plateaued or decreased.

Observations in the districts visited by the Mission indicate that referral of TB suspects among outpatients in health facilities is done mainly by the MOs. The WHO recommendation is to screen with microscopy adults with cough presenting to health facilities for any reason. Systematic questioning to elicit a history of cough was sometimes missed, particularly in patients presenting initially without respiratory complaints. In addition, due to the posts of MOs being vacant, patients coming to clinics in remote areas often met with only paramedical staff, such as the pharmacist. Screening for cough is not conducted at the registration desk or in the patient waiting area, where there are opportunities for picking up TB suspects, not only among patients coming to seek care for cough, but also among patients and their accompanying attendants/relatives visiting for other reasons. Additionally, patients with cough for less than two to three weeks were not informed that they needed to return to the facility for sputum examination if the cough persisted.

Figure 4: ***Changes in TB suspect examination rate correlated with changes in smear-positive case notification rate***



Health-care providers in the community, including PPs (all types of medicine), community health workers and community health volunteers did not consistently refer TB suspects for sputum examination. Since community workers are more likely to come across persons with cough for less than two to three weeks, it is important for them to communicate the address of the microscopy centre with a message to visit the microscopy centre in case the cough persists beyond two to three weeks. It was noted that patients often consulted several health providers, sometimes far from home or work and at high cost, before learning that the RNTCP services were provided by the general facilities or community staff near their home.

Health providers of all types, and appropriate channels and methods of information should be used to increase the awareness of the community about cough. This should include both the current linked message ("cough may be infectious TB, and TB is curable free of charge") plus an unlinked message (e.g. "if you have cough for a long duration, consult a health facility"). Unlinked brief messages must be displayed in health facilities (e.g. "if you have a cough, let us know") accompanied by graphic messages which can be understood by illiterate persons. Many of the present messages in health facilities contain too much written information, which cannot or will not be read or remembered.

An issue to reconsider is the duration of cough criteria for identifying TB suspects. The present duration is cough for more than three weeks. A study conducted by TRC, Chennai showed that changing the duration to two weeks of cough substantially increased smear-positive case detection (20). In general, microscopy laboratories can absorb more work, so this is not a barrier to consider changing the duration of cough to 2 weeks. This would require pilot testing, perhaps in a number of states, with strengthening of microscopy facilities where the workload exceeds realistic expectations.

Diagnosis

TB control has as its priority the detection and treatment of pulmonary smear-positive patients because they are the main sources of infection. However, pulmonary smear-negative cases also have an impact on prevalence and transmission; and diagnosis and treatment of all forms reduce human suffering and TB mortality, which are also goals of the TB programme. Improving patient care by increasing the capacity of facilities to diagnose smear-negative, paediatric and extrapulmonary TB (through training of MOs and availability of radiological equipment and culture) are important factors to reduce the burden of TB.

In field observations, it was noted that MOs often limited the referral for microscopy to patients with cough for more than three weeks. Although a limit (two or three weeks) must be established for screening, MOs are expected to refer for sputum microscopy patients with cough for any duration if the patient has other symptoms or signs suggestive of pulmonary TB (including abnormal X-rays, if X-ray is already available with the patient for any reason).

Identification by the laboratory of persons with a positive sputum test, particularly those with repeated positive smears where laboratory error is not probable, should be followed by treatment. The "initial default" rate is quite high in many areas. The Senior Treatment Supervisor (STS) and Senior Tuberculosis Laboratory Supervisor (STLS) should ensure that these persons are identified, found, informed of the results and started on treatment. This will increase the number of cases detected and treated. A system of mandatory notification of smear- and culture-positive cases by laboratories (public, corporate, NGO and private) would further increase information regarding case detection and the coverage of patients under the RNTCP. It would also allow follow up to involve diagnostic physicians or institutions in

the RNTCP, reduce the need for patients to pay for drugs and direct interventions to rectify inadequate practices.

The quality of medical diagnosis has improved substantially under the RNTCP. The proportion of new cases put on treatment after confirmation by microscopy increased from under 20% to over 50% in ten years. In the second quarter of 2006, 59% of the new pulmonary cases were smear-positive, falling within the expectations of the country's diagnostic capacity. This implies that 41% were smear-negative, including cases with clinical/radiological diagnoses and children who cannot produce sputum. This finding varied by region; e.g. in Gujurat, 72% of new pulmonary cases were smear-positive, which is higher than expected, raising concerns for the follow up of patients who were initially sputum smear-negative.

The proportion of retreatment cases varied greatly between states and districts. In some areas, e.g. some districts of Gujarat, between 25% and 45% of smear-positive cases were retreatment cases, frequently attributed to recent treatment in the private sector. In previously treated cases, radiology is much less effective as an auxiliary aid to diagnosis, because lesions from the past are still visible and symptoms can be due to other chronic or acute infections. Despite this, in some districts, it was observed that the proportion of retreatment cases diagnosed without bacteriological confirmation was high.

Monitoring of case detection activities

The key indicator for monitoring of case detection activities is persons examined for diagnosis, either in absolute numbers or as number per population, which is useful at district and higher levels. As the proportion depends strongly on the access and use of public health facilities by the population, national targets should not be established. Targets can be established locally, aiming at gradually increasing the absolute number while maintaining cost-effectiveness. The positivity of smear microscopy should be used at district level to decide if detection of suspects is sufficient. A gradual reduction of positivity should be observed over time, and when positivity is low (i.e. less than 5%) efforts should address selection of suspects and quality of sputum samples more than the number of persons examined.

Programme staff should assess the monthly clinic attendance at designated microscopy centres (DMCs) and PHCs by the number and trend of persons examined for microscopy, the trend in absolute numbers of persons examined, and the positivity of microscopy.

Over the past three years considerable progress has been made in involving medical colleges in RNTCP activities. In many cities medical colleges contribute substantially to the care of TB cases registered under the RNTCP. However, a few medical colleges are still not effectively involved.

Microscopy services are, in general, geographically accessible. In difficult and remote areas, the RNTCP guidelines provide for sputum collection and transportation, but the Mission observed that this system was not used, primarily because of reluctance of health staff to transport sputum in the absence of appropriate incentives.

Recommendations

(1) Implement systematic screening of adults with cough attending health facilities for any reason using, in addition to MOs, non-medical staff. In particular, train the registration officer or equivalent staff to ask the question regarding cough (or cough for more than three weeks) and refer patients to the laboratory while they wait for medical consultation or other services. The CTD may conduct a pilot prior to scaling up this intervention.

(2) Utilize all types of health staff, including PPs of all types of medicine, community health workers and volunteers, to refer suspects to microscopy units and to increase population awareness of the importance of cough and the location of microscopy units.

(3) Use TB-linked and unlinked messages by appropriate means to increase public awareness and consultation of public health facilities when there is cough for a long duration.

(4) Review the data available from routine Programme and research study sources to re-consider the duration-of-cough criterion, i.e. three or two weeks, by performing a pilot of such a change in criterion in a number of districts in one state.

(5) Conduct field evaluation studies to understand reasons for "initial default" better, and to subsequently develop and implement mechanisms to decrease "initial default".

(6) Support the NRHM to ensure full staffing of LTs, strengthen the capacity of health facilities to diagnose all forms of TB, and make maximum use of ASHA for community education in TB. Ensure follow up of initially smear-negative TB suspects with antibiotics and repeat sputum examination in order to diagnose, or rule out, TB.

(7) Encourage areas with large private laboratories to conduct active laboratory surveillance, as well as training and quality control to the greatest extent possible. Further, consider establishing certification standards for laboratories and implementing mandatory laboratory-based notification of smear-positive patients.

(8) Assess the sources of retreatment cases and the reasons for the large differences observed in the numbers and proportion of registered retreatment cases across states and districts.

(9) Eliminate national targets for the detection of suspected cases of TB and follow up trends of absolute numbers or rate per 100 000 inhabitants at district, state and national levels; and of absolute numbers and positivity rate at the district and microscopy unit level.

(10) Eliminate all targets and reporting for case detection rate below the district level. Instead, focus monitoring efforts for case-finding on the number and trend of people examined for TB. Similarly, discourage the use of case detection rate at the district level.

(11) Analyse the experiences of patients diagnosed to identify missed opportunities for earlier diagnosis.

(12) Continue additional activities to increase awareness of and access to RNTCP services among the urban slum population, but in doing so avoid micro-targets for monitoring case detection in slums.

(13) Consider regulatory mechanisms to ensure that at least public sector health-care providers diagnose, treat and notify TB according to the Programme guidelines and the international standards for TB care (ISTC).

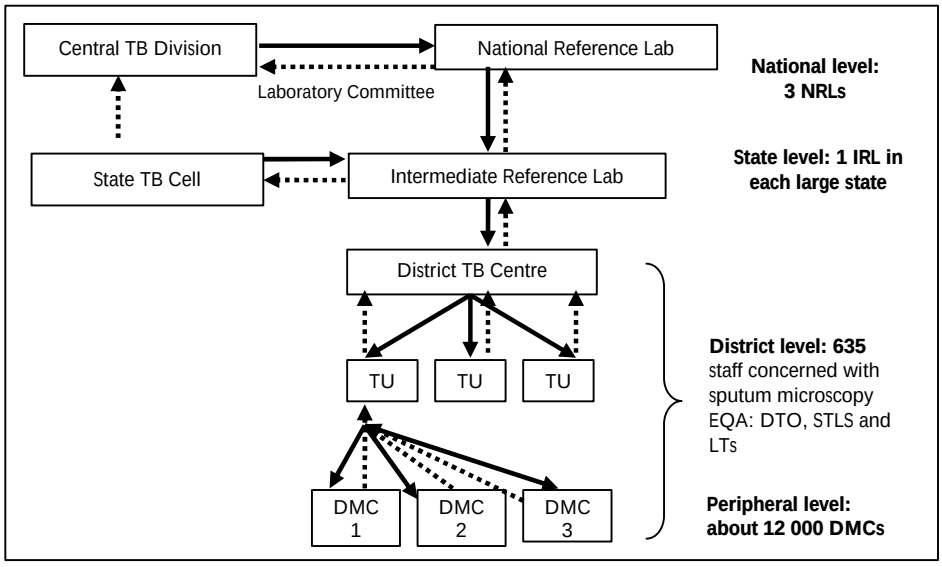
6. Laboratory networks and quality assurance systems

Laboratory network

Significant efforts have been made to consolidate the RNTCP laboratory network into a well-organized and coordinated one, with a clearly defined hierarchy for carrying out sputum smear microscopy, culture and DST, and DRS. A National RNTCP Laboratory Committee was constituted in late 2004 with the task of overseeing and guiding all laboratory-related activities of the Programme. Since then, nine quarterly meetings of the Committee have been held.

The RNTCP laboratory network (Figure 5) consists of three designated National Reference Laboratories (NRLs) – TRC, Chennai, the National Tuberculosis Institute (NTI), Bangalore and the Lala Ram Sarup Institute of TB and Allied Sciences, Delhi; 24 state-level Intermediate Reference Laboratories (IRLs), and around 12 000 RNTCP-designated smear microscopy centres (DMCs).

Figure 5: *Structure of RNTCP laboratory network*



The three NRLs are tasked with overseeing EQA activities in 11–12 states. A team from the respective NRL does an annual on-site evaluation (OSE) visit to each state allotted to it. During the OSE visit by the NRL team, a supervised panel test exercise is conducted with all LTs and microbiologists of the respective IRL. An evaluation of the ongoing random blinded rechecking (RBRC) of routine slides will also be undertaken during the OSE visit. In addition, the NRLs will oversee the accreditation procedures of the IRLs for mycobacterial culture and DST, and for quality assurance (QA) of ongoing culture and DST services at the IRLs.

Each large state will have a designated IRL for the purposes of training, supervision and monitoring of smear microscopy services provided by the DMCs in the respective state. The IRL can be sited at an STDC, the State Public Health Laboratory, or in the Microbiology Department of a medical college. Currently, the RNTCP is strengthening the capacity of 13 IRLs, including establishing quality-assured culture and DST services in these laboratories. The required upgrading of IRL infrastructure and procurement of new equipment has been provided for by the RNTCP. In addition, the RNTCP has made provision for hiring 19 contractual microbiologists to be posted at the IRLs. The RNTCP is undertaking a process of accreditation for culture and DST in the designated IRLs. The accreditation process has three components. A pre-assessment visit will be made to the IRL by an NRL/CTD team during which existing infrastructure and processes in the IRL will be examined, and corrective actions recommended. Then the IRL and the NRL will exchange the required number of cultures, and if concordance levels between the laboratories are satisfactory, the IRL is expected to apply to the CTD for accreditation. The national team will make a second visit to the IRL and, if conditions and processes are satisfactory, accreditation is awarded. Currently, IRLs in the states of Gujarat and Maharashtra are undergoing accreditation.

The RNTCP DMC in each district is the most peripheral laboratory offering RNTCP diagnostic services, and serves a population of 50 000-100 000. The RNTCP has provided the finances for upgrading the health facility in which the DMC is located, supplied over 10 000 binocular microscopes to DMCs, and hired contractual LTs to strengthen services in around 20% of the DMCs. A good logistics system is in place to ensure an adequate supply of reagents and consumables at the DMCs.

The network of DMCs offering quality-assured smear microscopy services has been expanded and their number almost reflects the estimated 2006 population. DMCs have been designated in all sectors, including private, NGO and corporate health facilities.

Staffing of the DMCs is satisfactory. In certain states with known weaker health systems, e.g. Bihar and Uttar Pradesh, the RNTCP is relaxing its norms for the proportion of contractual LTs hired under the Programme. Although smear microscopy services in a few states, e.g. Gujarat and Tamil Nadu, are still being provided by laboratories that are not RNTCP DMCs, this is a diminishing problem. Sputum collection centres and systems for transporting the sputa collected at such centres to the nearest DMC are being established, but remain limited in number.

Although good-quality binocular microscopes are generally available, and "annual maintenance contracts" are in place in a few states, there remain many challenges to the maintenance of binocular microscopes. In some districts, a significant proportion of the microscopes are either in need of repair or non-functional.

A common finding was that infection control guidelines and plans are not being implemented, and that the practices for biomedical waste management are generally weak, especially at peripheral health facilities.

Although most states have designated a state-level facility as their respective IRL, these IRLs function at variable levels in relation to the activities expected of them under the RNTCP. Challenges exist in almost all states with respect to staffing and training of staff at the IRLs, especially in undertaking quality culture and DST. Supervision of field-level activities by many of the IRLs is as yet suboptimal. To date, no IRL is as yet accredited to undertake culture and DST. In addition, the issue of biosafety in the IRLs needs to be given much more priority.

At the NRL level, there are similar issues related to staffing levels, unmet training needs, suboptimal infrastructure and limited availability of equipment. The fact that the laboratory at the TRC, Chennai is one of two WHO Supra-National Mycobacteriology Reference Laboratories in the Region is another challenge, as TRC staff are deputed to meet the laboratory-related needs of other SEAR countries.

Quality assurance systems

In April 2005, the RNTCP issued revised "Guidelines for quality assurance of smear microscopy for diagnosing TB". The three components of EQA being implemented under the RNTCP include OSE; panel testing; and RBRC. OSE of state-level IRLs and DMCs to assess the overall operational conditions in the IRLs and DMCs is performed by personnel from the higher-level laboratory. Each DMC is visited by the STLS at least once a month. The DTC is visited by a team from the IRL, and the IRL is visited by a team from the NRL, respectively, at least once a year. Standardized checklists have been developed to assist both laboratory and non-laboratory supervisors during the field visit and to allow collection and analysis of data for subsequent remedial action.

Panel testing is used only for evaluating the microbiologists and LTs of the IRLs, and the STLS of the districts during the annual OSE visit by the respective higher laboratories. This method evaluates the individual performance of an LT in staining and reading. It is not performed as a routine in DMCs as they have regular OSEs and RBRC of routine slides is done on an ongoing basis. RBRC is done at the district level and involves selecting a random sample of routine slides from every DMC for re-checking at a higher-level laboratory. The annual sample size is calculated for each DMC using the Lot Quality Assurance Sampling methodology. The STLS, who rechecks the slides from any DMC, is blinded in relation to the original smear result as given by the LT at the DMC. To prevent bias, it is general practice that the STLS who rechecks the slides should not belong to the same TU as the DMC from which the slides have been sampled. The sampling of slides is done monthly and the results compiled at the district level and sent to the IRL of the respective state. The IRL in turn sends the results for analysis to the allotted designated NRL and the CTD.

As of October 2006, 14 states and UTs were fully implementing the revised RNTCP EQA protocol and the remaining states/UTs were partially implementing it. It is planned to have 100% coverage by the end of June 2007. The JMM appreciated the efforts made by the RNTCP to implement the EQA system so widely in such a short period of time. An additional positive finding of the review teams was that internal quality control (IQC) of reagents was in place in many of the states visited and, in at least one state (Gujarat), IQC registers were being used and were examined by the review team.

Although the EQA protocol is now being widely implemented in the Programme, a number of concerns were raised during the field visits. It was commonly found that the blinding procedure of RBRC was not being done by the DTO as per the guidelines. A worrying and common observation was that skills appeared to be lacking for analysing the data generated by RBRC activities and for the planning of appropriate corrective actions. In two districts of Gujarat (Mehsana and Sabarkantha), it was observed that no errors, not even a single quantification error, were reported as yet during 2006. This is highly improbable and needs further investigation.

Recommendations

Laboratory network

(1) The network of DMCs needs to be reviewed and expanded to reflect the projected 2007 population in order to ensure adequate access to microscopy services. The network should continue to recruit laboratories in the non-public health sectors wherever workload criteria, etc., are met.

(2) Sputum microscopy should be actively discouraged in non-supervised, non-quality assured, non-designated laboratories. Sputum collection centres and transportation systems need to be more widely available to ensure that patient-friendly smear microscopy services are in place.

(3) All states should ensure that maintenance contracts for microscopes are in place and implemented effectively.

(4) Infection control needs to be prioritized, and all facilities should have a general infection control plan in place which is implemented, and which incorporates measures recommended by the RNTCP for TB infection control.

(5) As a priority, a network should be established of accredited IRLs for quality-controlled culture and DST to diagnose MDR-TB. All existing resources including medical colleges, national institutes and other appropriate laboratory facilities should be utilized for culture and DST. Accreditation by a reference laboratory is necessary, and the accreditation process by NRLs or IRLs should be developed.

(6) Vacant posts, both regular and contractual, for microbiologists and LTs at the IRLs should be filled urgently.

(7) A training plan for the appropriate laboratory staff members on culture and DST, as well as on Good Laboratory Practices needs to be developed and implemented before starting operations.

(8) All laboratories performing culture and DST for the RNTCP need to have a manual of standard operating procedures (SOPs) in place. All procedures at these laboratories must be quality controlled by the corresponding NRL.

(9) All major laboratory equipment supplied must be of the highest quality. Full safety certification of biological safety cabinets is an absolute priority before culture and DST are undertaken in the laboratory. Laboratory equipment must be constantly monitored, maintenance contracts should be obtained for each item of equipment, and the equipment must be certified annually.

(10) DST procedures in the laboratory must be proficiency tested annually by the corresponding NRL. Failure to meet the standards should lead to cessation of DST until the deficiencies are corrected.

(11) Medical monitoring of the health of IRL laboratory staff needs to be implemented immediately.

(12) Biomedical waste management practices, especially at peripheral health facilities, need to be reviewed and brought in line with the existing health services and RNTCP guidelines.

Quality assurance systems

(1) Complete implementation of the EQA guidelines must be done across the entire Programme.

(2) The EQA systems for microscopy must be reviewed, the usefulness of the different methods evaluated, and procedures, data collection, analysis and interpretation simplified. This could be done by conducting a detailed review of EQA implementation in a small number of districts.

(3) OSE should continue as per guidelines, with the OSE checklist pasted in the laboratory register.

(4) Panel testing can be done only when needed. IRLs need not prepare panel smears and patient slides can be used for panel testing.

(5) RBRC component:

(a) Investigate whether having a single sample size, e.g. eight slides/month/DMC for RBRC could be used across all DMCs. Systematic sampling of the slides for RBRC should be done.

(b) Blinding of rechecking should be ensured by the DTO, and this should be monitored by reviewing the records of Annexure C. A system should be developed to monitor the proficiency of reading by the first controllers and the umpire.

(c) Guidelines for analysis, interpretation, remedial action and feedback mechanisms should be prepared and an updated training plan developed.

(d) The umpire's RBRC readings should also be blinded for readers and for results.

(6) IQC should be implemented in all RNTCP DMCs.

(7) Laboratory performance indicators need to be calculated, analysed properly and remedial action taken as soon as the sources of errors are detected.

(8) To address the lack of expertise at the district and state levels to interpret and analyse data, a plan for capacity building of respective concerned staff needs to be developed and implemented.

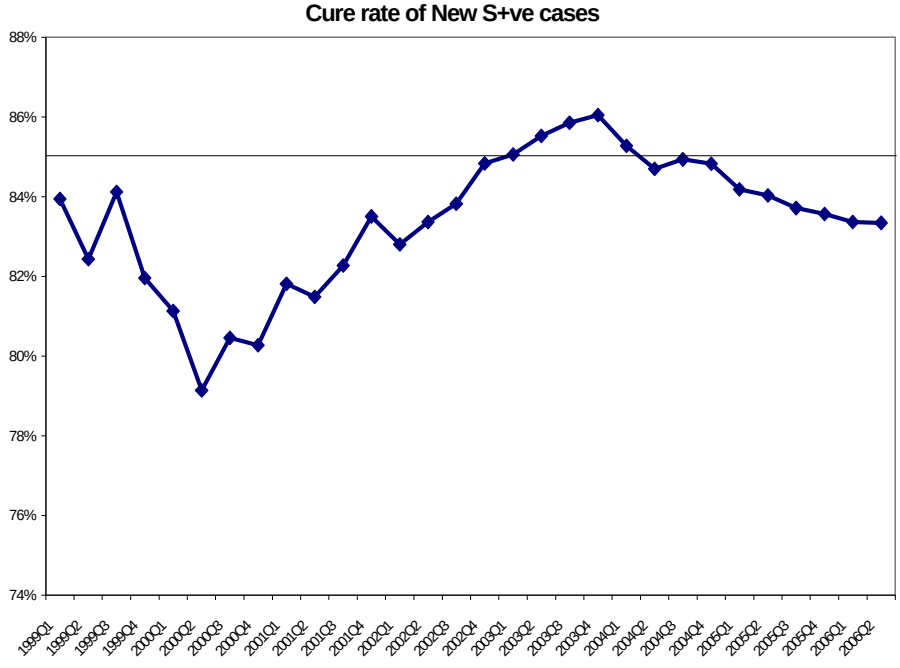
(9) As a large volume of laboratory-related data is now available, these data should be computerized for analysis and interpretation.

7. Treatment and Directly observed treatment

Since the previous review, there has been progress in reducing non-RNTCP treatment through better Programme management and improved coordination with medical colleges, Employees State Insurance (ESI) and some other sectors. This may have benefited from clear Programme guidelines for the registration of all TB patients, and official acknowledgement of the occasional use of two approved non-DOTS, non-rifampicin containing regimens in a small proportion of cases. Drug supplies have been reliable, although water and syringes for injection did not appear to always be available where needed for Category II patients.

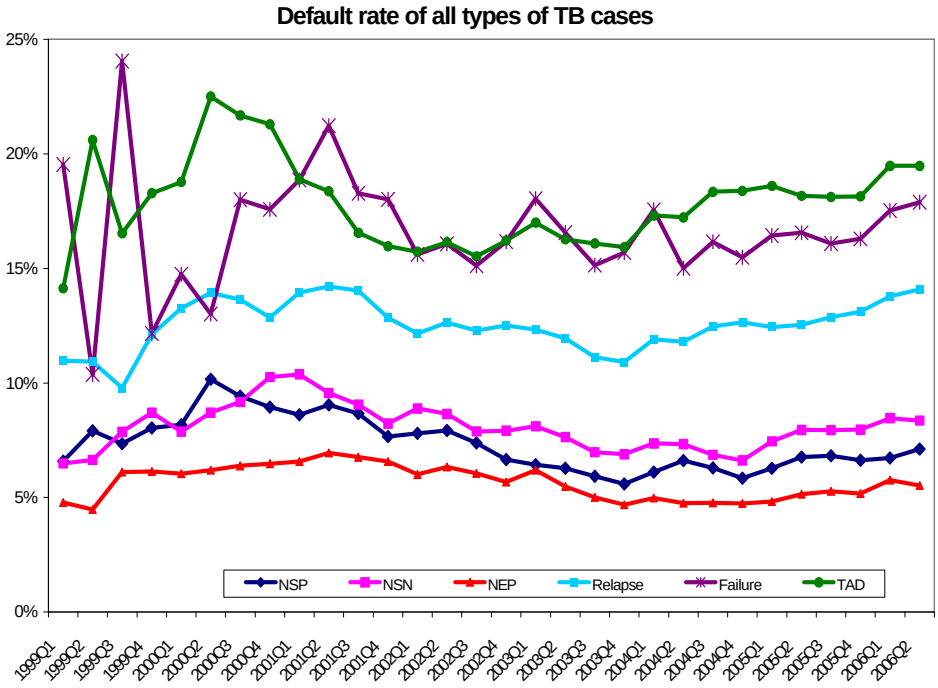
Overall, treatment results remain reasonably good among new patients. As shown in Figure 6, treatment outcomes had improved through the cohort beginning treatment in the middle of 2003, but have declined since.

Figure 6: ***Cure rates of new smear-positive cases, 1999–2006***



Default rates are particularly high among retreatment patients, and have also increased substantially over the past two years. While appreciating the accuracy of reporting that allows the reporting of a worsening trend in the Programme, the JMM team expressed serious concern regarding the implication of this finding for Programme supervision, as well as the effectiveness of DOT providers in preventing default from occurring. It was noted that among the visited districts, the district with the highest proportion of community DOT (Chikmagalur, 45%) had the lowest default rates (Figure 7).

Figure 7: ***Default rate of all types of TB cases, 1999–2006***



NSP new smear-positive, NSN new smear negative, TAD treatment after default

A mechanism exists for referral for treatment, both within and outside the district. This is a major advance, particularly for involving medical colleges and remaining TB hospitals. The availability of indoor DOTS using RNTCP-supplied prolongation pouches has also overcome a key barrier to convenient patient care. Where used, referral registers have helped

increase the accountability for patients and improve surveillance. In particular, feedback on out-of-district referrals was observed to be quite poor. There has been some use of the internet to transfer patients from one area of jurisdiction to another, although this is the exception rather than the rule.

Treatment observation appears to be provided in most cases, but non-observation is still often recorded as observation, and treatment observation is often not convenient for patients. This is a problem particularly for patients living in remote areas and for labourers in urban areas.

Decentralization of treatment provision out of the health system has been stressed repeatedly by the RNTCP, but its implementation is limited in many districts. Systematic data on who is observing treatment are not available and, in many districts, an increasing proportion of treatment observation is provided by *anganwadi* workers and other community-level staff who are more likely to be in place near the patient than other health-care sector field staff, such as the multipurpose worker (MPW) and ANM. All the teams noted that except in one district, the majority of patients receive DOT from clinics in the public health system. The perception of a ceiling on community DOT associated with financial guidelines for DOT honorariums was frequently cited as a barrier to decentralization of DOT. Regardless of this concern, honorariums were reportedly not provided to DOT providers in the districts visited. Additional reasons cited for reluctance were concern for the regular availability of funds at the district level under this budget head, fear of creating resentment among health staff not eligible for additional reimbursement (e.g. ANM), and a perception that the same persons were willing to do the job for free. There are some difficulties in ensuring that the MPW/ANM coordinates with the *anganwadi* or other community volunteer to provide back-up as needed.

In some areas, there appears to be too little attention paid to accurate diagnosis, effective treatment, and return to care of smear-positive retreatment patients who, for TB control purposes, are as important as NSP patients. Furthermore, there was little attention given to smear-negative and extrapulmonary patients.

The inability to provide evaluation of and treatment for patients who fail Category II regimens is creating problems for the Programme, including loss of credibility with both medical staff and patients. The widespread

availability of SLDs was commented on by all teams, and concern was raised among the team members regarding the potential for the development of SLD resistance.

Although there are now agreed-upon national policies for the diagnosis and treatment of paediatric TB and evaluation of possible lymphatic TB, capacity for the diagnosis and treatment of paediatric and extrapulmonary cases appeared to be limited in some of the locations visited. Currently, nearly 6% of the Programme caseload is due to paediatric TB. Paediatric patient-wise boxes (PWBs) were being provided in some states and are likely to be available widely for field use in 2007

The Programme also recommends treatment of latent infection with isoniazid (INH) for all children under 6 years of age who are in close contact with a smear-positive case. By all anecdotal reports, the inclusion of a specific area on the patient treatment card for recording this has substantially improved the uptake of this long-standing recommendation. However, INH chemoprophylaxis is not being given consistently. These data are not systematically monitored by the RNTCP, but the Mission team members observed that the practice was uneven in the sites visited, and that field workers frequently narrowly interpreted the recommendation to be limited to the children of patients, rather than any child in the house. In other words, health workers sometimes did not provide INH treatment to grandchildren, nephews, nieces, etc. who were staying in the same household. The teams also noted delays in starting chemoprophylaxis after initiating treatment for the index sputum-positive case. Active disease was also not systematically excluded before starting chemoprophylaxis.

Recommendations

(1) Ensure provision of DOT at a time and place convenient to patients. Promote decentralized DOT, and consider establishing a routine indicator for treatment decentralization.

(2) In addition to providing DOT close to patients' homes, expand the use of workplace treatment observation and, where necessary and where actual observation by a person other than a family member can be assured, consider using home-based direct observation.

(3) Make an intensive effort to reduce high treatment default, particularly among Category II patients and in urban areas.

(a) Review and ensure full posting of TBHVs and LTs in urban areas.

(b) Promote decentralization of DOTS and patient-friendly treatment observation.

(c) Improve address verification through patient counselling and motivation, with address confirmation on subsequent visits. Patients should not be required to produce documentary proof of address prior to treatment initiation.

(d) Ensure rapid and effective retrieval of patients who interrupt treatment.

(e) Further improve the process of patient transfer to other areas.

(f) Identify counselling and referral resources to address alcohol abuse and consider staff training on this issue, as this appears to be a common underlying cause of default.

(g) Evaluate interventions to rapidly identify patients who are at risk for default (e.g. those who miss doses or fail to come for sputum examination), and prevent default. One administrative intervention would be to change the way treatment cards are organized at busy DOT centres. If the DOT provider puts all the cards of patients expected that day into two groups, initial and continuation phase, and separates those that receive drugs, at the end of the session it would be easy to assess who has missed treatment, and who should be rapidly retrieved to continue regular treatment.

(h) Evaluate the use of incentives and enablers for patients in urban slum areas.

(4) Improve treatment observation by improving training and support of treatment observers in interpersonal communication (IPC) skills, the linkage between treatment observer and MPW/ANM, and organization of treatment observation so that it is more convenient for patients. Monitor, not through standard reporting but through periodic random evaluation, how long patients have to travel for treatment observation and work in order to assess the convenience to patients.

(5) All patients started on treatment at medical colleges and chest hospitals should be registered, with sufficient medication and referral

information provided to patients upon discharge; the referral-for-treatment mechanism should be strengthened to improve feedback regarding patient outcomes.

(6) Improve the management of paediatric TB by sensitizing paediatricians and paediatric societies.

(7) Improve the implementation of INH preventive treatment; on a periodic basis, programmes should evaluate if INH is being started within one month of the index patient starting treatment. Training should stress that the MO evaluates children for symptoms and rules out active TB disease prior to starting INH preventive treatment.

(8) Evaluate the yield of smears taken during follow up of patients who are initially smear-negative. Because such smears are so rarely positive, it is likely that the positive predictive value of a positive smear in this situation is very low and the policy can be changed so that fewer or no follow-up smears are obtained from patients who were initially smear-negative.

8. Recording, reporting, monitoring and Programme supervision

The recording and reporting system is extremely strong, with complete and generally electronic submission of quarterly reports. For the most part, the review team found the reports to accurately reflect reality, with some exceptions. However, in many places, treatment that is not directly observed continues to be recorded as observed in the treatment card. In some districts, smears that had not been taken were recorded in laboratory registers, treatment cards, TB registers and quarterly reports. While the team was informed that these patterns were known to the CTD through the internal evaluation process, inaccurate recording and reporting continued.

It was appreciated that the CTD had made efforts to ensure accuracy in reporting over the past three years, and emphasized that reports should reflect the actual situation. Over the past two years, an overall decline in case notification and a small but discernable decrease in cure rates have been reported. It is possible that these observed changes reflect an increase in reporting accuracy as a result of the internal evaluation and other processes (e.g. EQA), but there are no data to support this hypothesis.

Although recording and reporting is a strong point of the Programme, information collected and reported is, in many cases, excessive and overly complex. Many additional data fields have been added to the standard reporting formats, with the result that many field staff now spend inordinate amounts of time collecting and recording data to the detriment of activities that actually benefit patients. There is a need to simplify recording and reporting by eliminating some reporting fields, reducing the frequency of reporting of others, and including others only in locally reported information. For example, rather than adding the proportion of patients started on treatment within 7 days and registered within 30 days to quarterly reporting formats, this information might be collected from TB registers, analysed and used to improve performance at the local level.

In addition to the standard quarterly reports, some states have asked staff to collect and report additional information, such as monthly case detection rates and treatment outcomes, which has begun to adversely

affect the time available to key staff for supervision and has a potential for generating inaccurate information for decision-making. Furthermore, the inappropriate use of national targets for case detection at the subdistrict level was noted in several districts. The team identified several elements of the recording and reporting system as being of questionable utility to the Programme, including age and sex distribution of case finding, sex classification of treatment outcomes, and several aspects of the district Programme management report (PMR) which duplicate other more complete reports.

The internal evaluation process has proved very useful in verifying the accuracy of reporting and identifying problems related to quality of services, Programme management and supervision in districts. However, not all problems and issues identified in internal evaluations are effectively followed up and addressed. In addition, the current policy of internal evaluation of two districts per quarter leads to a lesser proportion of districts being evaluated in the larger states.

Collection, reporting and dissemination of routine data are done very effectively, and India is particularly praiseworthy in its publication, each quarter, of district-level data on the internet. However, analysis of data trends at all levels, and particularly at the state and district levels, is limited, and using data to take remedial action and improve performance is not done as consistently as it should be. The capacity to analyse, interpret and improve performance based on findings is limited. Furthermore, action taken based on reports is limited in states and districts, and there is a lack of accountability in the general health system for suboptimal performance.

Field supervisory visits from the CTD have been limited, mainly because of lack of regular government MOs. The frequency and intensity of supervision at state and district levels varies greatly. Subdistrict level full-time supervisors (STS and STLS) are the backbone of RNTCP supervision and therefore it is important to maintain and ensure the long-term viability of these supervisory posts.

Recommendations

(1) The CTD should convene a consultation of national, state and local stakeholders to review the recording and reporting system with the intent of simplifying it. Specifically, the data collected at each level, the periodicity of collection, and the action taken should be reviewed

and reconsidered. While some new elements may be required, the net result of such a consultation should be (i) markedly simplified reporting and recording systems, particularly for field staff, (ii) reduction in duplication of reports, and (iii) clarity in the analysis and use of data at the state and local levels.

(2) Particularly due to expanding opportunities for the Programme with the NRHM, it is essential to increase supervisory capacity at the Central and state levels, with six new regular posts of dedicated zonal-specific MOs within the CTD as recommended in the HRD section of this report.

(3) For effective supervision, it is particularly important for the RNTCP to maintain the network of full-time STS and STLS, even in the convergence process with the NRHM.

(4) States should refrain from routine collection of additional information or increasing the frequency of reporting, e.g. monthly case detection and treatment outcomes. If required, special studies can be conducted for collection of additional information for local-level planning and monitoring.

(5) Monitoring by establishing case detection targets for subdistrict areas should be avoided, and the use of district case detection targets reconsidered.

(6) Updated training should be provided for staff at all levels to improve the accuracy and interpretation of data. This includes training for DOT providers on recording of non-DOT doses, training for district- and state-level staff on interpretation and utilization of data, and investigations at the national level to better understand and act on the wealth of data being provided.

(7) As proposed by the Central TB Division, the STDC should report to the STO in order to provide additional supervisory capacity at State level. However, it should be recognized that STDCs engaged in laboratory and training responsibilities, and will not replace the need for strengthening the supervisory capacity of the State TB Cell.

(8) The capacity of consultants should be enhanced, their terms of reference revised to ensure their technical role and maintain their objectivity in feedback, and their involvement limited in data collection and administrative matters. To do this, it is necessary to

establish an intermediate level for the supervision and support of WHO consultants. If this cannot be done, WHO should consider reducing the number of consultants and developing a structure to maintain the technical capacity and supervision of the remaining consultants.

(9) Detection and action-taking in the event of inaccurately reported data should be improved.

(a) A mechanism should be established for anonymous reporting of inaccurately reported data to the State and Central TB Units (e.g. by letter or email to the CTD, e.g. reporting@tbcindia.org).

(b) Internal evaluation and other external review mechanisms should be used to rigorously investigate the accuracy of reporting in all districts with possibly inaccurate data.

(c) If external field review confirms falsification in more than a small number of cases, a follow-up programme should be implemented, which would include external monitoring on at least a six-monthly basis, with representatives from authorities outside the state.

(d) The findings of these reviews must be shared with all administrative and political leaders of the district, state government and relevant national authorities.

(e) The external review process should be continued until all inaccuracies have been resolved.

(f) It should be emphasized that accurate reporting is more important that meeting performance targets.

(10) A system needs to be established, possibly building on the internal evaluation programme, to recognize and reward both well-performing districts and districts that show substantial improvement. Districts reporting results either significantly better than the rest of the state, or significantly better than their past performance, could be appraised using the internal evaluation process, using standard and transparent criteria. If the findings are confirmed, then the district would be issued a certificate (either of excellence or improvement, or potentially of both) and could be recognized in the quarterly or annual report of the RTNCP. Districts could be "certified" as exemplary districts for some time period and listed as such. In addition, all TB control Programme

staff and DOT providers in the district could be recognized and awarded, perhaps with a small gift item. Resources could be provided to upgrade the facilities and working conditions of the general health-care system.

(11) An annual meeting should be convened for all State TB Officers (STOs) and competitively selected DTOs to present the analyses of operational research (OR) and analyses and interpretation of local Programme data. This would also promote interchange and lesson-sharing among areas.

9. Drugs and procurement

The system of drug management under the RNTCP continues to work well. The first expiry first out (FEFO) policy was followed, no stock-outs occurred and reconstitution of loose drugs was observed over the past two years in the states visited. Drug storage in the states and districts visited was mostly good, but the requirement for additional and improved storage facilities and infrastructure was universally observed. It was found that Gujarat and Haryana states have already begun construction of new state drug stores (SDSs) and/or additional depots. In most places, TB drugs are stored separate from other drugs.

The government medical drug stores (GMSDs) continue to function as the lifeline for the storage and distribution of anti-TB drugs to the states. However, a need was observed for strengthening the infrastructure of GMSDs to enhance the quality and quantity of the support they render to the RNTCP. Similarly, the Mission found that experienced staff capable of supervising those responsible for overall stock management was inadequate. Periodic stock-taking was not done in conformity with the norms and, in some states and districts, was not done at all. Consequently, there were discrepancies between the records and physical stock during the past year.

Generally, drugs were found well within their expiry dates. A significant finding by the teams visiting Gujarat and West Bengal was the near-expiry of substantial quantities of Category II drugs. Paediatric PWBs have been developed and were being rolled out by the RNTCP. Field training has been given to health workers on the proper use and reconstitution of these paediatric boxes. Nationwide distribution has been initiated.

At the same time, delays in delivery by certain manufacturers during the past year have led to reprogramming and, in some cases, diversion of drug deliveries by the RNTCP. While this was necessary to sustain Programme execution, it has reduced the buffer stock level in the country.

However, it is expected that this situation will be corrected and stabilized in early 2007 when deliveries will be normalized.

In stark contrast to the finding of the past review, the Mission found an excess supply of loose drugs, and estimated that a substantial quantity of these would expire before ever being supplied to patients. This observation was made in at least one SDS and GMSD. As a result, a halt on new procurement of loose drugs has been instituted and the constitution of PWBs using existing stocks is being discussed. However, strategic management of this situation remains a challenge for the RNTCP.

Since the last review, the RNTCP has obtained a five-year grant through the Department for International Development (DFID) for drug supply and technical assistance provided through WHO India. Under this arrangement, drugs are provided for a population of 500 million by the Global Drug Facility (GDF) of the Stop TB Partnership/WHO through its procurement agent,– formerly the Inter-agency Procurement Services Office (UNDP/IAPSO), now GTZ International Services. To manage and sustain the uninterrupted supply of quality drugs to the RNTCP, GDF has positioned a procurement specialist in India. The TB drug supply stream is also strengthened and supported by facilities from the GFATM, World Bank and USAID, as well as (direct procurement) by the Government of India. A WHO-supported agency remains entrenched within, and continues to offer logistical support to, the CTD. Generally, this partnership has had a very positive impact on Programme delivery.

Pre-shipment inspection and quality control have improved since the last review, even though the time lapse between completion of the exercise, provision of results and final delivery of drugs to the GMSDs is still not ideal. Movement of drugs from the GMSDs and district drug stores to the districts remains a challenge, largely due to avoidable reasons. GMSD Karnal, for example, is constrained by a transportation problem which has disabled optimal drug distribution.

Recommendations

(1) Review the stock of loose drugs at GMSDs and SDSs nationally, re-programme as necessary and/or take action necessary to avert loss due to expiry, e.g. reconstitute into PWBs, if feasible.

(2) Commission a strategic review of drug storage conditions at all GMSDs and improve the infrastructure for storage of drugs at SDSs (palletization, ambient lighting, etc.).

(3) Continue encouraging the building of SDSs, and "create", through expansion or new construction, additional drug storage space at GMSDs and SDSs (space rationalization).

(4) Train/retrain staff managing anti-TB drugs at all levels.

(5) Resolve transportation bottlenecks to ensure smooth drug movement throughout the supply chain.

(6) Develop and standardize RNTCP-wise forms and cards which would be used/required for TB drug handling and management by all.

(7) Routinely and transparently make information available to all stakeholders involved in procurement and drug supply activities of the RNTCP for better coordination and implementation.

10. Human resource development

With the attainment of 100% population coverage, the RNTCP enters a new, more complex phase with regard to HRD. An enormous amount of training activities have taken place to enable 100% DOTS expansion, and contractual staff has been put in place to support the general health system and facilitate Programme implementation.

The RNTCP HRD policy 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". The system and structure for HRD within the RNTCP is in place and includes the following:

- There is a separate unit for HRD at the CTD.
- HRD is well reflected in the revised Technical and operational guidelines for TB control; the functions of the CTD, State TB cell, STDC, TU team, NRLs and IRLs, and medical college task forces and core committees are clearly listed, as are the responsibilities of the State IEC officer and accountant, district-level and peripheral health institution (PHI)-level staff.
- A three-tier training structure, addressing the different needs of staff implementing the RNTCP has been developed: initial RNTCP training, retraining and update on new activities and initiatives.
- Standardized material and schedules for initial training in the RNTCP (revised modules), EQA, TB/HIV, initial training for medical college staff as well as schedules for retraining have been developed.
- Work is ongoing to develop training material for new initiatives, e.g. management of MDR-TB.

However, there are persisting weaknesses in the comprehensive long-term management of HRD activities which, if not addressed urgently, could seriously undermine the gains achieved. Many of the weaknesses of the system with regard to competence of staff and staffing issues were observed during the previous monitoring missions in 2000 and 2003, and pertinent recommendations were made to address these weaknesses. However, the implementation of these recommendations has been slow, as observed during the 2003 monitoring mission.

Issues related to the structure for HRD within the RNTCP

- Support from the CTD HRD unit for HRD activities at the state level and national institutes is limited.
- Support from the state level (STDCs, State TB cell, national institutes) for training at the district level is limited.
- The suboptimal functioning of many STDCs affects the assessment of HR needs and the quantity and quality of training.
- Comprehensive HRD action plans (for training and staffing-related issues), with timelines, priorities and future planning, are not in place at state or district level.
- Data from routine reporting are not used to ensure the timely training of new staff or ensure that action is taken to fill staff vacancies.
- Overall, management of HRD in the reviewed states is suboptimal. Salaries to contractual staff are not paid on time. Key positions are vacant. The distribution of existing contractual staff does not effectively take workload into consideration. Systematic planning of training courses, including priority setting, is not done. Quarterly reports are not used for planning. Training using the revised modules is lagging behind.
- The concept of HRD is not well understood at state and district levels.
- The ability of national consultants to support states in the ongoing management of HRD activities is limited.

Issues related to staffing within the RNTCP

- Staff motivation is highly variable, and health system deficiencies negatively affect motivation.
- The vacancies at all levels, both among RNTCP contractual staff positions and the general health systems, have enormous implications for the Programme.
- The high turnover of staff /frequent transfers affects continuity and quality.
- Staff shortages lead to overburdening of existing staff.
- The availability of MOs and LTs in rural areas is limited.
- Staffing in the State TB cell and STDC is often inadequate.
- There is no regular systematized assessment of staffing and training needs.
- Contractual employees' contracts are renewed without objective performance evaluation.
- There is often an over-reliance on contractual staff for implementation or conducting of RNTCP activities.
- National WHO consultants are heavily involved with Programme implementation.

Issues related to training within the RNTCP

- The quality of training is questionable and not routinely assessed – there is no regular audit on the quality of training.
- The "quality" of facilitators is suboptimal and there is a lack of continuous support and follow up of facilitators.
- Managerial capacity at district and state levels is poor.
- There is insufficient capacity to interpret data and take remedial action.
- Plans for update/refresher training are lacking.

- There are no plans for the continuing development of competence at state and district levels, including the Central institute.
- The complexity of training private sector partners is underestimated.
- Due to frequent transfers and suboptimal use of data to identify staff in need of training, a considerable proportion of staff involved in the Programme is not trained.
- Limited training activities are held during the last two quarters.

"Training status" is not a static situation and needs constant monitoring and planning for ongoing training activities to ensure that the policy goal is met. The existing routine reporting system provides excellent data to do this. However, at present, the data are generally not used. The section on training in annual district and state action plans is generally not needs-based and prioritized, and serves only as a basis for budgeting.

Recommendations

Improve capacity for supervision at the Central and state levels

(1) New regular posts should be developed for at least six dedicated zonal-specific MOs within the CTD to supervise and support state-level staff and monitor, assist and supervise each of six regions of the country.

(2) Effective curricula should be developed and implemented for training STOs and DTOs in management aspects, such as planning, budgeting, supervision, problem-solving and advocacy.

(3) At the state level, for every 10–20 million people, at least one additional full-time government MO should be recruited to supervise the TB Programme.

Strengthen management of HRD within the RNTCP at Central level

(4) The HRD unit at the CTD should take a stronger and more proactive role in addressing the responsibilities listed below:

   (a) Further development of procedures and standards for evaluation of training (skills as well as knowledge);

(b) Strengthening overall monitoring and quality control of training activities, including supervision of both state and national institute training management.

(c) Planning and monitoring of comprehensive curriculum-strengthening activities for basic training programmes of all staff categories involved in the RNTCP;

(d) Developing an advanced skills competency-based training course for STOs and DTOs on programme management;

(e) Providing support to state-level and national institutes for HRD;

(f) Strengthening the HRD unit at the Central level with persons having extensive experience of and interest in different aspects of HRD.

(5) The possibility of expanding the role of the NTI in HRD for the RNTCP should be reviewed. The NTI could potentially serve as a focal point for strengthening and providing ongoing support and supervision to the STDCs in the area of HRD for the RNTCP.

(a) Consider placing an RNTCP contract staff at the NTI to provide technical support in HRD to State TB cells and STDCs. This person should have extensive experience of and interest in different aspects of HRD.

(b) Establish an informal working group consisting of the CTD HRD Unit and representatives of national institutes to meet regularly to ensure strong and systematic support for all aspects of HRD to State TB cells and STDCs.

(6) Optimal use should be made at all levels of the data on HR included in the regular reporting system for ongoing planning and management of HR.

(7) A performance appraisal system should be developed as part of the renewal process of contractual staff.

(8) Opportunities should be explored under the NRHM for programme capacity building, including improved staffing and skills-based training.

Strengthen management of HRD at state and district levels

(9) Master trainers should be identified at the state level which, in some states may be the STDC, and the national institutes can be used to build their capacity to implement, evaluate and provide follow-up supervision on trainings.

(10) Staff management should be improved:

- (a) Ensure prompt payment of salaries to contractual staff.
- (b) Place contractual staff taking workload into consideration.
- (c) Ensure prompt filling up of critical vacancies.
- (d) Take actions to reduce frequent transfers.

(11) Comprehensive HRD plans should be developed at state and district levels. These plans should include:

- (a) Training of new staff of all categories
- (b) Retraining and upgraded training based on needs (use list of functions to determine training needs)
- (c) Training with the revised modules
- (d) Prioritizing training of key personnel such as DTOs, Medical Officers for Tuberculosis Control (MO-TCs), Medical Officers at peripheral health institutions (MO-PHIs) (PHC, rural hospital [RH], subdivision hospitals [SDH], block primary health centre [BPHC])
- (e) Using supervisory visits and meetings for on-the-job training and motivation
- (f) Schemes for staff motivation/non-monetary incentives (e.g. motivate MOTCs and MO-PHIs to perform more effectively in the RNTCP as this is a critical position for sustained performance of the Programme and patient care)
- (g) Coordinating TB/HIV training with the State TB Cell and State AIDS Control Society (SACS)
- (h) Training in "support areas", e.g. IEC/advocacy and social mobilization (ACSM) for relevant staff

(12) Having additional RNTCP contract staff at state level should be considered. They will be responsible for HRD support in the state

(including support to districts) and specific training on HRD for these persons should be planned.

(13) More supervisory and management staff should be recruited in large districts, e.g. consider an additional MO-DTC to assist the DTO.

Improve networks of consultants

(14) Capacity building should be done of consultants, their terms of reference revised to ensure their technical role and maintain their objectivity in feedback, while limiting their involvement in data collection and administrative matters.

11. Public–private collaboration

PPM to engage diverse care providers in TB control

Besides the large network of health-care facilities managed by the states across the country through which the RNTCP was initially implemented, India has a plethora of diverse public, private, voluntary and corporate health-care providers. Often, TB patients including the poor present to the RNTCP after having first visited one or more health-care providers outside the RNTCP. Over the course of its expansion, the Programme has taken systematic steps to begin engaging all care providers in TB control through a PPM DOTS approach.

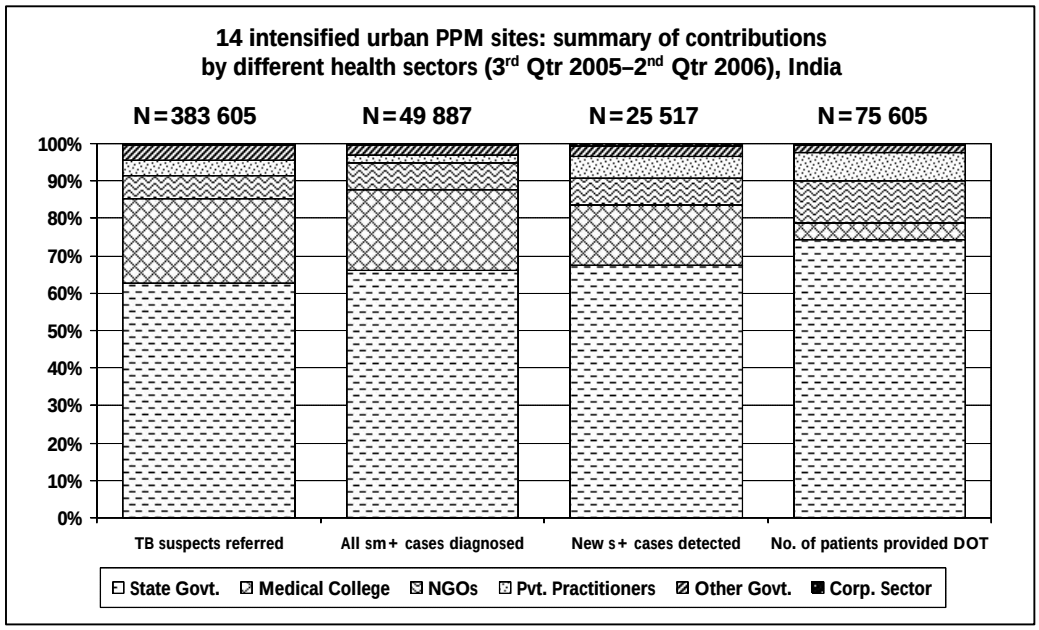
The RNTCP has developed guidelines for the involvement of NGOs and PPs. To facilitate involvement of the 250 medical colleges in the country, a network of national, zonal and state task forces has been developed. Specific steps have been taken at the Central, state and local levels to engage with other public sector departments which run their own health services such as the Ministries of Railways, Labour, Steel, Coal, Mines, Power, Ports and the Central Government Health Services (which services Central Government employees and their families). There have also been Central and local initiatives to involve the business and corporate sectors in TB control, supported by the Confederation of Indian Industry (CII) and the Federation of Indian Chambers of Commerce and Industry (FICCI).

The intensified PPM DOTS activities that began in 2003 in 14 urban districts with additional input and a supplemental surveillance system have now been expanded to 56 additional districts. The data regularly collected from the 14 sites have produced a wealth of information and give an idea of the contribution of different provider groups in these sites to TB case detection and treatment observation (Figure 8).

The increasing involvement of professional associations such as the IMA, Indian Academy of Pediatrics (IAP) and Family Physicians Association is noteworthy. The IMA has formed a "national cell for RNTCP" and has identified national coordinators to further public–private collaboration for DOTS implementation. The RNTCP and the IMA have both adopted the

recently launched ISTC, and the standards have been included in the RNTCP's existing training module for medical practitioners. Importantly, the IMA's proposal to implement PPM activities in five states has been supported through the Round Six application to the GFATM.

Figure 8: ***Summary of contributions by different providers in 14 cities scaling up PPM***

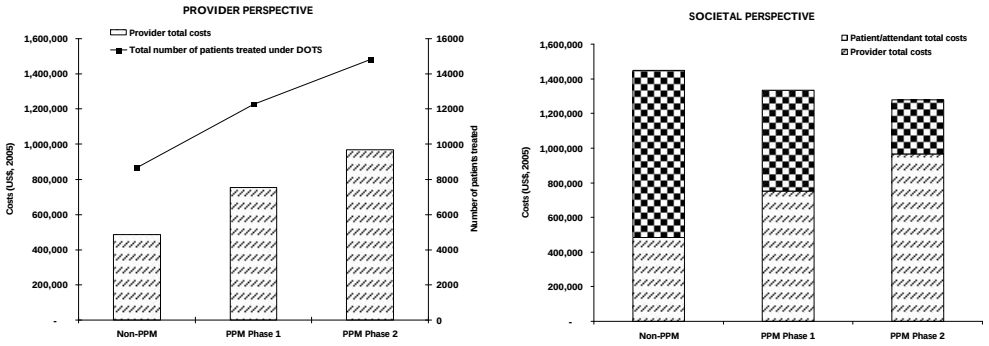


Operational research at some of the PPM DOTS sites (Hyderabad, Delhi and Bangalore) has shown that PPM and the scaling up currently being undertaken by the RNTCP provide good value for money, besides helping to improve access to and reduce costs of TB care for patients, including those from the lowest socioeconomic strata (Figure 9).

Given the nature and the complexity of multisectoral health-care organizations in India, it is not surprising that despite the RNTCP's pioneering and sustained efforts, engaging all public and private care providers in TB control continues to pose challenges. The Mission observed that considerable PPM activities were taking place in all the states visited. However, all teams identified a large, untapped potential for further action to involve providers not yet linked to the Programme. In many districts, PPM activities receive insufficient attention, and staff responsible for implementing the RNTCP is often not sufficiently equipped to efficiently scale up PPM.

Figure 9: ***Cost and cost-effectiveness of PPM scale up in Bangalore***

Total costs of no PPM vs. PPM - initial (Phase 1) and scale up (Phase 2) - in Bangalore



- Total costs to providers increase proportionally to increase in number of cases treated under DOTS
- Total costs, from a societal perspective, decrease with intensification of PPM due to reduced costs for patients when shifting from non-DOTS to DOTS treatment
- 50% of the patients were from the lowest Standard of Living household group

For future strategic direction, a thorough analysis of the wealth of information gathered so far from the intensified PPM activities and related OR is strongly advised. To enhance collaboration, the RNTCP staff at some sites may need greater orientation to PPM and encouragement for their contribution to PPM. Acceptance of the current schemes of engagement for NGOs and PPs is uneven. Some of the clauses in the schemes are misinterpreted and they act as barriers for establishing local collaboration. Involvement of allopathic PPs has been limited. Distinct coordination mechanisms at the national, state and district levels for systematic development of PPM are currently absent.

The JMM observed that although the efforts undertaken so far have been impressive, optimum scaling up of PPM in the coming years will require specific steps to be taken by the RNTCP, on the following lines.

Recommendations

(1) Strengthen the capacity of the CTD to further implement PPM. As a first step, assign staff to undertake a careful analysis and documentation of countrywide PPM experiences, starting with the PPM scale-up project in 14 cities.

(2) As emphasized in the recommendations of the JMM in 2003, expedite the establishment of a national coordinating body to review evidence and guide further scaling up of PPM.

(3) Revise the current guidelines for NGOs and PPs based on experiences so far and draft operational guidelines for each scheme. Add schemes and guidelines for involvement of the corporate sector and private/NGO hospitals.

(4) All Programme officers should consider PPM an integral part of the RNTCP, rather than a separate programme; similarly, all RNTCP consultants should support Programme officers in expanding PPM collaboration.

(5) Support clear articulation of district- and state-wise PPM plans into the annual state and district action plans, with well-defined objectives and targets.

(6) The IMA and medical college task forces should be involved in regular review meetings, including annual STO meetings.

(7) Ensure appropriate mechanisms for documentation of the sources of referral and feedback to referring providers in order to improve monitoring as well as to acknowledge the contribution of different providers. Develop mechanisms for sputum collection from the referring private provider's facility.

(8) Use the ISTC as an advocacy tool for engaging all providers, especially specialists and academic institutions; pursue endorsement of the ISTC by all major professional societies in India.

(9) As a first step towards making TB a notifiable disease in India, support the IMA to set up a voluntary notification system in IMA's GFATM Round 6 project areas.

12. Tuberculosis and HIV Programme collaboration

The number of people living with HIV/AIDS (PLHA) in India is estimated to be 5.2 million (0.88%), the second largest in the world. All states and UTs of the country have reported HIV/AIDS cases. However, the pattern of the epidemic shows great variation across the country. The worst-affected states are Andhra Pradesh, Karnataka, Manipur, Maharashtra, Nagaland and Tamil Nadu. Over the years the virus has moved from the urban to the rural and from the high-risk to the general population, disproportionately affecting women and the youth. With the increasing complexity of the HIV epidemic, policy frameworks and approaches of the NACP have changed. The focus has shifted from raising awareness to behaviour change, from a national response to a decentralized response and an increasing engagement of NGOs and networks of PLHA.

TB is one of the earliest opportunistic infections (OIs) to develop among persons infected with HIV. HIV infection is the most powerful risk factor for the progression of TB infection to TB disease. An HIV-positive person has a 10–15% annual risk of developing TB disease as compared to an HIV-negative person who has a 10% lifetime risk of developing TB disease (4). It has been estimated that 40% of the Indian population is infected with TB bacilli (5), and hence there may be estimated 2 million PLHA infected with TB bacilli in the country. Based on modelling, WHO has estimated an HIV prevalence of 5.2% among adult TB patients in India.

To address the intersection of TB and HIV and the potential impact of TB/HIV on both the HIV/AIDS Programme and the RNTCP, several measures have been taken. A Joint NACP/RNTCP Action Plan for TB–HIV Collaboration has been established (6). The objective of the Joint Action Plan is to reduce TB-associated morbidity and mortality in PLHA by (i) early diagnosis and treatment of TB disease, and (ii) the provision of optimal access to HIV care and support services for HIV-positive TB patients through collaboration between the NACP and RNTCP.

In **Phase I** of the Action Plan launched in 2001, coordination activities were initiated in the six high HIV-prevalence states of Andhra Pradesh,

Karnataka, Maharashtra, Manipur, Nagaland and Tamil Nadu. In 2003, **Phase II** activities were extended to eight additional states, namely Delhi, Gujarat, Himachal Pradesh, Kerala, Orissa, Punjab, Rajasthan and West Bengal. TB/HIV coordination activities presently cover an estimated population of 634 million. There are plans to extend activities to the other states of the country in 2007.

Training on TB/HIV is one of the key activities of the Joint TB/HIV Action Plan. The two Programmes in 2005 jointly developed TB/HIV training modules for different categories of field staff (7). Based on these modules, "training of trainers" courses have been organized at the national and state levels for state- and district-level trainers. All the DTOs of the 14 states have at one point been trained as trainers for their respective districts and training for the remaining field staff has been initiated.

As of September 2006, cross-referral mechanisms have been established between health facilities providing RNTCP services and 1143 functional NACP Voluntary Counselling and Testing Centres (VCTCs) in 14 States, including all states classified by NACO as having a high or medium HIV prevalence. In these states, all VCTC clients are to be screened for symptoms of TB disease and referred to the nearest facility providing RNTCP diagnostic and treatment services. On the other hand, TB patients with risk factors for HIV infection and/or behaviour are to be referred to VCTCs for HIV counselling and testing.

Collaborative efforts to educate patients and the public on the relationship between TB and HIV have been undertaken by both programmes.

Cross-referral activities are monitored by means of the monthly "VCTC–RNTCP cross-referral reports", submitted by the VCTCs to their respective states, and subsequently to both NACO and CTD using a shared e-mail address. Centrally developed guidelines and terms of reference for these state- and district-level TB/HIV coordination committees help ensure the participation of key policy-makers and stakeholders.

In 2005–06, the RNTCP in collaboration with NACO conducted a series of cross-sectional HIV seroprevalence surveys among TB patients. Surveys were conducted in four districts, one district each in Andhra Pradesh, Karnataka, Maharashtra and Tamil Nadu. Plans are in place to expand surveillance activities to 15 districts in 2006–07.

Six states with the highest HIV prevalence have been provided with additional technical support for TB–HIV activities by the placement of a WHO national consultant for TB–HIV in each of the states. These TB/HIV consultants and coordinators are responsible for the monitoring and supervision of all TB/HIV collaborative activities, including VCTC–RNTCP cross-referral linkages, training of service delivery staff on TB/HIV, reporting of cross-referrals and sensitization of NGOs.

Future plans in TB/HIV collaboration include the provision of co-trimoxazole preventative therapy (CPT) to HIV-positive TB patients as a pilot project in three districts of Andhra Pradesh, promotion of early referral of TB patients for antiretroviral treatment (ART), and establishment of "model TB/HIV collaboration districts" in two districts with a high HIV prevalence. In these model TB/HIV collaboration districts, OR on TB/HIV-related topics will be conducted. Initial topics prioritized for evaluation are:

(1) Routine referral of all TB patients for HIV counselling and testing;

(2) Provision of CPT to all HIV-positive TB patients; and

(3) Expanded diagnostic evaluation of HIV-positive persons for TB.

Although systems are in place for implementing and scaling up TB/HIV collaboration, the JMM team identified challenges in the establishment of TB/HIV coordination committees at the state and district levels, appointment of HIV district nodal officers (DNOs), sensitization of MOs, counsellors and LTs, and standardization of recording and reporting systems.

TB/HIV coordination committees have not been established in many high-prevalence states or districts. Although some committees have been constituted, meetings, if held, have not tangibly contributed to improved implementation of TB/HIV activities in the districts. The role of recently appointed DNOs in facilitating collaborative activities has yet to be clarified.

Although a concerted effort has been made to decentralize Integrated Counselling and Testing Centres (ICTCs), accessibility to such services is still suboptimal for TB patients who receive highly decentralized services. In most settings, ICTCs were few and far between and, in many districts, were non-functional due to a lack of staff, lack of trained staff, and lack of supplies and logistics. Although many MOs and ICTC counsellors have been sensitized regarding TB/HIV activities and the cross-referral process, referral and feedback are poor. High rates of patient loss were observed between referral of TB suspects from ICTCs and evaluation by the RNTCP.

The lack of national guidelines for care and support centres, and ART centres for TB–HIV screening, was noted. Care and support programmes and some ART centres do not systematically and routinely screen for symptoms of TB disease, do not refer patients with suspected TB to the RNTCP, and do not treat patients diagnosed with TB with RNTCP DOTS.

The RNTCP should take note of the challenges, build on the successes of current TB/HIV collaborative activities and on the synergies and opportunities provided by the evolution of and improvement in services of the NACP. This includes scaling up of TB–HIV collaborative activities as HIV services become increasingly decentralized, increasing engagement of NGOs and networks of PLHA, and increasing collaboration with ART and other care and support centres.

Recommendations

(1) Establish a national-level technical working group with routinely scheduled meetings, with representation from NACO, the RNTCP and implementing partners at the national level, to address challenges and take advantage of synergies to ensure the implementation and scaling up of TB/HIV collaborative activities.

(2) Ensure coordination and collaboration of TB/HIV activities at the national, state and local levels by constituting and holding TB/HIV coordination committee meetings, which would include representatives from other partner organizations and communities of affected persons.

(3) Strengthen and sustain current TB/HIV collaborative activities through ongoing training and supportive supervision from both programmes.

(4) Expand the coverage of TB/HIV activities beyond Phase I and Phase II high HIV-prevalence states, using available risk and HIV seroprevalence data to set priorities.

(5) Conduct OR studies to evaluate (i) routine referral of all TB patients for HIV counselling and testing, (ii) provision of CPT to all HIV-positive TB patients, and (iii) expanded diagnostic evaluation of HIV-positive persons for TB. Use the results of these research projects and HIV surveillance data to guide future implementation of collaborative activities.

(6) Evaluate and document existing collaborative activities, particularly (i) the access of HIV-positive TB patients to HIV care and prevention, including access to CPT and ART, and (ii) the efficacy of current practices of risk assessment and referral of TB patients for HIV counselling and testing.

(7) At the district level in high HIV-prevalence areas, strengthen the cross-referral mechanism by emphasizing monthly meetings between the RNTCP and ICTC staff to discuss operational issues, share programme performance data, provide updated information about the availability of HIV services, and participate in sensitization and opportunities for refresher courses.

(8) Ensure that jointly developed TB/HIV training and IEC materials are used for engaging the involvement of and training the expanding cadre of partners (NGOs, private sectors, medical colleges). Ensure the availability of TB/HIV training on an ongoing basis for new staff.

(9) Reduce the risk of nosocomial transmission of TB and HIV by developing national infection control guidelines to prevent the spread of TB in hospitals which provide care and support for HIV-positive patients, as well as policies to reduce HIV transmission, e.g. use of disposable syringes and safe disposal of used syringes. Implement simple administrative and environmental control measures to reduce nosocomial TB transmission such as training of health-care workers, rapid assessment of cough/prompt diagnosis of TB, collection of sputum in an open environment, limitation of hospitalization for TB patients, improvement of ventilation in hospitals, and use of hospital cleaning techniques that limit potential aerosolization of *M. tuberculosis*.

(10) Evaluate the feasibility of provider-initiated testing for HIV in settings where HIV care and support is available.

(11) Although the DTO should be closely involved with the HIV programme, he/she should not be given the additional responsibility of overseeing implementation of HIV activities in the district, as the quality of RNTCP implementation is likely to decline.

13. Management of MDR-TB

The exact extent of drug resistance in India is not known at present. District-level surveys conducted between 1999 and 2002 by TRC, Chennai, in collaboration with NTI, Bangalore revealed a prevalence of MDR-TB among new cases ranging from 0.7% to 2.8%. The third WHO/International Union Against Tuberculosis and Lung Diseases (IUATLD) report on *Anti-TB drug resistance in the world* published in 2004 states that resistance in a few settings in India is reportedly moderate (from 0.5% to 3% in new cases and around 12% in previously treated patients). However, the large numbers of total TB cases makes the actual burden of resistant cases very high. The presence of an ever-growing and unregulated private sector and over-the-counter access to a wide range of TB drugs (including SLDs) suggests an environment conducive to the development of drug resistance. Additionally, many states report a high proportion of retreatment cases in the RNTCP (ranging from 18% to 34% in the states visited by the JMM teams). The majority of these cases have a history of previous treatment in the private sector without direct observation and most probably with substandard regimens, indicating that there may be a high level of drug resistance among them.

Rational treatment of MDR-TB following the WHO Guidelines for the programmatic management of drug-resistant TB is essential to control MDR-TB and prevent amplification of resistance. The quality of SLDs is a fundamental component of rational treatment for MDR-TB. MDR-TB patients should be treated only with the best drugs available, quality assured by stringent drug regulatory authorities or meeting WHO Good Manufacturing Practices (GMP) standards at least.

To evaluate the current prevalence of drug resistance before implementing the DOTS-Plus component into the RNTCP, India has developed a plan to conduct surveillance of drug resistance, starting with surveys in two states during 2005–06 (Gujarat and Maharashtra), and gradually adding and re-surveying additional states over time. By 2010, a network of quality-controlled and accredited IRLs would be created to provide culture and DST, and continue DRS. One of the JMM teams visited

Gujarat state, which was selected to undertake a first round of DRS in 2005–06, and initiate treatment of MDR-TB patients in early 2007. At the time of the visit (October 2006), the intake of samples into the DRS survey in Gujarat had been completed and the preliminary results presented to the JMM team showed a 2.4% prevalence of MDR-TB among new cases, and 16.4% among those previously treated. A high level of MDR-TB (48.6%) was observed in the subgroup of Category II entry type "failures". Results from Maharashtra were not known at the time of the JMM.

The plan to address MDR-TB has been prepared. However, the programmatic conditions for the diagnosis and management of MDR-TB have not yet been implemented, and the pace of implementation is slow. In particular, RNTCP-accredited laboratory services are not available to diagnose MDR-TB. According to the RNTCP Plan, two states (Gujarat and Maharashtra) are due to start MDR-TB activities in early 2007, with drugs procured by the RNTCP. Other sites will gradually be added over the following years so that 8850 patients are put on treatment by 2011 in 25 sites. Patients on Category II treatment, who remain smear-positive after four months or more of treatment, will be suspected to have drug resistance. They will be evaluated with culture and DST, and placed on a standardized Category IV regimen recommended by the national DOTS-Plus guidelines: 6-9 months intensive phase including kanamycin, ofloxacin, ethionamicde, cycloserine, pyrazinamide, and ethambutol, followed by an 18 month continuation phase of ofloxacin, ethionamide, cycloserine, and ethambutol.. Para aminosalicylic acid (PAS) will be used as a substitute drug if any other drug is not tolerated.

Unfortunately, the IRL in Gujarat is not yet ready to be accredited. The major culture and DST equipment that was delivered to the laboratory is not installed. In addition, the poor quality of equipment does not guarantee biosafety and most of it needs to be replaced. At least half of the laboratory personnel require training to ensure high-quality performance. Due to these reasons, the actual culture and DST for the Gujarat state DRS survey was conducted by TRC, Chennai.

All over the country, treatment of MDR-TB is being carried out by chest physicians at medical colleges, major TB hospitals and sanatoria, and in the private and corporate sectors. Diagnosis is often based on clinical and radiological parameters, and smear microscopy alone. Culture and DST are being done in laboratories (at some medical colleges and in the private sector) which are not accredited and lack quality control by an NRL.

Monitoring of treatment is based on clinical evaluation, periodical chest X-ray and sputum microscopy tests. Patients treated in the private sector and in the majority of hospitals need to buy the expensive SLDs themselves, and direct observation of treatment is not practised. In a few hospitals, treatment is provided free of cost, but this can only be guaranteed while the patients are hospitalized. At the time of discharge, there is no DOT and patients need to procure the drugs themselves to continue treatment. Wards hospitalizing MDR-TB patients do not apply infection control measures, which increases the risk of nosocomial transmission to other patients and personnel. Where there are high numbers of HIV-infected patients, MDR-TB can spread very rapidly.

Infection control concerns, especially at initiation of treatment for MDR-TB, are very serious, and it is preferable to provide all treatment on an ambulatory basis. In view of this, unless infection control measures are implemented fully, the decision to hospitalize patients during the initial period of treatment could be reconsidered. Although treatment is arduous and inpatient initiation may make it easier, the link between inpatient and ambulatory treatment is almost inevitably problematic. If initial hospitalization is still considered, special attention is needed to ensure the seamless transfer of patients to ambulatory care.

Taking into account the estimated number of MDR-TB cases diagnosed every year, the pace of expansion of DOTS-Plus activities seems slow and, particularly in areas with a high prevalence of HIV infection, this may be problematic. Treatment of MDR-TB is important on humanitarian grounds, because every person who has a treatable but otherwise fatal disease should be treated. It is also important on Programme grounds, because the inability to treat patients who fail therapy undermines the credibility of the Programme with patients and the community. It is also important epidemiologically, particularly in areas with a high prevalence of HIV infection, because in such areas MDR-TB can spread very rapidly among, and have disastrous consequences for, immunosuppressed people; it can also infect and kill those caring for such patients.

Recommendations

(1) Implementation should be accelerated of the national programme plan for DOTS-Plus activities under the RNTCP. Clinicians currently treating MDR-TB in the private sector, medical colleges and TB

hospitals, should adhere to national policies based on international guidelines for diagnosis, treatment and management of MDR-TB.

(2) State governments should either immediately stop procuring SLDs, or do so only for programmes which follow the national DOTS-Plus guidelines, and including direct observation of treatment and regular bacteriologic follow-up examination.

(3) An accredited network of IRLs for quality-controlled culture and DST should be established (as planned). While the IRL network is being established, accredit and utilize the existing resources including those in medical colleges, chest institutes, TB hospitals and national institutes as a system for the provision of culture and DST to diagnose MDR-TB cases for treatment under the RNTCP.

(4) Rapid transport facilities to bring specimens to the IRLs, NRLs (TRC and NTI) and other RNCTP-accredited culture and DST laboratories need to be established.

(5) DST for SLDs (at least for the fluoroquinolones and aminoglycosides) should be considered wherever feasible, when scaling up treatment with the standardized Category IV regimen.

(6) Infection control in inpatient facilities needs to be improved; guidelines from the national programme may promote local implementation of basic infection control measures.

(7) The prevalence of MDR-TB should be evaluated in additional groups of patients such as Category I failures, Category II patients with positive smears at two months, and Category II patients with clear risk factors for MDR at initial registration. If a high proportion of patients in these groups have MDR-TB, consider expanding the laboratory and treatment capacity of DOTS-Plus to include these patients.

(8) If a chest physician or medical college professor of a Chest Diseases and TB Department is available in the concerned district, it is preferable that they should be the treating physicians and undertake the monthly follow up of MDR-TB patients rather than the DTO. The DTO remains responsible overall for the programmatic care of MDR-TB patients. Hence, the treating physician and the DTO will need to work together as a coordinated team to ensure quality management of MDR-TB patients under the RNTCP's care.

14. Advocacy, communication and social mobilization

Team members appreciated the key strategic achievements made in advocacy, communication and social mobilization (ACSM) activities to date. For example, a health communication strategy has been developed at the national level with technical and financial support from DANIDA. This strategy document articulates a range of component strategies, activities and Programme materials. The strategy has recommendations for implementation at the state and district levels with provision for support at the national level for IEC materials and Programme activities. A CD is provided to all states that contains video-based modules on health communication activities. A web-based IEC resource centre was created in 2005, also with technical and financial support from DANIDA. Furthermore, IEC activities for the World TB Day in most settings were appreciated as being well planned and executed. Stigma remains a problem for the Programme; however, with more successful outcomes of DOTS programmes, coupled with increased knowledge on the modes of TB transmission and treatment efficacy, stigma may gradually be reduced in many community and clinical settings.

Despite the achievements cited, there is enormous scope for improvement in IEC/ACSM. IEC/ACSM is given a low priority by state and district managers. Administrative delays in many states have also hampered IEC activities. Many inconsistencies exist between action plans, proposed activities and actual verified activities. Communication facilitators and IEC officers are frequently not appointed to the available posts.

There are few process indicators and no IEC/ACSM programme impact and outcome indicators utilized in Programme M&E. Although a communication and M&E framework for the IEC/ACSM programme exists in the national strategic planning model, no such planning documentation could be sourced at state or district level. Conversely, findings indicate that strategic planning at the state level has yet to be seriously considered. This is despite the institutionalization of strategic planning at the national level and development of strategic documents outlining the process.

The activities reviewed focused on producing materials and simply providing information, rather than incorporating more persuasive, behaviour-centred ACSM approaches. Similarly, the IEC materials produced often focus on providing information rather than being designed and pre-tested to elicit desired behavioural responses.

IEC efforts in states have been hindered by the non-availability of IEC funds under the specified head, the reluctance of programme managers and senior administrators to transfer funds to the IEC budget head, and the detailed scrutiny of IEC expenditures for high-profile public campaigns.

Stigma continues to lead to the isolation of patients, and impair effective referral, treatment and care. This has reduced the level of dialogue in communities, especially by people suffering from TB who, by and large, try to hide their condition from the rest of the community. The problems of stigma are more acute with specific groups such as young rural women who live in fear of being rejected by partners and potential spouses.

Efforts have been made to achieve broad coverage of clinics and DOTS centres across the country. However, there is no evidence that any corresponding efforts have been made to promote the location of new services or increase service demand by promoting these services through IEC/ACSM activities.

Although a range of activities related to IPC (e.g. workshops, sensitization, public meetings and novel community approaches including the use of magicians) have been developed, the delivery of some IPC activities may be hampered. This is a result of the limited training, experience, organizational skills and mobility of many health workers and IEC/ACSM staff at district and block level. With some exceptions, adequate IPC for TB at the "grassroots" level is not readily evident.

The capacity for M&E with regard to IEC in the states and districts is almost non-existent, with IEC and other staff not aware of any knowledge, attitude and practice (KAP) surveys or other research being undertaken.

Recommendations

(1) An IEC/ACSM Steering Committee should be established at the state level comprising multisectoral partners; states should finalize and endorse a state TB IEC/ACSM strategy, and develop corresponding workplans for adaptation at district and block levels.

(2) Communication planning for IEC/ACSM needs to be prioritized at the state level. A sustained, multilevel approach should be implemented for IEC/ACSM to optimize programme delivery and create an enabling environment for social change. The use of a strategic communication planning cycle at the state level will help to reduce a number of complex tasks into more meaningful processes, including the appropriate stakeholder checks and balances at each stage of the planning cycle.

(3) Capacity building through training of IEC staff and IEC/ACSM advocacy for programme managers is a high priority. More comprehensive ACSM action plans could be developed and training provided for district- and block-level ACSM staff.

(4) Synchronization of activities at the national and community levels should take place beyond World TB Day. A national "media umbrella" can be created to facilitate the delivery of a number of IEC/ACSM activities at the community level. This can optimize the impact of TB interventions through intensive efforts directed at one issue simultaneously at national, state and district levels.

(5) Private sector partners can be contracted to support the planning and implementation of state social marketing campaigns and dissemination of materials. The web-based Communication Resource Information System (CRIS) and resource centre should be reviewed, updated and maintained. Greater involvement of public–private partnerships is required for strategic campaigns including services for market research, creative message development, production of materials and logistics.

(6) Prioritize providers as an IEC target group, including private providers and government providers with after-hours private practices. In addition to activities under the PPM budget heads, the use of IEC funds for provider-targeted activities should be prioritized to improve the referral of chest symptomatics to DMCs for sputum examination. Lessons from the pharmaceutical industry should be utilized in changing provider practices, and contracting IEC activities out to private agencies experienced in dealing with providers should be considered.

(7) A simple M&E framework can be established, which provides realistic, achievable and measurable indicators of the IEC/ACSM programme.

(8) Qualitative and quantitative research should be used to guide IEC/ACSM implementation.

(a) Qualitative research will need to be scaled up and used in the formative stages of the IEC/ACSM strategy design to assist in problem identification, clarification of target group barriers and benefits of behaviour change, message design and pre-testing of communication concepts.

(b) Quantitative research will be required to evaluate the impact and outcomes of IEC/ACSM media campaign phases and community-based interventions through strategic, pre- and post-intervention operational surveys with adequate sample sizes.

(c) Larger-scale KAP surveys at the national level will also need to be maintained at regular intervals to identify a broader range of KAP indicators with sample sizes to provide more accurate assessment of overall programme success.

(9) National expertise and travel allowance (TA) should be used to design, produce and disseminate supporting community communication resources and provider communication resources – fact-cards, toolkits, flip-charts and merchandise such as T-shirts, caps and bumper stickers to support ACSM activities and events.

(10) Terminology used for IEC could be chosen to reflect a more proactive, community-based approach; consider the use of ACSM, social marketing and behaviour change communication (BCC).

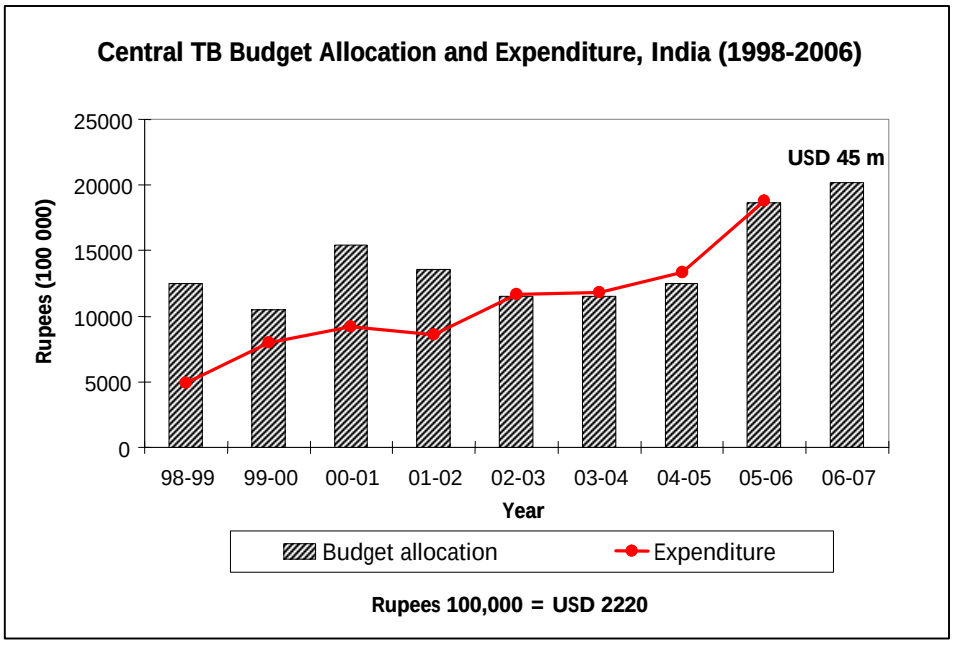
15. Financing TB control

Structure of RNTCP financing

Currently, the total expenditure on health in India accounts for 4.8% of the GDP. However, only 0.9% of the GDP, i.e. one-fifth of this amount, is spent on health by the Government, including the governments at Central, state and local levels.

As depicted in Figure 10, the expenditure incurred on TB control activities by the Government of India has increased steadily over the past three financial years, from a level of about Rs1000 million in financial year 1999–2000 to Rs1880 million in financial year 2005–06. In the last few financial years =100% was expended from the budgeted amount which is an indication that in future the conservative budgeting, based on the previously low expenditure pattern, may become a constraint.

Figure 10: ***Central TB budget allocation and expenditure, India (1998–2006)***



The CTD in the MOHFW is tasked with planning and budgeting for TB control activities in the country. Based on the approved plan, the Government of India makes allocations for TB control under five-year plans. The RNTCP five-year plan (2006–10) has already been approved by the national cabinet and this is expected to facilitate the approval of yearly allocation of funds for TB.

The RNTCP is implemented in all states and UTs of India as a centrally sponsored scheme. The state governments make available the primary health infrastructure for delivering services under the Programme, and also provide Programme Officers for TB control, health facilities and regular state government staff. Other recurring costs of running the Programme are borne by funds provided by the RNTCP at the national level; these costs include procurement of anti-TB drugs and other supplies, additional manpower, logistics, administration, etc. The services of the Programme are made available to the patients/end-users through the state-run public sector general health facilities and through NGO and private health facilities in the states. The quality of and access to RNTCP services therefore depends to a large extent on the general health system in the respective states and the adequacy of financial resources being provided by the state government for improving and maintaining the general health system.

The RNTCP is primarily (>60%) supported by funds from the Government of India, including the funds provided under the Development Credit Agreement with the World Bank. The remaining portion of the budget is provided through grants from the GFATM and USAID. In addition, DFID provides drugs procured through the GDF/WHO for a population of 500 million, equivalent to almost half of the anti-TB drug requirement of the RNTCP. The RNTCP is funded by GFATM Rounds 1, 2, 4 and 6, which support it fully in five states (Andhra Pradesh, Chhattisgarh, Jharkhand, Orissa and Uttaranchal) and partially in two other states (Bihar and Uttar Pradesh). USAID, via WHO, supports the RNTCP in one state (Haryana). Most donors are represented in the Country Coordination Mechanism (CCM) which reviews GFATM projects. There is also a National Inter-agency Coordination Committee (NICC) that includes all donors, but meetings have been infrequent. The separate reporting systems and review missions of donors was a problem in the past, which has been partially addressed.

The technical assistance provided by WHO is supported by CIDA, DFID and USAID. The CTD has identified the intensified WHO technical

assistance as one of the important factors for the success of the Programme and has strongly requested that this support to the RNTCP be continued. The continuity of funding from donors to support WHO technical assistance and the forthcoming WHO contract reforms are factors that could affect future WHO technical assistance to the RNTCP.

The Programme utilizes a system of funding via specially created "societies" at state and district levels. Disbursement of funds to state and district levels is based on annual state and district action plans. The State TB Control Society (STCS) receives funds from the Central level and disburses these to the district level through the respective District TB Control Societies (DTCSs). It was observed that disbursements were linked more to the previous expenditure pattern of the state/district and less to the annual action plan submitted by the state/district. This system has a potential to place some of the weaker states in a vicious cycle of under-disbursement because of past under-spending, which will make it impossible for them to improve. One of the reasons for not linking the disbursement to budgeted action plans is the absence of a system for the formal approval of budgets in the action plan.

Under the NRHM the specific societies created under individual disease control programmes (STCS and DTCS in case of the RNTCP) are now being merged into an integrated "health society" at the district and state level. At present, funds for the RNTCP are maintained in a separate account which makes spending and accounting easier, but it is not clear whether this could change in future. There are good examples of states that have used the new financial mechanisms under the NRHM to expedite disbursement of RNTCP funds from state to district levels, e.g. the new electronic fund transfer mechanism in West Bengal has dramatically reduced the time taken for funds to flow from state to district levels (from a few weeks in the past to 24 hours at present).

Expenditures at the state and district level

Over the past few years, the financial management system of the Programme has been decentralized and full powers of allocation and reallocation of funds have been delegated to the state level, within the guidelines of the Programme. Districts have also been delegated some powers of reallocation at their own level, based on local requirements. In

general, this delegation of authority of reallocation between budget heads has facilitated better utilization of funds.

However, in a few cases, timely reallocation was not made resulting in lack of funds under one head and an excess of funds under another head. It was also observed that most reallocations were prompted by an inadequacy of funds under a particular head, which in most cases was a result of delayed disbursement. Typically, such reallocations were made from budget heads pertaining to activities (such as training, IEC, NGO/PP collaboration) under the contractual services head, from which salaries of contractual staff are paid. While the importance of ensuring timely payment of remuneration to RNTCP contractual staff is realized, the concern is that such situations should not take away the funds allocated for activities that finally do not take place (e.g. training, IEC, etc.).

During the period April–December 2006, over a period of 9 months, the actual expenditure incurred by states was compared with the action plans submitted earlier by them for the same financial year. At the aggregate level for all states, it was seen that the budget heads which were least utilized (in the range of 20% or less) vis-à-vis the action plans proposed for those heads included NGO/PP support, Training, Vehicle Hiring, Research and Studies, Civil Works, Equipment Maintenance, Printing and Honorarium. At the same time, expenditures under the budget heads for remuneration to contractual staff and vehicle maintenance, which are more or less predictable and definite, amounted to well over 60% of the plan during the same period.

In most places it was observed that the budgetary norm of 25% for honorarium to non-salaried DOT providers was being taken as an upper limit and preventing the use of such DOT providers. In fact, in some districts/states because the total eligible amount exceeded 25%, no honorarium was being paid to anyone. While there have been clarifications on this issue from the CTD, it has not resulted in resolution at the state and district levels.

It was also observed that there is a lack of clarity on the norms for training/sensitization of PPs and such expenses are being booked under different budget heads in different districts/states. However, the new budget head created for medical colleges has greatly facilitated expenditure on medical college-related activities.

Overall, there have been considerable improvements in fund flow and absorption capacity since the last mission (September 2003). However, there is a potential for improvement, especially in the known weaker states where payments are still delayed because of lack of proper financial planning, management and administrative barriers to expenditure approval.

Recommendations

(1) Keeping in view the trend of rising expenditure and the increased absorption capacity of states, the RNTCP should consider revising budget estimates upwards for the next five years to account for the intensification of currently planned activities, and to include additional activities recommended by this review mission to improve case detection and quality of services. Additional resource requirements could be funded through the increased budgetary allocation for the health sector by the Government of India, or through applications to future rounds of the GFATM.

(2) It is recommended that the RNTCP implements a system for formal approval of budgets included in the action plans of districts/states and bases the disbursements on the action plan rather than on the previous pattern of expenditure. Fund allocation based on prior expenditure prohibits states with previously poor financial management from demonstrating their improved absorption capacity, and impairs the implementation of additional activities to improve the quality of the Programme. Similarly, states and districts should strive to implement action plans on a timely basis, which would facilitate expenditure and prevent unneeded funds from accumulating and disrupting budgetary planning.

(3) Since the RNTCP services are dependent on the general health system of individual states, it is recommended that the CTD proactively engages in projects which are intended to improve general health infrastructure and human resources in states (e.g. World Bank-supported health system development projects, initiatives under the NRHM, etc.) so that critical elements in the health system needed for TB control are adequately funded.

(4) A separate budget line should be protected for TB control at the national level and funds for TB control earmarked at state and district levels. The preferred way to achieve this would be to continue to

maintain separate accounts for the RNTCP under the state and district health societies. Alternatives such as creating a separate earmarked allotment for TB within the same account with authorization for use of the allotment by TB alone can be explored, but would be more complex.

(5) To achieve optimal levels of donor coordination, including in financial reporting and review missions, it is important that the RNTCP holds more frequent meetings of the NICC.

(6) For adequate funding of future WHO technical assistance, the RNTCP and WHO should identify gaps and consider inclusion of funds for WHO technical assistance in future GFATM proposals.

(7) Programme managers should use their authority to re-allocate funds between budget heads to ensure that funding is available to meet the action plan of all aspects of the Programme. Planned Programme activities should not be constrained because the budget head has been depleted to compensate for management-related shortfalls.

(8) Steps need to be taken to ensure that all districts and states follow standard recording systems and practices for financial information.

(9) The CTD should clarify to the states/districts the financial norms and accounting head under which activities for training and involvement of PPs can be implemented. For this purpose a separate accounting head could also be considered, as has been done for medical colleges.

(10) In view of the increasing involvement of community volunteers in DOT provision and the possibility of inclusion of the ASHA network as DOT providers, the RNTCP needs to remove the budgetary norm of 25% for payment of honorarium to non-salaried DOT providers, as this is interpreted as a cap by district/state authorities despite repeated clarifications from the CTD.

(11) There is a need for close monitoring at the Central level of states which have a history of delayed payments and disbursements.

(12) The opportunity created for faster financial disbursement mechanisms under the NRHM should be used by the RNTCP to expedite its flow of funds.

16. Operational research

The JMM team appreciated the progress in implementation of many recommendations of the 2003 JMM report regarding OR. The RNTCP Phase II OR agenda was reviewed, and the extensive publication list over the past 2 years was appreciated (available at http://www.tbcindia.org). Mechanisms for evaluating and funding OR proposals have been strengthened. Many investigations have resulted in changes in Programme policy and implementation. Specific examples include the referral-for-treatment system, evaluation of additional smear microscopy after a course of antibiotics in the RNTCP diagnostic algorithm, and evaluation of intensified PPM activities. Specific attention to OR has been given in the reach of the RNTCP among marginalized populations, access to TB services in urban slums and the economic impact of TB on patients. Recent efforts have been made to strengthen national OR capacity through workshops for medical colleges. A larger number of proposals have been received through OR mechanisms over the past two years than earlier.

The national institutes have had a good track record over the past three years of conducting and disseminating programmatically relevant research and OR. Data from the USAID-funded Model DOTS Project (MDP) area in Tamil Nadu have demonstrated proof of the principle that implementation of the RNTCP can lead to accelerated declines in TB incidence and prevalence.

However, the Programme has only now begun to tap the enormous potential of OR to improve Programme performance. OR funds have been clearly underutilized at state level, perhaps due to lack of information regarding the need for OR and fund availability, or simply a lack of prioritizing OR at all levels. Proposals that have been received, particularly from medical colleges, are often not synchronous with RNTCP research priorities. A large gap remains between data collection and analysis for Programme monitoring, particularly at the state and local levels. Perhaps as a result, few examples are available of states using OR to evaluate solutions to local Programme challenges. There remains a lack of clarity as to what

happens with the research after it has been completed, and few venues are available to present the findings and results of locally implemented OR activities. The capacity to evaluate and disseminate results is limited, resulting in few OR publications outside those by the national institutes.

Recommendations

Some key specific recommendations from the 2003 JMM report have not yet been implemented, and were re-emphasized by the team. However, the team primarily indicated that the RNTCP should more aggressively pursue commissioned OR, and devise a more effective means of sharing OR results on a regular basis. This may include national workshops and conferences as indicated. Furthermore, the team felt that states should be made responsible for the generation of at least one or two key need-based OR activities on an annual basis, with dissemination at the national level and awards given for exceptional activities.

(1) National capacity for OR should be strengthened, possibly through workshops in collaboration with national and international faculty.

(2) The application and award process for OR should be publicized in order to attract high-quality proposals.

(3) Consideration should be given to advertising in medical journals with calls for proposals in key OR areas.

(4) OR activities should be designed to generate actionable information on programmatic challenges, and the findings should be promptly translated into Programme policy and decision-making.

(5) The priority OR agenda needs to be revised in light of the 2006 JMM findings, and other immediate programme challenges such as reversing the decline in case detection, diagnosing TB more efficiently and effectively, improving treatment outcomes, engaging the private sector, TB–HIV, MDR-TB.

(6) States should be asked to conduct at least one significant OR activity annually, under the leadership of the STO and STDC. OR activities should be disseminated in a national forum with appropriate recognition of exceptional activities that generated

improved Programme performance. One option to improve uptake would be to prepare standard protocols for use by states.

(7) An annual meeting should be held at which state and district officers present analyses of the data derived from their OR activity, with a competitive acceptance process.

(8) OR should be prioritized for understanding and addressing:

(a) Initial default

(b) The reasons for the recently observed nationwide decline in case notification

(c) The reasons for default, especially among Category II patients, and designing and evaluating interventions to prevent default

(d) The prevalence of cough in adults attending the OPD for any reason, and subsequent diagnostic outcomes of such patients

(e) The impact of EQA activities on examination of TB suspects

(f) The convenience of sputum collection for diagnosis and follow up

(g) Continued refinement of diagnostic algorithms; additional evidence should be generated on duration of cough for two vs three weeks to define TB suspects, use of one vs two sputum examinations for follow up, impact of additional sputum examinations at the end of the antibiotic course in terms of additional yield vs patients lost in the diagnostic process.

(9) New initiatives should be supported to field-test new diagnostics and therapeutics as soon as such technologies or products are available, and rapid programmatic uptake of future advances facilitated.

References

(1) UNICEF. *Status of the world's children 2006: excluded and invisible.* Geneva, UNICEF, 2006.

(2) Central Tuberculosis Division. *TB India 2006: RNTCP status report.* New Delhi, Ministry of Health and Family Welfare, 2006.

(3) Gopi PG, et al. Estimation of burden of TB in India for the year 2000. *Indian Journal of Medical Research*, 2005, 122:243–248.

(4) Chadha VK, et al. Annual risk of tuberculous infection in four defined zones of India: a comparative picture. *International Journal of Tuberculosis and Lung Disease*, 2005, 9:569–575.

(5) Chadha VK, et al. The annual risk of tuberculous infection in the eastern zone of India. *International Journal of Tuberculosis and Lung Disease,* 2004, 8:537–544.

(6) Chadha VK, et al. Average annual risk of tuberculous infection in India. *International Journal of Tuberculosis and Lung Disease*, 2005, 9:116–118.

(7) Chadha VK, et al. Annual risk of tuberculous infection in the northern zone of India. *Bulletin of the World Health Organization*, 2003, 81:573–580.

(8) Chadha VK, et al. Annual risk of tuberculous infection in the western zone of India. *International Journal of Tuberculosis and Lung Disease*, 2003, 7:536–542.

(9) Kolappan C, et al. Estimation of annual risk of TB infection (ARTI) among children aged 1–9 years in the south zone of India. *International Journal of Tuberculosis and Lung Disease*, 2004, 8:418–423.

(10) Shashidhara AN, et al. The annual risk of tuberculous infection in Orissa State, India. *International Journal of Tuberculosis and Lung Disease*, 2004, 8:545–551.

(11) Styblo K. The relationship between the risk of TB infection and the risk of developing infectious TB. *Bulletin of the International Union of Tuberculosis and Lung Disease*, 1985, 60:117–199.

(12) Gopi PG, et al. Relationship of ARTI to incidence and prevalence of TB in a district of south India. *International Journal of Tuberculosis and Lung Disease*, 2006, 10:115–117.

(13) Gopi PG, et al. A baseline survey of the prevalence of TB in a community in south India at the commencement of a DOTS programme. *International Journal of Tuberculosis and Lung Disease*, 2003, 7:1154–1162.

(14) World Health Organization. *WHO Report 2006: global TB control – surveillance, planning financing*. Geneva, World Health Organization, 2006.

(15) Gopi PG, Subramani R, Narayanan PR. Trend in the prevalence of TB infection and ARTI after implementation of a DOTS programme in south India. *International Journal of Tuberculosis and Lung Disease*, 2006, 10:346–348.

(16) Subramani R, et al. Active community surveillance of the impact of different TB control measures, Tiruvallur, South India, 1968–2001. *International Journal of Epidemiology*, 2006,36(2):387–393

(17) Joshi R, et al. Chronic diseases now a leading cause of death in rural India--mortality data from the Andhra Pradesh Rural Health Initiative. *International Journal of Epidemiology*, 2006, 35:1522–1529.

(18) Gajalakshmi V, Peto R, Kanaka TS, Jha P. Smoking and mortality from TB and other diseases in India: retrospective study of 43 000 adult male deaths and 35 000 controls. *Lancet*, 2003, 362:507–515.

(19) Paramasivan CN, Venkataraman P. Drug resistance in TB in India. *Indian Journal of Medical Research*, 2004, 120:377–386.

(20) Santha T, et al. Comparison of cough of 2 and 3 weeks to improve detection of smear-positive TB cases among out-patients in India. *International Journal of Tuberculosis and Lung Disease*, 2005, 9:61–68.

Annex 1

Itinerary of Mission

Joint Monitoring Mission of RNTCP

Summary of field visits made during 4–12 October 2006

States visited	Team members	Districts covered	Additional activities assessed*
Madhya Pradesh	Fabio Luelmo** Tushar Ray R Prasad N Selvakumar	Vidisha, Damoh	Health system challenges
	K Lonnroth SS Lal PK Shridhar RV Asokan	Indore, Dewas	PPM/urban DOTS
West Bengal	A Finlay** AB Patil R Sarin Y Dholakia	Burdhman, Nadia	Coal-India, NGO involvement
	Po-lin Chan S Sahu ND Sahay R Solomon	North 24 Parganas, Kolkata	Medical colleges, involvement of other care providers
Karnataka	K Bergstrom** S Kapur VS Salhotra Dhiraj Gupta	Tumkur, Bangalore, including NTI	Human resource development, TB/HIV, medical colleges

States visited	Team members	Districts covered	Additional activities assessed*
	P Dewan Rose Pray VK Dhingra R Gopal	Chickmaglur, Mysore	TB/HIV
Gujarat	M Grzemska** A Laszlo R Cross A Thomas	Sabarkantha, Ahmedabad	MDR-TB, laboratory issues
	H Norman F Wares KR John JJD Pradhan	Mehsana, Anand	Laboratory issues
Punjab and Haryana	N Wilson T Turk SK Sharma A Mamgain	Patiala, Roopnagar	Migration, ACSM
	E Cooreman** L Witherspoon V Singh P Vaidhyanathan	Karnal, Rewari	Migration, drug logistics

* All teams assessed all the basic TB control activities. In addition, specific teams focused on assessment of specific activities.

** Team leaders

Annex 2

List of participants in field teams and debriefing meeting, by Agency affiliation

Agency	Name of field team participant
CDC, Atlanta	Alyssa Finlay
CORE (NGO)	Roma Solomon
CTD, MOHFW	VS Salhotra
DFID, UK	Hester Norman
GFATM	AB Patil
Global Drug Facility	Lorenzo Witherspoon
Govt. of Kerala	Rita Cross
Indian Medical Association	RV Asokan
InterAid (NGO)	Yatin Dholakia
IUATLD	Nevin Wilson
LRS Institute, Delhi	Rohit Sarin
Medical College – AIIMS	S K Sharma
Medical College – CMC, Vellore	KR John
Medical College – KGMU, Lucknow	R Prasad
Medical College – LH, Delhi	Varinder Singh
Medical College – PGI, Chandigarh	Dheeraj Gupta
New Delhi TB Centre	VK Dhingra
NTI, Bangalore	P Vaidyanathan
SACS, Gujarat	Rajesh Gopal
STO, Chandigarh	PK Shridhar
STO, Jharkhand	ND Sahay
STO, Sikkim	JJD Pradhan

Agency	Name of field team participant
STO, Uttaranchal	AP Mamgain
Stop TB Partnership	Tahir Turk
TRC, Chennai	N Selvakumar
TRC, Chennai	Aleyamma Thomas
USAID	Sanjay Kapur
WHO (Consultant)	Fabio Luelmo
WHO (Consultant)	Adalbert Laszlo
WHO Geneva	Malgorzata Grzemska
WHO Geneva	Karin Bergstrom
WHO Geneva	Rose Pray
WHO Geneva	Knut Lonnroth
WHO India	Suvanand Sahu
WHO India	Fraser Wares
WHO India	SS Lal
WHO India	Puneet Dewan
WHO India	Po-lin Chan
WHO SEARO	Erwin Cooreman
World Bank	Tushar Kanti Ray

Agency	Name of participants in the debriefing meeting
Bill and Melinda Gates Foundation	Peter Small
CTD, Ministry of H&FW	PP Mandal
CTD, Ministry of H&FW	Ritu Gupta
CTD, Ministry of H&FW	Tejaram
CTD, Ministry of H&FW	LS Chauhan
GFATM	Taufiqur Rahman
GFATM	Suman Jain
KNCV	Martien Borgdorff
KNCV	Kitty Lambregts
New York City Department of Health and Mental Hygiene	Tom Frieden
NTI, Bangalore (Director)	P Kumar
Stop TB Partnership	Marcos Espinal
Stop TB Partnership	Robert Mitaru
TRC, Chennai (Director)	PR Narayanan
TRC, Chennai (Ex-staff)	Shanta Devi
WHO Geneva	Leopold Blanc
WHO Geneva	Mukund Uplekar
WHO India (Consultant)	Aime de Muynck
WHO India (WHO Representative to India)*	Salim J Habayeb
WHO SEARO	JP Narain
WHO SEARO	Nani Nair

* Team Leader for 2006 WHO–GoI Joint Monitoring Mission

In addition, useful inputs were provided by WHO–RNTCP consultants posted at the CTD and in the states visited by the Mission.

Annex 3

Map of reviewed states and districts

Annex 4

State report summaries

Key findings and recommendations for Gujarat

Gujarat

State profile

Total population (2006):	55 million
Administrative set up:	30 districts, 125 TUs, 645 DMCs
RNTCP:	DOTS strategy implemented since 2000, full coverage achieved in 2004
Trends in key programme indicators:	CDR above the global target of 70% Treatment success rate consistently over 85%

Summary of findings

- TB programme activities well integrated into general health services (at programme delivery level). High level of awareness and involvement of state- and district-level officers. Regular quarterly and monthly review meetings at state and district levels. Budget allocations of funds for TB activities available; financial flow satisfactory;
- Government of Gujarat offers a social welfare scheme to TB patients whereby they receive financial assistance up to Rs 1500;
- STC fully staffed; Director STDC post vacant, MOs holding posts of Epidemiologist and Health Educator; microbiologist is a deputed Junior Lecturer from a medical college. In three out of four districts – HRD plans lacking, staff require re-training, budgeting for training in district action plans not done. Staff vacancies across medical grades hampering all health activities,

including the RNTCP. Staff vacancies, additional responsibilities of Programme Officers and lack of supervisors (STS);

- State and District TB Control Societies merged into State and District Health Societies; however, separate bank account for TB remains. Monthly Health Subcommittee meetings – will review TB programme along with malaria, leprosy, etc. Health Subcommittee of health societies not yet met – actual operational mechanisms not established. HIV/AIDS in a separate Subcommittee from TB. Use of Block Health Officer (BHO) for supervision as MO-TC seems to have diluted focus of RNTCP supervision in two blocks visited in which BHO is MO-TC (Mehsana);

- Patients on treatment well counselled and aware of disease and treatment duration. Cured patients started to be used both for advocacy and DOT. Social stigma appeared less in rural areas. Community group meetings happening. Large percentage of high-cost IEC activities budgeted – not well targeted. Material used – dense text, non-verbal, and non-visual. Communication facilitators not yet appointed;

- Case-detection, diagnosis – high NSP case detection rate (CDR) (>70%); number of suspects examined per 100 000 fairly constant; delay in diagnosis; low percentage of suspect referrals at PHI level; smear positivity at higher end of range; high rate of advanced disease at presentation; high percentage of re-treatment smear-positive cases (25–45%); diagnostic algorithm for detection of new smear-negative (NSN) not followed – low NSN case detection;

- Laboratory – microscopy network in place – staff, equipment, reagents, IQC, EQA, etc.; laboratory registers well kept, with visible signs of STLS OSE visits; annual maintenance contract of binocular microscopes – no actual maintenance conducted;

- Technical issues on EQA implementation – no major discrepancies found, even in scanty slides; management of biomedical waste poor at peripheral level;

- Treatment – generally DOT happening as policy; decentralized DOT provision (with multiple dedicated DOT providers in place); children on INH chemoprophylaxis; high default rate (25–36%) in Category II smear-positive cases – said to be due to alcohol abuse, low socioeconomic status of patients, migration for employment; sputum follow-up schedule at two months into continuation phase (CP) not adhered to; feedback of transferred patients irregular; indoor patients not being registered but prolongation pouches are being used for starting their treatment;

- Drugs and logistics – generally stores well run, in good order, with fairly complete and up-to-date documentation; reconstitution of PWBs being done at the district level with register in place; no stock-outs recorded; stocks at district level – some Category II boxes near-expiry (08/07); loose anti-TB drugs (first- and second-line drugs) being dispensed outside RNTCP to TB patients in all medical colleges; no paediatric PWBs available for use as yet;

- Information system, recording, reporting – generally records and reports available, up-to-date, and consistent; large amounts of data available, but little evidence of critical analyses of data and planning of appropriate action; despite frequent supervision tours done, little evidence of "effective supportive supervision" seen in the field;

- Involvement of other health-care providers – ever-growing private sector – involvement of PPs started; NGOs more involved – signed schemes underutilized; good involvement of medical colleges in all districts (with significant percentage of case detection in Ahmedadbad Municipal Corporation [AMC]); slum networking programme in AMC – opportunity for wider access to TB care;

- TB/HIV collaborative activities – staff trained (in both programmes); cross-referral, line listing and monthly reporting mechanisms started to work; toll-free HIV telephone information line available; no State or District TB/HIV Coordination Committee; one VCTC per district (more in AMC); one ART centre; few cross-referrals; TB patients found to be HIV-infected not routinely referred to ART centre and co-trimoxazole prophylactic therapy (CPT) is not provided ; confidentiality – TB doctor not aware of HIV status of TB patient referred ; HIV patient education material – no mention of TB;

- DRS and DOTS-Plus – DRS survey ongoing – final results awaited; Gujarat DOTS-Plus Committee and Action Plan in place; culture and DST facilities are available in state; although culture and DST facilities are available, at present not used as IRL lacks accreditation; wide usage of SLDs in both private and public sector facilities; some treatment is provided free of cost indoor in public sector, however, all patients have to purchase drugs after discharge; treatment of MDR-TB patients is haphazard in terms of regimen, follow up and managing adverse drug reactions; infection control is non-existent; IRL culture and major DST equipment needs to be totally replaced; 50% of IRL staff requires training; basic biosafety conditions are lacking at the IRL.

Recommendations

Health systems

- Use enhanced financing through the NRHM to improve building maintenance and equipment stock;
- Separate TB bank account to continue, with CDHO and DTO as signatories under the NRHM;
- Health Subcommittee of District Health Society should meet at the earliest to establish effective operational mechanisms.

Human resource

- Detailed HRD (state and district) plan for the next six months should be developed:
  - Train all levels of staff in all sectors, both for induction, updating and re-training
  - Re-allocate budget for training of community volunteers and PPs, re-training of staff, etc.
- Staff vacancies need to be filled, especially at DTO level.
- Post full-time STO and DTO; hire contractual STSs.

Supervision and monitoring

- BHO and MO-TC jobs should not be combined. However, if done, consider giving BHO extra days of touring (and travel expenses from the RNTCP) in addition to normal tour days to effectively supervise RNTCP activities, and BHO/MO-TC to attend the TB review meetings;
- Capacity building required for supervisory and programme managers in handling and critical analyses of data in order to plan appropriate action, and in effective supervision;
- District plans and budgets need reviewing in terms of use of revised norms, budget for NGO/PP schemes, etc.

Drugs and logistics

- Immediate district- and statewide stock-taking/physical verification of PWBs in relation to drug stocks and expiry dates, and liaise with CTD;
- Accelerate training, distribution and use of PWBs.

Involvement of other sectors

- More efforts should be made to actively involve other providers in already existing mechanisms;
- Involve more IMA and trained medical college faculty in RNTCP advocacy and sensitization of PPs.

TB/HIV

- Engage in coordinated training of PPs in collaboration with NACO and SACS;
- HIV counselling and testing services need to be decentralized to ensure access;
- State TB/HIV Coordination Committee to be established;
- All HIV-infected TB patients should be offered referral to the ART centre and receive CPT;
- Place RNTCP education material in VCTCs.

IEC/ACSM

- Greater emphasis to be given to community awareness and social mobilization activities with technical assistance from communication experts – district plans for IEC activities and budgets to be reviewed and re-allocated as required;
- Use of visual non-written material;
- Use of existing RNTCP IPC material during staff training and community meetings;
- Communication facilitators to be appointed at the earliest.

DRS and DOTS-Plus

- Current treatment practices with state-procured SLDs should be stopped until RNTCP MDR-TB treatment services are in place;
- Laboratory related:
  - IRL culture and major DST equipment to be totally replaced;
  - Interim mechanism for culture and DST needs to be in place pending accreditation of the state IRL.

- Patient management related
  - Staff need training (clinical, supervision, recording and reporting, etc.);
  - Patient selection to ensure enrolment of "true" MDR-TB suspects;
  - Careful selection of DOT provider for patients on MDR-TB regimen;
  - Basic infection control measures need to be implemented (for indoor facilities);
  - Availability of ancillary drugs for treatment of adverse reactions to be ensured.

Case detection and case-holding

- Training of health workers, community DOT providers and STS needs to be ensured to ensure early referral of symptomatics;
- Training of MOs on updated diagnostic algorithm to be ensured;
- Sputum collection and transportation mechanism to be established in tribal and scattered populations to ensure access to diagnosis;
- Reasons for high proportion of retreatment cases to be analysed; their source and time of previous treatment;
- Alternative DOT approaches to be considered (i.e. home-based) for patients who cannot access the DOT centre;
- Sputum follow-up schedule to be adhered to (refresher training)
  - DOT provider – referral
  - STS – supervision
  - MO – review
- Feedback of transferred patients to be ensured – actively ask for result;
- New mechanism for accounting of patients starting indoor treatment should be proposed by CTD;
- Old and non-functional equipment and vehicles to be replaced;
- Existing annual maintenance contract for binocular microscopes to be reviewed;

- Improved management of biomedical waste at the PHC and PHI levels to be ensured;
- More detailed and in-depth analyses of RBRC and OSE at IRL and NRL required;
- Linkage of TB patients to social welfare scheme to be ensured.

Key findings and recommendations for Haryana

Haryana

State profile

Total population (2006):	21 million
Administrative set up:	20 districts, 45 TUs, 209 DMCs, 4642 DOT centres
RNTCP:	DOTS strategy implemented since 2000, full coverage achieved in 2004/I
Trends in key programme indicators:	CDR slightly increasing to ~60%, treatment success rate consistently 82–83%

Summary of findings

Relatively new Programme and has made inroads. Basic elements for TB control are in place: physical infrastructure, critical mass of trained staff, uninterrupted drug supply, network of DOT providers, and reporting and supervision system. In addition, sensitization of key administrative staff and local self-governments has taken place. In support of the TB programme, an IRL has been established, and the largest medical college in the state is involved.

- Strong commitment at top bureaucratic level (Financial Commissioner of Health and Medical Education [FCHM]), but limited ownership of Programme by general health services;
- Post of DTO not universally sanctioned. Vacancies of core staff. MOTC overburdened with other, general duties affecting time devoted for TB. Absence of functional STDC affects assessment of HR needs, quantity and quality of training. National consultants burdened

with programme implementation. Over-reliance on contractual staff. Frequent transfers affect continuity and quality;

- Lack of clarity on design of NRHM; safeguarding TB funding under merged health societies;
- Need for better coordination between technical programme officers and other health functionaries;
- Supervision, monitoring and evaluation – lack of supervision of quality and lack of objective supervision with feedback;
- IEC activities are currently centred on production of materials rather than IPC and not community-based;
- Underdiagnosis of smear-negative cases, including children. Inadequate inclusion of various providers (including paediatricians);
- QA system patchy. IRL is not proactive in fulfilling its core responsibilities;
- Initial defaulters and issues concerning referrals and transfer of patients;
- Flow of drugs below TU level heavily dependent on STS. Arbitrary indenting of loose drugs as evidenced in PHI monthly reports;
- Successful involvement of medical college. Involvement of PPs, NGOs, corporate sector has yielded no results as no significant efforts have been made and no formal mechanism is established.

Key recommendations for the state, Government of India and WHO

Recommendations for the state

- The post of DTO should be established in each district.
- All DMCs should have trained LTs posted.
- The performance of poor-performing districts should be regularly monitored by the state till all major issues have been adequately addressed.
- The TU should be physically located in the main CHC of the area.
- Allow protected time for MO-TC for TB work.

- An HRD plan should be developed to address all training needs (induction, refresher, update).
- A pre-placement orientation should be offered to all staff joining in a new function.
- EQA activity by the IRL needs strengthening.
- Feedback loop on supervisory reports needs to be developed.

Recommendations for the Government of India

- NRL should provide more intensive support and know-how to the IRL.
- Focus direct support on poorly performing districts.

Key findings and recommendations: Karnataka

Karnataka

State profile

Total population (2006):	56 million
Administrative set up:	28 districts, 1116 TUs, 620 DMCs
RNTCP:	DOTS strategy implemented since 1998, full coverage achieved in 2004
Trends in key programme indicators:	Treatment success rate showing decline ~ 80% CDR is at around 60%

Summary of findings

Overall, there is good public health infrastructure in the state. The STS, STLS and TBHV's work constitutes the strong foundation of the Programme. Record-keeping is in general good; good logistics management and good EQA in place.

- Some staff are exceptionally talented, very motivated and dedicated who, despite very difficult circumstances, do very good work.
- In cities, a system with innovative ideas to obtain feedback for transfer-out patients has been developed and is working well.

- Hospitals/sanatoria and medical colleges are involved and the medical faculty met had a favourable attitude.
- IEC activities are aiming at raising the awareness of different groups of the RNTCP and TB control activities, e.g. street plays, different types of sensitization activities, TB–HIV collaborative activities, have started. A lot of effort has been made for this collaboration to be functional.

Constraints

- Suboptimal and declining programme performance
  - Case detection is below target. In bigger cities there is a high dependence on referrals by two TB hospitals/sanatoria and medical colleges. Referral of chest symptomatics from PHIs is low.
  - Treatment outcome is below target. The defaulters, referrals, death and transfer-out are of concern.
- Impending administrative change where project officers will be responsible for four programmes is of concern: with the current status and challenges for the RNTCP, and rapid expansion of other programmes it will not be possible to manage that workload and at the same time improve quality.
- Suboptimal use of supervision as a problem-solving and motivating tool including use of quarterly/monthly/weekly meetings; checklists are not used everywhere.
  - The STO is generally appointed for a very short period; suboptimal management at State TB cell and STDC; the contribution of the STDC is very limited.
  - Supervisory schedules are not followed and not implemented in full; no structured prioritization is made in the planning for subsequent quarters based on which districts were visited in the previous quarter.
  - Technical and managerial support to different levels (level below) is suboptimal.
  - Planning and follow up is suboptimal on action plans by staff in supervisory positions.
  - Financial management is weak.

- Implementation of annual plans is not monitored – the plan is more a budgeting tool and not a management tool.
- There is overdependency on consultants.

➢ HRD management is suboptimal – salaries, vacant positions, distribution of exiting staff, workloads, training planning including priority setting, lack of use of quarterly reports for planning, training with revised modules

- Considerable proportion of staff involved in the Programme are not trained: Specifically, MO (3939 total, 3753 trained); LT at designated MC (608 total, 542 trained); MPH supervisor (1710 total, 1539 trained); TO (42 total, 34 trained); MHW (19239 total, 11696 trained)

➢ Infrastructural gaps

- In cities, suboptimal placement of some DMCs is inconvenient for case detection, some DMCs are overwhelmingly burdened while others are underutilized.
- Drug logistics management is not taken by the State TB Cell as a priority and the state has so far failed to establish a State Drug Store.
- Progress in establishing the IRL is slow.
- Some laboratory equipment is non-functional and there is no AMC.

➢ TB/HIV collaboration is suboptimal – on the HIV side many VCTCs have been established but are not functional.

- DTOs have been designated as nodal officers for HIV/AIDS, without clear delineation of responsibilities, guidelines, funding for activities, or a regularized channel of communication with state authorities.
- Knowledge and practice regarding the assessment of HIV risk factors among TB patients, and among trained and untrained MOs is poor.
- Referral of TB patients for HIV testing is limited by the non-availability of functional ICTCs except at district HQ.
- Facilities for referral of HIV-infected TB patients for ART and other care and support are particularly limited.

- Information regarding the status and follow-up of TB patients referred for HIV counselling and testing is not shared with the RNTCP.
- Screening of ICTC clients for TB and referral of TB suspects to the RNTCP has been observed but much more effort can be made in this area, given the volume of potential referrals.

➢ Planning and prioritization of IEC activities needs more focus.

- IEC is not considered a priority by most of the RNTCP staff even though it plays a critical role in public information, advocacy and social mobilization leading to improved case detection rates and treatment success rates.
- IEC activities are not well planned, are diffuse and lack focus.
- At most places, IEC activities are carried out in an ad hoc manner in the limited budget available.
- There appears to be no plan for assessing the effectiveness of the IEC activities being carried out in the state, giving an impression of weak programming skills.
- The state IEC officers and DTOs are inadequately involved in IEC planning and supervision.
- In the absence of any planned innovations in IEC, there appears to be "message fatigue" setting in rapidly.

➢ There is limited use of community DOT providers.

➢ Involvement of PPs and professional bodies is limited.

Recommendations

Recommendations for improvement fall in two categories; recommendations related to having an optimal structure in place, e.g. human resource development, supervision, drug and logistics management; and recommendations related specifically to the outcome of activities – case detection and treatment outcome.

➢ Political and administrative commitment

- Ensure qualified staff recruited to and retained in sanctioned posts at all levels, particularly LTs in general health systems and ANMs.

- State: Post MOs in PHIs. Use "exceptional rates" or additional allowances for postings in difficult and remote areas if necessary to attract candidates.
- District: Minimize transfers and extend tenure of DTOs and MOs entrusted with the work of the RNTCP.

➢ Strengthen HRD.

- Improve staff management, e.g. salaries, workload, placement of staff, vacancies, motivation.
- Reconsider the allocation of multiple programmes to one purchase order (PO) – implementation of the RNTCP will have difficulties if this plan is implemented.
- Improve training – urgent training of new staff, training with revised modules, TB/HIV, retraining based on needs assessment, refresher training, use of supervisory visits and meetings for on-the-job training.
- Prepare a comprehensive HRD plan for the state.

➢ Strengthen supervision – move from a task that "has to be done" to a proactive tool for achieving programme goals.

- Improve planning of visits including prioritization.
- Ensure the use of supervisory checklists.
- Improve analysis of data and problem-solving.
- Increase staff motivation.
- Use supervisory visits for follow up of newly trained staff, identification of retraining needs and on-the-job training.
- Avoid double notification of patients with a TB number referred from other districts; include as transfer in without counting in quarterly reports.

➢ Improve case detection.

- Intensify IEC activities regarding availability of even the limited health-care services.
- Improve referral of chest symptomatics for sputum examination.

- Re-sensitize health workers for identification of TB suspects in the field.
- Expand community DOT to improve accessibility of services.
- Reorganize diagnostic facilities and ensure management of equipment – AMC (binocular microscopes)
- Intensely monitor treatment observation at the DOT centres.
- Intensely monitor transfer-out cases and get feedback on their treatment outcome from the transferred-out districts as a priority.
- Maximize the use of ASHA for suspect identification at local areas, particularly in difficult areas. Improve IEC.
- Strengthen PPM activities towards greater involvement of GPs in the private sector.
- Make optimal use of additional resources, e.g. PPM consultant.

➢ Improve treatment outcome.

- Ensure DOT including community DOT.
- Improve defaulter and transfer tracing, including interdistrict communication.
- Provide better patient information.

➢ Improve TB–HIV collaborative activities.

- Ensure the establishment of coordinating committees; regular review at district and state levels under the established coordinating committees mechanism.
- Ensure the functioning of established ICTCs for the referral of TB suspects.
- Strengthen ongoing supervision and monitoring of collaborative activities.
    - Strengthen the cross-referral mechanism by emphasizing monthly meetings between RNTCP and ICTC staff to discuss operational issues, share programme performance data, participate in sensitization and opportunities for refresher courses.

- Facilitate and strengthen the role of the district HIV nodal point by ensuring timely communication, guidelines and funds, and clarify his/her roles and responsibilities (three fourths are DTOs).

➢ Public–private collaborative activities
  - "Catch them young": Medical colleges can play important role in training/sensitizing medical/nursing students, the future implementers of the programme.
  - Monitor and supervise the institutions enrolled in private sector to ensure adherence to Programme guidelines.
  - Improve IEC to involve more individuals/hospitals in the private sector.
  - Utilize professional bodies such as the IMA, API, National College of Chest Physicians (NCCP), Indian Chest Society (ICS), Tuberculosis Association of India (TBAI,) etc. for advocacy and support to the Programme.

➢ Advocacy, communication and social mobilization
  - There should be more focus on IEC and social mobilization in the RNTCP at all levels.
  - Reorient staff (and provided refresher trainings) on IEC with a clear focus on the process of IEC planning and monitoring.
  - Strengthen supervision of IEC activities at various levels.
  - Involve other partners and stakeholders more comprehensively in IEC activities such as NGOs, Cobs, Rotary Clubs, IMA.

➢ Establish the state drug store
  - Drugs storage conditions are not optimal and require continuous monitoring.
  - Ensure ownership of drug management at all levels.
  - Train the DTO in drug management.

➢ Accelerate implementation of the IRL.

➢ Ensure the financial and managerial functioning of the RNTCP in the light of the implementation of the NRHM; administrative and financial autonomy of the DTO should be maintained.

Summary of state recommendations: Madhya Pradesh

State profile

Total population (2006):	66.8 million
Administrative set up:	45 districts, 142 TUs, 720 DMCs
RNTCP:	DOTS strategy implemented since 2000, full coverage achieved in 2004/IV quarter
Trends in key programme indicators:	CDR shows declining trend, current level of ~60%, treatment success rate consistently 82–83%

Summary of findings

- Though the state government considers RNTCP as an important programme, there is only limited ownership by the state. There is lack of clarity about the role of general health-care services in the RNTCP.
- The state TB health society has been merged into the state health society, but the funds have been parked separately. The same is true for the district level as well. Serious concern regarding mixing of funds at district level, especially in vehicle hiring and IEC, has been expressed. The State Health Plan for the project implementation plan (PIP) of the NRHM will include additional funds for activities and will not alter the structure of finance management of the RNTCP. The flow of funds has improved in the past year. Accounts are maintained properly. Flexibility in the use of funds is not applied at the district level and below.
- The current STO is not full time for the RNTCP and is in charge of several other programmes as well. He has been trained in the RNTCP but allots less than 10% of his time to it. Frequent changes of STOs in the past have been a constraint. A full-time STO as one of the five programme officers is in the offing.
- The post of MO-STC is vacant and has never been filled. None of the DTOs hold independent charge. An MO-DTC is not available in the majority of districts. Thirty-four posts of STS and 34 posts of STLS are vacant. Inability to fill up the vacancies is attributed to the reservation policy and eligibility criteria. Many high-level officers are "in charge" and transfers are very frequent. Absence of staff especially MOs in the PHIs is an important finding.

There are 253 vacancies for MOs. Shortage of doctors and the reservation policy are blamed.

- An STDC Director is in place. Efforts to establish an IRL are progressing. STDC staff is incomplete and less frequently used to support supervision of the DTC and for QA. Available data and records for programme monitoring are not effectively used for action.
- All the eight medical colleges including the private colleges are involved as designated microscopy centres (DMC) cum DOT centres and they contribute largely to the case detection in the state.
- There are 25 000 qualified doctors, 90 000 non-MBBS doctors, 57 000 informally trained and 90 000 untrained practitioners in the state (identified in a research project). By and large, the PPs have not been involved (less than 1%); 45 NGOs are involved in the RNTCP. There is very limited utilization of formal signed schemes by NGOs. The ESI, Railways and Prisons are involved in the RNTCP.
- At the state level, the IMA has not been brought in so far, though recent efforts have been made in this direction. There is coordination between the DTCS and Madhya Pradesh Voluntary Health Association (MPVHA, an NGO) which runs the Urban DOTS Project at Indore.
- There is insufficient funding for IEC at the state level. IEC activities are not reflected in the quarterly reports. Coordination with the state IEC wing is suggested.
- An IRL is being established. It is housed in an old dilapidated building unsuitable for culture activities. All the reports are generated manually, which is time-consuming. Separate e-mail connectivity is required. A microbiologist is in place. Monitoring of EQA is being done by the STDC Bhopal and MRTB hospital, Indore for 20 districts. MDR-TB cases are being managed and culture/sensitivity is done without QA and without coordination. The quality of implementation of EQA is not satisfactory in Vidhisha district. On-site visits to districts are regular. Panel testing is done.

Recommendations

- Strengthen the State TB cell.
  - Designate a full-time State TB officer, who will be in place for adequate time to function effectively, and a full-time MO to support the STO.

- Fill up vacancies of staff of the STDC and adapt the TOR, increasing the emphasis on monitoring and supervision, and training in these activities. Improve the physical infrastructure of the building where the STDC and IRL are situated.
- Prepare and carry out a plan for supervision of districts, particularly those with problems. The plan should be submitted to, and followed up by, the Health Commissioner and the Secretary of Health. The STO should receive supervision plans from DTOs and follow up on the field visit reports.
- The STO should instruct DTOs to ensure transportation for supervision, by hiring vehicles when regular transport is not available.

➢ Strengthen the managerial structure of the state TB programme.

- Involve the Divisional Joint Directors and Divisional Commissioners in monitoring the TB programme using selected indicators.
- Establish full-time DTOs with senior staff positions and keep them there for adequate time to be effective, and designate a second MO for the DTC to take care of clinic work when the DTO is touring.
- Ensure that the district TB committee or equivalent meets regularly; and that time for discussion on TB is secured in regular meetings of the DHS. DTOs, assisted by RNTCP/WHO consultants, can help the CMO and collectors to identify specific health systems insufficiencies through monitoring TB programme performance.

➢ Strengthen service delivery.

- Ensure that TB microscopy units are fully and permanently manned with microscopy and separate DOT, even if there is no MO in the PHI. All peripheral health workers in the field should be trained and involved in the referral of TB suspects, and treatment support.
- Establish systematic detection of suspects among all adults attending the OPD through registration counters, and adjust the procedures in each PHI to facilitate patient movement and screening. Monitor the trends in case detection and microscopy examination of smears of suspects as a major indicator of the Programme.
- Ensure that the responsibility for DOT is with the DOT provider and not a function of the LT, although he/she can collaborate if necessary.

- Use brief modules to provide MOs with essential knowledge and retrain the MO-TC to oversee the Programme. The contractual state pharmacist should be trained in RNTCP drug management, and drug management workshops should be urgently organized for all DTOs. Drugs should be regularly available, at least down to the DMC level.
- Improve the capacity for diagnosis of smear-negative cases by filling up the MO positions in PHIs and providing X-ray facilities where appropriate.

➢ Increase coverage of programme activities.

- The Health Commissioner should follow up on targets set for involvement of private providers and NGOs. A state action plan on PPM should be urgently submitted and monitored. DTOs should be encouraged to include PPM activities in the next year's district plan. The IMA should be involved in the sensitization and training of PPs. The experience of involving the ESI hospital in Dewas should be shared widely across the state.

Key findings and recommendations: Punjab

Punjab

State profile

Total population (2006):	86 million
Administrative set up:	19 districts, 180 TUs, 871 DMCs
RNTCP:	DOTS strategy implemented since 2001, full coverage achieved in 2004
Trends in key programme indicators:	Treatment success rate consistently over 85%, CDR gradually improving and is at around 60%

Summary of findings

➢ There is a high level of commitment to health in general and TB in particular.

- The Principal Secretary for Health and Family Welfare has a very high level of commitment to as well as involvement in the Programme.

- The Director of Health Services is also committed to the Programme.
- Review of the TB Programme is accorded a high priority by the Principal Secretary in his monthly review of Civil Surgeons.

- The NSP case detection rate is 62%, and success rate 85% (Q2, 2006).
- There is some community empowerment and involvement in DOT.
- Human resource management: TB Programme officers at state and district levels are junior in rank as compared to their service colleagues in the districts.
  - The post of STO equivalent to the rank of Deputy Director (TB) has been vacant for more than two years. The STO is not full time and is not trained in the revised modules of the RNTCP.
  - The post of Deputy STO and posts of DTOs in 5/17 districts have not yet been created.
  - The STDC Director is not full time.
  - DTCs have not been established for newly created districts (Mohali and Taran Tarn)
  - Updated training of MOs, LTs and DOT providers is not done.
  - There is delay in induction training of turnover staff.
  - MO-TCs are subjected to frequent transfers.
  - Almost all contractual positions are filled.
  - All STS and STLS are contractual, as well as 20% of LTs.
  - The process of selection and appointment of contractual staff is not streamlined.
- Capacity of the state TB cell in Programme monitoring
  - Overall capacity of the STC in programme management is satisfactory.
  - Supervision as well as monitoring by the STC is weak.
  - Quarterly review meetings at the State level are not held regularly.
  - The state is analysing data TU-wise and sending the feedback to districts and the CTD in accordance with the guidelines.

- Capacity of the state TB cell for financial monitoring
  - Delegation of administrative and financial power to the STO and DTOs is as per guidelines.
  - The system for flow of funds at various levels is smooth.
  - Financial monitoring at the STC is not adequate and funds under several budget heads, including IEC, are not completely utilized.
  - The state action plan for the financial year 2006–07 has been sent to the CTD.
  - The audit report and utilization certificate for the financial year 2005–06 have been sent to the CTD.
- Drug management system
  - The State health department is not procuring anti-TB drugs.
  - An SDS was established in December 2005. The SDS has a balance of approximately one quarter's utilization of drugs.
  - Drugs are distributed on a quarterly basis and the mode of transportation is through district vehicles instead of state vehicle(s).
- Advocacy, communication and social mobilization (ACSM) activities
  - There is a lack of documentation of strategic planning, and formative and operational research, from which to develop action plans and activities.
  - Relatively few IEC materials are available, particularly for patients, DOT providers and other advocacy activities.
  - Training and service provider material should be more comprehensive.
  - Budgeted funds for IEC activities are underutilized.
  - There is poor visibility at the community level (with signages) and low impact of material currently developed.
  - The M&E framework for IEC/ACSM is currently limited.
    - The Communication Resource Information System (CRIS) not evident.
    - No KAP surveys have been identified from which to make objective conclusions on patient provider attitudes, quality of service delivery and treatment compliance.
    - Problems in funding approval for action plan activities have been reported.

- TB–HIV linkages launched and being expanded
  - There is good coordination between the RNTCP and SACS, but no meeting of the State TB–HIV coordination committee has been held.
  - The post of the TB–HIV coordinator is vacant.
  - Approximately 50% of the VCTCs do not have counsellors.
  - HIV testing is available at the CHC level outside the VCTC services.
  - Cross-referral between TB services and the VCTC is very poor.
  - ART clinics are available in only two districts of the state.
- Community health service providers (MO, pharmacist, ANM) have been appointed for every 10 000 population.
- Involvement of other health sectors (public and private)
  - Involvement of PPs, NGOs and the corporate sector is limited.
  - Other government sectors are involved but their contribution is limited.
  - PPM projects have been launched in some districts.
  - Coordination with the IMA and major NGOs at the state level is limited.
- All medical colleges implementing organization of TB services in the state
  - Medical college involvement is limited to the Chest and TB departments.
    - State Task Force meetings are not held frequently.
    - Five posts of contractual MOs in five medical colleges are vacant.
- An STDC and IRL are established and functioning.
  - The IRL of the STDC in Patiala is doing OSE. IRL members have visited 11 districts of Punjab in 2006.
  - Supervision by the STDC (as compared to quality control) is lacking.
  - Reports on OSE, panel testing and RBRC are available with the IRL, but the feedback is generic and is not action oriented.
  - Civil work for the renovation of the laboratory component has started; however, it appears that plans for culture and DST may not materialize at all.

Recommendations

For smooth functioning of the RCNTCP in the State of Punjab:

- The state and district Programme Officers of TB should be of the same rank as the Programme Officers in other national programmes.
- The state requires urgent establishment of DTCs in the newly created districts.
- Quarterly RNTCP review meetings for reviewing programme performance in the districts/TUs, and addressing technical and operational challenges in quality programme implementation:
  - Monthly review meetings should be replaced by exhaustive quarterly review meetings. Issues other than performance indicators (NSP rates, sputum conversion and cure rates, etc.) may be discussed in the monthly meetings as status-of-performance indicators do not change significantly on a monthly basis and therefore do not provide scientific information.
- Supervision and monitoring should be strengthened at the STC and STDC level.
  - Assessment of performance of the RNTCP at district level by the Chairman and Vice-Chairman of DTCS should be objective.
  - There should be a system of review of performance of contractual staff and renewal of contracts should be linked to performance.
  - Advance tour programmes and tour diaries must be used at all levels.
  - Data recording, reporting, monitoring and supervision are being are done casually at some places; these should be done more comprehensively and intensively.
  - In order to ensure supervisory visits, MO-TCs and other programme officers should hire vehicles and not use their own vehicles for RNTCP tours.
- Extensive and comprehensive planning should be done of IEC and ACSM activities at the STC level.
- Financial monitoring at the STC level should be more systematic and intensive.

- All vacant posts need to be filled up at the earliest and all programme officers should be full time.
  - The process of selection and appointment of contractual staff should be streamlined and renewal of contracts should be performance based.
  - Update and induction trainings should receive priority.
  - Trained MO-TCs should not be frequently transferred in the interest of the Programme.
- Adequate buffer stock needs to be maintained at all levels. Drugs from the state to the districts should be distributed via state vehicle(s).
- Involvement of other health sectors in the RNTCP should be encouraged at all levels.
- The M&E framework for IEC/ACSM requires a more comprehensive approach in line with the treatment programme.
  - Capacity building through training of IEC staff is a high priority.
  - Greater involvement of public–private partnerships is required for strategic campaigns including market research, creative materials development, the media and logistics supply.
- Strengthen TB–HIV coordination and collaborative activities.
  - Coordination Committee meetings should be held regularly at state as well as district level.
  - The post of TB–HIV coordinator should be filled immediately.

Key findings and recommendations: West Bengal

West Bengal

State profile

Total population (2006):	26 million
Administrative set up:	19 districts, 57 TUs, 283 DMCs
RNTCP:	DOTS strategy implemented since 1998, full coverage achieved in 2003

Trends in key programme indicators: CDR above the global target of 70%
Treatment success rate consistently over 85%

Summary of findings

West Bengal is a high-performing state and has achieved a reported CDR of 64/100 000 population (74% of estimated case detection) and successful treatment outcome rate of 85% in 2005.

- Political, administrative and technical commitment is high at all levels.
  - This is reflected at the district level by the involvement of the Sabhadipathi and the DMs in the planning and implementation of the TB programme. The district of 24 North Parganas demonstrated high-level political commitment; the DM participated in the field visit with the JMM team.
  - The state signed an MOU with the GOI, indicating their commitment to the aim of the NRHM.
- Overall, the TB services in the state are well organized.
  - There is weak coordination between the State TB cell and the STDC, which impairs Programme implementation.
  - However, there is suboptimal coordination at the district level in Kolkata.
- Program monitoring
  - The STC conducts quarterly review meetings and analyses reported data.
    - The STO reports visits to each district every quarter.
  - The current role of the STDC in monitoring and supervision is limited.
  - Supervisory registers and district feedback reports were not used or available for review.
  - Analysis and use of data is limited – inadequate state and district supervision has resulted in unreliable Programme data from some TUs.

- The quality of implementation is suboptimal in certain districts. Several TUs had a high proportion of patients (35–55%) with a delay from diagnosis to treatment of more than seven days; there is a high proportion of defaulters among retreatment cases; In North 24 Parganas, among those receiving treatment after default (TAD) 32% were defaulters.

➢ Financial monitoring

- In 2003, the TB society was merged with other programmes under an umbrella health society facilitating transition to the NRHM. The individual funding streams, including TB, have maintained separate accounts and the flow of funds from the state to the district is electronic and often occurs in less than one day.
- In some districts, the flow of funds has, at times, been erratic causing delays in payment of salaries and other components influencing Programme supervision.
- Financial records are not maintained in a standardized format, leading to a potential for financial irregularity.

➢ Human resources

- Most sanctioned posts are filled; 9/19 (47%) newly appointed DTOs
- Positions for the State IEC officer and data entry operator are vacant.
- In 74/871 DMCs (8%) the LT positions are vacant.
- A comprehensive HRD plan is not in place – new staff training is needed, as well as retraining of experienced staff and training in new Programme initiatives.
- Attendance in large hospitals by MOs for RNTCP training is poor.

➢ Drug management system

- The SDS is physically located at the Central Drug Store for the state, which functions autonomously under the STC. Drug storage space is limited and inadequate.
    - Because of geographical size of the state, it is difficult to send drugs in time to the remotest districts.
- There were no stock-outs in the past year; only RNTCP drugs are procured.

- A pharmacist is in place, FEFO is practised, but the stock register was not available to verify this practice.
- About 300 000 expired rifampicin capsules were found in the SDS.
- In the districts, reconstitution of boxes is unsupervised resulting in errors in labelling the dates on the boxes and inclusion of drugs near expiry.

➢ Involvement of other sectors

- Other major public health sectors such as the Railways, Eastern Coalfield Limited (ECL) and ESI have been engaged and are implementing DOTS in collaboration with the RNTCP. However, the quality of RNTCP implementation is weak at some of the sites.
- Public–public collaboration such as with TB sanatoria and large general hospitals is currently minimal.
- Several potential partners have not been involved: corporations, private practitioners, homeopathic doctors.
- All the medical colleges (9/9) are implementing the RNTCP.
    - Core committees do not meet regularly and training of members is not yet complete.

➢ ACSM/IEC

- The current IEC state-level post is not yet filled and the IEC plan has not been implemented.
- A review of the budget shows that 7% of the budget in FY 2005–06 was spent on IEC.
- IEC is visible in several health facility buildings.

➢ TB–HIV

- HIV service programme coverage is limited compared to RNTCP coverage, which limits the potential for collaborative activities.
- Though referrals are made, feedback is available for only 30–50% of the patients referred from the VCTC to the RNTCP.
    - Many VCTC clients are referred to remote sites for DOTS.
    - Some VCTC sites are not DMCs.

- Currently there is no system to track PLWHA referred from the VCTC and RNTCP to ART services. There is no regular communication between RNTCP and ART sites to coordinate care and treatment.
- Awareness of HIV care and treatment services is limited in districts (and subdistricts); this impedes effective and timely referral to tertiary-level ART centres.

➢ IRL/MDR-TB

- An IRL currently under construction.
- The STDC office and training facility have recently moved and are in separate locations.
- SLDs are being used to treat suspected drug-resistant cases (Category II treatment failures) at a state-sanctioned TB sanatorium (Nadia).
- Category II treatment failures are put on SLDs on the basis of clinical suspicion. The treatment regimen and monitoring of such patients is at present not in accordance with the national/international guidelines.

➢ Other areas

- Patient-friendly DOTS – health facilities are usually only open from 9 am to 2 pm; and DOTS is provided only on Monday–Wednesday–Friday.
- Children
  - The use of INH prophylaxis for children <6 years is limited.
  - Training in paediatric drug use has not yet started.
- Infection control
  - Infection control guidelines and plans are not implemented. Sputum cups are not disposed of properly at some sites and handling of sharps is poor.
  - TB patients and suspected drug-resistant patients on SLDs share the same ward.

Recommendations

- The high level of commitment and support from the Central, state and local levels should be continued.
  - The State Health Secretary and Director of Health Services should take measures to optimize coordination between the STO and the STDC Director; the STO should have adequate authority over all aspects of the Programme, including the STDC, to ensure smooth functioning.
  - In Kolkata, the acting DTO should be given greater administrative authority commensurate with his current responsibilities.
  - Organization of services in large metropolitan cities should be optimized to achieve good coordination between agencies.
- A comprehensive state human resource development plan should be prepared and implemented; all districts should have an updated district training plan.
  - Conduct refresher training and upgrade training for existing implementing staff.
  - Prioritize training of key personnel such as newly recruited DTOs, MOTCs, MO-PHI (at the PHC, RH, SDH, BPHC).
  - Conduct training for the majority of MOs from other sectors (ECL, ESI, Railways, etc.) who have not undergone RNTCP sensitization/training.
  - Consider developing skills-based training in management and supervision for management staff.
- The STO, Deputy STO and the STDC Director should coordinate and conduct supervisory visits to cover all districts as per the RNTCP guidelines.
  - Large districts require additional supervisory and management staff, e.g. consider an additional MO-DTC to assist the DTO.
  - Motivate MO-TCs and MO-PHIs to perform more effectively in the RNTCP as these are critical supervisory and training positions.
  - Enhance analysis and use of data at the state and district levels, e.g. outcomes of retreatment cases are reported, but not discussed or monitored.
  - Consider employing a full-time statistical officer at the state level to assist in the analysis and use of TB programme data.

- Improve infrastructure for storage of drugs at the SDS; expand space for storage and insert more racks.
  - Expedite plans for implementing a second SDS in the northern part of the state.
  - Implement RNTCP standard records and recording practices for the SDS and all district stores.
  - The STC should regularly supervise and verify the stock available at the SDS to prevent serious errors such as stocking of expired drugs.
  - Reconstitution of drug boxes need to be supervised by DTOs and the dates of expiry should be clearly marked on the reconstituted boxes.
- Effective management of finances under one umbrella society, as recommended in the NRHM, is feasible and does not have an adverse impact.
  - Standardized financial recording and reporting should be ensured at the district and state levels.
- Scale up successful existing PPM models to cover all major industries.
  - Establish a permanent (non-rotating) functional RNTCP cell at national-, state- and district-level IMAs.
    - The IMA should prepare a written plan to sensitize over 30 000 PPs in the state, prioritizing those with high patient case loads.
  - A joint review of Programme performance by the state, CTD and other large sectors (e.g. ECL/Coal India, ESI, Railways, etc.) should be conducted.
  - Involvement of the medical colleges will provide a sensitized cadre of future physicians, and opportunities for OR.
    - The RNTCP should be reinforced and institutionalized in medical colleges. Core committees should be trained and should meet regularly.
  - Strengthen collaboration between ECL and the RNTCP by engaging the Mines Board.
- Limited availability of patient-friendly services leads to missed opportunities for case detection and access to treatment.
  - Widen the DOT provider network; include community volunteers, PPS, etc.

  - Improve DOT in migrant populations – consider involving NGOs working with migrant populations on HIV programmes/NACO.

- Expedite civil work for the IRL.
  - Shift the STDC office and training facility to the IRL building.
  - Improve coordination between the STO and the Director of the STDC.
- Establish functional TB–HIV coordination committees at the state and district level.
  - Coordinate TB–HIV training with the State TB Cell and SACS.
  - Expand TB–HIV training to all TB providers because there is an absence of TB–HIV referrals from the periphery.
  - Create and distribute an updated directory of HIV services in the state.
  - Ensure patients with TB and HIV have access to care and treatment.
  - Monitor and improve the referral and feedback process of patients between services.
- Print all the RNTCP training modules including the six-hour training module and TB–HIV module for medical practitioners.
- An IEC strategy should be developed for the state and district, in accordance with the national RNTCP strategy.
  - Innovative programmes should be implemented such as sensitizing of schoolchildren through the education department.
  - Consider involving the district publicity and district information officer.
- MDR-TB/drug-resistant TB
  - Create a DOTS-Plus committee to implement guidelines for hospitals using SLDs (in accordance with national and international recommendations) to treat drug-resistant or suspected cases.
  - In the interim, identify and link up with a laboratory with adequate capacity to perform quality-assured first-line DST.