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Joint Tuberculosis Programme Review, India

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Abbreviations

A		DOTS	Directly Observed Treatment, Short-course
AIDS	Acquired Immunodeficiency Syndrome	DPT3	Diphtheria, pertussis, and tetanus vaccine (third dose)
ANC	Ante-natal clinics	DRS	Drug resistance surveillance
ANM	Auxiliary Nurse Midwives	DTC	District Tuberculosis Centre
ARTI	Annual risk of tuberculosis infection	DTCS	District Tuberculosis Control Society
ARV	Antiretroviral treatment	DTO	District Tuberculosis Officer
AWW	Anganwadi Worker		
B		E	
BCG	Bacillus Calmette-Guerin (anti-tuberculosis vaccine)	E	Ethambutol
BPHC	Block Primary Health Centre	EP	Extra-pulmonary
		ESIS	Employees' State Insurance Scheme
C		G	
CDC	Centers for Disease Control and Prevention	GDF	Global Drug Facility
CGHS	Central Government Health Scheme	GDP	Gross Domestic Product
CHC	Community Health Centre	GFATM	Global Fund against AIDS, Tuberculosis and Malaria
COMBI	Communication for Behavioural Impact	GNP	Gross National Product
CTD	Central Tuberculosis Division	GOI	Government of India
D		H	
Danida	Danish International Development Assistance	H	Isoniazid
DDG	Deputy Director-General	HCW	Health care workers
DEO	Data Entry Operator	HIV	Human Immunodeficiency Virus
DFID	UK Department for International Development	HRZE	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol
DMC	Designated Microscopy Centre	HRZS	Isoniazid, Rifampicin, Pyrazinamide, Streptomycin,
DOT	Directly observed treatment		

I

ICDS	Integrated Child Development Scheme
IEC	Information, education and communication
IMA	Indian Medical Association
IUATLD	International Union Against Tuberculosis and Lung Disease

K

KABP	Knowledge, Attitude, Behaviour and Practices
KNCV	Royal Netherlands Tuberculosis Association

L

LHV	Lady Health Visitor
LRS	Lala Ram Sarup
LT	Laboratory Technician

M

MC	Microscopy Centre
MDR-TB	Multidrug-resistant tuberculosis (resistance to at least rifampicin isoniazid)
MO	Medical Officer
MOHFW	Ministry of Health and Family Welfare
MO-TC	Medical Officer-Tuberculosis Control
MPHS/MPW	Multipurpose Health Supervisor / Multipurpose Worker

N

NACO	National AIDS Control Organization
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NACP	National AIDS Control Programme
NGO	Nongovernmental organization
NIHFW	National Institute of Health & Family Welfare
NSP	New smear-positive
NTI	National Tuberculosis Institute
NTP	National Tuberculosis Programme

O

OR	Operational research
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P

PHC	Primary Health Centre
PHI	Peripheral Health Institutions
PLWHA	People living with HIV/AIDS
PP	Private practitioners
PPM	Public-private mix
PWB	Patient-wise boxes

Q

QA	Quality assurance
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R

R	Rifampicin
RNTCP	Revised National Tuberculosis Control Programme
Rs	Rupees

S

S	Streptomycin
S+ve	Smear-positive
S-ve	Smear-negative

SA	Statistical Assistant	UNICEF	United Nations Children's Fund
SC	Sub-centre		
SHRE	Streptomycin, Isoniazid, Rifampicin, Ethambutol	USAID	United States Agency for International Development
STC	State Tuberculosis Cell	V	
STCS	State Tuberculosis Control Society	VCTC	Voluntary Counselling and Testing Centres
STDC	State Tuberculosis Training & Demonstration Centre	W	
STI	Sexually transmitted infection	WHO	World Health Organization
STLS	Senior Tuberculosis Laboratory Supervisor	Z	
STO	State Tuberculosis Officer	Z	Pyrazinamide
STS	Senior Treatment Supervisor		
T			
T	Thioacetazone		
TA/DA	Travel allowance / dearness allowance		
TAI	Tuberculosis Association of India		
TB	Tuberculosis		
TB/HIV	Tuberculosis / Human Immunodeficiency Virus		
TB-HV	Tuberculosis Health Visitor		
TO	Treatment Organizer		
TPIS	Tuberculosis Programme Information System		
TRC	Tuberculosis Research Centre		
TU	Tuberculosis Unit		
U			
UNAIDS	Joint United Nations Programme on HIV/AIDS		

1. EXECUTIVE SUMMARY

The current review is the third comprehensive joint programme review for the tuberculosis (TB) control programme of India since 1990. Based on the recommendations of the first review held in 1992, the Revised National Tuberculosis Control Programme (RNTCP) was started on a pilot basis in 1993. This was followed by large-scale implementation of the RNTCP in 1997. The second joint programme review, conducted in February 2000, found the Programme to be successful and recommended rapid expansion of quality RNTCP services to cover the entire country by 2005.

This review was conducted from 15–26 September 2003 by a team of 20 national¹ and 22 international² TB experts. The team made field visits to 5 states (viz. Maharashtra, Orissa, Rajasthan, Tamil Nadu, and Uttar Pradesh). The 5 teams reviewed the Programme at the central level and visited more than 70 health facilities in 20 districts which began RNTCP implementation at least 6 months earlier; interviewed administrators, health staff, TB patients and community members; reviewed records of more than 10 000 patients; collected and analysed information on organization of services, diagnosis and treatment; and reviewed Programme data.

The TB burden in India is still staggering. About 40% of the adult population is infected with mycobacterium tuberculosis. Every year nearly 1.8 million persons develop the disease, of which nearly 800 000 are infectious; until recently, about 417 000 persons died of TB each year. Most TB patients are in the economically productive age group. The society and the country continue to incur huge costs due to TB—nearly US\$ 3 billion in indirect costs and US\$ 300 million in direct costs. The human immunodeficiency virus (HIV) epidemic could further increase the TB burden in India. It is estimated that HIV has infected 3.82–4.58 million persons (Ref. NACO website

¹From Indian Medical Association, National Institute of Health and Family Welfare, leading medical colleges, central TB institutes, nongovernmental organizations and Programme staff from state and district level.

²From Canadian International Development Agency, Centers for Disease Control and Prevention, Danish International Development Assistance, Department for International Development, Global Drug Facility, Global Fund against AIDS, Tuberculosis and Malaria, International Union Against TB and Lung Disease, Royal Netherlands Tuberculosis Association, United States Agency for International Development, and World Health Organization.

<http://www.naco.nic.in/indianscene/esthiv.htm>), of whom nearly 2 million are also infected with mycobacterium tuberculosis.

1.1 Key Findings

The RNTCP has achieved extraordinarily rapid expansion, has placed large numbers of patients on treatment, and has maintained high levels of treatment success. The population coverage has increased more than 5-fold from 135 million in the February 2000 review to 740 million at the time of the current review. The RNTCP has expanded faster than any other effective tuberculosis control programme in the history of DOTS, and its visibility has increased both nationally and internationally. There is now an increased consensus in the country about the effectiveness of the DOTS strategy, in comparison to that in the early years of implementation.

The RNTCP is highly economical, costing on an average less than Rs 2 (US 5 cents) per capita per year. Good infrastructure and management systems for TB control have been established and more than 300 000 staff have been trained. As a result, detection rates are increasing and cure rates remain high. Overall, the recording and reporting are excellent. The published data at the central level reflect the Programme activities in the field, including diagnosis of cases and outcomes of treatment. Treatment is usually directly observed. Baseline epidemiologic studies to measure the TB burden have recently been completed. Significant initiatives at central, state and local levels have resulted in greater involvement of non-governmental organizations (NGOs), private practitioners, and medical colleges. Co-ordination of activities between the RNTCP and the National AIDS Control Programme (NACP) is under way in the six high HIV-burden states.

While the Programme has been remarkably successful to date, the extraordinarily rapid expansion has outstripped management and financial capacity at central and state levels, creating a high likelihood of declining quality unless urgent action is taken.

There are several areas that require strengthening, particularly in view of the national decision to complete the implementation in the entire country by the end of 2005. The expansion will require substantially increased efforts to maintain the present quality of the programme. Failure to address the following concerns is likely to jeopardize the future of the programme:

- (i) The rapid expansion of the last three years has not been accompanied by an increase in staff at the central and state levels, outstripping the managerial capacity to continue to ensure expansion and high quality of implementation. Despite a more than 5-fold expansion in programme coverage since the previous review, the Central Tuberculosis Division (CTD) remains at the same staff strength. Unless central staffing is strengthened, there cannot be adequate supervision and monitoring. There are early indications of potential problems, which if not addressed are likely to compromise the quality of RNTCP. Examples observed during the review included inaccuracies in recording and reporting in some areas, delays in flow of funds from state to district and onwards, insufficient quality assurance of sputum microscopy in some sites, and use of non-RNTCP regimens in too many patients.
- (ii) Managerial capacity for planning, implementing, supervising, monitoring and financial management at the state level is insufficient and requires urgent attention. This is particularly a concern in the larger states.
- (iii) Although funds are available, their flow from the states to districts and onwards presents problems, resulting in delays in payment to contractual staff and reimbursement of regular staff for travel to conduct supervisory visits.
- (iv) Although no significant drug shortages have occurred for more than two years, the absence of a sufficient buffer stock in the country creates a risk of drug shortages in the future. This could occur if there are unforeseen delays in procurement, or if more than the expected number of cases are detected during expansion.
- (v) A significant number of patients diagnosed at government health facilities are not registered or offered RNTCP regimens. In addition, many patients are not recorded and monitored by the government health system, although important progress has been made in engaging other health sectors. A large proportion of medical practitioners are still unaware of the availability and advantages of the RNTCP for their patients.
- (vi) Many vacancies of key staff in regular and contractual positions are still unfilled.

1.2 Future

The programme is entering a new and challenging phase. Many of the most difficult areas of the country are yet to be covered. While this represents an enormous challenge, the greatest risk to the programme at this time is the possibility that RNTCP quality may decline in implementing areas. In addition to the currently rigorous initial appraisal process, continuous and intensified supervision and monitoring are required to ensure good quality of diagnosis and treatment. A careful planning process and intensive supervision at the district level with regular state oversight and periodic central in-field supervision is crucial to the success of the programme. Unless the weak areas in the programme are fixed now, they could result in a steady downward spiral in the quality and impact of RNTCP.

1.3 Key Recommendations

The Key recommendations are as under:

- (i) In order to maintain quality, given the huge current coverage and continuing expansion, managerial capacity and staffing at central and state levels should be increased:
 - (a) Staff at the CTD should be increased and units for specific activities, namely supervision and monitoring; human resource development; advocacy and information, education, and communication (IEC), and epidemiology/surveillance should be created.
 - (b) The level/status, staff and managerial capacity of the State TB Cells (STCs) should be increased. The State TB Demonstration and Training Centres (STDCs) and other intermediate units of the state should be strengthened to provide effective training, quality assurance and supervision; staffing, especially in large states also needs to be increased. The flow of funds to districts for essential activities should be monitored and the capacity of state in financial management should be strengthened.
 - (c) Although a large number of supervisory visits are undertaken, there is a need to plan and implement improved field supervision to detect and solve problems promptly in recording and reporting, flow of funds, laboratory quality and other key areas.

- (d) The human resource development component of RNTCP should be further strengthened by implementing and monitoring plans for training of new staff, and re-training in topics identified as problematic during the course of implementation.
- (ii) The coverage, case-detection and quality of diagnosis and treatment should be increased.
 - (a) The RNTCP should continue to expand. Strict attention to full adherence to the already established appraisal criteria should be ensured, including the full complement of District TB Centre staff who work only on TB.
 - (b) Current efforts should be intensified to ensure that RNTCP policies are officially adopted and implemented widely including district hospitals, Employees' State Insurance Schemes (ESIS), Central Government Health Services (CGHS), The Railways, medical colleges, nursing schools, and correctional facilities, and are promoted in NGOs and the private sector should be intensified.
 - (c) The laboratory quality assurance plan should be tested and implemented, and the capacity of STCs and STDCs to identify, analyse, interpret and solve problems be strengthened.
 - (d) Focus should be on increasing the case-detection activities rather than the case-detection targets or rates. Case-detection activities should not be relaxed when the minimum targets have been reached.
 - (e) All patients, whether receiving RNTCP or non-RNTCP regimens, should be registered in one TB Register, and efforts made to increase the proportion of patients receiving RNTCP regimens.
 - (f) The collaboration between the HIV/AIDS programme and the RNTCP should be expanded, with focus on high-burden states, and facilities offered for diagnosing TB and giving TB treatment to HIV-infected persons; referrals should be offered for voluntary HIV counselling and testing to appropriately selected TB patients.
 - (g) Efforts should be continued to make treatment observation more convenient to patients.

- (iii) The quality and regular availability of drugs should be ensured.
 - (a) A minimum buffer stock for 9–12 months should be established in the country, including a buffer stock in states; more than one drug store may be required in the larger states.
 - (b) The results of drug quality control should continue to be periodically analysed, and the methods and results involved therein should be publicized.
 - (c) The Global Drug Facility can and should support the Programme and act as a “back- up” procurement agent.

- (iv) A wider dissemination of information about and support for RNTCP at all levels should be ensured.
 - (a) Advocacy to increase political and administrative commitment from the central and state governments and donors should be intensified, as well as acceptance by the medical community promoted.
 - (b) Advocacy, programme communication, and social mobilization at the national and state levels should be strengthened in order to develop and maintain an effective relationship with mass media; states should be supported in undertaking advocacy and IEC activities.
 - (c) The existing national plan for IEC should be implemented.
 - (d) RNTCP conferences should be organized annually in coordination with the TB Association of India.
 - (e) A coordinating body of all key partners needed for effective and sustained implementation of the RNTCP should be established.

- (v) The long-term Programme sustainability should be promoted.
 - (a) Apart from immediate arrangements to strengthen the CTD, the process to create additional regular positions, in order to appropriately staff the CTD commensurate with its current extensive responsibilities, should be started.
 - (b) All aspects of TB control (diagnosis, treatment, monitoring) should be incorporated in pre-service and in-service training, and in-routine service delivery of the general health services.

- (c) The Government of India, donor agencies, the World Bank, the World Health Organization and other partners should ensure the long-term success of the Programme through sustained financial and technical support.

2. INTRODUCTION

India is the second-largest country in the world with a population of 1 068 million in 2003. Twenty-nine per cent of the country's population live below the national poverty line (Annex 1). Despite increasing urbanization, 72% of the population are rural. The country is administratively divided into 35 states/union territories, which are sub-divided into about 600 districts/reporting units. There is a striking diversity between the states in size, terrain, culture, socioeconomic development and health status.

The TB burden in India is enormous. About 40% of the adult population are infected with mycobacterium tuberculosis. Every year nearly 1.8 million persons develop the disease, of which nearly 800 000 are infectious. Most TB patients are in the economically productive age group. The society and the country continue to incur huge costs due to TB—nearly US\$ 3 billion in indirect costs and US\$ 300 million in direct costs.

India has had a National Tuberculosis Programme (NTP) in operation since 1962. A comprehensive joint review in 1992 found that despite the existence of the NTP, TB patients were not being accurately diagnosed and that most diagnosed patients did not complete treatment. Based on the recommendations of the review, the Revised National Tuberculosis Control Programme (RNTCP) incorporating the DOTS strategy was started on a pilot scale in 1993 by strengthening government commitment and resources for TB control (Annex 2).

The large-scale implementation of the RNTCP began in 1998 with a World Bank credit of Rs 604 crores (US\$ 142 million). The 5-year credit period starting May 1997 was later extended until September 2004. In addition, the RNTCP is supported by the Danish International Development Assistance (Danida); UK Department for International Development (DFID); Global Drug Facility (GDF); Global Fund for AIDS, Tuberculosis and Malaria (GFATM), and the United States Agency for International Development (USAID). DFID is providing US\$ 26 million to cover the entire State of Andhra

Pradesh. Danida is providing US\$ 14 million under phase I, and an additional US\$ 6.7 million (pending signature of final agreement) under phase II to continue the current implementation, and to cover the remaining 14 districts of Orissa. USAID is providing a grant assistance of US\$ 6.58 million over 5 years for covering the entire 21 million population of Haryana. The GFATM will be providing US\$ 8.6 million to cover a population of 56 million in the 3 states of Chhattisgarh, Jharkhand and Uttaranchal in the first round, and US\$ 29 million to cover a population of 110 million in Bihar and Uttar Pradesh in the second round. The GDF is providing anti-TB drugs for Orissa, and also for an additional 200 million population as a commodity grant valued at US\$ 2 million per year.

A joint programme review conducted in February 2000 found the RNTCP implementation to be a success, with a striking increase in the proportion of patients cured. The review recommended rapid expansion of quality RNTCP services to cover the entire country by 2005 in order to make a significant impact on the TB epidemic.

The current review, jointly organized by the Government of India (GOI) and the World Health Organization (WHO), was conducted from 15–26 September 2003 by a team of 20 national experts (from Indian Medical Association, National Institute of Health and Family Welfare, leading medical colleges, central TB institutes, non-governmental organizations (NGOs) and Programme staff from state and district level) and 22 international TB experts (from Canadian International Development Agency [CIDA], CDC, Danida, DFID, GDF, GFATM, International Union Against TB and Lung Disease [IUATLD], Royal Netherlands Tuberculosis Association [KNVCV], USAID, and WHO) (Annex 3).

The objectives of the current review were to:

- (i) Assess the technical policies and performance of the RNTCP in India;
- (ii) Examine the progress of RNTCP vis-à-vis the review carried out in 2000;
- (iii) Formulate recommendations for the RNTCP to meet the global and national targets for TB control by 2005, and
- (iv) Promote effective political commitment for expansion and sustainability of the RNTCP for the next 5–10 years.

States having at least four districts implementing the RNTCP for at least two quarters were included in the randomization process. Five states, viz. Maharashtra, Orissa, Rajasthan, Tamil Nadu, and Uttar Pradesh were randomly selected for the review. From each of the 5 states, 3 districts were randomly selected and one district was conveniently selected adding up to a total of 20 districts (Annex 4 and 5). These 20 selected districts covered a population of 36.4 million (5% of the total RNTCP population covered by quarter 2, 2003). Two Microscopy Centres (MCs) were randomly selected from each of the 20 districts.

The teams visited more than 50 health facilities in the 20 districts and interviewed administrators, health staff, TB patients and community members, reviewed records of more than 10 000 patients, collected and analysed information on organization of services, diagnosis and treatment, and reviewed Programme data.

This report summarizes the findings of the joint review and presents the main conclusions and recommendations. Additionally, state-specific findings and recommendations are given in Annex 6. It should be noted that the review did not assess the recently implemented districts and therefore cannot comment on the quality of implementation in these most recently (less than six months) implemented districts.

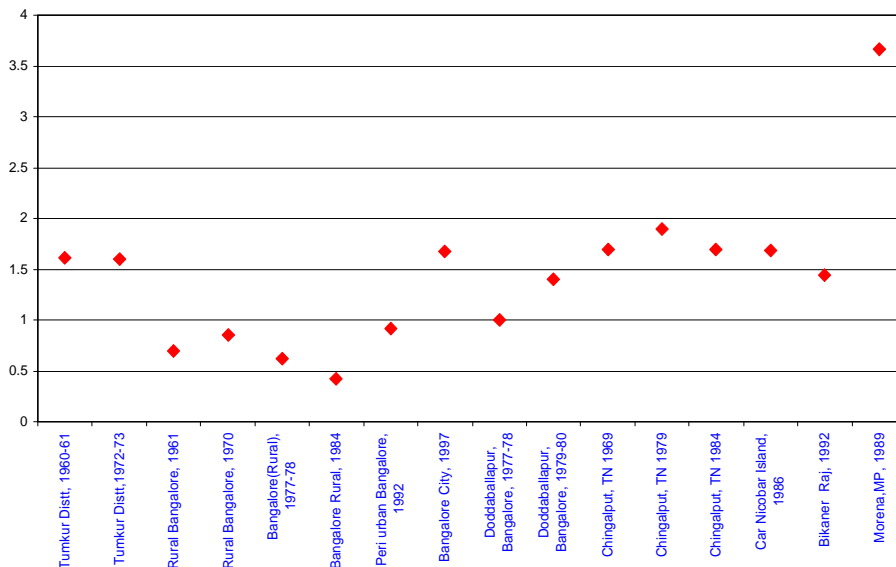
3. EPIDEMIOLOGY OF TUBERCULOSIS

India has more people with active tuberculosis (TB) than any other country in the world. Each year, there are approximately 1.8 million new cases of TB disease, of which nearly 800 000 are infectious (smear-positive) TB; and approximately 417 000 people die of TB.

3.1 Annual Risk of Tuberculosis Infection

The annual risk of tuberculosis infection (ARTI) estimates in India, available from studies conducted in small geographical areas over the last 30 years are shown below in Figure 1.

Figure 1: Annual risk of tuberculosis infection in various studies from India



Recently, the National Tuberculosis Institute (NTI), Bangalore in collaboration with the Tuberculosis Research Centre (TRC), Chennai completed a countrywide cross-sectional survey, which for the first time provides the current national and regional estimates of ARTI in India.

A consensus meeting to discuss the results was held on 22–23 April 2003 in Delhi and a working group process was initiated to review and finalize the results. Although the consensus review of the results is still on, the provisional estimated prevalence of infection in each zone and the computed ARTI rates are given in Table 1 below.

The zonal ARTI estimates were pooled to estimate the national ARTI level, which was computed to be 1.5%. The ARTI in urban areas (2.1) was higher than rural areas (1.2–1.3).

Table 1: Provisional prevalence and annual risk of tuberculosis infection in India (2001)

	Method I (cut-off)		Method II (mirror)	
Zonal differences				
Zone	Prevalence of infection (%)	ARTI (%)	Prevalence of infection (%)	ARTI (%)
North	10.3 (8.4–2.2)	1.9 (1.5–2.2)	10.5 (7.4–13.5)	1.9 (1.3–2.5)
South	6.1 (4.9–7.2)	1.1 (0.9–1.3)	6.4 (4.5–8.3)	1.2 (0.8–1.6)
West	9.3 (6.8–11.8)	1.8 (1.3–2.3)	8.5 (5.4–11.6)	1.6 (1.0–2.2)
East	6.9 (5.6–8.3)	1.3 (1.0–1.6)	6.85 (5.53–8.17)	1.3 (1.05–1.57)
Rural–urban differences				
Rural	6.7 (5.9–7.5)	1.2 (1.1–1.4)	7.0 (5.9–8.1)	1.3 (1.1–1.5)
Urban	11.6 (9.9 – 13.2)	2.1 (1.8–2.5)	11.4 (9.8–13.0)	2.1 (1.8–2.4)
Total	8.2 (7.4–8.9)	1.5 (1.3–1.6)	8.1 (7.2–9.0)	1.5 (1.3–1.7)

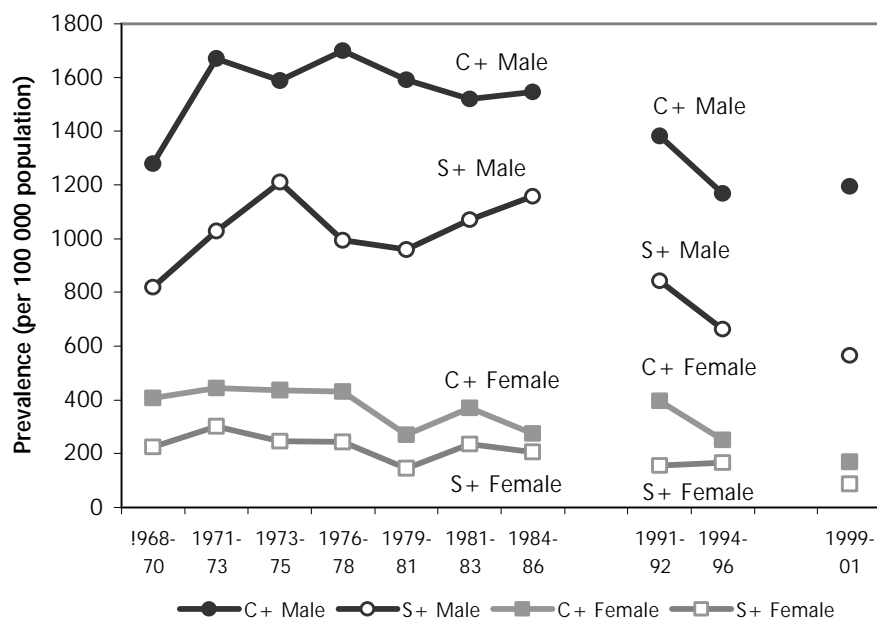
Values in parenthesis denote 95% confidence interval

The currently used national ARTI of 1.7% provides an estimated annual incidence of new smear-positive pulmonary TB cases of 85/100 000 population. However, the consensus meeting participants agreed that it would be appropriate to use the zonal estimates to derive the national estimate, which was calculated to be 1.5%. In order to address the (possible) wide variations in ARTI between states in the zones, state-specific ARTI studies are being planned in a few states (e.g. Kerala) under the Revised National Tuberculosis Control Programme (RNTCP) operational research (OR) funding. Finally, to monitor trends and impact of RNTCP on the TB burden, a repeat survey using a zonal sampling approach will be undertaken in approximately 5 years.

3.2 Prevalence of Tuberculosis

The only national survey to measure disease prevalence was conducted during 1955–1958. Numerous regional surveys have been conducted since then, but their methods differ. Studies of TB prevalence conducted in different parts of India have shown wide variations, but surveys conducted over time have shown little change in the disease burden over the past several decades. Longitudinal disease prevalence surveys (1968–2001) conducted in Tiruvallur district (formerly Chingelput) in Tamil Nadu indicate that the annual decline of culture-positive TB over the past three decades was 1.8% (1.6% in males vs. 3.2% in females) and that of smear-positive TB was 2.1% (1.8 in males vs. 3.6 in females) (Figure 2).

Figure 2: Trends in the prevalence of culture-positive (C+) and smear-positive (S+) tuberculosis by sex, South India (1968–2001)



According to the recent estimates of TB burden for year 2002, by the World Health Organization (WHO), the prevalence of all forms of TB and smear-positive TB in India is 344 and 155 per 100 000 population, respectively. In other words, there are currently an estimated 3 610 144 prevalent TB cases in India of which 1 622 992 are smear-positive.

3.3 Primary Drug Resistance

Primary rifampicin resistance and multidrug resistance (to both rifampicin and isoniazid) started to appear in the 1980s, and has been less than 3% in most studies. Recent information about primary drug resistance is available from the national population-based drug resistance surveys in different parts of the country undertaken by TRC, Chennai in collaboration with NTI, Bangalore using the WHO/ International Union Against TB and Lung Disease (IUATLD) guidelines. Table 2 below provides information about primary isoniazid resistance and primary multidrug resistance, based on data collected from six districts.

Table 2: Primary drug resistance, India (1999–2002)

State, district (zone)	Intake period	Number of patients	Primary isoniazid resistance %	Primary multidrug resistance %
Tamil Nadu, North Arcot (South)	1999	282	23.4	2.8
Karnataka, Raichur (South)	1999–2000	278	18.7	2.5
Maharashtra, Wardha (West)	2000–2001	197	15	0.5
Madhya Pradesh, Jabalpur (West)	2001–2002	273	17	1.0
West Bengal, Hoogly (East)	2000–2001	350	10.3	3.0
Orissa, Mayurbanj (East)	2000–2002	343	2.5	0.7

3.4 TB and HIV/AIDS

India is among the world's 22 highest TB-burden countries and is second only to South Africa in having the highest number of human immunodeficiency virus (HIV)-infected people in the world. The potential impact of the HIV epidemic on TB control in India, coupled with the high morbidity and mortality from TB among people living with HIV/AIDS (PLWHA) suggests that

collaboration between TB and HIV programmes is essential to ensure control of both diseases. Recognizing this, the Government of India (GOI) has already taken important steps to strengthen the co-ordination between TB and HIV control programmes, particularly in states with the highest burden of HIV in the general population (Maharashtra, Tamil Nadu, Andhra Pradesh, Karnataka, Nagaland, and Manipur).

The RNTCP is expanding rapidly across India and it should reduce TB mortality, and its prevalence and transmission by over 5% per year. The TB incidence will depend on the expansion of the HIV epidemic, the number of co-infected persons and their health care management. Therefore it is important for TB control to know the prevalence of HIV infection, co-infection and their trends in time.

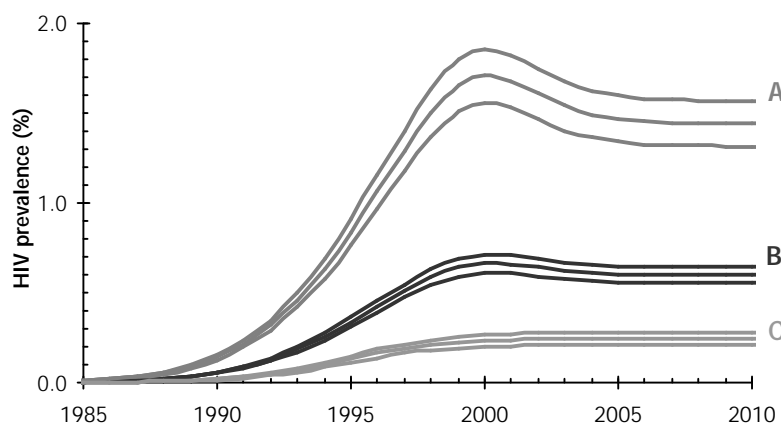
The National AIDS Control Organization (NACO) has compiled data on the prevalence of HIV/AIDS from many sources, including women attending public ante-natal clinics (ANC), adults attending sexually transmitted infection (STI) clinics, blood donors, men who have sex with men, and intravenous drug users (Table 3).

Table 3: *NACO estimates of prevalence of HIV infection in India*

Year	Prevalence %
1990	0.05
1994	0.35
1998	0.68
1999	0.72
2000	0.76
2001	0.78

In 2002, an estimated 3.82-4.58 million people were found to be infected with HIV in India (Ref. NACO website <http://www.naco.nic.in/indianscene/esthiv.htm>). Recent analyses indicate that the prevalence of HIV has levelled off in India, and further substantial increases are unlikely to occur (unpublished data) (Figure 3).

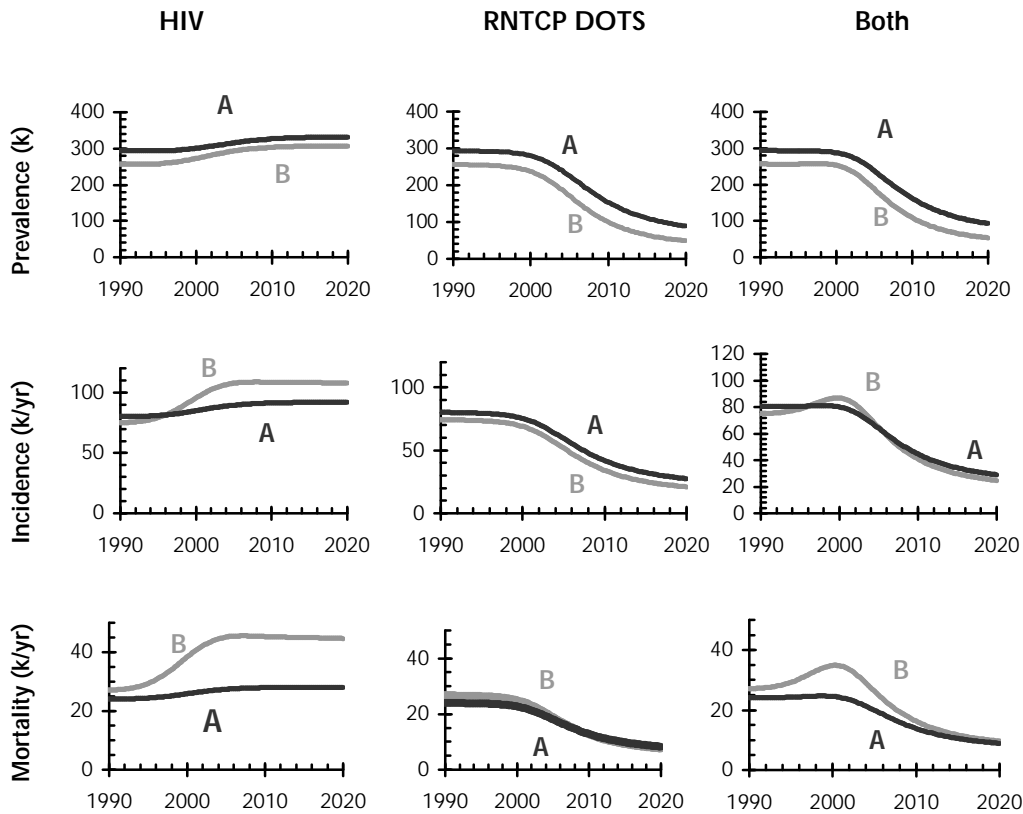
Figure 3: Estimated/projected prevalence of HIV infection among women attending antenatal clinics. A: South India (Maharashtra, Mumbai, Andhra Pradesh, Tamil Nadu and Karnataka); B: all India; C: North India (and Kerala). Weighted best fits with 95% confidence intervals.



Even though the magnitude of prevalence of HIV in India is less than it is in East and Southern Africa, it is likely that without the improvements in TB control associated with the RNTCP programme, HIV would have given rise to an additional 5 million TB cases and 2.5 million AIDS deaths between 1990–2010.

Preliminary analyses from a recent WHO-RNTCP-NACO modelling exercise indicate that RNTCP will be able to contain the impact of AIDS and maintain the overall incidence of death rates due to TB at the current level even in all the HIV-high burden states (viz. Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland, and Tamil Nadu) over the next 10 years. As a direct result of the RNTCP it is likely that the number of TB cases will in fact fall by about 2 million while the number of deaths will fall by about 100 000 during this period, even with the AIDS epidemic. Without HIV/AIDS, the RNTCP would have reduced these numbers by about 4.5 million and 1.4 million. When both the effect of the HIV epidemic and the impact of RNTCP is considered, RNTCP would compensate for the impact of HIV in the long term and decrease the incidence to 65% (Figure 4).

Figure 4: Model of the impact of HIV on TB in India. The impact of HIV (first column), the RNTCP DOTS (second column) and both (third column) on the prevalence of TB (first row) the incidence of TB (second row) and TB deaths (third row); A=S-ve, B=S+ve.



Further analyses are needed to examine the effect of HIV/AIDS in higher prevalence areas such as Mumbai. In Mumbai, some of the increase in TB rates over the last two years is likely to be attributable to the HIV epidemic. However, the projections suggest that under the RNTCP it will be possible to contain the impact of AIDS on TB in Mumbai probably over the next ten years but unless additional steps are taken to deal with the HIV cases, the gains derived from a good DOTS programme will be balanced by the losses due to AIDS.

4. PROGRAMME MANAGEMENT

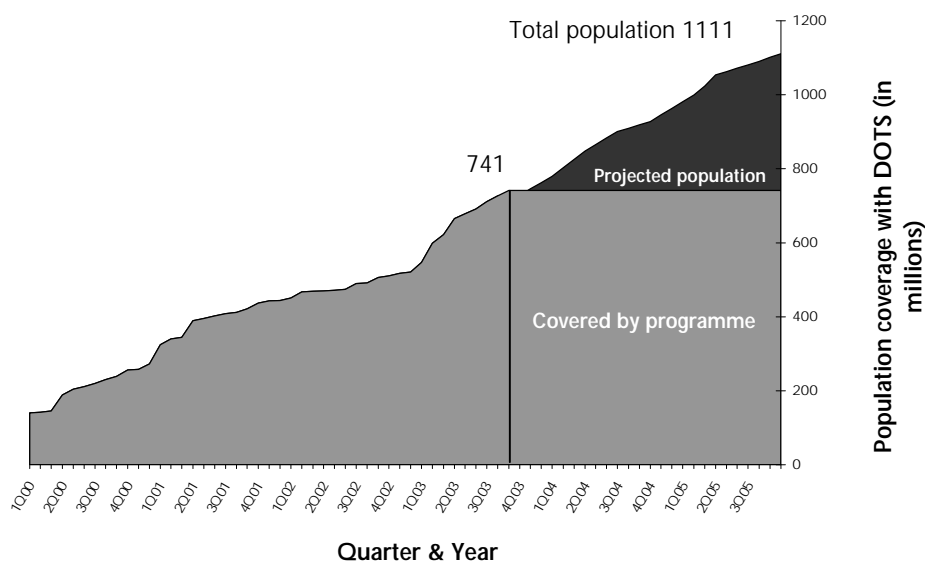
4.1 Expansion

There has been extraordinary expansion of the RNTCP in the past 3 years, the fastest such expansion in the history of DOTS. The Programme has expanded from 135 million in 2000 to 741 million at the time of the review. The RNTCP now covers 70% of the population in 400 districts of the country (Annex 7).

Prior to RNTCP implementation, the Central Tuberculosis Division (CTD) rigorously monitors preparatory activities and fulfilment of the appraisal criteria in each district. Although the appraisal process has been an important means of ensuring quality, actions recommended by the appraisal team are not always tracked systematically before the start of service delivery, thereby diluting the purpose of stringent appraisal processes.

The Government of India (GOI) has already decided to expand RNTCP to the entire country by the end of 2005 (Figure 5). Substantially increased efforts will be required to maintain the present quality. Many of the most difficult areas of the country are yet to be covered; these include large populations in the states of Bihar and Uttar Pradesh. Implementation in these areas will be an enormous challenge and will require special attention.

Figure 5: Multi-year DOTS expansion plan for India, 31 August 2003



4.2 Staffing and Managerial Capacity

The rapid expansion during the past 3 years has not been accompanied by a proportional increase in staff at the central and state levels, outstripping the managerial capacity required for ensuring high quality of expansion and implementation. Despite a more than 5-fold expansion in programme coverage since the previous review, the CTD remains at the same staff strength. With a staff strength of 4 regular professional staff positions (of which two were vacant at the time of the review), CTD heavily relies on contractual staff funded by WHO to manage the programme at the centre. Without an increase in central staffing, field supervision and monitoring from the central level cannot be adequate. Lack of optimal in-field central supervision is reflected in early signs of deterioration in RNTCP quality. Examples of declining quality observed during the review included inaccuracies in recording and reporting in some areas, delays in flow of funds from state to district and onwards, insufficient quality assurance in some areas, and use of non-RNTCP regimens in too many patients.

As planned, finance and programme activities have been decentralized to the state level. However, the infrastructure and managerial capacity for planning, implementing, supervising, monitoring and financial management at the state level are not adequate. Insufficient staffing is of particular concern in larger states. For example, although Uttar Pradesh is the largest state (>170 million population) of the country and the State Tuberculosis Officer (STO) has a deputy STO and a Medical Officer (MO), they are not formally trained and do not travel for supervision; considering that there are a total of 71 districts (of which 28 are currently implementing RNTCP) and with the above staffing limitations, it is impossible to make supervisory visits at optimal frequency in implementing districts to ensure adequate preparation of new districts for expansion. Maharashtra with around 120 million population faces similar limited staffing at the State TB Cell (STC) and the STO's travel is restricted to trains. One of the key recommendations of the previous review was to appoint at least one full-time MO with facilities for transport, travel allowances and petrol for each 3–4 new or 6–8 continuing districts covered (Annex 8). This recommendation has resulted in Deputy STOs being appointed in at least two states.

The State Tuberculosis Training and Demonstration Centres (STDCs) are mostly non-functional and contribute little to the supervision, monitoring and quality assurance activities of the state due to the absence of facilities,

infrastructure and staff. In addition, they usually carry out clinical work, a practice which the 2000 review recommended should be eliminated.

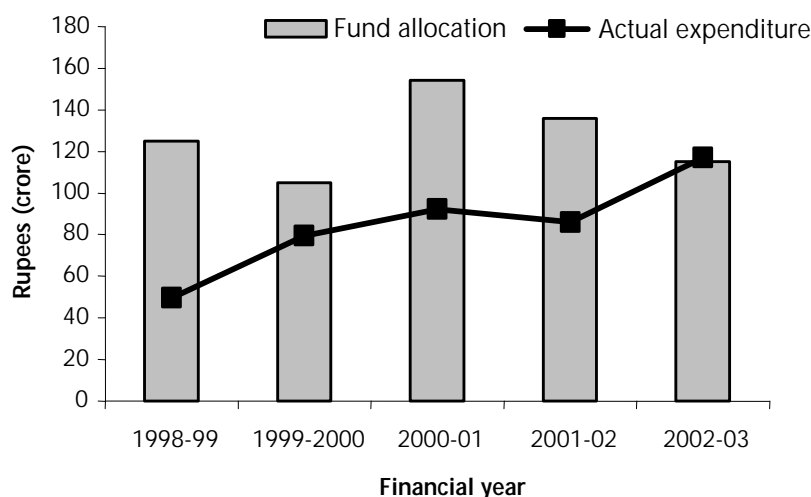
At the district level, most of the older districts have a well-established structure as per RNTCP guidelines, but not usually so in many of the newly carved out districts. It is of concern that many newly carved out districts still do not have full-time dedicated District Tuberculosis Officers (DTOs). Further, the capacity for planning, budgeting, and accounting is very weak at the district level. Written district plans are usually unavailable and budgeting is not linked to programme activities.

A large number of key regular and contractual posts are vacant at the Tuberculosis Units (TUs) and in Microscopy Centres (MCs), and the problem is worsening in some states. This undermines the quantum and quality of service delivery at the periphery.

4.3 Financial Management

The total annual budget for TB control at the central level was Rs 115 crores (US\$ 23 million) in 2002–2003. The disbursement of finances at the central level is recently showing an improved upward trend (Figure 6). The current World Bank credit ends in September 2004. The possibilities of extending the current project and preparation of a new project with retroactive financing are being discussed.

Figure 6: Fund allocation vs. actual expenditure, tuberculosis control, India (1998–2003)



As part of the decentralization efforts, CTD now disburses funds to State Tuberculosis Control Societies (STCSs) for onward disbursement to the district. Lack of financial management capacity at state and district levels has led to major problems with flow of funds and their effective utilization. This has resulted in delays in payment to contractual staff and delay in reimbursement of travel money to staff for conducting supervisory visits. Moreover, there is limited flexibility in the optimal utilization of funds, because of limited flexibility for reallocating funds from one budget head to another.

Considering the rapid expansion and given the insufficient managerial capacity at the national, state and district levels, the greatest risk to the programme at this time is the possibility that RNTCP quality may decline in implementing areas. In addition to the currently rigorous initial appraisal process, continuous and intensified supervision and monitoring are required to ensure good quality service delivery in implementing areas. A careful planning process and intensive supervision at the district level with regular state oversight and periodic central in-field supervision is crucial to the success of the programme. Unless the weak areas in the programme are fixed now, they could result in a steady downward spiral in the quality and impact of RNTCP.

4.4 Recommendations

The following are the recommendations:

- (i) Plans should be finalized vis-a-vis the long-term funding of the programme (e.g. World Bank [WB] extension, new WB project, bilateral and Global Fund for AIDS, TB and Malaria [GFATM] support, etc.)
- (ii) Immediate arrangements should be made to strengthen the CTD, and the process begun to create additional regular positions in order to appropriately staff the CTD commensurate with its current extensive responsibilities. The increase in CTD staffing should be done with an emphasis on creating specific units for supervision and monitoring, human resource development, advocacy and IEC, and epidemiology/surveillance.
- (iii) The status/level (e.g. to be at least on par with other programmes) of staff should be increased and the managerial capacity of the State TB

Cells (STCs) enhanced. Staffing, particularly in larger states, should also be increased.

- (iv) Smooth flow of funds should be ensured by sending accounting staff of the CTD to visit STCs, in addition to training of accountants at STCs and programmatic supervision. Indicators should be developed and flow of funds from state to districts for essential activities such as staff salaries, and reimbursement of travel allowance/dearness allowance (TA/DA) should be monitored. Within eligible limits, funds should be allowed to be transferred between heads at the district level.
- (v) Provision for Full-time DTOs, Senior Treatment Supervisors (STs), and Senior TB Laboratory Supervisors (STLSs) exclusively for TB work, should be ensured.
- (vi) Vacant staff positions (regular and contractual) should be filled at the peripheral level by regular monitoring of key vacant positions and advocacy with state/district authorities responsible for recruitment/redeployment of staff.
- (vii) Expansion of the RNTCP should be continued. Strict attention to full adherence to the already established appraisal criteria should be ensured, including the full complement of District TB Centre (DTC) staff who work only on TB. For expanding RNTCP in difficult areas, alternative models (e.g., external operational support as done successfully in Orissa by Danida, or direct funding from the centre to districts, etc.) should be considered.
- (viii) Post-appraisal spot checks of implementing districts will help maintain accountability in the current appraisal process (e.g. pre-appraisal, appraisal, STO verification, implementation, spot check to ensure deficits identified during appraisal have been addressed). As the appraisal process draws to a close with most districts already having been appraised, the appraisal process should be evolved into regular and intensive supervisory visits from central/central institute levels to states and districts to ensure good quality service delivery.

- (ix) The current state-based internal evaluation processes should be continued with participation of WHO-RNTCP consultants and central level staff.
- (x) STDCs and other intermediate units in each state should be strengthened to support STCs in training, supervision and laboratory quality assurance capacity. The implementation of state strengthening should be monitored, including the training and re-training of the STO and the state TB staff.
- (xi) States should be encouraged to re-direct funds/resources to implement RNTCP (e.g. downsize hospital-based TB services and procurement of loose drugs for non-RNTCP patients).

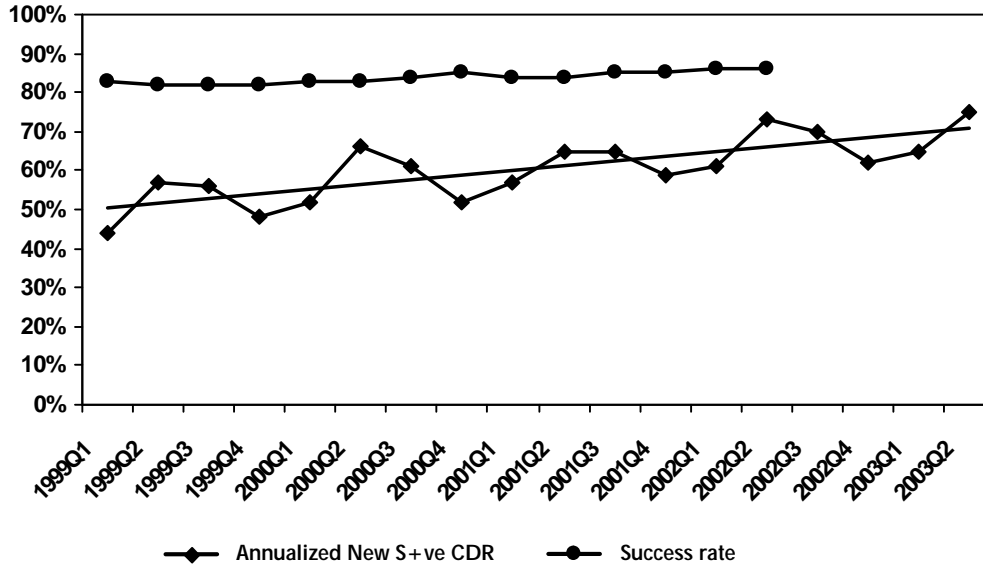
5. CASE-DETECTION AND DIAGNOSIS, AND LABORATORY NETWORK

The numbers of patients treated under the RNTCP have increased steadily over time. To date, more than 2 million patients have been placed on treatment. Since the past review, the RNTCP population coverage has increased 5-fold and the total and new smear-positive tuberculosis (TB) cases have increased 7-fold (Annex 9). This indicates that in addition to the geographic extension of RNTCP, the intensity of case-detection has increased within the RNTCP areas.

In the recent quarter (Quarter 2, 2003), 66% of the expected new smear-positive cases were detected considering an annual incidence of 85 per 100 000 population. The trend in the association between DOTS population coverage and the proportion of estimated new sputum smear-positive case-detection suggests that the global case-detection target of 70% is likely to be met or exceeded when 100% of the country's population is covered (Figures 7 and 8).

State-specific analyses show an improvement in case-detection rates while maintaining cure rates in almost all states (Annex 10). It is likely that nearly all states will achieve the 70% case-detection targets when 100% of their population is covered (Annex 11).

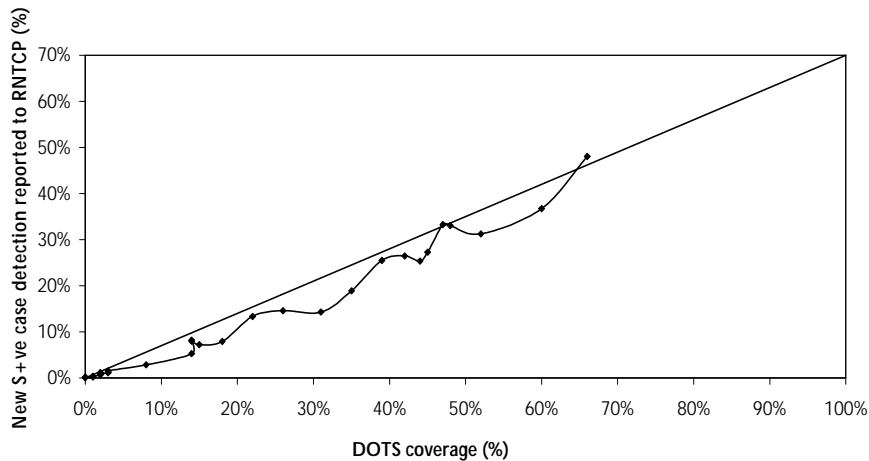
Figure 7: Annualized new smear-positive case-detection rate and treatment success rate, 1999–2003, India*



Population projected from 2001 census

* Estimated no. of NSP cases – 75/100 000 population (Provisional estimate based on unpublished Zonal ARTI report)

Figure 8: Percentage of estimated new smear-positive cases reported to RNTCP vs. DOTS coverage, 1993–2003, India*



Population projected from 2001 census

* Estimated no. of NSP cases – 75/100 000 population (Provisional estimates based on unpublished Zonal ARTI report)

The review team observed that the indicator “detection of TB suspects” often uses as denominator the “attendance to the health facilities with microscopy only”, while the numerator includes “suspects referred by other facilities”. The indicator is therefore valid only for the health facility, and not for use by the district level or above, which should use a different denominator. The review team also found that the laboratory infrastructure was in place and good quality functional binocular microscopes were generally available (some microscopy centres [MCs] had poorly functioning binocular microscopes and service contracts were often not in place). Under the RNTCP, one designated microscopy centre (DMC) on average per 100 000 population is planned. However, the review observed that: (1) many districts start with lesser number of MCs than required as per population norms (e.g. Uttar Pradesh); (2) some districts start with the correct number of MCs but some of them close down later (e.g. Uttar Pradesh, and many other states), (3) in some southern states (e.g. Tamil Nadu) additional MCs have been set up for almost 30 000 to 50 000 population, some of which are functioning with sub-optimal supervision and quality assurance. Additionally, some of the existing MCs are heavily attended, increasing workload on the staff and therefore compromising the quality. In some areas, sputum microscopy is being done at non-designated centres by untrained staff without quality assurance (QA).

Laboratories have been upgraded as per RNTCP criteria and generally well maintained. There is no significant delay in treatment initiation with more than two-thirds of patients being started on treatment within one week of the date of the first sputum examination. Categorization of cases is usually appropriate.

A major area of concern is that a significant number of patients continue to be diagnosed and treated outside the RNTCP and are not notified, even in government facilities. While some progress has been made in involving nongovernmental organizations (NGOs) and the private sector, involvement of large public hospitals, including tuberculosis (TB) hospitals and hospitals under other ministries/departments remains poor. In many of the large public hospitals visited, the medical staff and clinicians had low awareness about RNTCP and were not referring TB suspects for sputum microscopy although an RNTCP District Microscopy Centre (DMC) existed within the same premises. Sputum positivity in 50% of the MCs reviewed was roughly 15–25% suggesting that a process of selective referral of patients may be occurring.

The quality of diagnosis is good in the majority of districts reviewed. In the second quarter of 2003, less than 9% of districts had a higher-than-

optimal (>1.2) ratio of sputum smear-negative to sputum smear-positive cases. The average ratio of sputum smear-negative to sputum smear-positive cases in the country is 0.8, and has been maintained over the past several years. However, it is of concern that some smear-negative cases may be excluded from notification under the RNTCP in order to maintain the expected ratio of smear-positive to smear-negative cases. A related concern is that the RNTCP diagnostic algorithm is often not adhered to in the diagnosis of smear-negative TB (Annex 12). The X-ray results in most instances are not documented and a course of antibiotics before an X-ray examination is often not administered.

A comprehensive sputum smear microscopy QA protocol has been prepared and is currently under review. It is expected that the protocol will be implemented after pilot testing. Before implementation, a large number of laboratory technicians and their supervisors will require training in the new QA protocol.

Analysis of data obtained from the review showed that more than 95% of patients had three sputum smears examined for diagnosis and two smears during follow-up. While the Laboratory Registers were well maintained, inconsistencies and data inaccuracies were noted in some areas. The results of each of the three sputum samples for a patient were often "repetitive", raising the suspicion that in some cases three smears were prepared from only one sputum sample or that only one of the three slides was read. Another problem observed during the review in a few cases was the fabrication of results of the end-of-treatment sputum examination.

Some of the problems identified by the review team had not been detected during routine supervision. The capacity of the supervisory staff to identify, analyse, interpret and solve problems needs to be strengthened and the training improved.

There are still vacancies and shortage of Laboratory Technicians (LTs) in many areas, and the situation is worsening in some areas. Due to lack of adequate manpower, the duties of LTs are often carried out by non-dedicated staff. In many areas, the Senior Tuberculosis Laboratory Supervisor (STLS) is not in place, or not functioning effectively due to multiplicity of responsibilities, such as performing the additional duties of the LT.

While good-quality binocular microscopes were generally available, there is no system in place to maintain the microscopes. A concern in many areas is that binocular microscopes cannot be used because of lack of electricity.

The quality of reagents was found to be generally good. In some areas, instead of the recommended freshly-prepared laboratory reagents, pre-prepared stains are being used, the concentration and specifications of which are doubtful.

The state laboratories/State TB Training and Demonstration Centres are not adequately equipped or staffed for performing culture and drug susceptibility testing.

5.1 Recommendations

The following are the recommendations:

(a) Case-Detection and Diagnosis

- (i) Focus should be on increasing case-detection activities rather than meeting the case-detection targets/rates. There should be no relaxation when the minimum case-detection targets/rates are reached. Because of likelihood of large variations in any one geographic area, reliance on case-detection rates/targets at the district and sub-district level is inappropriate.
- (ii) The capacity of State TB Cells (STCs), District TB Officers (DTOs) and other supervisors should be strengthened in detecting and solving problems by hands-on training in the field. Written records of supervision should be left at the health facility. Falsification of patient records damages programme credibility and should be taken seriously (e.g. responsible staff should be disciplined). Accurate reporting, regardless of whether targets are met, should be promoted.
- (iii) All TB patients should be recorded in the RNTCP Register. Maintenance of alternate registers should be stopped. If possible, all patients should be registered and treated under RNTCP DOTS regimens. However, districts should be instructed to record all patients diagnosed regardless of targets stating that less than 10% should be placed on non-DOTS regimens.
- (iv) Current efforts should be intensified to ensure that RNTCP policies are officially adopted and implemented widely including in district hospitals, Employee's State Insurance Schemes (ESIS), Central Governmental Health Services (CGHS), Railways, medical colleges, nursing schools, correctional facilities, and are promoted in NGOs and the private sector. One method for this is the creation of a national

coordinating group including representatives of the organizations, so that they develop institutional ownership of the strategy (refer to Intersectoral Coordination on Page 41).

- (v) Referrals from TB hospitals should be increased and in coordination with State governments TB hospital bed strength should be reduced, and these institutions, whenever possible, should be integrated into the general hospital system. Annual tracking should be established by the Central TB Division of TB hospital bed strength and diagnostic and treatment activities.
- (vi) Diagnostic facilities where the sputum positivity is high (>20%) should be closely monitored to ensure appropriate screening and referral of chest symptomatics.
- (vii) DTOs and Medical Officer-Tuberculosis Control (MO-TCs) should conduct periodic reviews of pulmonary smear-negative cases during supervisory visits to ensure if a trial of antibiotics has been given according to guidelines and that X-ray readings are appropriate.

(b) Laboratory Network

- (i) In order to ensure adequate access to microscopy services, the number of established MCs should at least reflect the projected 2003 population. MCs and LTs should be planned according to the workload. If required, additional LTs may be provided at busy MCs.
- (ii) Sputum microscopy should be discouraged at sub-optimally supervised non-designated microscopy centres having low workload. A pilot testing and/or evaluation of a transport system for smear slides prepared by trained staff should be considered.
- (iii) Vacant LT and STLS positions should be filled up urgently.
- (iv) The testing of the revised quality assurance protocol for sputum microscopy should be piloted and implemented without delay. LTs and STLSs should be re-trained prior to implementation of the protocol.
- (v) It should be ensured that microscopy maintenance contracts are in place at the state level. A system for proper maintenance of binocular microscopes should be established which may include an annual maintenance contract and training of STLS in preventive maintenance and minor repair of microscopes; documentation of the status of microscopes and transmitting the same to STC at the earliest.

- (vi) Alternative energy/lighting sources should be pilot-tested to provide quality microscopy services where electricity supply is erratic.
- (vii) Facilities at the state/STDC laboratory should be strengthened, including establishing quality-assured culture and drug susceptibility testing in laboratories.

6. TREATMENT, TREATMENT OBSERVATION AND MONITORING

The RNTCP has achieved high treatment success rates and low death rates, which have been maintained over time (Figures 9, 10, and Annex 13). Virtually all patients receive free drugs and the vast majority are satisfied with the service provided. Treatment is being initiated promptly in the majority of patients and is generally directly observed. The network of directly observed treatment (DOT) providers has expanded to include nongovernmental and community providers in addition to Peripheral Health Centre (PHC) staff. In some states, e.g. Orissa, the involvement of nongovernmental providers, including cured patients, is exemplary.

Figure 9: Per cent of RNTCP-registered new and relapse tuberculosis patients with a successful outcome (cured and treatment completed), India (1993-2003)

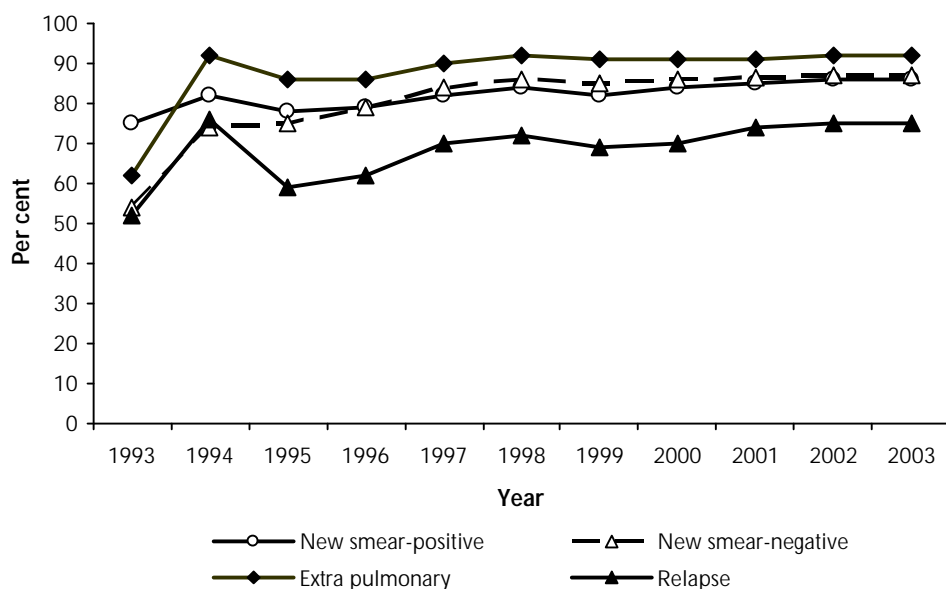
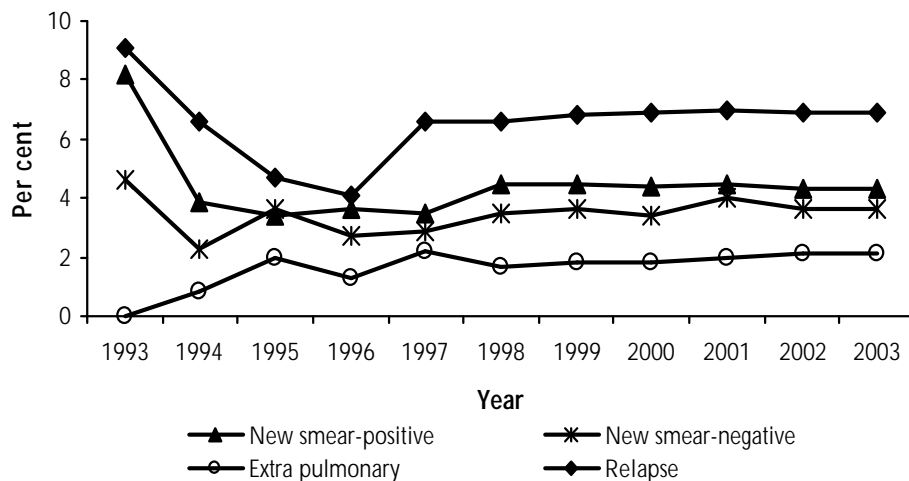


Figure 10: Per cent of RNTCP-registered newly-detected tuberculosis patients with an outcome of death, India (1993–2003)



While the treatment and monitoring of patients registered under the RNTCP regimens is extremely efficient, a significant number of patients diagnosed at the governmental health facilities are not registered or offered RNTCP treatment regimens. In other words, there appears to be a pre-selection of patients for RNTCP—those likely to complete treatment are given RNTCP regimens and others are given loose drugs without DOT. Such patients are either recorded in a separate “non-RNTCP” register or are not recorded anywhere, and are therefore not monitored or accounted for. Inter-district patient transfers are unusually low everywhere. This further provides grounds for suspecting that patients are being pre-selected for registration and treatment.

The DOT provider networks are expanding, and are being decentralized to make DOT more convenient to patients. However, mechanisms for supervision and support of community DOT providers have not been evolved. Auxiliary Nurse Midwives (ANMs), Multi-purpose Workers (MPWs) and other government outreach workers are not participating fully in supervision of DOT providers. Supervision of DOT providers thus relies heavily on the Senior Treatment Supervisors (STs) who are contractual staff and have many other key responsibilities.

Facilities for DOT provision are still inadequate at most centres. Safe water and clean cups are not always available at the DOTS centres. One of the major concerns with respect to DOT is that Treatment Cards do not

always reflect actual DOT practices—self-administered doses are also marked as DOT doses.

Defaulter retrieval, before and after a patient started treatment, was found to be sub-optimal in many areas. Default rates are particularly high in urban centres. The practice of address verification before the start of treatment is not being followed in some areas. Defaulter tracing at PHCs is absent, delayed or ineffective. Interactions among DOT providers, medical officers and STSs are not routine, thereby precluding the flow of information about defaulting patients and delays in updating of Treatment Cards.

Some of the RNTCP policies are not well understood or followed in the field. First, children diagnosed in RNTCP are given loose RNTCP drugs without supervision, i.e. rifampicin containing regimens being given without DOT, and are not registered in the Tuberculosis (TB) Register. Second, guidelines for incentives to community DOT providers are interpreted differently within districts/sub-districts. Finally, the programme policy on DOT vis-a-vis “home-based DOT” is not well understood in some areas.

6.1 Recommendations

The following are the recommendations:

- (i) It should be ensured that all diagnosed patients are registered for treatment, both those receiving RNTCP and those receiving non-RNTCP regimens, in ONE TB register. Efforts should be intensified to increase the proportion of patients receiving RNTCP regimens while discouraging pre-screening and encouraging honest reporting of diagnosed patients.
- (ii) Work should be continued to keep the programme patient-focused. Treatment observation should be made more convenient to patients, while the quality of DOT should be monitored by ensuring adequate supervision of DOT providers. Specifically, it should be ensured that the Treatment Cards are kept up to date and are accurately filled (e.g. self-administered doses are marked accordingly). DOT for in-patients should be implemented.
- (iii) Delays should be avoided in starting patients on treatment while ensuring that address verification is done as laid out in the RNTCP guidelines. It is also important to register patients in hospitals so that

they are also given DOT/RNTCP standard of care. Mechanisms for default retrieval and monitoring should be improved.

- (iv) Patient “referrals for treatment” should be improved within districts by developing and testing standard “referral for treatment” forms and procedures; and tracking of inter-district patient transfers should be improved using appropriate channels.
- (v) In urban areas, new models (e.g. intensive patient support, use of TB-Health visitors (TB-HV) should be piloted to improve patient tracking and reduce default.
- (vi) ANMs/MPWs should be involved in supervision of DOT providers. Models for supervision of community DOT providers should be developed and tested.
- (vii) RNTCP policies should be reemphasized in relation to “home-based DOT” and provision of incentives to nongovernmental DOT providers.
- (viii) Consensus-building should be pursued regarding diagnosis and treatment practices for children, including provision of special patient-wise boxes (PWBs) for children.

7. RECORDING, REPORTING AND SUPERVISION

Overall the recording and reporting under the RNTCP are excellent. More than 90% of quarterly reports are submitted from the district to the central level electronically, facilitating accurate and timely quarterly cohort analysis and wide dissemination of information. While the data are analysed and disseminated at the central level, an increasing number of states in parallel have begun district and sub-district specific analysis. The availability of World Health Organization (WHO’s) locally-hired consultants has greatly facilitated the timely receipt of reports and increased capacity to analyse data locally.

The data published at the central level generally reflects the programme activities. However, lack of effective in-field supervision has resulted in inaccuracies in data recording and reporting to the extent of 3–4% in some areas. The common examples of inaccurate recording and reporting observed by the review team included: recording of all suspects as providing three smears, non-recording of patients in the Laboratory Register until all sputum tests are done, fabrication of last sputum examination results, preparation of

three slides from a single sputum sample, a common pattern of sputum results, tick mark on the Treatment Card when directly observed treatment (DOT) was not actually given and treatment outcome of "Cured" when dead, absence of end-of-treatment sputum result among cured patients, and maintenance of a non-RNTCP register with patients who are unlikely to adhere to DOT. Although these are isolated examples, the inaccuracies are serious and can be considered as "early signs" of declining quality of DOTS implementation, which if not corrected urgently can significantly reduce the impact of the programme in the coming months.

In order to identify the programme's strengths and weaknesses and assess the accuracy of recording and reporting, a countrywide internal evaluation in 35 randomly-selected districts was undertaken in 2002 with participation of programme staff from different districts. The internal evaluation teams reviewed records, interviewed staff and randomly selected patients. The evaluation team found that supervision was sub-optimal at all levels, documentation of follow-up sputum results was absent for 10% of patients, and there was over-reporting in cure rates of up to 3%. In addition to providing valuable information about the accuracy of records and reports, the internal evaluation created a strong sense of involvement among the programme staff, facilitated exchange of constructive programme practices across regions, and built capacity among staff for in-depth programme review.

The capacity to supervise is weak at all levels. This weak supervision is due to:

(1) lack of staff; (2) insufficient capacity of supervisory staff to carry out effective supervision for identifying, analysing, interpreting and solving problems, and (3) restrictions on utilization of funds for travel allowance/dearness allowance (TA/DA) (e.g. State TB Officers [STOs] in large states are not allowed to travel by air).

In order to strengthen supervision, the previous review had made several recommendations, including, increasing the staff strength at the central level; strengthening State TB Cells (STC) by appointing one Medical Officer (MO) per 3–4 new or 6–8 continuing districts; ensuring a full-time District TB Officer (DTO) for a population of more than 1 million; and hands-on supervisory retraining of DTOs and STOs. Many of these recommendations, however, have not been implemented, indicating insufficient political and administrative commitment.

Although STOs and DTOs prepare a monthly plan for supervisory visits, documentation of the field visit findings and follow-up action are generally non-existent. The feedback of supervisory visits was found to be poor with a few exceptions. Even when supervision is undertaken, it does not necessarily result in identification and problem-solving. Additionally, it is unlikely that STOs and DTOs extend supervision to the patient level and verify records with actual patient interviews. The review team found many problems that were not identified by local staff.

Besides a lower capacity to supervise, an important reason for weak supervision in some areas is lack of funds and delays in reimbursement of supervision expenses. In other places, there are structural limitations on supervision (e.g. in Orissa, TA/DA for overnight stay for STOs is insufficient at only Rs 65, in Maharashtra the STO is only allowed to travel long distances by train, etc.). Supervision at sub-district level is particularly weak, as the MO-Tuberculosis Control (MO-TCs) in most of the states are not touring and supervising as per RNTCP guidelines.

Some teams noted an acute shortage of printed forms and registers at the district and peripheral levels. The use of an additional register maintained at the Peripheral Health Centre (PHC) level in some districts has caused confusion in addition to increasing the likelihood of falsification of data.

Routine reporting of gender-specific treatment outcome consumes significant time and is not used locally or centrally. The lack of data entry operators (DEO) in many of the districts also adds to the problem.

Referral of patients from non-designated MCs is not streamlined and these patients are not recorded anywhere. This results in potential loss of patients.

7.1 Recommendations

The following are the recommendations:

(a) Supervision

- (i) Effective in-field supervision should be intensified from district, state and central levels. Documentation of supervisory activities and on-site problem-solving at each level should be improved. Potential inaccuracies should be anticipated in data and recording and reporting validated by cross-checking records and interviewing randomly-selected patients.

- (ii) Supervision should be used to provide positive feedback and encouragement to line staff. Accuracy in recording data as opposed to meeting targets should be emphasized. Supervision should provide an opportunity for programme updates and technical clarifications. Training of supervisors should be modified to focus on improving their effectiveness in the field.
- (iii) Focus should be on quality of supervision, not just frequency of visits. The ongoing professional development of supervisors, including those of central, state, district, and WHO staff should be supported.
- (iv) "Poorly performing" districts should be intensified and targeted for additional supervision and support. Poorly performing districts should be spotted early and correct practices established immediately.
- (v) State internal evaluations should be continued. Country-wide internal evaluations of randomly selected districts should be repeated every 2–3 years.
- (vi) Information from WHO-RNTCP consultants in the field should be integrated to rapidly resolve problems.

(b) Recording and Reporting

- (i) Accurate recording should be ensured particularly on Treatment Cards and of follow-up sputum examinations.
- (ii) It should be considered to add to the quarterly statement of expenditure, a single Yes/No question along the lines: Because of lack of available funds at the District TB Control Society (DTCS), were any contractual staff or STS/STLS not paid salary/TA/DA/fuel reimbursement within 30 days in the most recent quarter?
- (iii) If good quality registers cannot be provided by the states, then consider printing the Tuberculosis Registers and quarterly forms should be printed centrally.
- (iv) The use of the Peripheral Health Institution (PHI)-level Register should be discontinued.
- (v) Reporting should be simplified from districts: gender-specific reporting of treatment outcomes on routine basis should be discontinued. Special studies/research projects can be undertaken if there is need for non-routine information. The programme management report should be shortened

- (vi) Monitoring of Epi-centre reports should be intensified. The auto feedback function of the Epi-Centre should be strengthened and systemized. Process should be started of making Epi-Centre Windows compatible using latest Windows version of Epi-info. The development of TB Programme Information System (TPIS) web-based surveillance system should be continued.
- (vii) A pilot study should be conducted to develop an electronic case-based (line-listed) information system, initially at the district level.

8. DRUGS AND OTHER SUPPLIES

The drug management system under the RNTCP works well, with virtually no significant drug shortages having occurred in the past two years. However, the Mission noted that the supply of loose drugs was sub-optimal in some areas. As recommended in the previous review, the shelf life of rifampicin has been increased from 2 to 3 years. In all the states visited, drug supplies were well within expiry dates. Storage of drugs was found to be proper at the visited sites. An important initiative in recent years has been the establishment of drug storage capacity at the state-level; 13 states now have state level drug stores. However some large states (e.g. Uttar Pradesh) do not have TB drugs in the existing essential drug stores. Timeliness, accuracy and feedback information about drug logistics is being strengthened through development of a web-based reporting system.

Although no drug shortages have occurred in the past 2 years, the absence of a sufficient buffer stock in the country creates a risk of drug shortages in the future. This could occur if there are unforeseen delays in procurement, or if more than the expected number of cases are detected during expansion.

In order to monitor the quality of drugs, an external drug quality assurance protocol is followed at the central level. However, the methods and results of drug quality control are not disseminated.

The drug management system is dependent on two single central points at the Central Tuberculosis Division (CTD): (1) Strategic Alliance to quantify needs, and (2) the current procurement agent (MECON) to arrange for distribution. While Strategic Alliance is fully integrated into the RNTCP, there is no back-up, should the World Bank/MECON procurement process fail. This problem has been witnessed recently; the latest legal actions against the

procurement agent and change in World Bank procurement policy have seriously delayed the current procurement system and resulted in RNTCP having to find emergency options, should procurement be stopped.

The use of loose drugs within the RNTCP, when patient-wise boxes (PWBs) cannot be used for children, patients who develop reactions, and over- and under-weight patients, has created two separate drug management systems—one for PWBs and one for loose drugs. This places an unnecessary burden on what is otherwise a very simple and well-functioning system. Also, many states have duplicate supply systems for TB drugs, in addition to the RNTCP drug management system (e.g. Tamil Nadu), which is inefficient and makes large amounts of loose drugs including rifampicin available.

Other supplies, including reagents for microscopy, were adequate, but districts require extensive time and effort to call for tenders of laboratory supplies.

8.1 Recommendations

- (i) Buffer stocks at different levels should be calculated and analysed. A minimum buffer (reserve) stock for 9–12 months should be established in the country, including a buffer stock in states; more than one drug store may be required in the larger states.
- (ii) A back-up procurement mechanism should be maintained for the RNTCP. Global Drug Facility can support the programme and act as a “back-up” procurement agent.
- (iii) The results of drug quality should continue to be analysed periodically and the methods of drug quality control should be publicized.
- (iv) A policy and process for supply of non-PWB (loose) drugs should be developed. A solution for drug treatment of children, e.g. special PWBs should be found. Duplicate procurement and supply system at state level for RNTCP implementing districts should be discouraged.
- (v) A policy and process for reconstitution of prolongation pouches and PWBs should be developed and tested and a procedure formed on how to account for these.
- (vi) Bundling of streptomycin with water and syringe and procurement of the bundle at the central level should be considered.
- (vii) A web-based TB drug management system should be implemented.

- (viii) Drug management practices should be improved by finalizing a drug management training manual and course.
- (ix) States should develop links to provide RNTCP drugs to large hospitals and sanatoria under RNTCP.
- (x) A centralized procurement and distribution of laboratory materials at the state level should be considered.

9. HUMAN RESOURCE DEVELOPMENT

In most areas, RNTCP staff are well-trained, knowledgeable about their tasks, highly motivated and hardworking. Large numbers of staff are trained and, in general, all staff undergo initial training (Table 4). The quality of initial training has been good and training materials and methodology seem adequate. In addition to basic modules for initial training, new modules for training in interpersonal communication, management and financing/accounting have been developed or are in the process of development.

Table 4: Number of staff trained under RNTCP

Category of staff	Sanctioned	In place	Total trained in RNTCP	% trained
State TB Officer (STO)	35	35	35	100
District TB Officer (DTO)		313	302	96
Statistical Assistant		176	150	85
Medical Officer (MO), District TB Centre (DTC)	376	350	333	95
MO-TB Control (MO-TC)	1 311	1 280	1 206	94
Senior Treatment Supervisor (STS)	1 363	1 299	1 248	96
Senior TB Laboratory Supervisor (STLS)	1 375	1 323	1 281	97
Laboratory Technician (LT)		312	310	99
Treatment Organizer (TO)	501	437	430	98

Category of staff	Sanctioned	In place	Total trained in RNTCP	% trained
MO (BPHC/CHC/PHC/other)	42 592	38 053	33 96	88
Pharmacist	16 501	15 853	11 247	71
Lady Health Visitor (LHV)	9 544	8 191	6 125	75
Staff Nurse	28 231	25 243	11 420	46
Health Assistant	26 756	22 577	19 714	87
Multi-purpose Health Supervisor (MPHS)	21 975	17 538	15 390	88
Multi-purpose Worker (MPW) or equivalent	1 24 237	1 10 713	96 854	87
TB-Health Visitor (TB-HV)	921	795	779	98
Angan Wadi Worker (AWW)	1 75 600	1 59 874	79 289	50
Trained <i>Dai</i>	54 990	53 320	1 601	3
Community Volunteer		23 861	14 565	61
Total	5 06 308	4 81 543	2 95 875	77

However, the progress in implementation of the recommendations of the earlier review has been slow. Few of the previous recommendations have been implemented. Currently, no plans exist at the state level for training or retraining of staff. A systematic analysis of training needs has not been undertaken. State TB Cells (STCs) and State TB Training and Demonstration Centres (STDCs) do not have adequate infrastructure and capacity for effective training. One of the pressing needs is to develop plans and methodology for training and refresher training. Massive transfers are leading to many vacancies in key staff positions (viz. STS, STLS, LT) and add to the demand on training resources. Though trained in RNTCP, MOs at Peripheral Health Institutions (PHIs) without a Microscopy Centre are not involved in diagnosis, categorization and supervision. Supervisory and managerial skills of DTOs and STOs and other supervisory staff are weak. The quality of training is not assessed and training and supervision are not linked. Acceleration in training activities is needed at all levels.

9.1 Recommendations

The following are the recommendations:

- (i) A training needs assessment should be performed, with emphasis on re-training of RNTCP staff.
- (ii) A comprehensive strategic training plan should be developed for refresher training of staff at all levels and appropriate methodology prepared for refresher training. The topics for training should include those that are found problematic during internal evaluations and field supervision (e.g. referral of TB suspects by MO, promotion of sputum testing by LT, accurate recording by ANM/AWW, effective defaulter retrieval by ANM/STS/MO, defaulter prevention through convenient DOTS, and particularly, capacity for supervision).
- (iii) Effective curricula should be developed for training STOs and DTOs in management aspects, such as, planning, budgeting, supervision, problem-solving, and advocacy.
- (iv) Guidelines for post-training evaluation should be developed. *All training should be followed up closely by supervisory visits to provide additional reinforcement and on-the-job training.* Regular supervision should be strengthened to include specific follow-up of course participants, especially in the first 6 months following training.
- (v) Modules should be revised, particularly to highlight the field supervision component at all levels. The summary module M5–10 should be finalized to allow for shortened, effective trainings of MOs.
- (vi) Materials on the principles and practice of the RNTCP for medical school professors and chest physicians should be developed, taking into account existing levels of knowledge and time limitations for training.
- (vii) A plan needs to be developed and implemented at the national level for integrating RNTCP training into the routine training curricula of the health professions. The National Institute of Health and Family Welfare (NIHFW) as well as representatives from participating medical colleges could play an important role in this process.
- (viii) Monitoring and reporting on training and re-training should form an integral part of programme reports at the national, state and district levels (e.g. inclusion in the quarterly performance report).

10. INFORMATION, EDUCATION AND COMMUNICATION

The visibility of the DOTS programme at national and international levels has improved and there is now a greater consensus in the country about the effectiveness of DOTS as the standard for care. In order to disseminate information about tuberculosis (TB) and the performance of RNTCP, the Government of India maintains a website, www.tbcindia.org.

Until the beginning of 2002, large-scale IEC activities were not attempted as the majority of districts in the country were not yet implementing the RNTCP. With the rapid expansion of RNTCP, and achievement of consistently high cure rates, the focus of the programme has now shifted to increasing case-detection. This has led to an intensification of IEC activities including the following achievements:

- A countrywide Knowledge, Attitude, Behaviour, Practice (KABP) study was conducted by a professional agency for the RNTCP. The study provides a wealth of baseline data and information, and also forms the basis for the communication and social mobilization strategy.
- A plan/strategy has been prepared through broad consultation and involvement of national and state-level participants.
- The budget for the IEC plan is financially supported by World Bank funds. The budget covers roll-out at the national, state, district and sub-district levels.
- A professional advertising agency has been selected and contracted for the development, design, production and dissemination of IEC materials, including products for the mass media.
- Nearly all the states have a dedicated State IEC Officer for TB, as part of the State TB Cell (STC) team. A WHO-supported coordinator is overseeing implementation at the national level.
- Most of the State IEC officers have attended a series of regional workshops for elaboration/preparation of state IEC plans.
- Good examples of patient education materials, namely flip charts, have been developed in conjunction with the Tuberculosis Association of India, among others and disseminated to districts. Orissa has very good examples of IEC materials, which could serve as a model for other states/districts in the country.

There are a number of constraints facing the programme in the area of IEC. Although the programme was first introduced in the country 10 years ago, awareness about RNTCP among many clinicians remains very low. For example, during the Joint Monitoring Mission, Medical Officers (MOs) of government hospitals and some medical colleges often reported not being aware of the RNTCP.

- Despite extensive preparations, the roll out of the national-level IEC plan through the mass media has been delayed for nearly 4–5 months. The sub-national-level IEC activities (including social/community mobilization) are being carried out with variable quality and there is no district action plan for IEC activities. The lack of mass media support is proving to be a serious hurdle, and may have already affected the progress to date negatively.
- Staffing at the central level in the area of IEC is inadequate and there is a need for a much stronger multidisciplinary communication team at the national level to provide ongoing support and technical assistance to the various states. A single coordinator at the national level is inadequate for overseeing the wide range of activities (advocacy, programme communication, social mobilization, media relations, partnership-building, nongovernmental organizations (NGOs) participation, public–private mix (PPM) strategy, web-site support, Communication for Behavioural Impact (COMBI) implementation, Partners Forum preparations, World TB Day support, communication research, monitoring and evaluation, etc.) that have been planned for this very rapidly-expanding programme.
- While dedicated state-level IEC focal points exist, there is great variation in the involvement of functionaries in IEC activities at the district/sub-district level. Although nearly all states and districts have health education officer posts, many of the posts have been lying vacant or filled by temporary and inadequately qualified staff. The primary function of these cadres has been to support family welfare tasks, reproduction and child health activities, and polio eradication.
- The advocacy and communication efforts towards popularizing RNTCP schemes for the involvement of NGOs and private medical practitioners has been less than optimal. During the review, some confusion was observed among NGOs and private practitioners with regard to the interpretation of the content of the schemes. While the

schemes themselves are reasonably well articulated, they have been poorly communicated due to the lack of a clearly elaborated communication strategy.

- To date, no formal (process or impact) indicators have been included in the national or sub-national reporting formats to assess or monitor political/social commitment, public awareness and behavioural change, with regard to TB.

10.1 Recommendations

The following recommendations are made:

- (i) A much stronger multidisciplinary communication team should be created at the national level. The national level unit should provide ongoing support/technical assistance and oversee the wide range of activities that have been planned for this very rapidly expanding programme. Focus areas should include: advocacy, programme communication, social mobilization, media relations, partnership-building, NGO participation, PPM strategy, web-site support, COMBI implementation, Partners Forum preparations, World TB Day support, communication research, monitoring and evaluation.
- (ii) Wider support should be ensured for RNTCP at all levels. Dissemination of key messages and advocacy should be intensified to increase political and administrative commitment from the central and state governments including formal resolutions to elevate the importance of IEC. Efforts to promote acceptance by the wider medical community should be strengthened. Additionally, front-line workers (e.g., directly observed treatment [DOT] providers, NGOs, school teachers) should be considered for training as advocates of the Programme.
- (iii) Advocacy, programme communication, and social mobilization should be strengthened at the national and state levels to develop and maintain an effective relationship with the mass media, and states supported in undertaking advocacy and IEC activities. Multi-disciplinary communication and social mobilization groups should be formed at national and state levels, comprising communication focal points of RNTCP, key partner agencies, donors and communications/media/social science specialists.

- (iv) The national plan for IEC should be implemented, including the planned mass media campaign. IEC should be given higher priority in states that are in the maintenance phase of implementation. Specifically, all vacant IEC posts at the state, district and block levels should be filled with trained/experienced staff backed up by formal government orders to ensure that RNTCP is a priority. Additionally, ongoing specific IEC training/capacity building should be provided as part of the RNTCP re-fresher training effort. IEC activities, processes, and materials should be strengthened. "Market research" should be undertaken on the impact of IEC messages and materials on the community and health care providers including those from the private sector. Periodic formal evaluations of IEC methods should be performed.
- (v) A national quarterly newsletter should be developed to document RNTCP success stories (a shorter e-mail version should be considered). Quarterly messages should be published on RNTCP status in journals, such as the Journal of the Indian Medical Association, Indian Journal of Tuberculosis, etc.
- (vi) Additional national and international partners should be identified and engaged in advocacy and IEC efforts including NGOs in the health and non-health sectors (e.g. International Union Against Tuberculosis and Lung Disease [IUATLD]), bilaterals (Danida), technical agencies (e.g. WHO) and the private sector (e.g. RK Swamy).
- (vii) Annual RNTCP conferences should be organized in coordination with the TB Association of India and with participation of RNTCP staff at the national level to share programme implementation experiences, successes and challenges.
- (viii) It should be considered to develop, pilot test and then introduce communication indicators as part of recording and reporting.
- (ix) TB/HIV advocacy messages should be developed.
- (x) Innovative approaches should be developed to strengthen partnerships with the English and non-English press at the national, state and district levels (e.g. press conferences that include expert journalists as panelists, WHO-Government of India journalist fellowships, excellence in media awards, etc.). More attention should be paid to efforts to engage the non-English press.

- (xi) The current website should be revised with focus on engaging additional partners including individuals, NGOs, the corporate sector, mass media, etc. It should be linked with major TB and HIV/AIDS-related websites. The scope of the website should also be broadened to provide routine updates, press releases, presentations, etc. for use by the general public.

11. INTERSECTORAL COORDINATION

In recent years, partnerships with NGOs, the private sector, and medical colleges have gained momentum. Intersectoral advocacy meetings and workshops have been held at national and regional levels to take this initiative forward. Presently, 128 of the 150 medical colleges situated in the RNTCP-implementing districts are participating in the programme. Several initiatives are under way to involve the corporate sector in TB control. Coal India, tea gardens and other major employers are now collaborating with the RNTCP. The RNTCP has more than 50 corporate sector collaborations.

Many public-private mix (PPM) DOTS projects are being implemented throughout the country. To date, 550 NGOs and more than 2 000 private practitioners (PPs) are officially providing RNTCP services. Documentation from a number of projects has shown promising results (e.g. Delhi, Hyderabad, Kannur, Kollam, Pune, Meerut, tea gardens, and Thane).

The RNTCP has developed guidelines for the involvement of NGOs and PPs in the programme. The guidelines for NGO and PP involvement include various schemes representing different levels of service delivery, such as referral, IEC, directly observed treatment (DOT) provision, the operating of a designated microscopy centre with or without DOT provision and the management of a TB Unit (TU).

Some barriers to effective intersectoral partnerships exist. There is a lack of awareness of the DOTS strategy and RNTCP among the partners and many private practitioners, academics and NGOs still believe that RNTCP DOTS is a limited, rigid strategy. Also, there is a lack of effective training materials for the private sector.

With regards to involvement of medical colleges, state task forces have been established but these are only marginally functional because of the lack of funds flow. Additionally, pharmacists and nurses have not been included in efforts to involve health care professionals in TB control efforts.

Most importantly, while significant progress has been made in involvement of nongovernmental sectors, there is much scope and requirement to increase the involvement of other public sectors, such as Employee's State Insurance Schemes (ESIS), Central Government Health Services (CGHS), Railways, etc. Official arrangements with other sectors (Ministry of Labour, Railways, etc.) are lacking.

11.1 Recommendations

The following are the recommendations

- (i) A national coordinating body should be established of all key partners needed for effective and sustained implementation of the RNTCP.
- (ii) Awareness and collaboration with other sectors should be increased, most importantly with other public-institutions, e.g. district hospitals, TB sanatoria, medical and nursing colleges. It should be ensured that RNTCP guidelines are specifically adopted. Given the slow uptake by major public sector institutions (e.g. ESIS, Railways, etc.) and the large numbers of patients involved, the PPM should be the highest priority.
- (iii) The private sector and NGOs should continue to be involved. Specialized training materials should be developed for private providers at the national level. The Indian Medical Association (IMA) should be involved in the development of these training materials.
- (iv) The success of PPM projects such as Kannur should be documented and disseminated widely, and similar projects replicated at other sites. Where appropriate, private laboratories as well as providers should also be involved.
- (v) Under Confidence-building measures should be undertaken between private and public sectors. IMA could act as a nodal agency to interface between the government and the private sector.
- (vi) Schemes for private practitioners and private hospitals should be reviewed and modified and separate budget heads for the PPM be created.
- (vii) It should be ensured that the flow of funds is adequate to facilitate functioning of state task forces established for medical colleges. At a minimum, establish a separate head for the medical colleges initiative should be established; some direct support to state task forces and nodal centers be considered.

12. TUBERCULOSIS AND HIV/AIDS

12.1 TB/HIV

Considerable progress has been made by the RNTCP and National AIDS Control Organization (NACO) in addressing tuberculosis (TB)/human immunodeficiency virus (HIV) including:

- Development of a Joint National TB/HIV Action Plan (2001);
- Strengthened coordination between TB and HIV control programmes at the central, state and district levels;
- Development of supplementary training materials on TB/HIV, and
- Appointment of 5 World Health Organization (WHO)-RNTCP TB/HIV consultants.

Currently, the emphasis of TB/HIV activities is in the states with the highest burden of HIV, namely Andhra Pradesh, Karnataka, Maharashtra, Manipur, Nagaland and Tamil Nadu. In these 6 states, key policy-makers have been sensitized to TB/HIV activities, training of staff at Voluntary Counselling and Testing Centres (VCTC) has been organized, district-level linkages between the two programmes have been established, and HIV-positive persons attending are assessed for symptoms of TB and referred for investigation as needed.

On an average, 5–15% of the HIV-positive persons attending VCTCs are found to have pulmonary TB. Additionally, HIV-negative persons with chest symptoms (e.g. three weeks cough) referred from VCTCs are also being detected and managed under the RNTCP. A clinical trial on treatment and prevention of TB among HIV-infected persons has been initiated at the Tuberculosis Research Centre, Chennai.

Despite recommendations of the previous review, the Central TB Division (CTD) has not disseminated widely the guidelines on measures to decrease the risk of nosocomial transmission of TB in high-risk settings. Also, non-disposable syringes are still being used for streptomycin, and unsafe waste disposal still being practiced at some health facilities, posing a risk of HIV transmission.

Systematic national and state HIV surveillance has been going on since 1998, but surveillance of HIV among TB patients has not yet begun. Therefore

there is a lack of information about the extent of the burden of HIV among TB patients in the high HIV-burden states.

While new materials for TB/HIV have been prepared, the currently-used modules for initial training of RNTCP staff need to be revised to include information about TB/HIV.

The maintenance of confidentiality regarding the HIV status of patients is of serious concern, especially when information is being transferred between programmes. Additionally, the field staff often unnecessarily record the HIV status on TB Treatment Cards and TB Registers.

The package of care available for HIV-positive TB patients (and other people found to be HIV positive at VCTCs) is limited to treatment of opportunistic infections. There is limited psychosocial support and no provision for preventive TB therapy or co-trimoxazole prophylaxis.

12.2 Recommendations

The following are the recommendations:

- (i) Collaboration between TB and HIV programmes should be continued on training of all staff, including basic counseling skills. They should also continue and strengthen efforts to develop joint training materials for all health care workers involved in caring for HIV or TB patients.
- (ii) The TB/HIV activities should be concentrated initially in the 6 high-burden states; this should be reviewed regularly on the basis of HIV surveillance information and resource availability.
- (iii) Pilot operational research studies should be conducted to assess HIV prevalence among all categories of TB patients and if the burden is high, a system for routine surveillance should be established.
- (iv) Special attention should be paid to ensuring the confidentiality of HIV-infected people. Breaches in confidentiality may have serious negative effects on the programme's ability to detect and control TB and may also compromise HIV/AIDS prevention activities.
- (v) It should be ensured that joint TB/HIV IEC materials are carefully planned and do not add to the considerable stigma that already exists among health care workers and in the community.

- (vi) Efforts should be made to expand the package for care and support available for HIV-positive TB patients and other people living with HIV/AIDS (PLWHA), such as co-trimoxazole prophylaxis, and preventive TB therapy, and psychosocial support before HIV testing is strongly promoted.
- (vii) TB patient and PLWHA support groups should be developed and assistance provided to them to provide ongoing psychosocial support to those with HIV.
- (viii) It should be explored how HIV-positive TB patients can gain better access to antiretroviral (ARV) drugs and develop regimens that minimize interactions between TB drugs and ARVs.
- (ix) The risk of nosocomial transmission of TB and HIV should be reduced by: (a) publishing simple and implementable guidelines to prevent the spread of TB in hospitals where HIV-infected patients are cared for, and (b) ensuring adherence to recommended policies by the national, state and district authorities for decreased risk of HIV transmission (e.g. the exclusive use of disposable/auto-destruct syringes and the safe disposal of used syringes).
- (x) The national information about existing TB/HIV activities should be reviewed and compiled, and the same disseminated through publications, scientific workshops and other communications. Specifically, (a) the current VCTC-RNTCP pilot surveillance project regarding referral of patients from VCTC to RNTCP in 4 districts in Maharashtra should be evaluated and, if successful, it should be implemented in all VCTCs in the high-prevalence states, and (b) the results of the current WHO-CTD-NACO TB/HIV modelling exercise should be completed and disseminated.

13. OPERATIONAL RESEARCH

The previous review suggested a detailed list of operational research topics to strengthen the RNTCP implementation. Impressive progress has been made in initiating and completing many of the recommended research projects. A selected list of ongoing research, and at recent publications is attached at Annex 14 and 15, respectively.

The Government of India (GOI) has developed an agenda for operational research and is seeking proposals for funding. Funds have been

made available to all states for inviting proposals and funding research activities in the respective states. Two central committees have been formed to review and sanction research proposals; however, very few proposals have been received in proportion to the size of the programme. In most of the states, operational research activities are virtually non-existent, resulting in under-utilization of operational research funds. Possible barriers to a more effective national and state-level operational research programme could include lack of information on mechanisms to access funds and priorities for research (for districts and institutions); slow approval and disbursement of funds (mentioned in review); and lack of clarity regarding what happens afterwards with the results of research.

Three centrally-funded research projects are near completion. First, the annual risk of tuberculosis (TB) infection survey led by the National Tuberculosis Institute (NTI), Bangalore in collaboration with Tuberculosis Research Centre (TRC), Chennai provides for the first time the current region-specific information on the TB burden in the country. Second, the national Drug Resistance Surveillance (DRS) survey led by TRC and supported by NTI is also in progress and is providing baseline information on the problem of multidrug-resistant (MDR) TB. Third, a study on the utilization of RNTCP services by marginalized groups, such as scheduled castes/scheduled tribes, women, people living with HIV/AIDS (PLWHA) may help in guiding the policy on increasing the access to vulnerable population groups.

Several other epidemiological studies, operational research projects and basic science studies are currently under way in national institutes, NGOs, and academic settings. With financial support from the United States Agency for International Development (USAID), a model DOTS project conducted by TRC in Tiruvallur District, Tamil Nadu is collecting information on the epidemiological impact of RNTCP implementation at the community level. In addition to its collaboration with NTI and TRC, WHO's India Country Office supports a number of ongoing and future operational research initiatives including piloting a new Voluntary Counselling and Testing Centre (VCTC)-based TB/HIV surveillance system, an assessment of the feasibility of an intra-district "referral for treatment" mechanism, a field survey of diagnostic algorithms in use for extra-pulmonary TB, the examination of the role of hand-cranked and battery-powered light sources for smear microscopy, ongoing evaluations of select public-private mix programmes (e.g. Kannur,

Meerut, tea gardens, Thane, etc.) and the role of community volunteers in delivering directly observed treatment (DOT), etc.

13.1 Recommendations

The following are the recommendations:

- (i) Potential revisions in the RNTCP technical policies, based on findings of operational research to date should be pilot-tested, so that lessons learned from pilots can be appropriately applied when RNTCP is expanded to the entire country. For example, the impact of the following should be assessed:
 - (a) Screening outpatients with cough of three weeks versus two weeks' duration
 - (b) Follow-up using one sputum sample versus two sputum samples, and
 - (c) Development of a "referral for treatment" system from medical colleges and large hospitals to the peripheral DOTS centres.
- (ii) The RNTCP operational research priorities should be widely disseminate to RNTCP programme staff, academic institutes, medical colleges, NGOs, and private sector.
- (iii) National capacity should be strengthen for operational research through workshops in collaboration with national and international faculty. The national operational research application process should be streamlined to speed up the review of proposals and disbursement of funds. The application and award process should be publicized in order to attract additional high-quality proposals.
- (iv) Quarterly briefings should be held with national institutes/researchers to ensure that field research findings are fed into data-driven programme policy/technical decision-making.
- (v) Undertake state-specific ARTI studies in selected states.
- (vi) A strategy should be developed for strengthening the National DRS Laboratory network, and for testing the proficiency of DRS.
- (vii) Specific analyses should be undertaken of programme data. For example, outcomes of patients in category II who were in category I and had failed treatment. Outcomes of such patients should also be

compared with: other failure cases; trends in smear grade of diagnosed patients, and trends in death rates.

- (viii) Other priority areas should be continued/initiated for operational research including: development and evaluation of strategies to improve urban DOTS implementation; delays in diagnosis; cause of death among patients; actual diagnosis of smear-negative patients; development and evaluation of tools for the implementation of schemes in the private sector; role of incentives/disincentives for increasing the involvement and commitment of primary health care system staff, and determining the social, economic and epidemiologic impact of RNTCP.

Annex 1

BASIC INDICATORS

General Indicators

Population (2001)	1.03 billion
Estimated population (2003)	1.07 billion
Population density (2001)	324 persons/square kilometers
Urban population (2001)	28%
Life expectancy at birth (2001)	64 years
Sex ratio (2001)	933 females per 1 000 males

Fertility and Mortality Indicators

Annual average population growth (1991–2001)	1.80%
Total fertility rate per woman (2001)	3.1
Maternal mortality ratio (1995)	440 per 100 000 live births
Infant mortality rate	67 per 1 000 live births
Under-five mortality rate	93 per 1 000 live births

Health Nutrition and Sanitation Indicators

Under-five children who are moderately or severely underweight (1995–2000)	47%
Under-five children who are moderately or severely stunted (1995–2001)	46%
Urban population with sustainable access to improved drinking water sources (2000)	95%
Rural population with sustainable access to improved drinking water sources (2000)	79%
Urban population with sustainable access to improved sanitation (2000)	61%
Rural population with sustainable access to improved sanitation (2000)	15%

One-year olds fully immunized (2001)

BCG	73%
DPT3	64%

Polio3	70%
Measles	56%
Population with sustainable access to affordable essential drugs (1999)	0–49%

Literacy Indicators

Male literacy rate (2000)	69%
Female literacy rate (2000).....	42%
Male primary school enrolment ratio (1995–2000)	98%
Female primary school enrolment ratio (1995–2000).....	98%
Male secondary school enrolment ratio (1995–1999)	59%
Female secondary school enrolment ratio (1995–1999)	39%

Economic Indicators

GNP, income per capita (2001).....	US\$ 450
GDP per capita, adjusted for purchasing power (2001)	US\$ 2 840
GDP per capita annual growth rate (1990–2001).....	4%
Public expenditure on health as % of GDP (2000)	0.90%
Population below national poverty line (1987–2000).....	29%
Average annual rate of inflation (1990–2001)	8%
Population below \$1 a day (1990–2001)	35%
Human Development Index rank (2001)	127

Sources: Census of India 2001; UNICEF, The State of the World's Children 2003

Annex 2

ORGANIZATION OF TUBERCULOSIS CONTROL SERVICES

National Level

The Central Tuberculosis Division (CTD) (see CTD Organogram on Page 51) under the technical arm of the Ministry of Health and Family Welfare (MOHFW) is responsible for preparation of technical policies, procurement of drugs, preparation of training modules, programme and financial monitoring, quality assurance, advocacy, operational research priorities, and mobilization of funds. The overall supervision of the CTD and all RNTCP activities is under the Deputy Director-General TB (DDG-TB). The CTD is assisted by 3 national tuberculosis institutes, namely, National Tuberculosis Institute, Bangalore, Tuberculosis Research Centre, Chennai, and Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases, New Delhi.

State Level

India consists of 35 states/union territories with populations ranging from less than 0.7 to 175 million. All states are governed by a common policy framework and have a uniform health infrastructure. TB control programmes in the states is under the purview of the Director of Medical Services. All states have a State TB Cell (STC) supervised by a State TB Officer (STO). The STO is assisted by a Medical Officer (MO), an accountant, an IEC officer, a secretarial assistant, a data entry operator, and other support staff.

The STO is responsible for planning, training, monitoring and supervising TB control activities in the state.

State TB Training and Demonstration Centre (STDC)

The STDCs are the technical support unit to the STC and assist in training, monitoring and supervision of the programme, quality assurance of sputum microscopy, advocacy and IEC, and operational research. The level of involvement of STDCs varies from state to state.

District Level

District is the basic demographic, economic, administrative and political unit in India. There are nearly 600 districts/reporting units in the country, with populations ranging from: 0.3 to 12.4 million. A district is further divided into *taluks* and community development blocks.

The district level (municipal corporation in large metropolitan areas) is the service delivery unit of health care. The health institutions in a district include:

1. One district hospital in the headquarter town and a District Tuberculosis Centre (DTC), usually located within or near the District Hospital.

2. Community health centre (CHC), usually one for 100 000 population
3. Primary health centre (PHC), one per 30 000 population
4. Sub-centre (SC), one per 5 000 population

The DTC is the nodal point for TB control activities in the district and also functions as a specialized referral centre. The District Tuberculosis Officer (DTO) at the DTC has the overall responsibility of the TB control programme at the district level and is assisted by the MO, statistical assistant, laboratory technician (LT), treatment organizer (TO) and other paramedical staff.

Sub-district Level

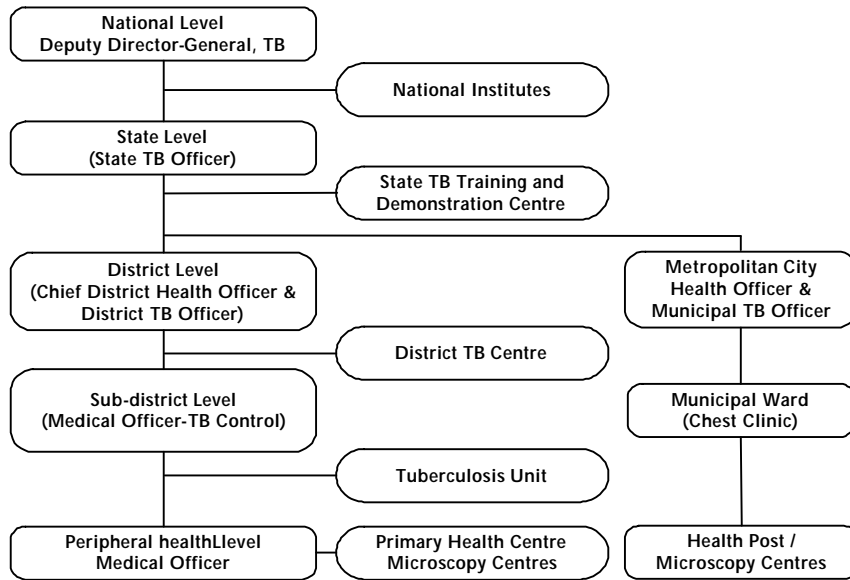
Also called the Tuberculosis Unit (TU) and usually located in one of the CHCs, the TU caters to 500 000 population (2.5 lakhs in tribal and hilly areas). The TU has a Senior TB Laboratory Supervisor (STLS) and a Senior Treatment Supervisor (STS), both formally trained in the RNTCP. One of the MOs of the TU, called Medical Officer-TB Control (MO-TC), has the overall responsibility for TB work of the TU which includes implementation, monitoring and supervision of TB control activities in its designated geographical area, maintaining TB Registers, and preparing quarterly reports.

Under the RNTCP, the diagnosis and treatment of TB are functions of the general health services using programme guidelines and hence are part and parcel of primary health care. Microscopy Centres located in the CHC, PHC or Taluk hospital are designated by the RNTCP to cover a population of 100 000 (50 000 in tribal and mountainous areas). The staff at the Microscopy Centres (MC) includes the MO, LT, and Multi-purpose Health Workers (MPWs). Directly observed treatment is provided by MPWs and a network of community health workers and community volunteers.

Urban Areas

The municipal corporation assumes the responsibility of TB control in its area. A Corporation Tuberculosis Officer is responsible for the organization of TB services within its jurisdiction. The city is divided into geographical areas of responsibility, each under the jurisdiction of a TB dispensary or chest clinic, with laboratory and X-ray facilities as well as physicians experienced in TB. These chest clinics serve as TUs for their earmarked population. Delivery of TB services is carried out by trained staff (treatment organizer [TO] and LT) based in the general health facility, assisted by peripheral health workers and community volunteers. One general health facility caters to 100 000 population. TB Health Visitors are also employed to assist the programme at a ratio of 1:150 000 population.

Organizational Chart of the Revised National Tuberculosis Control Programme in India under the Directorate-General, Health Services, Ministry of Health and Family Welfare



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Sh. Rajinder Singh,
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Sh. Sarvan Kumar,
STLS
Lokpriya Hospital

Dr. Raj Kr. Sagar,
MO-TC
PHC Jani

Sh. Narendra Bharti,
STLS
PHC Jani

Ms. Raj Bala,
STS
PHC Jani

Lab. Technician
PHC Jani

Dr. LP Rawat,
STO
Lucknow

Dr. S P Mathur,
Director National Programmes
Lucknow

Dr. HP Kumar,
DDG, Uttar Pradesh
Lucknow

Annex 5

MAP OF INDIA SHOWING STATES SELECTED FOR THE REVIEW



Annex 6

KEY FINDINGS AND RECOMMENDATIONS OF THE REVIEWED STATES

Maharashtra

State Profile

Total population (2003)	:	1 00 771 367
Urban population	:	39%
Literacy rate	:	65%
Infant mortality rate per 1 000 live births (1998)	:	49
Total number of districts	:	49
Total number of districts implementing RNTCP	:	47

Summary of Findings

- High-level political and administrative commitment at the state and district levels.
- Rapid expansion achieved while maintaining case-detection and high cure rates.
- Good infrastructure and well-kept laboratories with functional binocular microscopes.
- Drug supplies are reliable with no stockouts. Octroi is being levied on RNTCP drugs in Aurangabad and Nagpur.
- Most key regular and contractual staff are in place and trained in RNTCP.
- There is a good system of defaulter retrieval.
- Sub-optimal cooperation between STLS and LTs in many places. In many areas there are poorly qualified STLSs with less ability and experience compared to LTs.
- Lack of prompt payment of contractual staff due to administrative reasons.
- Budget utilization, especially for IEC and NGO partnerships, is sub-optimal. There is no separate budget head for involvement of the private sector and medical colleges.
- Referrals between MCs, TUs, districts, and other services are sub-optimal; weak referral system of chest symptomatics in peripheral areas.
- The STDC in Nagpur is functioning more as a service provider instead of performing training, supervision, monitoring and quality assurance activities.
- Initial steps are being taken to involve medical colleges in RNTCP.
- Programme reviews are taking place monthly and quarterly, at the PHI, sub-district, district, divisional and state levels. Close regular quarterly reviews are being done of poorly performing districts.

- TB/HIV activities are impressive, though mostly in Mumbai area, with two-way referrals between VCTCs and TB services. There is limited data on the burden of HIV on TB patients.
- Frequent transfers of MOs especially at the PHC level creates difficulty in training and motivation.

Key Recommendations

- Strengthen and elevate the status of the State TB Cell, upgrade the STO post to Joint Director level and create deputy STO post(s). State cell needs considerable strengthening to meet supervision needs—consideration should be given to establishing regional supervisors.
- Supervision should be strengthened at all levels. Targets should be de-emphasized, accuracy in record-keeping should be emphasized and falsification should be met with appropriate disciplinary action. Improve quality, recording, reporting and feedback of supervisory visits. DTOs should be encouraged to “triangulate” using the available records including random patient interviews to verify record-keeping accuracy and ensure accountability.
- Continue internal evaluation process and ongoing review of marginally performing districts.
- DOT provision requires closer supervision by STS and DTO at the patient level. STO should spot check all levels of supervision. Increase the number and variety of accessible DOT providers.
- Vacant key staff posts should be filled as a priority and key staff positions especially managers should be in post for a minimum of 3 years. The considerable number of vacancies in contractual staff should be filled at the earliest.
- All staff should receive RNTCP training within 1 month of commencing the post duties and in-service refresher training should be provided to all RNTCP staff at least every 3 years.
- Ensure timely payment of contractual staff salaries and travel allowances.
- Ensure all state budget heads are fully spent and improve speed and efficiency of inter-district transfer of unspent funds.
- In Mumbai, decentralize budgetary control to zonal DTOs and ensure that the municipal zonal DTOs are fully functional. Separate budget heads should be created to support involvement of PPs and medical colleges.
- Prioritize sensitization and ongoing support of all non-RNTCP public sector health care workers (HCWs). Develop and implement a long-term plan to increase the involvement of PPs and NGOs. Involve public sector health care workers especially in medical colleges as a priority.

- Strengthen the laboratory quality assurance system where the STDC should play a major role. STDC should be used more effectively and staff should be involved in training and supervision, not service provision.
- Develop innovative methods to increase case-finding in remote areas and marginalized groups.
- Ensure that address verification of patients is done and RNTCP should provide address verification and defaulter retrieval for participating PPs. The IMA could play a crucial role in increasing the involvement of PPs.
- Consider piloting and introducing standardized referral forms for all levels.
- Regulate over-the-counter dispensing of TB drugs by pharmacists and the use of non-RNTCP regimens in hospital inpatients.
- Improve the IEC activities targeted at health care providers/authorities and patients and ensure that the full budget is spent. IEC materials for HCWs and partners should be developed to improve involvement of other stakeholders in RNTCP.

Orissa

State Profile

Total population (2003)	:	37 809 014
Urban population	:	13%
Females per 1 000 males	:	971
Literacy rate	:	49%
Infant mortality rate per 1 000 live births (1998)	:	98
Total number of districts	:	30
Total number of districts implementing RNTCP	:	18

Summary of Findings

Orissa has achieved good results and has undertaken innovative and successful interventions in IEC, intersectoral collaboration, and other areas. However, the lack of adequate management arrangements for TB control at the state, district, and sub-district levels threaten to result in a steady downward spiral in programme quality.

Key Recommendations

- Strengthen the State TB Cell. Upgrade the STO to full-time Joint Director level only for TB. Appoint DEO/Statistical Asst/Accountant at State level. In order to strengthen state ownership of the programme, ensure the long-term service of an effective STO.
- Rapidly complete pre-appraisals, request appraisals, and start service delivery so that training completed in April 2003 does not become even more stale.

- Supervise intensively. Emphasize convenient DOT, accurate recording on the Treatment Card, and maximal action in cases of wilful falsification.
- Ensure Treatment Cards are accurate (e.g. self-administered doses noted as such) and up to date by regularly updating cards at each monthly PHC meeting. Sector supervisor should improve coordination with Integrated Child Development Scheme (ICDS) workers, including the monitoring of updating of patient cards during ICDS meetings.
- Establish infrastructure for TB at the district level including DTO, 2nd MO, DEO, SA, STS, and STLS. These posts could be staffed state-wide, with the exception of STS/STLS, by appropriate reduction in TB hospital beds and staffing with concomitant re-direction of resources. DTO should be full-time and sufficiently senior to be able to function effectively with other senior medical staff in district.
- Appoint STS/STLS on contractual basis.
- Re-training staff at all levels, particularly on problem-solving skills and establishing a treatment observation plan for each patient.
- Focus on case-detection activities rather than detection rates. Since actual rates vary widely among districts, no district should reduce its efforts based on the detection rate. For example, focus could be on increasing the percentage of outpatients examined for diagnosis, and examination rate of adult residents per year.
- Strengthen the STDC so that it supports the State TB Cell/Programme per new STDC guidelines.
- Supervise intensively and monitor RNTCP activities at state and district levels.
- Monitor the funds release to resolve issue of non-release of funds from state to districts. Urgently release funds from State Health and Family Welfare Society to districts. Simplify the process for timely release of funds because staff are not being paid TA/DA/fuel; critical activities are not taking place because of non-release of funds.

Rajasthan

State Profile

Total population (2003)	:	59 361 898
Urban population	:	23%
Females per 1 000 males	:	910
Literacy rate	:	39%
Infant mortality rate per 1 000 live births (1998)	:	83
Total number of districts	:	30
Total number of districts implementing RNTCP	:	18

Summary of Findings

Rajasthan is functioning at a high level as it is performing as per expectations and is achieving WHO targets for case detection and cure of smear-positive TB patients.

- Political and administrative commitment is high at all levels.
- Case-finding and laboratory services are performed well and logistics are adequate, although minor improvement could be made in these areas.
- A large number of patients are, as yet, not captured in the RNTCP system although care is being provided by a number of other providers.
- DOTS is administrated according to RNTCP guidelines and direct observation of treatment is usually practised.
- Recording and reporting are done as per guidelines, though they require more attention. Initial training is undertaken by all staff, but follow-up training appears to be lacking.
- Although IEC activities are on, are performed well and are reaching the target populations, increased efforts need to be made to target communities at risk, to coordinate activities at the district level, and to increase collaboration with private practitioners and NGOs.
- Staff retention (either retention of current staff or recruitment of new staff) is an issue for the state.
- Patient interviews prove to be a strong testament of the high-quality of the programme. The key issue for Rajasthan will be to maintain its excellence in the future by increasing case-finding and ensuring that the quality of its Programme is sustained.

Key Recommendations

- Ensure staff retention and improve recruitment of staff. Reduce the amount of transferred staff. Fill positions quickly and provide a mechanism of compensation for positions not allowed to engage in private practices or not receiving non-practising allowance.
- Provide timely reimbursements associated with work travel and increase work associated per diems to adequate levels.
- Review guidelines prepared by the state to appoint contractual staff.
- Increase case-detection and case management through increased involvement of private practitioners and NGOs.
- Create a policy for continued training and increased monitoring of staff.
- Increase effectiveness of IEC via development of appropriate IEC materials for communities and standardize the IEC approach for all districts in the state.
- Encourage the development of District Action Plans for TB control and explore options (e.g. DOTS-Plus) for chronic or multidrug-resistant TB cases.

Tamil Nadu

State Profile

Total population (2003)	:	63 442 786
Urban	:	34%
Females per 1000 males	:	974
Literacy rate	:	63%
Infant mortality rate per 1000 live births (1998)	:	53
Total number of districts	:	30
Total number of districts implementing RNTCP	:	30

Summary of Findings

- There is strong political and administrative commitment for RNTCP, even at the level of the State Secretary for Health. The State has been fully covered under RNTCP since January 2002, and since that time through to July 2003, more than 125 000 patients have been placed on treatment under the programme. Efforts to improve case-finding to reach the 70% target have been successful (65% in 2nd quarter, 2003) and treatment outcomes have improved considerably (87% treatment success in 2nd quarter, 2002).
- In general, there are good levels of staffing in the districts at the various levels.
- Early, but critical cross-linkages linkages between RNTCP and district level VCTC are being established, such that RNTCP medical officers are referring TB patients at risk for HIV to the VCTC and VCTC staff members are referring HIV-infected attendees with symptoms of TB for evaluation of TB.
- The drug supply system is also working well. The state receives GDF drugs, which on arrival are easily integrated into the existing system. Overall, the supply system is routine but demonstrates flexibility with drug reallocation from district to district occurring when shortfalls are anticipated. Additionally, inventory control and drug storage are working well, and PWBs have facilitated inventory control. At all levels of the system, everyone understands and has confidence in the system, and communication within the system is very good, with personnel at all levels being aware of supply issues.
- The State TB Cell (STC) lacks staff, particularly a deputy State TB Officer (STO), which is essential to expanding state-level supervisory and administrative capacity, and a STC medical officer. The financial management systems are on occasions problematic such that submission of the statement of expenses (SOE), utilization certificates (UC) and audit reports is late at times. Situations such as this delay the actual disbursement of funds. Specifically, there are no comprehensive annual state and district action plans, including activity plans with timelines and budgets.

- Paediatric TB cases are generally not being reported and in many cases are being treated with short course chemotherapy (i.e. rifampicin-containing regimens) without direct supervision by DOT providers.
- The status and role of the STDC is unclear. The TB Research Centre (TRC) in Chennai has greatly facilitated essential training for implementation and expansion of RNTCP within Tamil Nadu. However, TRC's mandate is not to serve as the STDC.
- IEC activities, processes, and materials are insufficient to support and enhance programme activities and performance.
- Multiple laboratories (MCs, hospitals, sanatoria) within the state do not follow RNTCP guidelines and demonstrate very poor infection control practices for solid waste disposal and for administrative controls related to respiratory precautions (sanatoria).
- Specific constraints exist in the drug supply system. The PWBs are difficult to reconstitute when necessary and prolongation pouches are being used for a variety of purposes; both of these situations are however difficult to quantify. Other constraints include loose drugs (e.g. stock outs, lack of procurement capacity, supplies from Tamil Nadu Medical Services Corporation with short expiry dates); the keeping of a separate inventory for GDF drugs; and there being no logistic advantage to the duplicate supply system at the state level. Additional constraints are that the drug supply system is dependent on a single central point and the essential quality control process is not well understood.

Key Recommendations

- Strengthen the STC with staff and, in turn, improve STC management capacity.
- Streamline financial mechanisms to facilitate more efficient disbursement of funds for essential activities and hiring of essential contractual staff.
- Develop an annual state action plan to better coordinate and facilitate essential activities especially when the state is shifting from the implementation and expansion mode to the maintenance mode.
- Review the status of the STDC. Establish a viable STDC which is essential to facilitate the wide array of training and demonstration needs, such as staff re-training.
- Strengthen IEC activities, processes, and materials. Identify a leadership mechanism at national and state levels to radically increase the profile of the RNTCP. Recruit professional IEC officer(s).
- Develop tools to strengthen the existing "referral for treatment" system between large institutions (medical colleges, sanatoria) to peripheral DOTS centres. A large number of referrals are being made from these institutions to RNTCP within the state, yet the total volume of referrals is not clear, nor the quality of the referral process.

- Survey all microscopes, repair those that are non-functional, and establish an annual maintenance contract for microscopes.
- Reduce expenditures on loose drugs, develop appropriate links to provide drugs to large hospitals and sanatoria under RNTCP, and evaluate the current distribution system to ensure efficiency and drug security.
- The STC should develop a clear and well coordinated plan to further strengthen and build the network of partnerships with the RNTCP according to CTD guidelines.
- Strengthen infection control practices (e.g. administrative controls, solid waste disposal, etc.) among staff and to promote adherence to national standards.
- Expand TB/HIV collaborative activities between RNTCP, TB sanatoria (e.g. Tambaram Thoracic Institute, Kancheepuram District), and the state's HIV/AIDS programme and network.

Uttar Pradesh

State Profile

Total population (2003)	:	173 852 902
Urban population	:	20%
Females per 1000 males	:	879
Literacy rate	:	42%
Infant mortality rate per 1000 live births (1998)	:	85
Total number of districts	:	70
Total number of districts implementing RNTCP	:	28

Summary of Findings

- In RNTCP implemented areas, the observed quality of services is very good. Forty five per cent of the population in 28 districts have been covered by the RNTCP. In the last quarter, over 20 000 patients were initiated on DOTS of which over 8 600 were new smear-positives.
- Case-detection in the latest quarter is 63 per 100 000 for implementing districts and treatment success has been maintained over 80%.
- There is insufficient management capacity for rapid expansion at the state level.
- The RNTCP has not been incorporated into the general public health services; too many key staff are working on contractual basis.
- The STDC is non-functional.
- In RNTCP implemented districts, the collaboration between other major partners providing health care is limited.

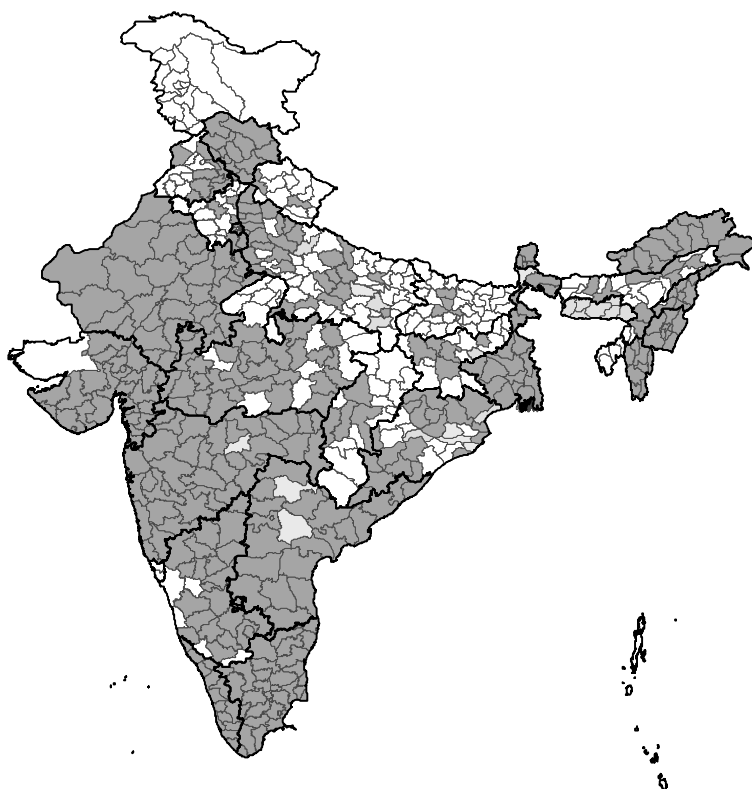
- Planning and budgeting are weak. The process of planning and budgeting is not based on district plans. Written plans for key activities for expanding and sustaining the programme are not available.

Key Recommendations

- The State TB Cell needs to be strengthened by providing additional staff (considering the population and number of districts in the state), and some logistics training particularly in the area of management, planning and budgeting.
- Establish 2 or 3 regional training teams for training, supervision and monitoring. This may include the existing STDC. In addition, make use of model districts for the purpose of training and expansion.
- Prepare a mid-term development plan for expansion. Also develop annual activity plans based on district activity plan, including a related budget.
- Consider establishing buffer stocks at state/regional levels to avoid stock-outs during expansion. This should include staff trained and assigned for management of these stocks.
- Consider a maintenance contract arrangement for microscopes and maintain a stock of microscopes for replacements.
- Involve all sectors (ESI, medical colleges, Railways, Labour, Industry, professional bodies, etc.) in societies, task forces, working groups, etc in the RNTCP.
- Create regular posts for future sustainability of the programme in districts implementing the RNTCP; consider absorption of contractual staff; and fill up vacant posts in districts (e.g. LT posts).
- Regularly review designated Microscopy Centres and maintain/expand established services to ensure access and credibility of the programme.

Annex 7

INDIA RNTCP (DOTS) IMPLEMENTATION STATUS BY DISTRICT,
31 AUGUST 2003



Type of district	No. of districts	Population as per 2001 census	Population (in millions)*
■ Implementing	400	714	741
▬ Appraisal done	13	15	16
▮ Ready for appraisal	90	17	18
□ Preparing	205	279	291

* Projected population of 2003 based on 2001 census

Annex 8

STATUS OF IMPLEMENTATION OF KEY RECOMMENDATIONS OF THE 2000 JOINT PROGRAMME REVIEW

Component	Recommendation	Status
Political commitment	Increase profile and disseminate information at central, state, and local levels	Partial
	Ensure sufficient budgetary allocation by GOI	Done
	Increase staff of CTD	Not done
	Upgrade STO post	Some states (19/35)
	Mobilize resources for expansion	Partially done
Case-detection	Establish plans for expansion	Done
	Systematically increase case-detection in health care facilities	Partially done
	Fill vacant LT positions	Partially done
	Implement blinded QA	Begun
	Refresher training of LTs and STLs	Not done
Drug supply	Improve timeliness of drug logistics information at all levels	Partially done
Treatment	Make RNTCP treatment available to all patients in implementing areas	Partially done
	Promote patient-friendly modes of treatment observation	Partially done
	All governmental health services should adopt the RNTCP	Not done
	Develop and analyse models of providing care for floating and socially vulnerable populations	Not done
Supervision and Monitoring	Strengthen State TB Cells. 1 MO per 3–4 new or 6–8 continuing districts. Quarterly meeting and quarterly reports at state level covering district/sub-district	Partially done

Component	Recommendation	Status
	Hands-on supervisory training for STOs and part of DTO training	Partially done
	Quarterly bulletin with results and feedback	Done
	Change STDC role, eliminating clinical care and increasing training, monitoring, supervision, and advocacy	Begun
	State TB cells should ensure that each DTO, STO, STLS develops and follows a monthly plan for supervision	Partially done
	All districts with population of 1 million or more should have full-time DTO	Partially done
	Ensure MO-TC is willing to travel and undertake responsibilities	Begun
Training	Revise current training materials	Begun
	Integrate RNTCP training into routine health professionals training, with NIHFV and other institutions	Not done
	Develop materials for medical colleges	Begun
	Training materials for private practitioners	Not done
	Develop and disseminate patient counselling materials	Partially done
	Establish re-training curricula, emphasizing hands-on skills, particularly supervision	Not done
Research	ARI survey should be supported and monitored	Done
	DRS surveys should be done	Done, ongoing
HIV/TB	Disseminate guidelines to prevent transmission of TB in HIV-care settings	Not done
Other	Increase involvement of NGOs	Done
	Increase use of RNTCP transfer form within and between districts	Not done

Annex 9

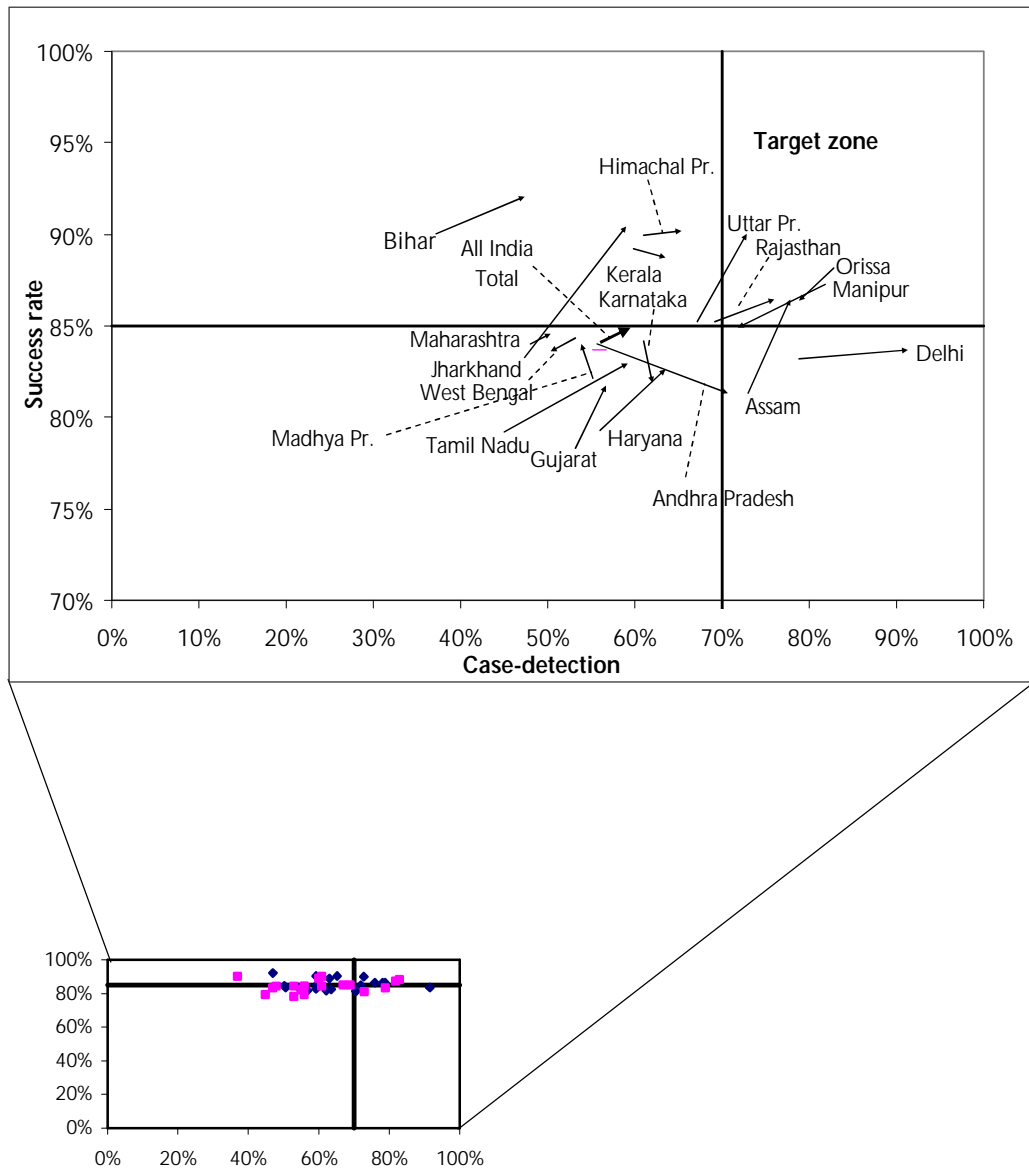
NUMBER OF TB PATIENTS DETECTED UNDER RNTCP (1994-2003)

Year/ Quarter	No. of districts implementing	Population covered (in million)	Total cases	New registrations			
				S+ve cases	S-ve cases	EP	Relapse
1994 Q1	5	2	345	189	184	40	69
1994 Q2	6	3	574	264	338	81	122
1994 Q3	6	3	646	312	363	95	126
1994 Q4	7	4	528	295	294	72	93
1995 Q1	7	7	639	400	288	108	104
1995 Q2	8	7	844	467	332	166	168
1995 Q3	14	13	1167	607	556	152	246
1995 Q4	16	13	1443	665	755	179	158
1996 Q1	18	15	2396	1189	974	354	239
1996 Q2	19	18	3401	1654	1529	466	209
1996 Q3	20	19	4613	1787	2078	498	223
1996 Q4	20	19	4409	1734	1617	496	197
1997 Q1	20	19	4879	1961	1772	519	222
1997 Q2	20	19	5042	2068	1697	637	265
1997 Q3	20	19	5209	1913	1844	530	301
1997 Q4	21	23	4764	1754	1762	483	230
1998 Q1	23	25	5586	2004	1998	649	310
1998 Q2	23	25	6505	2324	2320	782	364
1998 Q3	27	30	7574	2829	2507	843	461
1998 Q4	52	75	13841	5271	4300	1720	795
1999 Q1	61	142	24272	9771	7321	2915	1377
1999 Q2	62	142	38664	15227	12300	4490	2120
1999 Q3	62	142	38932	14828	12431	4382	2063
1999 Q4	64	147	35914	13385	11660	4273	1949
2000 Q1	80	180	40222	14986	12947	4969	2232

Year/ Quarter	No. of districts implementing	Population covered (in million)	Total cases	New registrations			
				S+ve cases	S-ve cases	EP	Relapse
2000 Q2	101	222	63538	25283	18876	7764	3394
2000 Q3	124	262	71025	27705	21465	7972	3622
2000 Q4	149	310	70566	27084	22196	7757	3566
2001 Q1	170	364	94202	36363	30276	10568	4493
2001 Q2	196	404	120843	49130	35532	13935	5711
2001 Q3	209	433	129685	51032	39897	14554	6602
2001 Q4	221	451	127120	48773	41634	13735	6643
2002 Q1	239	471	138137	53541	44923	15817	7190
2002 Q2	248	489	160039	65333	48234	18727	9023
2002 Q3	262	507	164476	64931	50921	19069	9553
2002 Q4	285	539	160760	61367	53362	19066	8630
2003 Q1	339	644	187785	73536	59173	23253	9662
2003 Q2	370	708	238201	96221	75414	29108	12385

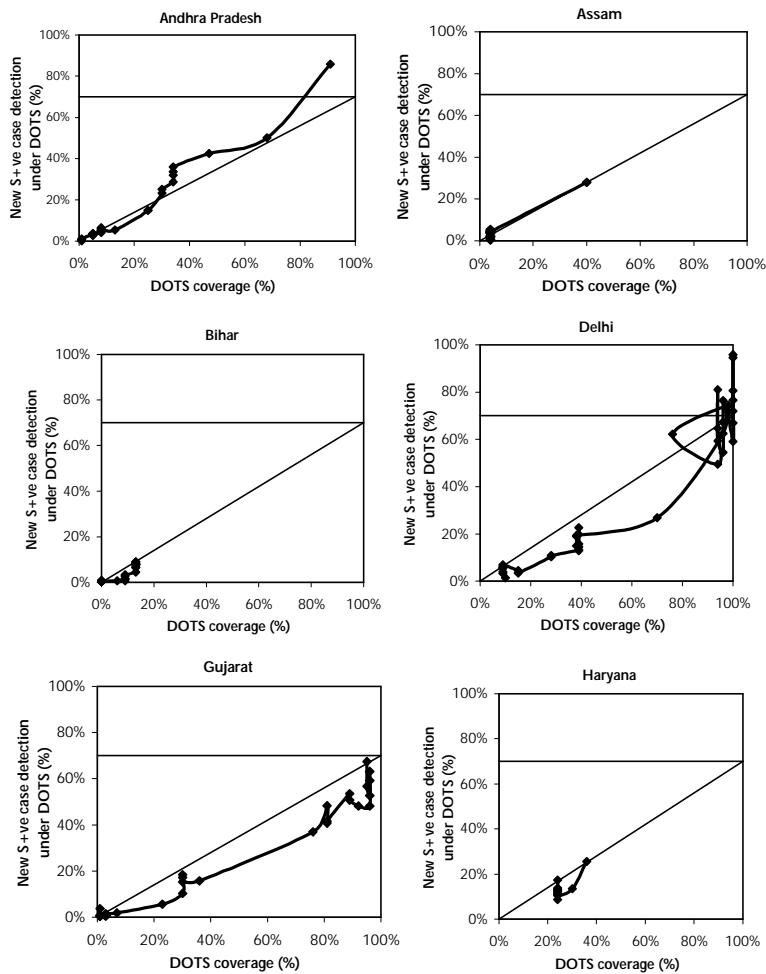
Annex 10

PROGRESS IN RNTCP PERFORMANCE IN STATES OF INDIA (2001-2002)

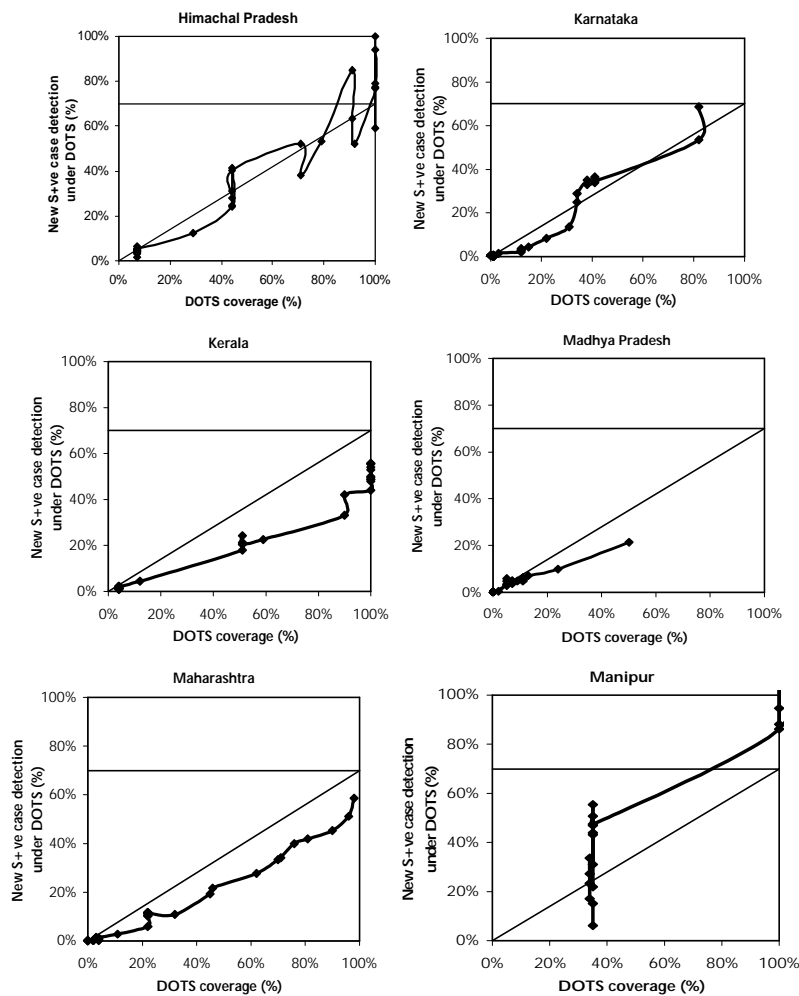


Annex 11

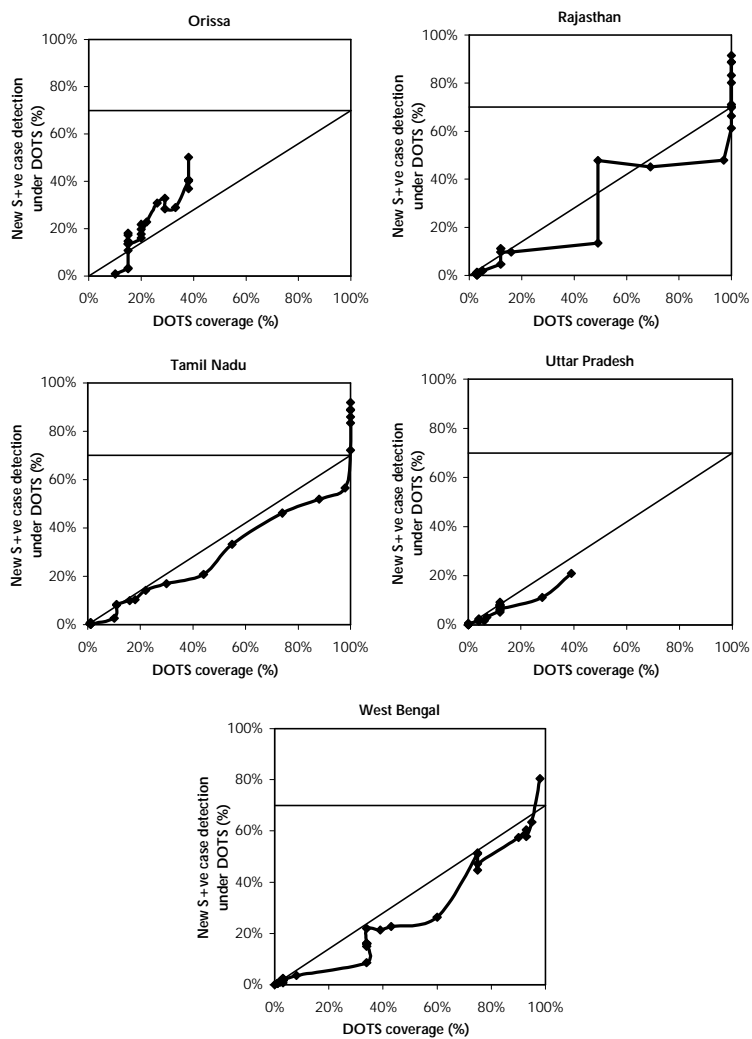
NEW SMEAR-POSITIVE CASE-DETECTION UNDER DOTS IN RELATION TO DOTS COVERAGE



As per new ARTI rates: Andhra Pradesh (Incidence=60 NSP cases/100 000 population); Assam (Incidence= 65 NSP cases/100 000 population); Bihar (Incidence=65 NSP cases/100 000 population); Delhi (Incidence=95 NSP cases/100 000 population); Gujarat (Incidence=80 NSP cases/100 000 population); Haryana (Incidence=95 NSP cases/100 000 population). Note: Zonal ARTI: East Zone=1.3; West Zone=1.6; North Zone=1.9; South Zone=1.2



As per new ARTI rates: Himachal Pradesh (Incidence=95 NSP cases/100 000 population); Karnataka (Incidence=60 NSP cases/100 000 population); Kerala (Incidence=60 NSP cases/100 000 population); Madhya Pradesh (Incidence=80 NSP cases/100 000 population); Maharashtra (Incidence=80 NSP cases/100 000 population); Manipur (Incidence=65 NSP cases/100 000 population). Note: Zonal ARTI: East Zone=1.3; West Zone=1.6; North Zone=1.9; South Zone=1.



As per new ARTI rates: Orissa (Incidence=65 NSP cases/100 000 population); Rajasthan (Incidence=80 NSP cases/100 000 population); Tamil Nadu (Incidence=60 NSP cases/100 000 population); Uttar Pradesh (Incidence=95 NSP cases/100 000 population); West Bengal (Incidence=65 NSP cases/100 000 population). Note: Zonal ARTI; East Zone=1.3; West Zone=1.6; North Zone=1.9; South Zone=1.2

Annex 12

TECHNICAL SUMMARY

Case-Finding

- Sputum examination (3 samples–spot, early morning, spot) of patients attending health facilities who have cough for 3 weeks or more
- Evaluation of household contacts of smear-positive patients, in particular children under 6 years of age
- Evaluation of patients with abnormal chest X-rays.

Diagnosis

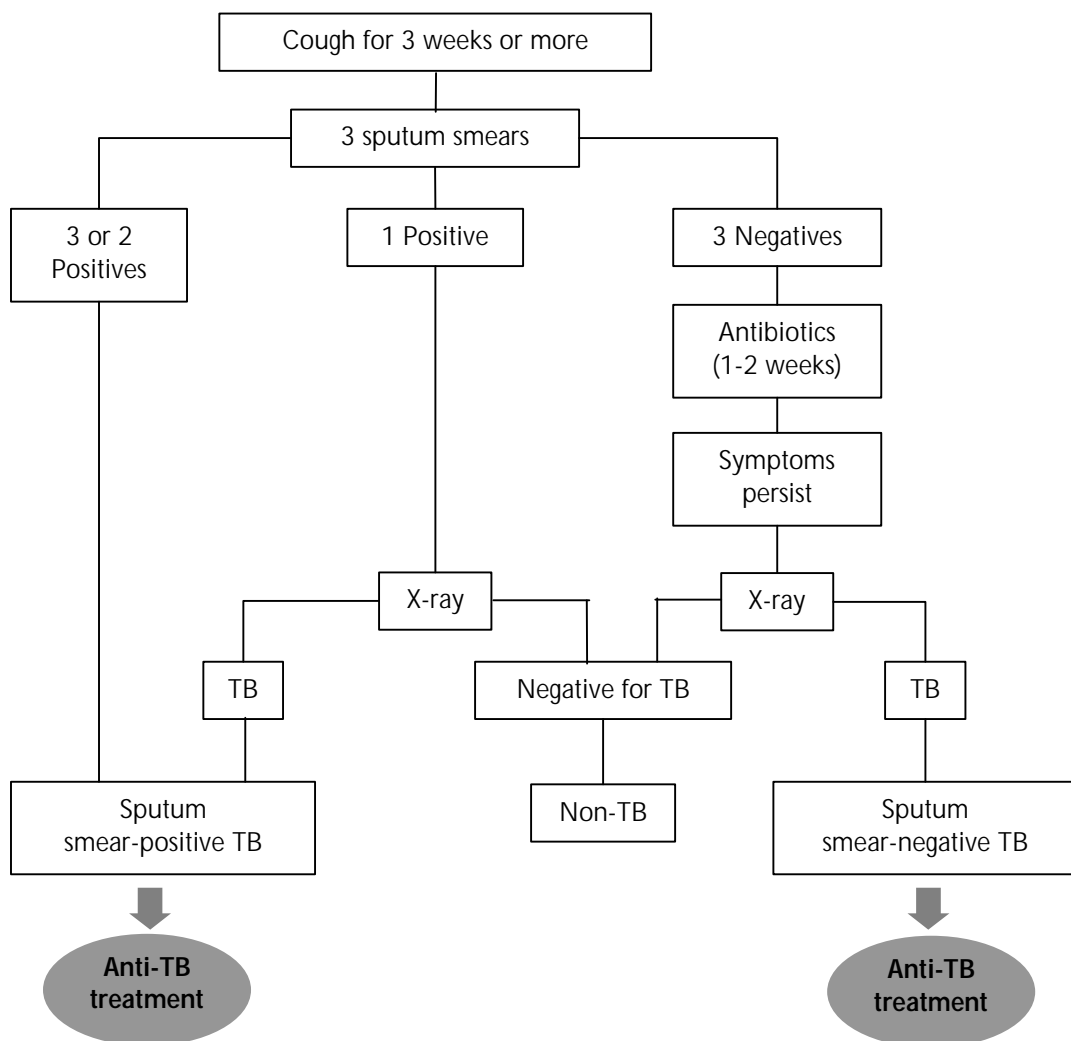
- Smear examination (3 samples) of patients seeking consultation for respiratory symptoms of cough for 3 weeks or more
- Clinical and radiological investigation of smear-negative patients who do not respond to a course of antibiotics (not including fluoroquinolones, streptomycin, or rifampicin) [see flow diagram]
- Clinical, X-ray and other methods for extra-pulmonary TB and TB in children.

Cases are classified as:

Pulmonary tuberculosis, smear-positive: TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB, or: TB in a patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO, or: TB in a patient with one sputum specimen positive for AFB and culture positive for *M. tuberculosis*.

Pulmonary tuberculosis, smear-negative: TB in a patient with symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by MO, followed by a decision to treat the patient with a full course of anti-tuberculosis therapy, or: Diagnosis based on positive culture but negative AFB sputum examinations.

Extra-pulmonary tuberculosis: TB of organs other than the lungs, such as the pleura (TB pleurisy), lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, tubercular meningitis, tuberculoma of the brain, etc. Diagnosis should be based on one culture-positive specimen from the extra-pulmonary site, or histological evidence, or strong clinical evidence consistent with active extra-pulmonary TB followed by MOs decision to treat with a full course of anti-TB therapy. Pleurisy is classified as extra-pulmonary TB. A patient diagnosed with both pulmonary and extra-pulmonary TB should be classified as pulmonary TB.



Treatment

Category I: New pulmonary sputum-positive, seriously ill sputum-negative pulmonary and seriously ill extra-pulmonary cases:

2 H₃R₃Z₃E₃ / 4 H₃R₃

Initial phase extended by 1 month if smear is positive after 2 months

Category II: Re-treatment cases

2 S₃H₃R₃Z₃E₃ / 1 H₃R₃Z₃E₃ / 5 H₃R₃E₃

Initial phase extended by 1 month if smear is positive after 3 months

Category III: New non-seriously ill sputum smear-negative and extra-pulmonary cases:

2 H₃R₃Z₃ / 4 H₃R₃

If smear is positive at 2 months, categorized as failure case and treated afresh

The abbreviations are as follows: H=isoniazid, R=rifampicin, Z=pyrazinamide, E=ethambutol, S=streptomycin. All drugs are administered thrice weekly. The prefix indicates the duration of drug administration in months. The subscript indicates number of doses per week. During the intensive phase of treatment, every dose of medicine is to be taken under direct observation. During the continuation phase, at least the first dose of the thrice-weekly schedule is taken under direct observation. Patients who cannot take directly observed treatment are to be given a standard 12-month self-administered drug regimen which does not contain rifampicin. Guidelines state that this should not be more than 10% of newly diagnosed smear-positive cases.

Treatment Evaluation

Follow-up of patients initiated on treatment is done by examining 2 sputum samples per patient each time at 2/3 months, 4/5 months and at the end of treatment. Outcome evaluation is done on quarterly cohorts of patients. Treatment results are classified as follows:

- *Cured:* Sputum smear-positive patients who complete treatment and are smear-negative on at least 2 occasions, one at the end of treatment.
- *Treatment completed:* Sputum smear-positive cases who complete treatment with negative smears at the end of the intensive phase but none at the end of treatment, and pulmonary smear-negative or extra-pulmonary patients who have completed a full course of treatment.
- *Defaulted:* Patients who interrupted their treatment for more than 2 months.
- *Failure:* Pulmonary TB patients who remain smear-positive at 5 months or later during chemotherapy or who are smear-negative at the start of the chemotherapy and become smear-positive during treatment.
- *Died:* Patients who die due to any cause while on chemotherapy.
- *Transferred out:* Patients who are transferred to another TU/district and the results are not known.

Annex 13

**TREATMENT OUTCOME BY TYPE OF PATIENT,
4TH QUARTER 1993-2ND QUARTER 2002**

	Patients evaluated	Cured number (%)		Completed treatment number (%)		Died number (%)		Remained smear-positive (failed) number (%)		Defaulted number (%)		Transferred out number (%)	
New smear-positive patients registered	4 82 258	399 888	(82.9)	5 641	(1.2)	21 454	(4.4)	13 542	(2.8)	36 640	(7.6)	2 735	(0.6)
New smear-negative patients registered	3 84 221			3 28 416	(85.5)	14 121	(3.7)	4 217	(1.1)	32 947	(8.6)	1 806	(0.5)
New extra-pulmonary patients registered	1 40 359			1 26 453	(90.1)	2 838	(2.0)	313	(0.2)	8 650	(6.2)	605	(0.4)
Relapsed smear-positive patients registered	64 585	45 337	(70.2)	1 829	(2.8)	4 478	(6.9)	3 736	(5.8)	8 106	(12.6)	586	(0.9)
Failure smear-positive patients registered	16 670	9 284	(55.7)	551	(3.3)	1 411	(8.5)	2 323	(13.9)	2 793	(16.8)	159	(1.0)
Defaulted smear-positive patients registered	92 202	60 521	(65.6)	3 184	(3.5)	6 760	(7.3)	4 743	(5.1)	15 509	(16.8)	587	(0.6)
Others smear-positive patients registered	39 425	5 465	(13.9)	25 003	(63.4)	2 180	(5.5)	688	(1.7)	5 203	(13.2)	407	(1.0)

Annex 14

ONGOING RESEARCH AND PLANNED RESEARCH ACTIVITIES AT THE NATIONAL TB INSTITUTES

Epidemiology/Surveillance

- Surveillance of drug resistance in tuberculosis in the state of Delhi
- Pattern of drug resistance among mycobacterial isolates from extra-pulmonary tuberculosis patients
- National Sample Survey to estimate the annual risk of tuberculous infection in different parts of India
- Drug resistance surveillance in Hoogli district in West Bengal, Mayurbhanj in Orissa, and Nagaon in Assam
- Estimation of annual risk of tuberculous infection in Khammam district of Andhra Pradesh in collaboration with DFID
- Estimation of annual risk of tuberculous infection in Orissa in collaboration with DANTB, Orissa
- Community-based study of TB mortality in Bangalore
- Baseline survey to estimate the annual risk of tuberculous infection in rural and urban areas of Himachal Pradesh and Rajasthan
- Assessment of the impact of a rural DOTS programme by community-based disease prevalence and annual risk of infection survey
- Proportion of patients who relapse after successfully completing treatment under DOTS
- Emergence of drug resistance among patients who have a relapse or fail treatment
- Surveillance of drug resistance in tuberculosis in four districts (North Arcot, Wardha, Raichur and Jabalpur) of India
- Transmission of *M. tuberculosis* using molecular and conventional epidemiology
- Community infection ratio as a tool to measure the burden of tuberculosis

Case-Finding and Diagnosis

- Accessibility and utilization of TB services by slum dwellers of Bangalore city
- Utilization of RNTCP services by gender, age and distance in a rural population of Bellary district
- Multicentric study on smear microscopy optimization – A collaborative study with AIIMS, TRC and LRS

- Yield of smear-positive tuberculosis cases among outpatients with cough
- Delay in diagnosis and treatment of tuberculosis
- Examination of 2 versus 3 sputum specimens for diagnosis of pulmonary tuberculosis
- Follow-up of patients with chest symptoms who are found to be sputum smear-negative
- Care-seeking behavior of patients with chest symptoms
- Evaluation of the quality of smear microscopy under RNTCP
- Evaluation of new techniques to improve the sensitivity of sputum smear microscopy
- Value of bronchodilators and repeat sputum microscopy in improving the diagnosis of smear-negative tuberculosis
- Diagnostic algorithms in use for extra-pulmonary TB
- Role of hand-cranked and battery-powered light sources for smear microscopy
- Examination of the interaction between rapid expansion and case-detection

Treatment and Treatment Monitoring

- Profile of default patients under DOTS
- Improving DOTS delivery by involving community DOT providers
- Efficacy and safety of levofloxacin in multidrug-resistant pulmonary tuberculosis patients
- Factors predicting non-conversion of new smear-positive pulmonary TB patients at the end of 2 months therapy under DOTS
- Profile of extra-pulmonary TB patients on DOTS in an urban set-up
- Validity of sputum conversion at the end of intensive phase as an early treatment outcome indicator
- Operational determinants in the acceptance and non-acceptance of DOTS by the patients
- The effectiveness of shopkeepers as DOT providers under RNTCP in Bangalore Mahanagara Palike
- Follow-up of smear-positive patients treated under DOTS in Bangalore Mahanagara Palike
- Pattern of default and retrieval actions for new smear-positive TB patients treated under RNTCP in a rural set-up
- Defaults and patient retrieval among new smear-positive patients treated in RNTCP under different geographical settings

- Development and validation of a scoring system to predict default among new smear-positive cases treated under RNTCP – A collaborative study with JSS Medical College, Mysore
- Randomized study to evaluate efficacy of an oral 8-month regimen with a non-rifampicin continuation phase in the treatment of sputum-positive pulmonary tuberculosis
- Randomized clinical trial to study the efficacy of intermittent regimens containing ofloxacin in the treatment of smear-positive pulmonary tuberculosis
- Evaluation of DOT providers in RNTCP
- Treatment of multidrug-resistant tuberculosis
- Assessment of reasons for initial default
- Assessment of reasons for patient default during treatment
- Tuberculosis knowledge, attitudes and practices among doctors in Delhi, India
- Feasibility of an intra- and inter-district referral for treatment process
- Analyses of outcomes of retreatment cases under RNTCP

Partnerships

- Cost-effectiveness of public–private mix in DOTS: evidence from 2 pilot projects in India (Delhi – Mahavir)
- Current status of functioning of tuberculosis sanatoria and chest diseases hospitals in Karnataka
- Feasibility of involving private practitioners in RNTCP
- HIV seroprevalence in tuberculosis patients under DOTS strategy
- Tools for involvement of Private Practitioners in RNTCP
- Evaluation of contribution of private laboratories to TB control (Kannur and Kolam Districts, Kerala)
- Role of community volunteers in delivering DOT
- Role of *anganwadi* workers in delivering DOT
- Extent of involvement of the corporate sector in TB control
- Tea garden involvement/contribution to RNTCP
- Evaluation of contribution of a Muslim NGO to RNTCP (Meerut, UP).
- Review of India's experience in implementing public–private mix programmes
- Pilot project: using WHO-RNTCP PPM consultants to augment case-detection through increased involvement of the private sector

TB/HIV

- A study to evaluate the diagnosis of tuberculosis among HIV-infected persons

- Randomized clinical trial to evaluate the treatment of TB among HIV-positive patients
- Randomized clinical trial to study the efficacy of 2 preventive treatment regimens in the prevention of TB in HIV positive individuals
- Piloting a new VCTC-based TB/HIV surveillance system
- Modelling the potential impact of HIV on TB control in India

Special Groups

- The extent and clinical characteristics of childhood and adolescent tuberculosis in patients
- Gender differences in diagnosis and treatment of TB–A case study in an urban district in Bangalore
- Assessment of gender disparities in tuberculosis using qualitative methods

Other

- Cost analysis of post anti-tubercular treatment in patients with multidrug resistance
- Constraints faced by MO-TCs in implementation of RNTCP through structured questionnaires
- Comparison of costs to tuberculosis patients in a DOTS and non-DOTS area

Annex 15

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